

Developing and evaluating interventions of diet and weight control to reduce the risk for gestational diabetes

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Abstract

Gestational diabetes mellitus (GDM) is a type of diabetes which develops, or is first recognised during pregnancy. GDM increases the risk of medical complications during pregnancy, and its consequences extend to later in life, as both women and their children are at high risk of developing cardio-metabolic disease. Obesity and excessive gestational weight gain (GWG) are modifiable risk factors for GDM development. Therefore, the research in this thesis aimed to develop and evaluate dietary interventions to help prevent GDM. I initially explored the full burden of the disease using data from a big UK cohort. I found that women with GDM are at high risk of premature death. GDM increases the risk of subsequently developing cardiovascular disease (CVD) risk factors (diabetes, hypertension, dyslipidaemia), and increases the risk of incident CVD by 50% compared to no GDM. There was no evidence that the CVD risk factors explained the association of GDM with CVD, suggesting that all women with GDM are at increased risk of cardio-metabolic disease post-partum, and should be monitored. I then developed a dietary intervention of moderate total carbohydrate reduction, suitable for use in pregnancy, to help prevent GDM (RECORD). It combined a 30-minute dietary behavioural consultation, with structured written materials, brief telephone support throught pregnancy, and weekly self-weighing. In designing the behavioural component, I sought ways to increase motivation and adherence. I thought about using Motivational Interviewing (MI), a popular counselling style in behavioural weight management programmes (BWMPs). Due to increased training and time required for its delivery, I conducted a systematic review and meta-analysis to explore MI's independent effectiveness over other behavioural approaches in BWMPs for weight loss or maintenance, but found that it only leads to a small short-term weight benefit (-1 kg), and only when compared to no/minimal interventions, which makes it not a worthwile addition to weight management programmes with standard behavioural support. In a feasibility trial, I tested if it is possible to deliver the RECORD intervention alongside routine antenatal appointments, and how successful women with obesity would be in following it from early or mid-pregnancy until delivery. The trial's retention rate was excellent (96%), but recruitment was difficult. Adherence was highly variable, and on average, the

reduction in total carbohydrate intake in women receiving the intervention was small (-19.5 g/day and -24.6 g/day absolute and adjusted changes from baseline), which limits the likelihood of achieving the desired goal to prevent GDM. I observed potentially favourable effects of the intervention on blood glucose, GWG, and blood pressure, but the trial was not powered to detect differences in these outcomes. In qualitative interviews, participants praised the intervention for its structure and simplicity, and generally found it acceptable, but a sub-sample reported barriers to adherence, such as competing priorities, and emotional relationship with food. Combining qualitative and quantitative data from this research, I identified opportunities for refinement of the intervention, recruitment strategy, and for routine practice, which could be explored in the future.

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Statement of contribution

I declare that this thesis is entirely my own work, completed under the supervision of Professor Susan Jebb, Dr Nerys Astbury, and Dr Lucy Mackillop at the Nuffield Department of Primary Care Health Sciences, University of Oxford, and the Oxford University Hospitals NHS Foundation Trust. I led all aspects of the work presented in this thesis, including the design, conduct, and analysis of all studies, as well as the writing of Chapters and related journal articles.

Dr Carmen Piernas-Sanchez and Dr Min Gao contributed to the big data project presented in Chapter 2, by assisting me with the development of the statistical analysis plan, the logic, and the code for the analysis.

Myself, Dr Anne Ferrey, Lucy Goddard, Georgina Harmer, Professor Paul Aveyard and Professor Susan Jebb, all contributed to the protocol of the systematic review presented in Chapter 3, with Lucy Goddard writing most of the protocol for Prospero. Dr Anne Ferrey and Lucy Goddard conducted initial scoping searches, worked with the research librarian on refining the search strategy, and developed the study inclusion criteria checklist. Nia Roberts, the research librarian, carried out all the searches for the systematic review. Dr Anne Ferrey set up the project on Covidence, and developed the data extraction template, which was then finalised through discussions with the entire group (myself, Dr Anne Ferrey, Lucy Goddard, Georgina Harmer, Annika Theodoulou, Dr Maryam Kebbe, Professor Paul Aveyard and Professor Susan Jebb). Also, myself, Dr Anne Ferrey, Lucy Goddard, Georgina Harmer, Annika Theodoulou, and Dr Maryam Kebbe, conducted the screening and data extraction of the included studies. Professor Paul Aveyard assisted me with the analysis of the systematic review.

Dr Lucy Mackillop and Dr Jane Hirst provided input on clinical aspects during the development of the intervention, and conduct of the feasibility trial described in Chapters 4 and 5 respectively. Professor Susan Jebb, Dr Nerys Astbury, and Dr Pamela Dyson were involved in the detailed design of the intervention described in Chapter 4. Dr Pamela Dyson helped me develop the intervention materials, with additional input from Professor Susan Jebb, Dr Nerys Astbury, Dr Lucy Mackillop, Dr

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All tables and figures contained within this thesis are my own creation or are appropriately referenced. I hereby declare that no part of this thesis has been submitted for any other degree at this or any other University. Parts of this thesis have been previously published as peer reviewed journal articles.

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Moscho Michalopoulou, Trinity 2023

Abbreviations

ADA	American Diabetes Association
A-levels	Advanced level qualifications
APEASE	Affordability, Practicability, Effectiveness, Acceptability, Safety, Equity
AS-level	Advanced subsidiary level
BCW	Behaviour Change Wheel
BCT	Behaviour change techniques
BMI	Body Mass Index
BRC	Biomedical Research Centre
BWMP	Behavioural weight management programme
CHD	Coronary heart disease
COM-B model	Capability Opportunity Motivation – Behaviour model
CSE	Certificate of secondary education
CVD	Cardiovascular disease
CVMM	Cardiovascular and metabolic morbidity
95% CI	95% Confidence Interval
DAG	Directed Acyclic Graph
DL	DerSimonian-Laird
DTP	Doctoral Training Partnership
FFA	Free fatty acids
FPG	Fasting plasma glucose
GCT	Glucose challenge test
GCSE	General Certificate of Secondary Education
GDM	Gestational diabetes mellitus
GI	Glycaemic index
GLOW trial	Gestational weight gain and optimal wellness trial
GP	General practitioner
GWG	Gestational weight gain
HAPO	Hyperglycaemia and Adverse Pregnancy Outcomes
HbA1c	Glycated haemoglobin
HCP	Healthcare professional
HDL	High density lipoprotein
HES	Hospital Episode Statistics
HNC	Higher national certificates
HND	Higher national diplomas
HOMA-IR	Homeostatic Model Assessment of Insulin Resistance
HKSJ	Hartung-Knapp-Sidik-Jonkman
HR	Hazard Ratio
IADPSG	International Association of Diabetes and Pregnancy Study Groups
ICD-10 code(s)	International Classification of Diseases 10th Revision code(s)
IMD	Index of multiple deprivation
IOM	Institute of Medicine
IPD	Individual participant data
IQR	Interquartile range
IRR	Incident risk ratio
IV	Inverse variance
Kg	Kilogram(s)
LDL	Low density lipoprotein

LGA	Large-for-gestational-age
MD	Mean difference
MET	Metabolic equivalent of task
MI	Motivational interviewing
MRC	Medical Research Council
NDNS	National Diet and Nutrition Survey
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NICU	Neonatal Intensive Care Unit
NIHR	National Institute for Health Research
NVQ	National vocational qualification
OGTT	Oral Glucose Tolerance Test
O-level	Ordinary level
ONS	Office for National Statistics
OR	Odds ratio
OSPREA	Oxford Safer Pregnancy Alliance
OUH	Oxford University Hospitals
PPI	Patient and public involvement
RCT	Randomised controlled trial
RR	Risk ratio
SAEs	Serious Adverse Events
SD	Standard deviation
SE	Standard error
SGA	Small-for-gestational-age
SMD	Standardised mean difference
T1DM	Type 1 diabetes mellitus
T2DM	Type 2 diabetes mellitus
TGL	Triglycerides
UPBEAT	UK Pregnancies Better Eating and Activity Trial

Chapter 1: Introduction

1.1 Obesity in pregnancy

Over the past four decades, the prevalence of obesity (as defined by the body mass index – BMI) in adults has risen dramatically (1). According to the World Health Organisation (WHO), in 2016, 13% of the world's population was affected by obesity, which translates to approximately 650 million adults worldwide (2). The Health Survey for England 2021 reported that more than a quarter of the country's population is affected by obesity, and the proportion has almost doubled, from 14.9% to 28% since 1993 (3).

Box 1.1. Body Mass Index classification (4); units are kg/m^2

Underweight: <18.5

Normal weight: 18.5-24.9

Overweight: 25-29.9

Obesity class I: 30-34.9

Obesity class II: 35-39.9

Obesity class III: ≥ 40 (severe obesity)

The prevalence of obesity is higher in women compared with men (5), and obesity has become one of the most commonly presenting risk factors in obstetric practice. In the UK, obesity affects about a quarter of women of reproductive age (24% of women aged 25-34, and 27% of women aged 35-44) (3). The prevalence of obesity in pregnancy rose from 9-10% in the early 1990s, to 16-19% in the subsequent decade (6, 7), and in 2017, data taken from the UK Maternity Services Dataset from the first antenatal appointments with a midwife (booking appointments), showed that 18.3% of women presented with obesity, and 3.3% with severe obesity (8).

Obesity significantly increases the risk of pre-pregnancy, pregnancy, and postpartum complications. For example, it increases the risk for pre-pregnancy type 2 diabetes mellitus (T2DM)

and chronic hypertension (9-12), which in turn increase the risk of adverse outcomes for both the mother and the offspring, including preeclampsia, requiring induction of labour, miscarriage, fetal macrosomia or delivery of large-for-gestational-age (LGA) infant, congenital abnormalities, pre-term delivery, caesarean section, and perinatal death (12-14). Obesity also independently directly affects these outcomes (15-25). In later stages of pregnancy, women with obesity are 4-9 times more likely to develop gestational diabetes mellitus (GDM) (17), and 3-10 times more likely to develop preeclampsia (17, 26, 27), compared to women of healthy weight. Both GDM and preeclampsia directly increase risk for adverse maternal and neonatal outcomes, and are also associated with long-term morbidity post-partum (28-30).

GDM is the most common obesity-related complication during pregnancy (31), and most strongly associated with chronic disease for the mother and the offspring in the long-term (28). Therefore, this thesis focuses on GDM, and in the following sections, I provide an overview on knowledge around it, research gaps to date, and the aims of this thesis.

1.2 Gestational diabetes mellitus (GDM)

1.2.1 What is GDM?

Historically, GDM was defined as *any* degree of hyperglycaemia first detected during pregnancy (32). This definition allowed a uniform strategy for the diagnosis and treatment of hyperglycaemia during pregnancy, but it encompassed a broad range of hyperglycaemia, ranging from mild impaired glucose tolerance, to overt diabetes, and did not distinguish women who had undiagnosed pre-existing diabetes, from women whose hyperglycaemia first began during pregnancy (32). The rapid rise in obesity has led to increasing incidence of hyperglycaemia in women before they become pregnant, and because there is no routine screening, more women than ever have pre-diabetes or diabetes, which remains undiagnosed prior to pregnancy (33-35). In more recent years, the definition of GDM has been updated to: ***diabetes that develops or is recognised for the first time during pregnancy, mainly in the second or third trimester, that does not include pre-pregnancy overt diabetes*** (36).

1.2.2 Why is it a problem?

GDM increases the risk of maternal complications during pregnancy and labour, including preeclampsia, and need for induction of labour, and caesarean section. GDM also leads to adverse neonatal outcomes, such as LGA, macrosomia, hypoglycaemia, shoulder dystocia or birth injury, which mainly pertain to accelerated fetal growth and accumulation of adipose tissue, caused by maternal hyperglycaemia (sometimes combined with maternal obesity and excess gestational weight gain [GWG]), which exposes the fetus to a high-glucose environment, and excessive nutrient availability (37-40). The landmark Hyperglycaemia and Adverse Pregnancy Outcomes (HAPO) study, a large, international, prospective cohort study, recruited over 25,000 women during pregnancy, and examined the association between maternal glucose levels at an oral glucose tolerance test (OGTT) (75g) at 24-32 weeks, with perinatal outcomes (38). The study showed an independent, consistent, graded, linear association between maternal glycaemia, and the risk of adverse maternal and neonatal outcomes, even for glucose levels below levels diagnostic of diabetes outside of pregnancy, with no evidence of a threshold at which the complications significantly increased (38). This was confirmed in a systematic review and meta-analysis of individual participant data (IPD), with the pattern of association remaining robust across study characteristics and geographical regions (41).

In the longer-term, women with a history of GDM are at markedly high risk of developing subsequent T2DM (up to 20 times higher), compared to those without GDM, which is evident from as early as 3-6 years following a GDM diagnosis (42-45). Large observational cohort studies have also demonstrated that women with GDM have up to twice higher risk of developing overall and type-specific cardiovascular disease (CVD), independently from having conventional CVD risk factors, or developing subsequent T2DM (46, 47). Other, less well documented maternal complications include increased risk for subsequent hypertension (43), non-alcoholic fatty liver disease (48), and chronic kidney disease (49). The most common long-term complication for offspring of mothers with a GDM-affected pregnancy, is the development of childhood obesity as a result of accumulation of adipose tissue from the fetal stage (50, 51). Persistence of childhood obesity into adulthood, increases the risk

of metabolic syndrome (52), T2DM and CVD in the offspring (53). In view of the above, GDM is considered a major public health issue.

1.2.3 Prevalence

It is hard to determine accurately the global prevalence of GDM, with estimates varying from 1 to 45% of live pregnancies (54, 55). Whilst differences in screening, testing, and diagnostic thresholds (**Table 1.1**), make it difficult to compare GDM rates between countries and regions, a recent study endeavoured to generate a comparable estimate of the global and regional prevalence of GDM, using the International Association of the Diabetes and Pregnancy Study Groups' (IADPSG) diagnostic criteria (56). The global prevalence of GDM, standardised based on screening strategies and age, was 14%, which would equate to more than 17 million live births annually in women 20-49 years old. High-income countries have the highest standardised prevalence of GDM, compared to low- and middle-income countries (56). The widest variation in crude GDM prevalence has been previously reported in Europe (range 1.8% to 31%) (28). In the UK, approximately 16% of all women who are pregnant develop GDM (41).

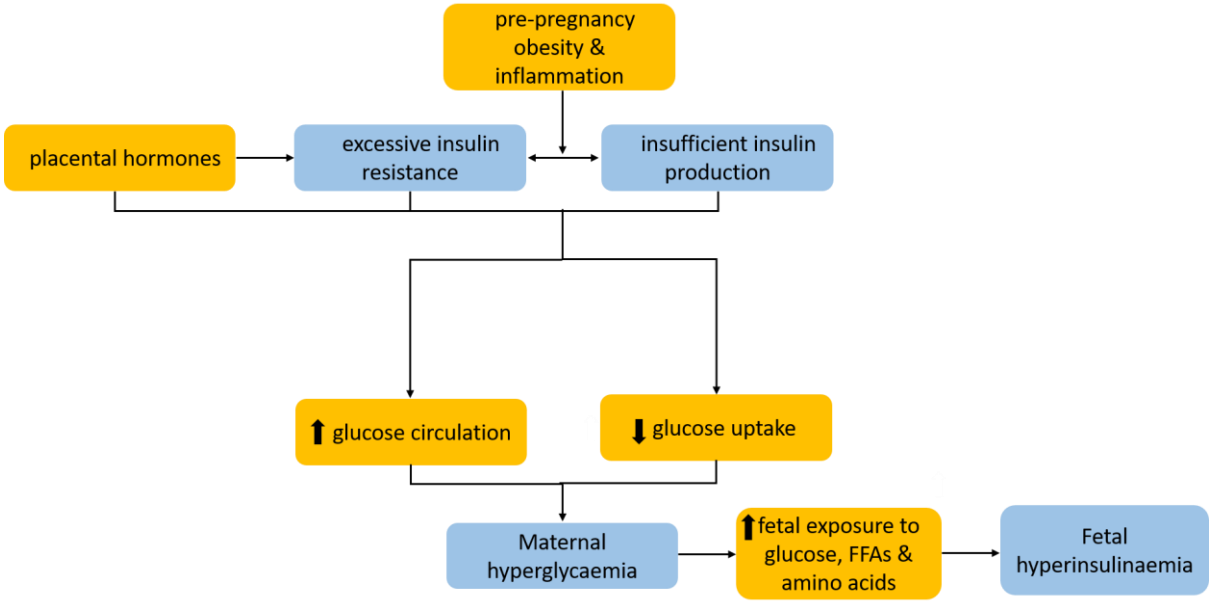
The incidence of GDM is increasing globally. Whilst this can in part be attributed to changes in screening and diagnostic criteria (details in section 1.2.5), this rise may also be attributed to advanced maternal age, and the rise in overweight and obesity (57-60). In the UK, GDM prevalence reaches up to 25-30% among women with obesity (41).

1.2.4 How does GDM happen?

Normally in pregnancy, the body increases hepatic glucose production, in order to meet the increased energy needs (61). At the same time, increase in placental hormones (e.g. lactogen, prolactin, estrogen, progesterone), lead to progressive decrease in the body's ability to uptake glucose in skeletal muscle and adipose tissue, known as insulin resistance (62-65). This increased insulin resistance leads to increased postprandial maternal glucose and circulating free fatty acid (FFA) concentrations (64, 66, 67), and as a result, there is an increased uptake of these from the placenta,

leading to higher exposure of the fetus for growth (62). In normal pregnancy, the resulting hyperglycaemia due to these metabolic changes, is mitigated so that blood glucose levels are kept normal. For example, especially in early pregnancy, the plasma volume decreases, and the uptake of glucose from the placenta increases to support growth, therefore glucose concentrations decrease. In addition, the body responds to the increased insulin resistance in early pregnancy, by increasing insulin secretion by 2-3-fold, to maintain healthy glucose levels (62, 66, 68). GDM develops due to insufficient insulin production to meet increased pregnancy needs, and/or excessive insulin resistance, as described in **Figure 1.1**.

Figure 1.1. Pathophysiology of GDM*



GDM: gestational diabetes mellitus; **FFAs:** free fatty acids
*Adapted from McIntyre et al. 2019 (28).

- GDM develops when pancreatic β-cells cannot produce sufficient insulin to compensate for the progressive rise in insulin resistance during pregnancy (69, 70), probably due to dysfunction in β-cell mass expansion (71).

- In some cases, such as in women with obesity, insulin resistance and/or β-cell dysfunction may already exist before pregnancy (72), and the metabolic changes during pregnancy add to them, resulting in hyperglycaemia (73).

- In women with obesity who are pregnant, the presence of increased adipose tissue can also further reduce insulin sensitivity, which contributes to further increased FFA levels in maternal circulation (lipolysis) in later stages of pregnancy (66, 74). Increased FFA circulation exacerbates insulin resistance by inhibiting maternal glucose uptake and stimulating hepatic gluconeogenesis (74, 75). The increased lipid levels may also cause lipotoxic β-cell injury, further limiting insulin secretion (76, 77).

- Another factor associated with obesity that disrupts insulin sensitivity, is inflammation. Inflammatory markers, such as tumour necrosis factor, activate a signalling pathway which interferes with insulin receptors, and disrupts the role of insulin in reducing glucose levels (78).

- As a result of maternal hyperglycaemia, the fetus is exposed to high levels of glucose, lipids and amino acids, leading to fetal hyperinsulinaemia, which results in fetal overgrowth, increased adiposity, as well as long-term consequences, such as cardio-metabolic disease (79, 80).

1.2.5 Identification of GDM: screening, testing, and diagnosis

There is lack of consensus on the optimal screening and diagnostic approaches for GDM (**Table 1.1**). Some countries adopt universal screening for GDM, while in other countries, women are screened early in pregnancy for the presence of a number of risk factors, and only those who have one or more risk factors, are offered a diagnostic test later in pregnancy for GDM, or in a two-step approach, all women initially undergo a glucose challenge test (GCT) to identify potential overt undiagnosed diabetes, and those with a normal GCT, are later tested for GDM (selective screening) (41). All screening practices come with their pros and cons. Whilst selective screening helps to limit false positives, and conserves resources, it may miss nearly half of women with hyperglycaemia who may benefit from treatment (41, 81-83). On the other hand, universal testing may result in unnecessary testing of women at low risk, but more women will be identified, and therefore more may benefit from treatment, though it is unclear which screening and testing approach is most clinically helpful or cost-effective (41, 84, 85). Alternative screening methods such as fasting plasma glucose (FPG) or glycated haemoglobin (HbA1c), are easier to use and require fewer resources, however, they often lack sensitivity and/or specificity to be used as the only diagnostic test (86).

In the UK, the National Institute for Health and Care Excellence (NICE), recommends the following process for screening and diagnosing GDM (59):

- Women who are pregnant are screened at their booking appointment for the following risk factors: obesity (BMI ≥ 30 kg/m^2, previous macrosomic baby (> 4.5 kg), previous GDM, family history of diabetes in a first-degree relative, or ethnicity associated with a high prevalence of diabetes (Middle Eastern, Afro-Caribbean, South Asian, or Chinese), and if one or more of these are present, they are offered an OGTT at 24-28 weeks' gestation, to test for GDM.

- Women with a history of GDM, are offered an earlier OGTT at around 16 weeks' gestation. If hyperglycaemia is detected, then women enter the GDM care pathway. If the early OGTT is normal, women are offered another OGTT at 24-28 weeks' gestation to test for GDM.

- Women undergo OGTTs with the one-step approach, during which a plasma blood sample is collected after an overnight fast, then a 75g glucose drink is ingested, and further plasma blood samples are collected 1 hour and 2 hours after the drink.

- Hyperglycaemia both at an earlier OGTT or the routine one in the third trimester, is diagnosed if FPG is ≥5.6 mmol/L, or 2-hour glucose is ≥7.8 mmol/L, without specification of how these thresholds were derived, and despite lack of consensus on whether the same criteria used in the third trimester, can also be used at earlier stages of pregnancy (86).

Table 1.1. Current screening, testing, and diagnostic approaches to GDM*

Organisation/ Country	**Screening approach**	**Risk factors considered** (if selective screening)	**Screening method**	**Diagnostic test**	**Positive screening blood glucose thresholds (mmol/L)** (if two-step screening)	**Diagnostic plasma glucose thresholds for GDM (mmol/L)**
IADPSG (87) WHO (88) ADIPS (89) FIGO (90) JDS (91) EBCOG (92) Endocrine Society (93) China (94)	Universal		One-step	75g 2-hour OGTT		One or more of: Fasting ≥ 5.1 1-hour ≥ 10.0 2-hour ≥ 8.5
ADA (36)	Universal		One-step	75g 2-hour OGTT		One or more of: Fasting ≥ 5.1 1-hour ≥ 10.0 2-hour ≥ 8.5
			Two-step	50g GCT and if normal (<7.2 to 7.8 mmol/L), then subsequent 100g 3-hour OGTT	≥ 7.2 to 7.8 at 50g GCT (choice of threshold based on the trade-off between sensitivity and specificity)	Two or more abnormal values at 100g OGTT, based on: either Carpenter & Coustan (95): Fasting ≥ 5.1 1-hour ≥ 10.0 2-hour ≥ 8.6 3-hour ≥ 7.8 (plasma or serum glucose) or NDDG (32): Fasting ≥ 5.8 1-hour ≥ 10.6 2-hour ≥ 9.2 3-hour ≥ 8.0

Table 1.1. continued

Organisation/ Country	**Screening approach**	**Risk factors considered** (if selective screening)	**Screening method**	**Diagnostic test**	**Positive screening blood glucose thresholds (mmol/L)** (if two-step screening)	**Diagnostic plasma glucose thresholds for GDM (mmol/L)**
ACOG (96)	Universal		Two-step	50g GCT and if normal (<7.2 to 7.8 mmol/L), then subsequent 100g 3-hour OGTT	≥ 7.2 to 7.8 at 50g GCT (each practice can choose a consistent threshold based on factors such as GDM prevalence in a particular community)	Two or more abnormal values at 100g OGTT, based on: either, Carpenter and Coustan (95): Fasting ≥ 5.1 1-hour ≥ 10.0 2-hour ≥ 8.6 3-hour ≥ 7.8 (plasma or serum glucose) or, NDDG (32): Fasting ≥ 5.8 1-hour ≥ 10.6 2-hour ≥ 9.2 3-hour ≥ 8.0
CDA (97)	Universal		Two-step (preferred)	50g GCT, and if normal (<7.8 mmol/L), then subsequent 75g 2-hour OGTT	≥ 7.8 at 50g GCT, but if ≥11.1, no need for subsequent 75g OGTT	One or more of: Fasting ≥ 5.1 1-hour ≥ 10.0 2-hour ≥ 8.5 at 75g OGTT
			One-step (alternative)	75g 2-hour OGTT		One or more of: Fasting ≥ 5.3 1-hour ≥ 10.6 2-hour ≥ 9.0

Table 1.1. continued

Organisation/ Country	**Screening approach**	**Risk factors considered** (if selective screening)	**Screening method**	**Diagnostic test**	**Positive screening blood glucose thresholds (mmol/L)** (if two-step screening)	**Diagnostic plasma glucose thresholds for GDM (mmol/L)**
CNGOF (98)	Selective	One or more of: Maternal age ≥ 35 years BMI ≥ 25 kg/m^2 Family history of diabetes Previous GDM Previous macrosomic baby	Two-step	First trimester fasting plasma glucose test, and if <5.1, then subsequent 75g 2-hour OGTT	≥ 5.1 at first trimester plasma glucose test	One or more of: Fasting ≥ 5.1 1-hour ≥ 10.0 2-hour ≥ 8.5
NICE (59)	Selective	One or more of: Obesity (BMI ≥ 30kg/m^2) Previous macrosomic baby (> 4.5kg) Previous GDM Family history of diabetes Ethnicity with a high prevalence of diabetes	One-step	75g 2-hour OGTT		One or more of: Fasting ≥ 5.6 2-hour ≥ 7.8
DDG/DGGG (99)	Universal		Two-step	50g GCT, and if normal (<7.5 mmol/L), then subsequent 75g 2-hour OGTT	≥ 7.5 at 50g GCT, but if ≥11.1, no need for subsequent 75g OGTT	One or more of: Fasting ≥ 5.1 1-hour ≥ 10.0 2-hour ≥ 8.5
			One-step (preferred)	75g 2-hour OGTT		One or more of: Fasting ≥ 5.1 1-hour ≥ 10.0 2-hour ≥ 8.5
DIPSI (100)	Universal		One-step	75g 2-hour OGTT		2-hour ≥ 7.8

Table 1.1. continued

GDM: gestational diabetes mellitus; **IADPSG:** International Association of the Diabetes and Pregnancy Study Groups; **WHO:** World Health Organisation; **ADIPS:** Australasian Diabetes in Pregnancy Society; **FIGO:** International Federation of Gynecology and Obstetrics; **JDS:** Japan Diabetes Society; **EBCOG:** European Board & College of Obstetrics and Gynaecology; **ADA:** American Diabetes Association; **ACOG:** American College of Obstetricians and Gynecologists; **NDDG:** US National Diabetes Data Group; **CDA:** Canadian Diabetes Association; **NICE:** National Institute for Health and Care Excellence; **CNGOF:** National College of French Gynaecologists and Obstetricians; **DDG/DGGG:** German Diabetes Association/ German Association for Gynaecology and Obstetrics; **DIPSI:** Diabetes in Pregnancy Study Group of India; **BMI:** body mass index; **GCT:** glucose challenge test; **OGTT:** oral glucose tolerance test

*Adapted from Sweeting et al. (101).

1.2.6 Risk factors

GDM is a multifactorial disease, which develops as a result of genetic, epigenetic and environmental factors.

1.2.6.1 Previous GDM

Having a history of GDM in a previous pregnancy, is the strongest clinical risk factor for developing GDM, with reported recurrence rates between 30-84% (102). Higher rates of GDM recurrence are observed in non-White ethnic groups (52-69%), and lower, in non-Hispanic White women (102).

1.2.6.2 Ethnicity

The prevalence of GDM is higher in women from ethnic groups that have an increased risk for T2DM, such as South and East Asians, women from the Middle East, Black and Native Americans, and Aboriginal populations, compared to all other groups (103, 104). Cohort studies from the UK and the Republic of Ireland, have reported highest prevalence of GDM among women of Asian and South Asian origin (105, 106).

1.2.6.3 Advanced maternal age

Over the past four decades, the average age of women at the time of pregnancy has increased (107). Advanced maternal age is an independent risk factor for the development of GDM. In the US, data from the large prospective Nurses' Health Study II, showed that maternal age 40 years and older, was associated with more than 2-fold increased risk for GDM compared to women aged 25-29 years, even after adjustment for major risk factors, including pre-pregnancy BMI, family history of diabetes, ethnicity, parity, and pre-pregnancy physical activity (103). The mechanism explaining the association potentially relates to increased insulin resistance, or higher levels of adipokines, inflammatory markers, and oxidative stress with advanced maternal age (108, 109).

1.2.6.4 Family history of diabetes

A family history of diabetes markedly increases an individual's risk of developing T2DM, especially if the mother or both parents are affected, because of an interaction between genetic and

environmental factors (110-112). Williams et al.(113), observed that women whose either parent had diabetes, had more than 2-fold higher risk for GDM, compared to women whose parents did not have diabetes. Women with a sibling affected by diabetes, had 8.4-fold higher risk of GDM, than women with siblings not affected by diabetes.

1.2.6.5 Modifiable risk factors

1.2.6.5.1 Overweight, obesity, and GWG

Maternal pre-pregnancy overweight and obesity are both associated with high risk of GDM (114-117), with obesity being the strongest predictor of GDM and future diabetes, among modifiable risk factors (116, 118-121). The risk of GDM is almost 3-fold higher in women with class I obesity, and 4-fold higher in women with class II obesity, compared to women with a BMI <30 kg/m^2 (118). In a recent systematic review and meta-analysis (121), the pooled estimates (adjusted odds ratios [OR]) of GDM risk in women in the underweight, overweight, and obese categories, were 0.68, 2.01, and 3.98 respectively, and there was a dose-response relationship between increasing BMI and GDM risk, with GDM risk increasing 4% per unit increase in BMI, in both unadjusted and adjusted models for confounders (121).

Whilst evidence has consistently demonstrated that starting pregnancy with excess weight increases risk of GDM, there seems to also be an increased risk associated with GWG (the amount of weight gained during pregnancy). Evidence from observational studies has shown that increased GWG is associated with adverse pregnancy outcomes, including GDM, as well as caesarean delivery, hypertensive disorders of pregnancy, and LGA infants (109, 122, 123). More specifically, a greater rate of, and excessive GWG, especially in the first trimester, have been associated with 3-to-4-fold increased risk of GDM (124-126). In 2009, the US Institute of Medicine (IOM), issued guidelines for the appropriate amount of GWG, according to women's BMI at the beginning of pregnancy, including recommendations for rate of weight gain in each trimester (127) (**Table 1.2**). These recommendations have not been formally adopted in the UK, and currently, there are no UK-specific guidelines on the ideal GWG (128). This is because the IOM guidelines were developed based on observational data,

thus, they are subject to reverse causality, and based on the US population. Importantly, these guidelines were not developed based on risk of GDM as an outcome. Only a few studies with small numbers of women in the UK have examined the relationship of GWG from before pregnancy to the point of GDM screening, providing conflicting findings on whether the risk of GDM increased by increasing GWG (129-131).

Table 1.2. Recommendations for gestational weight gain, by pre-pregnancy BMI*

	Pre-pregnancy BMI category			
	Underweight (<18.5 kg/m^2)	**Normal weight** (18.5-24.9 kg/m^2)	**Overweight** (25.0-29.9 kg/m^2)	**Obese** (≥30.0 kg/m^2)
Total weight gain range, kg	12.5-18	11.5-16	7-11.5	5-9
Mean rate of weight gain (range), kg/week	0.51 (0.44-0.58)	0.42 (0.35-0.50)	0.28 (0.23-0.33)	0.22 (0.17-0.27)

BMI: body mass index
*Adapted from 2009 Institute of Medicine guidelines (127).

As a result, UK national guidance does not provide GWG thresholds, and healthcare professionals (HCPs) are not encouraged to proactively discuss obesity and weight management in pregnancy (128, 132). It is advised that weight and height are measured at the booking appointment, but thereafter, that women should not be routinely weighed during pregnancy, unless it is clinically necessary, or (mal)nutrition is a concern. Instead, women who are pregnant are advised to talk to their General Practitioner (GP) or midwife if they are concerned about their weight, placing the onus of responsibility on the individual, and not the healthcare system. It is advised that any discussions around weight management in pregnancy should emphasise the importance of avoiding excessive GWG, however, it is not specified how this can be practically achieved (128, 132). Moreover, women are advised to avoid dieting during pregnancy as it may harm the health of the fetus, and to seek expert advice on healthy eating and physical activity (128, 132), but specific practical advice on how to achieve these is lacking (128, 132, 133), which might deter weight control practices. For women with a BMI of 30 and above, NICE also recommends referral to a HCP for personalised lifestyle advice, and to be encouraged to lose weight after pregnancy (128, 132), though there is little evidence that

this occurs, because according to local practices, referrals are sometimes at the HCP's discretion, based on necessity and available services, and no local guidelines make recommendations to address women's concerns specifically around diet (133).

Since the publication of the NICE guidance on weight management in pregnancy, systematic reviews (134-137), cohort studies (138-142), and randomised controlled trials (RCTs) (143-146), have shown that GWG above or below the IOM recommendations increased adverse pregnancy outcomes. More recently, a systematic review, meta-analysis, and meta-regression of diverse international cohorts, looking at the association of GWG above or below IOM thresholds, with pregnancy outcomes, confirmed the earlier findings, although could not assess the impact on GDM, because of heterogeneity in the definitions used, inconsistency in findings regarding GDM risk, and in treatments used (147). Recent evidence from RCTs has also suggested that dietary interventions to reduce overweight or obesity during pregnancy are not harmful to the mother or the fetus (135). Therefore, in clinical practice, many clinicians now consider weight maintenance for women with obesity during pregnancy acceptable.

Inter-pregnancy weight gain is also consistently associated with a higher risk of GDM and other perinatal complications, while inter-pregnancy weight loss is associated with lower risk of LGA infants (148). In women with GDM with overweight or obesity, a reduction in inter-pregnancy BMI of ≥2.0 kg/m^2 reduces the risk of GDM in a subsequent pregnancy by 74% (359), which supports guidelines encouraging women to lose weight post-partum before conceiving again (128).

1.2.6.5.2 Diet

Longitudinal evidence suggests that increased dietary fat intake, especially saturated fat, during pregnancy, increases the risk of developing GDM (149-151). Foods and food groups associated with higher risk of GDM include sugar-sweetened beverages (152), potatoes (153), fried foods (154), sources of haem iron (155), and animal sources of fat and protein (149, 156), while consumption of nuts (156), and sources of fibre (157), have been associated with lower GDM risk. In large prospective

cohort studies, pre-pregnancy consumption of a dietary pattern low in carbohydrate, high in protein, and including fat derived from vegetable sources (158), as well as a Mediterranean-style pattern (159), were associated with a reduced risk for GDM, independently of adiposity and physical activity, whilst "Western" dietary patterns (high intake of red and processed meat, high glycaemic-index [GI] foods, refined grain products, sweets, sugar-sweetened beverages, low consumption of dietary fibre), have been associated with increased risk of GDM (160).

1.2.6.5.3 Physical inactivity

Physical inactivity has been reported as a risk factor for GDM. Some systematic reviews support that physical activity independently reduces the risk of GDM (161, 162), while others show no significant protective effect (163-165). The heterogeneity may be due to the low quality of studies, as well as differences in participant and intervention characteristics of included studies. UK NICE advises women who are pregnant to maintain or engage in/up to 150 minutes of moderate-intensity physical activity (e.g. walking, yoga, dancing, swimming), spread throughout the week, as well as muscle strengthening activities twice a week, and to reduce sedentary behaviour as much as possible (e.g. start walking more, taking the stairs instead of the lift) (166).

1.2.6.5.4 Cigarette smoking

Prenatal cigarette smoking is associated with increased risk of GDM, after adjusting for known risk factors, and independently of BMI category and GWG (167). Maternal heavy smoking during pregnancy (≥25 cigarettes/day), doubles the risk of GDM in the daughter, independent of pre-pregnancy BMI and other risk factors (168).

1.2.6.6 Other risk factors

Independent of body weight, low maternal blood vitamin D levels have been associated with increased risk of GDM, with adjusted ORs ranging from 1.18 to 1.9 for vitamin D deficiency compared to sufficiency (169-173). Supplementation with vitamin D reduces the risk of adverse perinatal outcomes, including GDM (approximately by 50%), and a higher than the currently recommended dose may

reduce GDM risk further (174, 175). Other risk factors include increasing parity (115), twin pregnancy (115), previous macrosomic baby (176), a history of perinatal complications (115), maternal small-for-gestational-age (SGA) or LGA (115), use of glucocorticoids and anti-psychotic medications (177, 178), and maternal hypertension before and during early pregnancy (179). Some (180), but not all (181, 182) cohort studies to date, have also suggested that Polycystic Ovary Syndrome increases the risk of GDM, through increased insulin resistance in these women (180), but there is evidence that the increased risk could be explained by other risk factors, such as maternal age and BMI, and there is heterogeneity among study designs (183). Emerging evidence indicates a potential association between environmental pollutants and substantially increased risk for GDM (OR 1.79, 95% confidence interval [CI] 1.18 to 2.74) (167, 184). Finally, depression in the first and second trimester of pregnancy has been prospectively associated with increased GDM risk, especially in women without obesity (185).

Many of the above determinants may co-exist. In a retrospective cohort study, combination of older age with overweight/obesity and excessive GWG, was associated with more than twice increased risk of GDM, compared to women with no risk factors (186). Observational studies suggest that approximately 45% of GDM cases could be prevented by adoption of a healthy diet before pregnancy, maintaining a healthy BMI, engaging into at least 30 minutes of moderate-intensity physical activity daily, and quitting smoking (187). Given that obesity is the strongest modifiable risk factor for GDM, weight control strategies are an important part of management of established GDM, and have also been explored as preventative strategies for GDM. However, even when GDM is well managed, and good glycaemic control is achieved, women and their offspring are still at increased risk of morbidity in the longer-term (188-195), which suggests that the benefits of treating GDM are limited to short-term perinatal outcomes, and it is imperative to find effective strategies to prevent GDM in the first place (196). Therefore, this thesis will focus on GDM prevention, rather than management. A brief summary of GDM management interventions and practices is presented in

section 1.2.7, while more detailed information on previous GDM prevention trials is presented in section 1.2.8.

1.2.7 Management and treatment

Advice to modify diet is the mainstay treatment for GDM, and aims to provide adequate energy and nutrient intake, to protect maternal health, ensure glycaemic control, promote appropriate GWG, and ensure healthy fetal growth (197, 198). A range of dietary strategies have been tested in RCTs, such as low-to-moderate-glycaemic index (GI) vs moderate-to-high-GI diet, energy restriction vs no energy restriction, the Dietary Approaches to Stop Hypertension diet, and low-carbohydrate vs high-carbohydrate diet (199). Intervention effects have varied across different dietary strategies, but collectively, dietary modifications alone or as part of a care package, are effective in reducing most adverse perinatal outcomes (199, 200). However, there is no uniformly accepted dietary advice for women diagnosed with GDM, and trials have been limited by small sample sizes, and inadequate statistical power to detect differences in outcomes, and draw conclusions on which types of dietary advice are appropriate for GDM management. Many interventions are often poorly described, which makes it difficult to identify the most effective intervention components, and there is paucity of information regarding intervention intensity, duration, and compliance (199).

Given that carbohydrate intake directly affects postprandial glycaemia, early approaches to GDM treatment aimed to decrease total carbohydrate intake to 33-40% of total energy intake. This approach has been associated with reduced postprandial glucose levels and fetal overgrowth (201, 202). Subsequent evidence showed that higher carbohydrate intake at 60-70% of energy intake, focusing on choosing low-GI foods, also reduced markers of glucose intolerance (e.g. FPG, insulin resistance), however, postprandial and overall daytime glucose values were higher in the higher-carbohydrate diet groups (203-205). The controversy is further complicated by the fact that not all studies to date, comparing lower- to higher-carbohydrate diets in women with GDM, reported effects on perinatal outcomes. Evidence from systematic reviews and meta-analyses of RCTs does not support

the specific use of low-carbohydrate diets for the management of GDM, given that, overall, there is no significant difference on the effect on maternal and neonatal outcomes compared to controls, though the quality of evidence is low (197, 198).

Available dietary recommendations for GDM management, published in major organisations, can be found in **Table 1.3**. There is general consensus that the diet plan should not contain excess amount of carbohydrates, with an equal distribution throughout the day (e.g. across 3 main meals, and 2-3 snacks), and that the intake of refined starchy carbohydrates and sugars should be limited (90, 206-208). However, there is high variability among recommendations even within the same country. The recommended carbohydrate intake currently ranges from 33% to 55% of energy intake (90, 96, 206, 207). Some organisations (57, 209) endorse the IOM's recommendation to keep carbohydrates to at least 175 g/day to avoid ketonaemia, and ensure sufficient fetal growth, and cerebral development and function (207). For women with overweight or obesity who have GDM, some organisations recommend moderate energy restriction to help with controlling GWG (210, 211). In the UK, NICE recommends that women with GDM eat a "healthy diet" during pregnancy, choosing low-GI foods to replace those with a high GI (59), in common with some other organisations (57, 211).

Dietary modification advice, is usually accompanied with advice to engage into moderate-intensity physical activity, such as walking, cycling, swimming, and resistance activities (59, 209), however, any type of physical activity of at least moderate intensity infers benefits for women with GDM, including improvements in glucose control, and reductions in need to insulin use or insulin dose requirements (212). Lifestyle advice alone, has been shown to be sufficient in achieving glycaemic control in 70-85% of women with GDM (209, 213), however, if glycaemic targets are not met, pharmacotherapy in the form of metformin/sulfonylurea and/or insulin is added (209, 214-217). In two large RCTs, lifestyle advice, combined with self-monitoring of blood glucose (SMBG), supplemented with insulin treatment when necessary, reduced the rates of LGA by approximately 50%, as well as the risk of a number of other complications, including shoulder dystocia (40, 218).

Table 1.3. Current national nutritional recommendations for management of GDM*

Organisation	Recommendations
ADA (209)	• Individualised nutrition plan with the help of a registered dietitian. • No specific amounts for calorie or carbohydrate intake, but dietary reference intake values for pregnancy should be met: 175g of total carbohydrate, minimum 71g of protein, and 28g of fibre per day.
Diabetes Canada (57)	• Assessment, counselling, and follow-up by a registered dietitian. • Healthy diet, with a minimum of 175 g of total carbohydrate/day, distributed over 3 moderate-sized meals, and 2 snacks (one at bedtime). • Replace high-GI foods with low-GI foods.
Endocrine Society (211)	• Carbohydrate intake at 35-45% of energy intake, distributed over 3 small- to moderate-sized meals, and 2-4 snacks (including evening snack). • Choose lower-GI foods. • Moderate caloric restriction at 1600-1800 kcal/day, or 33% reduction, for women with overweight or obesity.
NICE (59)	• Referral to a registered dietitian. • Healthy diet, with emphasis on low-GI foods to replace high-GI foods.
International Diabetes Federation (210)	• Referral to a HCP with expertise in GDM medical nutrition therapy • Individualised and culturally sensitive nutrition plan. • The type, quality, and quantity of carbohydrate foods should be matched to insulin type and dose. • Low-GI diet. • Moderate reduction of no more than 30% of habitual caloric intake for women who are considerably overweight (no specific BMI thresholds given).

GDM: gestational diabetes mellitus; **ADA:** American Diabetes Association; **GI:** glycaemic index; **HCP:** healthcare professional

*Adapted from Mahajan et al. (219).

1.2.8 Prevention

There has been a substantial amount of research evaluating interventions aiming at reducing the risk of GDM. Carrying or gaining excessive weight during pregnancy, increases the risk of GDM, and by the time GDM is diagnosed in the third trimester of pregnancy, many women have already gained excessive weight, their fetuses have been exposed to hyperglycaemia, and fetal overgrowth may have already occurred (220). We know that dietary intake affects both weight and blood glucose levels, however, it is not clear what dietary advice is best to help prevent GDM. In the UK, guidelines recommend that general healthy eating advice should be offered early in pregnancy at the booking appointment, but the content and structure of the advice is not specified for the purpose of preventing GDM (221). Similarly, although physical activity recommendations are more specific than dietary recommendations, there is no advice about specifically preventing GDM (166). In a priority setting exercise among women with established GDM, the role of diet in GDM development, and dietary interventions as a preventative strategy for GDM, were among the top 10 research priorities for the condition (222). Several interventions have aimed at limiting GWG, often as a surrogate measure for clinical outcomes, based on the assumption that lower GWG will in turn improve maternal and neonatal outcomes, including preventing GDM (223, 224). The characteristics and content of some known interventions are detailed in **Appendix 1.1**, and summarised below.

1.2.8.1 Content of preventative interventions

Most dietary interventions promoted general healthy eating advice according to national recommendations, with emphasis on restriction of sugar intake, and increased fibre intake. In women with overweight or obesity, some, but not all interventions also encouraged reduced energy intake (223, 224). The majority of dietary interventions have been combined with some physical activity advice or programme. The behavioural basis for the interventions is often not described, but where it is, interventions were informed by elements from the control and/or social cognitive theories, and involving goal setting, self-monitoring of goals and weight, problem solving, and in some cases, social support, and motivational strategies (223, 224).

For example, in the landmark UK Pregnancies Better Eating and Activity Trial (UPBEAT) (143), 1555 women with obesity, of multiple ethnicities residing in the UK, were offered from approximately 17 weeks' gestation, a complex intervention on behaviour change and self-monitoring of diet and physical activity, or standard antenatal care of lifestyle advice at the booking appointment. To improve glucose tolerance, women in the intervention group were encouraged to follow a healthy eating pattern, but to not necessarily restrict their energy intake. The dietary advice emphasised swapping carbohydrate-rich foods of medium-high GI, with lower-GI foods, to reduce glycaemic load of the diet, as well as reducing foods high in saturated fat. Physical activity advice focused on gradual increases in walking to reach moderate intensity, with options for additional physical activity/exercise. In the Finnish Gestational Diabetes Prevention (RADIEL) study (225), women with a history of GDM and/or pre-pregnancy obesity, were randomised to either individualised diet, physical activity, and weight management counselling, or to receive leaflets with general information on diet, physical activity, and weight control during pregnancy, as well as health education according to standard practice. In this study, intervention participants with obesity were advised to not gain weight during the first two trimesters. The dietary advice was based on the Nordic Nutrition Recommendations (226), and aimed to optimise participants' consumption of fruit and vegetables, berries, high-fibre foods, low-fat dairy products, unsaturated fats, fish, and low-fat meat products, and to minimise the intake of sugary foods and drinks. Women were encouraged to follow the "plate model", filling half of the plate with vegetables, one quarter with complex carbohydrates (e.g. potato, rice, pasta), and one quarter with protein foods (e.g. meat, fish, eggs, beans). The diet provided 1600-1800 kcal/day, with 40-50% of energy coming from carbohydrates, 30-40% from fat, and 20-25% from protein. Physical activity recommendations included 150 minutes of moderate-intensity activity per week, and reduction in sedentary lifestyle. Both the diet and the activity plan in this study, were monitored, and tailored to each woman's abilities, progress, and preferences. For example, if a woman was struggling with physical activity, the focus would shift towards diet.

A few trials promoted a Mediterranean-style diet (227). For example, ESTEEM was a multicentre RCT across 5 maternity units in the UK (228), in 1,252 women with metabolic risk factors (obesity, chronic hypertension or hypertriglyceridaemia), which assessed whether a Mediterranean-style diet reduces adverse pregnancy outcomes compared to usual antenatal advice on diet, physical activity, weight management and hypertension in pregnancy. The components of the diet included high intake of fruit and vegetables, non-refined grains, and legumes, moderate to high consumption of fish, small to moderate intake of poultry and dairy products, low consumption of red and processed meat, and minimal intake of sugary drinks, fast food, and foods rich in animal fat. ESTEEM particularly emphasised increased intake of unsaturated fat from nuts (30 g/day) and extra virgin olive oil (0.5 L/week). The intervention package included dietary education sessions, advice on grocery shopping, ideas for recipes, and healthy eating advice for when eating out.

1.2.8.2 Characteristics of preventative interventions

Dietary interventions have been delivered mainly by experienced dietitians and nutritionists, or trained study nurses, and occasionally by trained health coaches or research staff (223, 224). Most interventions commenced before 20 weeks' gestation, and were delivered until 34-37 weeks' gestation, or until delivery (223, 224). The number of face-to-face visits has ranged from 2-8 per participant, either as part of, or on top of routine antenatal appointments, usually supplemented with a range of remote contacts (range 2-11). The frequency of intervention delivery was almost equally distributed among the studies, between every 2-3 months, monthly, and weekly. Intervention sessions lasted roughly 60 minutes on average (223, 224).

Interventions were delivered mostly through individual face-to-face sessions, but some studies delivered remote interventions, through the telephone, or mobile applications. For example, Herring et al. (229), delivered a telephone-based behavioural lifestyle intervention to run alongside routine antenatal appointments, including advice to reduce sugar intake, limit fast foods and foods high in fat, and control portion sizes, incorporate daily walking, and to weekly monitor weight gain to

meet IOM recommendations, supplemented with daily text messages for encouragement with the programme and enhancing self-efficacy. In the Gestational weight gain and optimal wellness (GLOW) trial by Ferrara et al. (230), women in the intervention group received an adapted version of the National Diabetes Prevention Programme designed to be delivered as a mix of in-person and telephone sessions. More recently, an intervention by Ding et al., using a mobile social media application, offered a free instant messaging platform for women during pregnancy, to interact with their healthcare professionals at any time regarding nutrition and weight management topics (231).

Beyond counselling, intervention packages included several materials, such as leaflets, fact sheets, newsletters, handbooks, recipe ideas, goal logbooks, diet, physical activity, and weight monitoring charts and notebooks, text messages for self-monitoring and encouragement, pedometers, online websites for extra information, and DVDs with physical activity regimens. In the RADIEL study, participants also had access free of charge to public swimming pools, and/or guided exercise groups (225). In the ESTEEM and St Carlos Mediterranean interventions, key foods, such as nuts and/or extra virgin olive oil, were provided to participants on top of counselling (228, 232).

1.2.8.3 Effects of preventative interventions on GDM risk

An IPD meta-analysis of trials of diet and physical activity interventions in women with overweight or obesity in pregnancy, showed that the intervention groups gain less weight than usual care groups (from booking appointment until before delivery), with mean difference of -0.70 kg and 95% CI -0.92 to -0.48 kg, and relatively low heterogeneity (I^2=14.1%), consistent across various subgroups of women based on age, parity, BMI, ethnicity, and pre-pregnancy medical conditions (233). However, there was considerable variability in the intensity of the interventions and definitions of outcomes. The majority of trials failed to reduce GDM risk (OR 0.89, 95% CI 0.72 to 1.10) (233). A potential benefit from lifestyle interventions in preventing GDM was shown only when aggregated and IPD data were combined, and not in the IPD meta-analysis alone (233), but the accuracy of this approach is doubtful (233, 234).

In a recent Cochrane overview of systematic reviews and meta-analyses, quality of evidence from preventative lifestyle RCTs for GDM was reported as low, due to variations in the definitions of GDM, type and intensity of interventions and controls, sparse data on compliance, heterogeneity in patient and study characteristics, and selection criteria (224). Overall, low quality of evidence from systematic reviews, shows no benefit or harm from physical activity or exercise interventions alone, against routine antenatal care, on the risk of GDM (risk ratio – RR 1.10, 95% CI 0.66 to 1.84) (224), although higher quality systematic reviews have demonstrated significant reductions in incidence of GDM (162, 235). The effect of dietary advice alone on GDM risk is also unclear. The small number of Mediterranean-style diets have shown a significant benefit compared to routine antenatal care (OR 0.66, 95% CI 0.52 to 0.82), with no heterogeneity (227). However, overall, low quality of evidence again suggests that dietary interventions alone do not seem to confer a benefit or harm regarding GDM risk (RR 0.60, 95% CI 0.35 to 1.04) (224). Low-quality evidence has also shown unknown benefit or harm of low-GI diets vs moderate-high-GI diets on risk of GDM (RR 0.91, 95% CI 0.63 to 1.31) (224).

Conversely, moderate-quality evidence suggested that a combination of diet and exercise can possibly reduce the risk of GDM (RR 0.85, 95% CI 0.71 to 1.01) (224). But it is unclear if these beneficial effects apply to all women or only to high-risk women (e.g. high BMI, age, high-risk ethnicity). In addition, many lifestyle interventions lack detailed reporting about the type, intensity, content, theoretical basis, and setting of the intervention, as well as cost-effectiveness analysis, which prevents their delivery in a scalable way. The mechanism behind the success of some dietary interventions over others in preventing GDM is also unknown. A meta-analysis and meta-regression, suggested that key aspects which confer benefit among successful interventions are: targeting a high-risk population based on risk evaluation models (including important GDM risk factors and not just BMI), early implementation of the intervention (e.g. before 20 weeks' gestation, or ideally, in the first trimester), and attenuation of GWG through intense diet and exercise programmes (236).

Although pregnancy is a unique time when women are in frequent contact with their clinical care team, and are motivated to make lifestyle changes to protect the health of their baby, intensive lifestyle modifications, especially those requiring face-to-face counselling and multiple visits, may be hard to follow, can decrease treatment efficacy, and may not be feasible in routine care (237). The UPBEAT trial with good attendance rates (7 of 8 sessions), led to only a small difference in GWG between the groups (-0.42 kg from before pregnancy up to 28 weeks' gestation, intervention vs control), and an increase in exercise by 7.5 metabolic equivalent of task (MET)-hours/week, with no differences in moderate or vigorous activity between the groups (143), while data have shown that an increase of 16-MET-hours/week of exercise may be required as a minimum to reduce GDM, with increase in vigorous exercise when appropriate (238). The small number of trials that have shown effectiveness in GDM prevention so far, have included intensive face-to-face dietetic support and/or provision of key foods to study participants, but they provide no indication of how these strategies could be delivered in routine antenatal care (225, 228, 232, 239, 240). The RADIEL study reduced GDM incidence by 39% in women at high risk, but required extra face-to-face visits and a group session as described above, to deliver standard healthy eating and physical activity advice, which may not be manageable in routine practice, given the amount of appointments women are already required to attend and competing priorities they face (e.g. childcare, work) (225). The ESTEEM and St Carlos trials implemented Mediterranean-style dietary advice supplemented with extra virgin olive oil and nuts, provided as part of the trial, from early or mid-pregnancy, and showed a similar reduction in GDM risk (228, 232). Nevertheless, wide scale implementation of a Mediterranean-style diet in the UK could be challenging. Studies outside pregnancy in England and Northern Ireland, show that people have favourable attitude towards this type of diet, but there are a number of barriers to adoption. The diet exists in many different versions, and is perceived in various ways (241, 242). Knowledge of its composition is limited, and the pattern is quite different from established UK dietary patterns, particularly regarding consumption of olive oil and nuts, and lower red meat consumption. This diet may also not be acceptable to people of all ethnic backgrounds, and the cost of foods such as extra

virgin olive oil is higher (243-245). A possibility also exists that in the UK context, liberal use of olive oil may lead to increased energy intake. In addition, supporting people in the UK to make the substantial dietary change to a Mediterranean dietary pattern would be resource-intensive, and may exceed the knowledge and skills of the routine workforce, hindering delivery of such interventions in routine care.

Data also support the effectiveness of technology-assisted interventions for weight control, offering convenience, and facilitating engagement, retention, and delivery at high intensity, but at low cost (246-248). For example, in women with established GDM, telehealth has been shown to increase efficiency and to improve perinatal outcomes (249). Herring et al., in a high-intensity preventative trial in women of African descent, with overweight and obesity (i.e. high-risk women), tested an inexpensive technology-assisted behavioural intervention requiring little health coaching, involving regular contact with HCPs via text messaging and phone calls, as well as social support through a social media forum, and showed that the intervention significantly reduced GWG and prevalence of excess GWG, compared to usual care (also involving guidance on optimal GWG) (229). The benefits in GWG did not translate into reduction in GDM incidence, however, this study was not statistically powered to detect such difference. Ding et al., used social software to assist with delivery of the intervention, but this was still intense, as it involved interaction with HCPs at any time for personalised counselling and information, on top of general education, daily exercise plan, and weekly messaging from HCPs. In this study, the incidence of GDM was significantly lower in the intervention group (24%) than in the control group (37.8%). However, reported differences in rates of GDM between the two groups in this study were unadjusted for known confounders, which could have changed the direction or significance of the results (231).

Consequently, lack of clarity about effective components and mechanisms of complex diet and/or physical activity interventions remains. What the results of some successful interventions suggest however, could be that dietary modification with or without physical activity, can have an effect on GDM risk, independent of GWG control, since the weight gain difference between the two

trial arms was only -1.2 kg in the ESTEEM (228), and -0.5 kg in the RADIEL study (225), in favour of the intervention. But the optimum dietary composition is unknown. In the RADIEL study, there was only a small improvement reported in adherence to the diet recommendations in the intervention group, compared with the control group, as indicated by a diet quality score (225). In the Mediterranean dietary interventions, it was speculated that increased unsaturated fat and polyphenol consumption might have been beneficial with regards to insulin sensitivity and inflammation (228, 232). However, a reduction in dietary carbohydrate as a natural result of higher fat and protein consumption, in conditions when energy intake remains similar, may have also played a role. Indeed, successful interventions to date included some advice for reducing sugar consumption and/or moderating starchy foods, but detailed dietary data are not reported in most of them, so as to explore this. In the recent remote intervention by Ding et al., both groups were consuming a diet high in carbohydrates (average of 283 g/day and 277 g/day in the intervention and control group respectively), from baseline until the point of testing for GDM, with no difference between the groups, throwing doubt on the need for carbohydrate restriction, though again notably, analyses were not adjusted for confounders (231). The authors attributed the benefit in GDM risk to early implementation before 12 weeks' gestation, and to the higher than usual frequency of contact of women with their HCPs, although they do not report engagement data.

1.3 Summary of research gaps

After conducting a comprehensive literature review around GDM in this Chapter, I identified two research gaps which I tried to address in this thesis:

1. First, GDM is an established risk factor for future T2DM (44), but there is also increasing evidence from large observational cohort studies that GDM is associated with future CVD in the mother (47). In fact, more and more researchers recognise that GDM should be treated as a pre-CVD state (250). However, the magnitude of the long-term effect of GDM on CVD risk is unclear (251), and not all studies have adequately adjusted for confounders, or taken into

account post-pregnancy factors such as diabetes, hypertension or dyslipidaemia, that could explain potential mediating pathways underlying the associations. There is also limited evidence on the direct association of GDM with other subsequent CVD risk factors (hypertension, dyslipidaemia) (43, 252), and no longitudinal evidence on all-cause mortality. As such, the full burden of GDM remains unknown.

2. Carrying or gaining excess weight during pregnancy is a strong risk factor for developing GDM (116, 118-121, 124), but only a small number of trials to date in women with overweight or obesity have shown effectiveness in preventing GDM, with unclear mechanisms of success, and including intensive dietetic support and/or provision of key foods, which may not be feasible to incorporate in routine antenatal care (225, 228, 232, 239, 240). Alternative, less intensive, effective interventions, applied early in pregnancy to prevent excess GWG, and hyperglycaemia in women at high risk of GDM (e.g. women with obesity), are needed.

   One way that might help to attenuate GWG, and control blood glucose in pregnancy, is to follow a moderately reduced-carbohydrate diet, as it may help reduce hyperglycaemia, independent of effects on weight gain, and may also help attenuate GWG by reducing energy intake, without leading to malnutrition or increasing ketosis. This strategy has been shown to work outside of pregnancy with regards to weight and glucose control, in people with T2DM in the short-term (3-6 months), as well as in women with established GDM (201, 202, 253). However, there is paucity of RCTs examining the specific role of moderate carbohydrate reduction in the prevention of GDM, and how such an intervention could be delivered in routine care. To my knowledge, only one previous RCT specifically aimed at reducing total carbohydrate intake as part of an intensive healthy eating intervention (254). In this study, women were randomised to receive healthy eating alone, or physical activity advice alone, both, or usual care, and as part of the dietary advice, they were encouraged to eat more non-

starchy vegetables, and reduce intake of both starchy carbohydrates, and sugary foods and drinks. Women in any of the intervention arms did not significantly limit their GWG compared to usual care, before the time point of GDM diagnosis (<20 weeks' gestation until 24-28 weeks' gestation). This study was underpowered to detect difference in GDM, and although it resulted in significant reduction in total carbohydrate intake in favour of the healthy eating only group compared to usual care at 24-28 weeks' gestation, the degree of reduction was small (less than 1 portion/day). Thus, the effect of a reduced-carbohydrate diet, as a preventative strategy for GDM remains to be investigated. Given that physical activity typically declines throughout pregnancy (255), and my expertise as a dietitian, in this DPhil project, I was interested in developing and testing diet only modifications, rather than adding physical activity components.

1.4 Aims and objectives of this thesis

To address the aforementioned gaps, my thesis had five aims:

1. To use data from a big UK cohort, to explore the associations between having GDM in a previous pregnancy, and the incidence of subsequent CVD events, T2DM, hypertension, dyslipidaemia, and total mortality (Chapter 2).
2. To consider whether a specific counselling style (motivational interviewing), would enhance engagement with an intervention to prevent GDM (Chapter 3).
3. To develop a dietary intervention of moderate carbohydrate reduction, combined with behavioural support, for use in pregnancy, to help women with obesity to reduce their chances of developing GDM (Chapter 4).
4. To conduct a RCT to test if it is feasible to deliver the dietary intervention alongside routine antenatal appointments, and how successful participants would be in following it for the second and third trimester of pregnancy (Chapter 5).
5. To explore the experiences of the participants who received the intervention, with the aim to assess its acceptability and suitability, as well as refine it (Chapter 5).

Chapter 2: Association of gestational diabetes with cardio-metabolic risk factors and outcomes, and all-cause mortality

2.1 Summary

GDM is an established risk factor for later onset of T2DM, and recent evidence shows that it also increases the risk for CVD. However, the magnitude of the long-term effect on CVD remains unclear. There is also limited evidence on the direct association of GDM with post-pregnancy CVD risk factors (diabetes, hypertension, dyslipidaemia), and evidence on whether it is associated with all-cause mortality is lacking, such that the full burden of the disease is unknown.

I used data from the UK Biobank prospective cohort study, which recruited more than 500,000 adults between 2006 and 2010, with follow-up until 2021. I used multivariable Cox proportional hazards models to investigate prospective associations between GDM and CVD-incidence, as well as CVD risk factors (diabetes, hypertension, dyslipidaemia), and all-cause mortality. To better understand the link between GDM and total CVD, I explored whether the observed association was mediated by incident diabetes, hypertension or dyslipidaemia, and whether the effect of GDM on CVD risk differed according to the presence of these risk factors later in life, as well as age, ethnicity and BMI group.

A total of 220,726 women with at least one birth, without pre-pregnancy diabetes, comprised the eligible cohort, of which 1,225 either self-reported having had GDM, or had a hospital episode record for GDM. After adjusting for confounders, GDM was associated with increased risk for CVD outcomes (all CVD incident cases: hazard ratio [HR] 1.50, 95% CI 1.30 to 1.74; fatal CVD: HR 2.38, 95% CI 1.63 to 3.48; non-fatal CVD: HR 1.41, 95% CI 1.20 to 1.65). GDM was also associated with higher risk for all-cause mortality (HR 1.44, 95% CI 1.12 to 1.86). Most women with GDM (90%) progressed to develop diabetes later in life. The risk for incident diabetes, hypertension and dyslipidaemia was higher in women with GDM compared to women without GDM [diabetes: HR 14.37, 95% CI 13.51 to 15.27; hypertension: HR 1.49, 95% CI 1.38 to 1.60; and dyslipidaemia: HR 1.30, 95% CI 1.22 to 1.39]. However, the incidence of these CVD risk factors did not appear to mediate the association between

GDM with total CVD. GDM conferred a greater increased risk of CVD among women who did not develop diabetes in later life, than those with a later diagnosis of diabetes. For each of CVD, diabetes, hypertension, and dyslipidaemia outcomes, a sensitivity analysis excluding women who developed each of them before enrolment into the UK Biobank, did not materially change the effect estimates, but showed an even higher risk for incident diabetes (almost 20-fold).

I concluded that GDM has an adverse impact on long-term maternal health outcomes, by increasing the risk of CVD risk factors (diabetes, hypertension, dyslipidaemia), CVD events, and all-cause mortality. There was no evidence in this sample that development of conventional CVD risk factors later in life explained the association of GDM with total CVD, suggesting GDM is an independent CVD predictor. The findings therefore suggest that all women with GDM are at increased risk of cardio-metabolic disease post-partum, emphasising the importance of monitoring and treating common CVD risk factors post-partum, and perhaps applying interventions to prevent GDM.

2.2 Introduction

Although GDM usually disappears after giving birth, evidence from longitudinal cohort studies consistently shows that the adverse impact on maternal health persists beyond gestation and childbirth. For example, GDM is an established risk factor for future development of T2DM in the mother (44), with a lifetime risk of up to 70% (42, 256, 257). Nearly half of the women who develop GDM, are expected to develop impaired glucose tolerance within the first decade after a pregnancy affected by GDM (42, 256). Even women with a milder degree of hyperglycaemia in pregnancy, not meeting diagnostic thresholds for GDM, have increased risk for future impaired glucose tolerance and T2DM (258). The potential mechanism explaining the association is the presence of insulin resistance and beta-cell dysfunction (259), particularly in women with excess adiposity (260). Since the association between GDM and subsequent T2DM has been known for more than 50 years, GDM is included in algorithms used to quantify risk of developing T2DM (261).

In recent years, a series of large population-based cohort studies have also shown increased risk for CVD events in women who develop GDM (43, 46, 47, 262). A systematic review and meta-

analysis of the available observational evidence by Kramer et al. (46), suggested that women with GDM have 2-fold higher risk of future total CVD compared to women without GDM, and when analysis is confined to the first decade post-partum, the risk increases more than 2-fold. In a more recent systematic review and meta-analysis, involving more than 8 million women, a history of GDM was associated with 45% increased risk of overall cardiovascular and cerebrovascular diseases (47). It has therefore been proposed that GDM should be regarded as a pre-CVD state (250).

However, whilst annual postpartum diabetes screening is recommended, UK national recommendations do not advise health professionals to screen or monitor women with history of GDM for CVD and other CVD risk factors, such as hypertension or dyslipidaemia (59). The limited clinical recognition of the association between GDM and CVD risk, is partly due to the fact that studies to date have yielded varying estimates of the magnitude of the effect of GDM on CVD risk, as well as uncertainty as to whether the CVD risk is entirely, partly, or at all, dependent upon subsequent development of T2DM (251). Kramer et al. (46), showed that incident T2DM did not affect the risk of later CVD for women with a history of GDM. Even the women with history of GDM who did not later progress to T2DM, had 56% higher risk of CVD compared to women without history of GDM. However, more recent studies have reported that T2DM may partially mediate the association between GDM and CVD (263). Nevertheless, most studies to date have not explored the effect of GDM on future CVD development based on other known CVD risk factors, such as hypertension and dyslipidaemia. Exploring whether CVD risk in women with a history of GDM can be explained by later onset of hypertension or dyslipidaemia, is warranted, given that these conditions are involved in the pathogenesis of CVD (264-268), and that evidence suggests that GDM is associated with almost 2-fold higher risk for onset hypertension (43), and with higher risk for incident dyslipidaemia (252). Further exploration of these risk factors will shed light on whether women with GDM need to be prioritised, after giving birth, for monitoring and treatment of not only glucose levels, but also blood pressure and blood lipids, to reduce their chances of developing CVD. This is of great importance because CVD remains the leading cause of death in women (269).

Previous observational studies on the impact of GDM on future maternal health are limited by the short-term period of follow-up of between 10 and 20 years after pregnancy (43, 251, 262, 270-274), and many studies have not adequately controlled for confounders in the observed associations. I therefore planned a study using data from UK Biobank to address these gaps, and pre-registered my protocol on the Open Science Framework (https://osf.io/9dbqr). After my protocol was registered, a similar study, using UK Biobank data was published (263). This study showed that GDM is an independent risk factor for later onset CVD, and that this risk is partly explained by development of subsequent T2DM, hypertension, and dyslipidaemia, in the years post-partum. However, in their main analysis, the authors followed-up women from the time point of enrolling into the UK Biobank, not from the index pregnancy (median follow-up 10 years), and they defined development of CVD risk factors (T2DM, hypertension, and dyslipidaemia), based on whether these were present by the time of enrolling in the UK Biobank, ignoring the years following enrolment.

In this Chapter, I sought to conduct a comprehensive analysis to:

- quantify the magnitude of future CVD risk in women with a history of GDM;
- determine whether CVD risk is mediated by subsequent development of diabetes, hypertension or dyslipidaemia;
- examine the direct association of GDM with subsequent diabetes, hypertension and dyslipidaemia; and
- explore the impact of GDM on future risk for all-cause mortality.

2.3 Methods

2.3.1 Study design and participants

UK Biobank is a large-scale prospective study, which recruited more than 500,000 UK participants between 2006 and 2010. People aged 40-69 years were invited to take part because they are at risk of a wide range of diseases, such as heart disease, diabetes, and cancer, in the next few decades, thus allowing for the investigation of common causes of morbidity and mortality. At baseline (2006-2010),

participants self-reported most information about themselves, through self-completed Touchscreen questionnaires, and nurse-led verbal interviews, including information on socio-demographic factors, medical history, lifestyle, and health behaviours. Participants also had physical assessments where blood pressure, height, and weight were measured, and blood, saliva, and urine samples were collected for analysis. These assessments were repeated after a year or two in a representative sample of individuals, to correct for random measurement error, and for short-term variability in risk factors. To account for potential dilution effects of risk factors on health outcomes over the course of decades, and to allow for effects of longer-term within-person variability, the UK Biobank has been inviting a sample of the cohort to repeat the assessments every 2-3 years. The participants were also asked to provide consent for linking the research data collected as part of the UK Biobank cohort, with health-related information from NHS digital, which has been, and continues to be collected from primary care and national care records (including Hospital Episodic Statistics – HES). The HES data include information about hospital inpatient, day case, and outpatient episodes, including clinical information about diagnoses and procedures (275). Death records from the Office for National Statistics (ONS) are also linked to the UK Biobank cohort. Full details about the UK Biobank study and protocols are openly available (http://www.ukbiobank.ac.uk/wpcontent/uploads/2011/11/UK-Biobank-Protocol.pdf). The UK Biobank study was conducted according to the Declaration of Helsinki, and ethical approval was granted by the North West Multi-Centre Research Ethics Committee (reference number 06/MRE08/65). At recruitment, all participants gave informed consent to participate and be followed-up through data-linkage.

2.3.2 Procedures

I obtained the data for analysis from all available sources, including self-reported and measured data during the UK Biobank assessment centres, and the linked HES (main inpatient information, diagnoses, operations), and ONS death records, to maximise the information I could analyse.

2.3.2.1 Population

Eligible participants were women with at least one birth (live or not), determined by the self-reported Touchscreen questionnaire (live births only), or presence of at least one delivery episode recorded in the linked HES data (both live and not live births). From these women, I excluded those with pre-pregnancy diabetes, determined from self-reported and/or HES data. I determined the entry point for all women, regardless of whether and when they had GDM, as the age when they gave birth to their first baby, using the youngest age available from self-reports in the Touchscreen questionnaire and HES data. The reasons for this assumption for the entry point are discussed in the limitations section (2.5.4.2). All eligible women were followed-up until the earliest occurrence of an outcome of interest, death from any causes, or the latest collection of data.

2.3.2.2 Exposure

Women who had GDM in any pregnancy, comprised the exposed group. Occurrence of GDM was defined as any of the following:

- Reporting diabetes that occurred *only* during pregnancy in the UK Biobank Touchscreen questionnaire.
- Reporting GDM in the verbal interviews.
- Presence of ICD-10 (International Classification of Diseases, 10th version) code O24.4 (diabetes mellitus arising in pregnancy) or O24.9 (unspecified diabetes in pregnancy) in the linked HES.

2.3.2.3 Comparator

Women who did not have GDM (as defined in section 2.3.2.2 above), comprised the comparator group.

2.3.2.4 Outcomes

The primary outcome of interest was a new occurrence (incidence) of total CVD. Secondary outcomes of interest were incidence of fatal CVD, non-fatal CVD, incidence of diabetes, hypertension, dyslipidaemia, as well as all-cause mortality. All outcomes were defined as primary or secondary

events by combining self-reported data, with data from HES and death registry where applicable, linked to the UK Biobank (**Table 2.1**).

Table 2.1. Definition of outcomes in UK Biobank analysis

Outcome	Definition and source
CVD	Any of the following: - Reporting diagnosis of heart attack, angina, or stroke by a physician. (Touchscreen or verbal interviews) - HES: total CVD was defined as a hospital admission/episode or death with ICD-10 codes including coronary heart disease (I20-I25), congestive heart failure or cardiomyopathy (I50, I50.1, I50.9, I11.0, I13.0, I13.2, I42, I43.1), and total stroke (I60-I64). - Fatal CVD events were defined by I00–I25, I27–I88, and I95–I99 in any of the causes of death in the ONS death record.
Diabetes	Any of the following: - Reporting diabetes diagnosis by a physician. (Touchscreen or verbal interviews) - Reporting insulin use. (Touchscreen questionnaire) - Reporting metformin use. (Verbal interviews) - HbA1c measurement at the assessment centre, of 48 mmol/L and above (proxy). - HES: hospital admission/episode with ICD-10 codes for insulin-dependent diabetes (E10.0-E10.9), non-insulin dependent diabetes (E11.0-E11.9), malnutrition-related diabetes (E12.0-E12.9), other specified diabetes (E13.0-E13.9), unspecified diabetes (E14.0-E14.9), pre-pregnancy type 1 diabetes (O24.0), pre-pregnancy type 2 diabetes (O24.1), pre-pregnancy malnutrition-related diabetes (O24.2), and pre-pregnancy unspecified diabetes (O24.3).
Hypertension	Any of the following: - Reporting high blood pressure diagnosis by a physician. (Touchscreen or verbal interviews) - Reporting blood pressure lowering medication use. (Touchscreen) - Systolic blood pressure measurement at the assessment centre, of 140 mmHg or more, and/or diastolic blood pressure measurement of 90 mmHg or more (average of two measurements for each – proxy). - HES: hospital admission/episode using ICD-10 code including essential (primary) hypertension (I10).

Table 2.1. continued

Dyslipidaemia	Any of the following: - Reporting cholesterol lowering medication use. (Touchscreen) - Reporting high cholesterol diagnosis by a physician. (verbal interviews) - Biomarkers at assessment centre: total cholesterol (TC) >5 mmol/L, or High Density Lipoprotein (HDL) cholesterol <1.2 mmol/L, or Low Density Lipoprotein (LDL) cholesterol >3 mmol/L, or non-HDL (TC minus HDL) >4 mmol/L, or non-fasting triglycerides (TGL) >2.3 mmol/L, or TC/HDL ratio >6 mmol/L (276). - HES: hospital admission/episode with ICD-10 code E78.0-E78.9 (disorders of lipoprotein metabolism and other lipidaemias).
All-cause mortality	Ascertained from ONS death records.

CVD: cardiovascular disease; **HES:** hospital episode statistics; **ONS:** Office for National Statistics; **ICD-10:** International Classification of Diseases, 10th version

2.3.3 Statistical analysis

2.3.3.1 Participant characteristics

I analysed participant characteristics using descriptive statistics. I explored the normality of continuous variables with the sktest for skewness and kurtosis, and histograms. I report the mean and standard deviation (SD) for normally distributed continuous variables, and for non-normally distributed variables, I also provide the median and interquartile range (IQR). I used proportions to report categorical variables. Since collection of data for the UK Biobank happened after enrolment into the study, typically several years after most women had first given birth, most of these characteristics do not correspond to the exposure time point (which I defined as the first birth), but to a time point later in life (2006-2010). Demographic characteristics of participants at enrolment into the UK Biobank are displayed in **Table 2.2**.

2.3.3.2 Associations between GDM and outcomes of interest

2.3.3.2.1 Identifying variables for which to adjust models

To guide my analysis, I created Directed Acyclic Graphs (DAGs) for the associations between GDM and each outcome of interest using the software DAGitty. This allowed me to identify variables that may act as confounders, or are in the confounding pathway in the observed associations. For the main

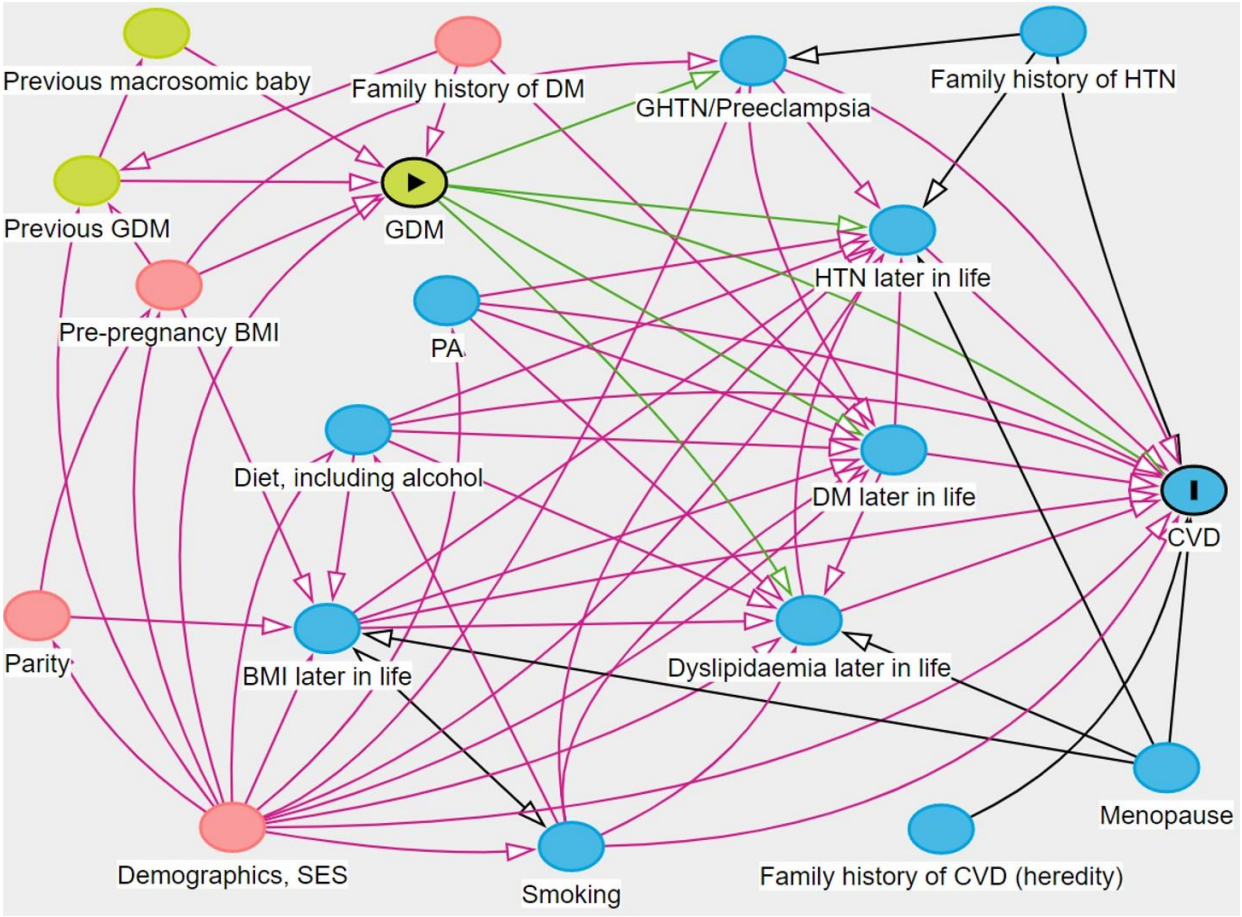
outcome (CVD) this is shown in **Figure 2.1** and for other outcomes, in **Appendices 2.1-2.4**. These graphs display assumptions about causal relationships between variables. Causality was assumed if a relationship were supported by evidence from RCTs, and the existence of a plausible mechanism explaining it, or, since most of the evidence comes from observational studies, from the existence of consistent observational evidence, and a proposed or hypothesised mechanism which could explain a causal relationship. I then used the DAGs to determine for which variables to adjust my models.

Some variables for which I decided to adjust my models, may not be true confounders, however, they were included if they were in the confounding pathway, or if they are risk factors for the outcome of interest. In addition, it is the principle of observational cohort studies to adjust for plausible confounding variables that are collected at the point of exposure. In my cohort, data collection happened after enrolment in the UK Biobank, so in most cases a long time after GDM (exposure) may have occurred. However, I still adjusted for these variables (e.g. BMI and lifestyle factors later in life), because there is evidence that they may influence the outcomes of interest (277-281), and may explain some of the residual confounding.

Missing data in categorical variables were coded as "unknown" and entered as a separate category, with exceptions for gestational hypertension/preeclampsia, where missing data were assumed to mean no occurrence of the condition. All analyses were adjusted for ethnicity (White, Black, Asian, all others), Townsend index of deprivation (a composite measure of deprivation based on unemployment, non-car ownership, non-home ownership, and household overcrowding, categorised in quintiles 1-5, with higher scores indicating more deprivation) (282), education group (higher degree, any school degree or vocational qualification , unknown), smoking status (never, current, previous, unknown), physical activity (meeting recommendations, not meeting recommendations, unknown), fruit and vegetable consumption (meeting 5 portions a day, not meeting 5 portions a day, unknown), saturated fat intake (none, low, moderate, high, unknown), alcohol consumption (none, occasional, moderate, heavy, unknown), BMI group (underweight,

healthy weight, overweight, obesity class I, obesity classes II & III, unknown), and self-reported number of live births as a proxy of parity (Touchscreen questionnaire only, because HES data were very limited). Especially for the number of births, I decided to adjust for it in the models, because, although for practical purposes I determined the entry point for all women as the first birth, which means any subsequent births would not be relevant to the exposure, in reality, some GDM cases may have happened at subsequent pregnancies, and also the number of births a woman has had is in the confounding pathway for outcomes (e.g. Figure 2.1). In addition to the above main variables, I also adjusted for self-reported family histories and menopausal status where relevant. For more details on the definition of all confounders, see footnotes of DAGs in **Figure 2.1 & Appendices 2.1-2.4**, and for details on their derivation, see **Appendix 2.5**.

Figure 2.1. Directed Acyclic Graph for the association between GDM and the risk of incident CVD



Variables for which I decided to adjust (either true confounders, or in the confounding pathway):

Population demographics:

- **Age** (Touchscreen and HES maternity): age when had first child
- **Ethnicity** (Touchscreen): White vs Black vs Asian vs Other (mixed, other, not recorded)

Socioeconomic status:

- **Townsend score** calculated for individual participants: quintiles 1-5, plus unknown
- **Education** (Touchscreen): higher degree (college, university or professional degree/qualification) vs any school degree or vocational qualification (A-level, AS-level, O-level, GCSE, CSE, NVQ, HND or HNC) vs unknown

***Family history* of CVD, diabetes, HTN** (Touchscreen): no vs yes vs unknown

NB1. Black arrows for family history of CVD and HTN, but still adjusted for, because family history of heart or circulatory diseases affects the outcome (283).

Health behaviours:

- **Smoking** (Touchscreen): never vs previous (ex-smoker) vs current vs unknown
- **Physical activity** (Touchscreen): meeting vs not meeting the recommendations for at least 150 minutes of moderate activity or at least 75 minutes of vigorous activity per week (284), based on MET score, vs unknown
- **Dietary intake** (Touchscreen):
    - **Fruit and vegetable intake:** meeting vs not meeting the recommendation of 5 portions of fruit and vegetable per day (285), vs unknown
    - **Saturated fat intake:** none vs low (less than once week) vs moderate (1-4 days/week) vs high (5 days per week or more), based on frequency of saturated fat intake from beef, pork, lamb, cheese, and spreads, vs unknown
    - **Alcohol consumption:** none vs occasional (<1 unit/week) vs moderate (1-14 units/week), heavy (>14 units/week) (286), vs unknown

  NB2. These dietary factors were selected because of evidence for their role in the development of CVD, and/or HTN, diabetes, and mortality (287-290).

Physical factors and medical conditions:

- **BMI group** (average of height and weight measurements across assessment time points): underweight (<18.5 kg/m^2) vs healthy weight (18.5 to <25 kg/m^2) vs overweight (25 to <30 kg/m^2) vs obese I (30 to <35 kg/m^2) vs obese II & III (35+ kg/m^2) vs unknown
- **GHTN or Preeclampsia:** no vs yes
    - Not available from Touchscreen questionnaire
    - Coded as combined GHTN-Preeclampsia in verbal interviews
    - HES: hospital admission/episode for pregnancy-induced hypertension without significant proteinuria (ICD-10: O13) or pregnancy-induced hypertension with significant proteinuria (ICD-10: O14.0-O14.9)
- **Number of live births** (Touchscreen): as proxy of parity
- **Menopausal status** (Touchscreen): no vs yes vs unknown

NB3. Pre-pregnancy BMI was not available.
NB4. Black arrows for menopause, but still adjusted for, because of consistent evidence that it affects the outcome (291).
NB5. Although GHTN/Preeclampsia has a green arrow, it usually happens around the same time as the exposure (GDM), therefore, was adjusted for in the main model, rather than being explored as mediator.

<u>Inferred potential mediators:</u>

- Incident DM (DM later in life)
- Incident HTN (HTN later in life)
- Incident Dyslipidaemia (Dyslipidaemia later in life)

GDM: gestational diabetes mellitus; **CVD:** cardiovascular disease; **DM:** diabetes mellitus; **BMI:** body mass index; **SES:** socioeconomic status; **PA:** physical activity; **GHTN:** gestational hypertension; **HTN:** hypertension; **HES:** hospital episode statistics; **A-level:** advanced level; **AS-level:** advanced subsidiary level; **O-level:** ordinary level; **GCSE:** general certificate of secondary education; **CSE:** certificate of secondary education; **NVQ:** national vocational qualification; **HND:** higher national diplomas; **HNC:** higher national certificates; **MET:** metabolic equivalent of task; **HES:** hospital episode statistics

2.3.3.2.2 Testing the associations

For the analysis of each separate outcome, I excluded participants for whom the outcome occurred at an age younger or equal to maternal age at first birth. This ensured that for each separate analysis, the remaining, were incident postpartum cases for each outcome.

I used multivariate Cox proportional hazard models with age (years) as the underlying time covariate, to obtain HRs with 95% CIs, for having had history of GDM compared to no history of GDM. I created nested models by sequentially adjusting for the variables I identified in the previous section. I assessed the proportional hazards assumption using Schoenfeld residuals' plots for the exposure (GDM), and it was not violated. Person-time follow-up was calculated from the age at first birth for all participants (considered as the age becoming "at risk"), until the age at which the outcome of interest happened, or death from any cause (latest available data on 30th September 2021 for England and Wales, and 31st October 2021 for Scotland), or the end of censoring (30th September 2021 for England, 31st July 2021 for Scotland, and 28th February 2018 for Wales), whichever happened first. For people who developed an outcome of interest, if there was no age at which it occurred, I used the age of interview or questionnaire completion as the age of occurrence, which was the age at which participants attended the assessment centre.

2.3.3.2.2.1 Mediation analysis

To further explore the association of GDM with the main outcome (total CVD), I used the DAG (**Figure 2.1**) to identify potential mediators underlying the association. Because I sought to explore incident diabetes, hypertension, and dyslipidaemia later in life as mediators, this mediation analysis also further excluded women with pre-pregnancy hypertension and dyslipidaemia (pre-pregnancy diabetes was anyway excluded since defining the eligible cohort). Incident diabetes, hypertension, and dyslipidaemia that developed prior to CVD, were added stepwise into the main model, and an additional model was fitted including all potential mediators.

2.3.3.2.2.2 Interaction analysis

I also fitted multiplicative interaction terms in the final model to examine heterogeneity in the association of GDM with total CVD, by development of incident diabetes, HTN, dyslipidaemia, as well as by age group, self-reported ethnicity, and BMI group. I calculated likelihood ratios to determine P values for heterogeneity without correction for multiple testing.

2.3.3.2.2.3 Sensitivity analysis

Finally, since data collection happened when participants were older, the outcomes of interest may have occurred before enrolment into the study, and thus data on variables for which I adjusted my models may refer to a time point after outcome occurrence, which can bias the results. I therefore, conducted sensitivity analyses excluding participants who developed an outcome of interest (except for all-cause mortality) after pregnancy but before enrolment to the UK Biobank, to explore whether it affected the effect estimates.

All analyses were conducted using Stata (version 16; StataCorp LP). A two-sided P value of <0.05 was defined as statistically significant.

2.4 Results

2.4.1 Participant characteristics

From the initial sample of 273,325 female participants in the UK Biobank, a total of 220,726 comprised the eligible cohort. The participant flow is in **Appendix 2.6**. **Table 2.2** presents the characteristics of the cohort. Women gave birth on average in their mid- to late twenties, the majority were White (94.4%), and had a median (IQR) BMI of 26.2 (6.2) kg/m^2. Compared to women without GDM, more women with GDM lived in areas of greater socio-economic deprivation. A greater proportion of women with GDM reported family history of diabetes, but a lower proportion of them reported family history of CVD, compared to women without GDM. Women with GDM also had greater prevalence rates of obesity, gestational hypertension or preeclampsia, but lower rates of menopause than women without GDM. Differences in health behaviours between women with and without GDM were

generally subtle. More women with GDM reported never having smoked, but fewer of them reported meeting physical activity recommendations, compared to women with no GDM. Although heavy alcohol intake rates were lower in women with GDM than women without GDM, women with GDM had largely missing information about alcohol consumption.

Table 2.2. Characteristics of participants with and without history of GDM in the UK Biobank

	Total (N=220,726)	GDM (n=1,225)	no GDM (n=219,501)
Demographics			
Age at first birth (years)			
Mean (±SD)	25.9 (±5.2)	27.7 (±6.2)	25.9 (±5.1)
Median (IQR)	25.0 (7.0)	27.0 (9.0)	25.0 (7.0)
Ethnicity (%)			
White	94.4	82.1	94.5
Black	1.7	4.0	1.7
Asian	2.1	9.0	2.0
Other (mixed, other, unknown)	1.8	4.9	1.8
Socioeconomic status			
Townsend index (quintiles) (%)			
Q1	19.9	17.7	20.0
Q3	20.0	18.3	20.0
Q5	20.0	28.3	19.9
Unknown	0.1	0.3	0.1
Education group (%)			
Any school degree or vocational qualification (A-level, AS-level, O-level, GCSE, CSE, NVQ, HND, HNC)	36.0	35.8	35.9
Higher degree (college, university or professional degree/qualification)	44.0	47.3	44.0
Unknown	20.0	16.9	20.1
Family history (%)			
CVD	62.5	57.9	62.5
Diabetes	20.2	42.5	20.0
Hypertension	41.4	40.3	41.4
Physical factors and medical conditions			
BMI (kg/m^2)			
Mean (±SD)	27.1 (±5.1)	29.2 (±6.0)	27.1 (±5.1)
Median (IQR)	26.2 (6.2)	28.1 (7.7)	26.2 (6.2)
BMI group (%)			
Underweight (<18.5)	0.7	0.2	0.7
Healthy weight(18.5 to <25)	37.7	24.8	37.7
Overweight (25 to <30)	37.6	36.7	37.6
Obese I (30 to <35)	15.9	21.7	16.0
Obese II & III (35+)	7.7	15.8	7.7
Unknown	0.4	0.7	0.4
Gestational hypertension/preeclampsia (%)	1.1	4.1	1.1

Table 2.2. continued

	Total (N=220,726)	GDM (n=1,225)	no GDM (n=219,501)
Physical factors and medical conditions			
Menopausal status (%)			
Yes	65.1	44.7	65.3
Unknown	0.1	0.4	0.1
Live births			
Mean (±SD)	2 (±1)	3 (±1)	2 (±1)
Median (IQR)	2 (1)	2 (1)	2 (1)
Incident CVD (%)			
Total	12.2	14.8	12.2
Fatal	1.5	2.2	1.5
Incident diabetes (%)	13.9	90.8	13.5
Incident hypertension (%)	52.4	55.4	52.4
Incident dyslipidaemia (%)	85.1	81.4	85.2
All-cause mortality (%)	5.6	5	5.6
Health behaviours			
Smoking (%)			
Never	59.2	63.7	59.2
Previous	31.9	27.4	32.0
Current	8.5	8.4	8.5
Unknown	0.4	0.5	0.4
Physical activity (%)			
Not meeting recommendations	48.2	54.6	48.1
Meeting recommendations	47.8	41.5	47.9
Unknown	4.0	3.9	4.0
Dietary intake (%)			
Fruit & vegetables			
Not meeting recommendations	64.7	65.9	64.7
Meeting recommendations	35.1	33.8	35.2
Unknown	0.1	0.3	0.1
Saturated fat intake group			
None	0.2	0.1	0.2
Low (<1 day/week)	47.2	48.5	47.2
Moderate (1-4 days/week)	22.0	20.9	22.0
High (>=5 days/week)	30.6	30.4	30.6
Unknown	0.0	0.1	0.0
Alcohol group			
Occasional (<1 unit/week)	7.0	10.8	7.0
Moderate (1-14 units/week)	37.4	30.9	37.4
Heavy (>14 units/week	29.5	22.3	29.5
Unknown	26.1	36.0	26.0

Table 2.2. continued

GDM: gestational diabetes mellitus; **SD:** standard deviation; **IQR:** interquartile range; **CVD:** cardiovascular disease; **Q1/Q2/Q3:** quintiles; **A-level:** advanced level; **AS-level:** advanced subsidiary level; **O-level:** ordinary level; **GCSE:** general certificate of secondary education; **CSE:** certificate of secondary education; **NVQ:** national vocational qualification; **HND:** higher national diploma; **HNC:** higher national certificate; **BMI:** body mass index

The time point at which each of these data refer to, are detailed in **Appendix 2.5**, because some data were collected only at enrolment, while other data were collected with repeated assessments at different time points which I combined (e.g. taking the average among time points of assessment), or sometimes I needed to only use the data from the most recent assessment time point.

2.4.2 Follow-up

In the total cohort, the median (IQR) follow-up period for incident CVD risk factors was 34 (15) years for diabetes and hypertension, and 33 (14) years for dyslipidaemia. A total of 30,727 developed incident diabetes, 115,691 developed incident hypertension, and 187,967 developed incident dyslipidaemia since first giving birth. The follow-up period for incident total CVD was 40 (16) years, for incident fatal CVD 49 (10 years), and for all-cause mortality, 47 (11) years. A total of 12,439 participants died during follow-up. Of these, 3,292 were deaths from CVD.

Comparing women with and without GDM, most women with GDM developed subsequent diabetes (90%), and the proportion developing hypertension, dyslipidaemia and CVD was higher in these women (**Table 2.2**). Incident diabetes, hypertension, and dyslipidaemia were diagnosed within mean (range) 23 (1-57), 25 (1-58), and 24.7 (1-59) years since first giving birth respectively in women with GDM, while total CVD developed within average 33 (1-63) years, and death occurred on average 44.1 (9-61) years later. In women without GDM, incident diabetes, hypertension, and dyslipidaemia developed later than in women with GDM, and more specifically, within mean (range) 33.6 (1-64), 33 (1-67), and 31.5 (1-67) years since first birth respectively, while total CVD developed within average 39.3 (1-65) years, and death occurred within average 45.8 (4-65) years.

2.4.3 Association between GDM and outcomes of interest

GDM was associated with a 50% increased risk for total CVD, 41% increased risk for non-fatal CVD, and more than twice the risk of a CVD-related death, in the fully adjusted model (Model 6, **Table 2.3**). The associations between GDM and CVD outcomes were attenuated after including socioeconomic

factors, and further by inclusion of BMI in the model. Sensitivity analysis excluding participants who developed CVD after pregnancy but before recruitment to the UK Biobank (n=8,895), did not materially change the association of GDM with total CVD (HR 1.50, 95% CI 1.24 to 1.82, **Appendix 2.7**).

Table 2.3. Associations between GDM and hard outcomes

	All CVD†	Fatal CVD†	non-fatal CVD†	All-cause mortality§
Model 1: minimally adjusted (age underlying time covariate)				
GDM	1.89 (1.63-2.18)	2.84 (1.95-4.15)	1.77 (1.51-2.08)	1.58 (1.23-2.03)
Model 2: Model 1 + sociodemographics*				
GDM	1.77 (1.53-2.05)	2.70 (1.85-3.95)	1.66 (1.41-1.94)	1.54 (1.20-1.98)
Model 3: Model 2 + family history of CVD, diabetes, and hypertension				
GDM	1.73 (1.50-2.01)	2.68 (1.83-3.92)	1.62 (1.38-1.90)	1.53 (1.19-1.97)
Model 4: Model 3 + BMI				
GDM	1.57 (1.36-1.82)	2.48 (1.70-3.62)	1.47 (1.26-1.73)	1.48 (1.15-1.90)
Model 5: Model 4 + health behaviours**				
GDM	1.56 (1.35-1.81)	2.42 (1.65-3.54)	1.46 (1.25-1.72)	1.46 (1.14-1.88)
Model 6: Model 5 + pregnancy-related factors^‡				
GDM	1.50 (1.30-1.74)	2.38 (1.63-3.48)	1.41 (1.20-1.65)	1.44 (1.12-1.86)

GDM: gestational diabetes mellitus; **CVD:** cardiovascular disease; **BMI:** body mass index

Adjusted hazard ratios and 95% confidence intervals of GDM obtained using Cox proportional hazard regression, and likelihood ratio tests. Age at risk adjusted for by using age as the underlying timescale variable for Cox regression.

† Women with at least one birth, without pre-pregnancy diabetes, and without pre-pregnancy CVD (n=220,581).
§ Women with at least one birth, without pre-pregnancy diabetes (N=220,726).

* Sociodemographic characteristics: ethnicity, Townsend index of deprivation, education
** Behavioural risk factors: smoking, fruit & vegetable intake, saturated fat intake, physical activity, and alcohol intake
^ Pregnancy related factors: gestational hypertension/preeclampsia, number of live births (proxy for parity), and menopausal status

‡ Full model adjusted for age, sociodemographics, family history of CVD, diabetes and hypertension, BMI, behavioural risk factors, and pregnancy-related factors.

In mediation analyses, the addition of diabetes, hypertension, and dyslipidaemia to the fully adjusted model (Model 6), individually or simultaneously, did not attenuate the association between GDM and total CVD (**Figure 2.2**). A significantly higher risk of total CVD was observed among women with GDM who did not develop diabetes later in life (HR 5.55, 95% CI 4.20 to 7.34), compared to

women who developed diabetes (HR 1.22, 95% CI 1.02 to 1.46) (**Figure 2.3**). Although there were no further significant interactions due to wide 95% CIs, results suggested a similar pattern where GDM led to a greater increase in CVD risk factors and at a younger age than in women who did not later develop hypertension or dyslipidaemia. In addition, I observed a pattern of GDM affecting the risk of CVD to a lesser extent for older women, those with higher BMI and non-White ethnicity (**Figure 2.3**).

Figure 2.2. Association between GDM, and the risk of total cardiovascular disease, further adjusted for potential mediators



GDM: gestational diabetes mellitus; **CVD:** cardiovascular disease; **HR:** hazard ratio; **95% CI:** 95% confidence interval

Women with at least one birth, without pre-pregnancy diabetes, without pre-pregnancy CVD, and without pre-pregnancy hypertension and dyslipidaemia (n=216,278).

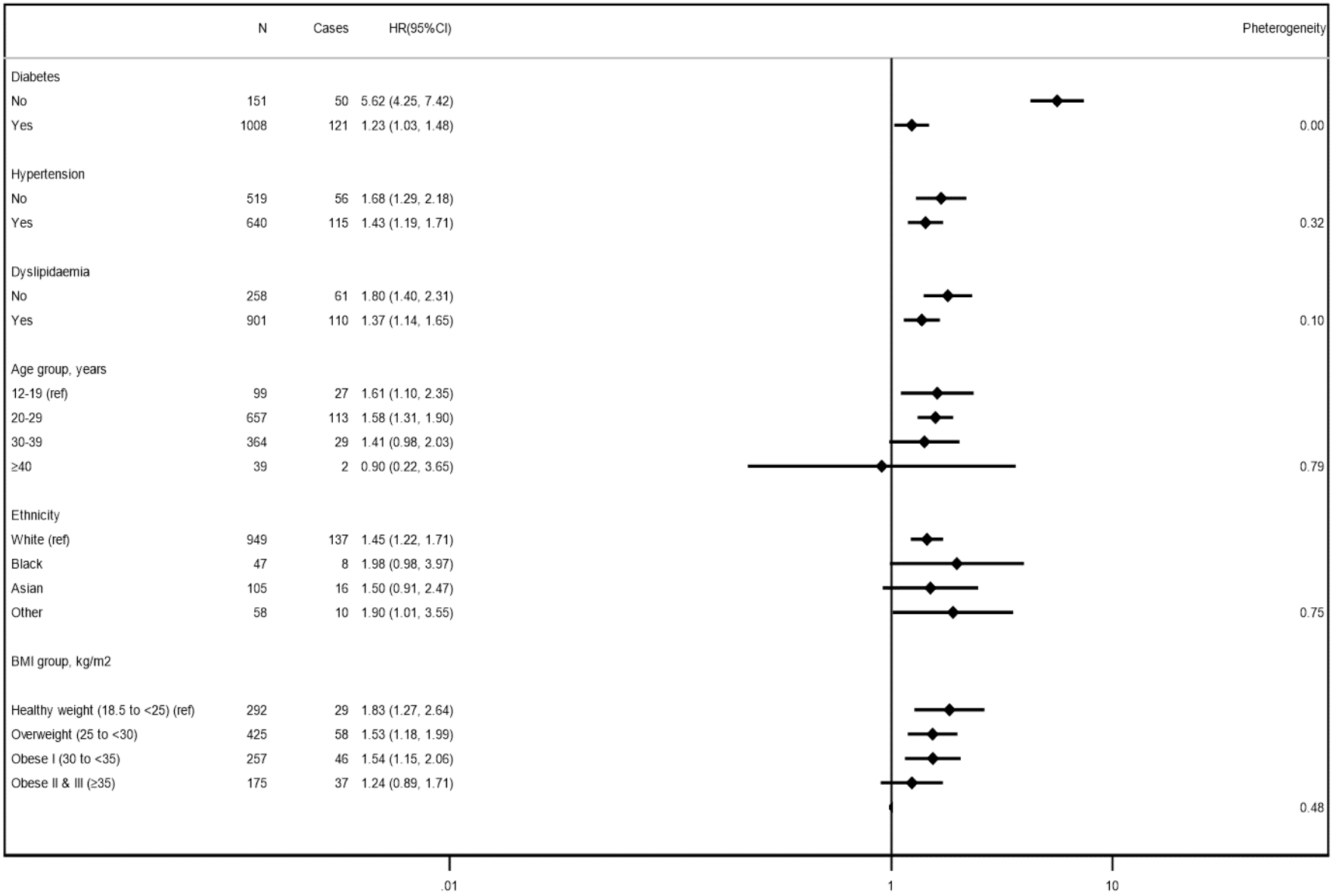
All models were adjusted for age (underlying timescale variable), sociodemographics (ethnicity, Townsend index of deprivation, education), family history (CVD, diabetes, and hypertension), behavioural risk factors (smoking, fruit & vegetable intake, saturated fat intake, physical activity, and alcohol intake), and pregnancy-related factors (gestational hypertension/preeclampsia, number of live births, and menopausal status).

Diabetes, hypertension and dyslipidaemia, all refer to incident cases after first birth. For the mediation analysis, these conditions were not considered as present if their diagnosis or first reporting happened after developing CVD (i.e. if age of first diagnosis/reporting of diabetes, hypertension, dyslipidaemia was higher than the age of first diagnosis/reporting of CVD).

All potential mediators included incident diabetes, hypertension, and dyslipidaemia together added to the main model.

P values were calculated by likelihood ratio test each time a potential mediator was added to the main model and when all potential mediators were added together. All P values were <0.0001.

Figure 2.3. Association between GDM, and the risk of total cardiovascular disease, by morbidity, age group, ethnicity, and BMI group



GDM: gestational diabetes mellitus; **CVD:** cardiovascular disease; **BMI:** body mass index; **HR:** hazard ratio; **95% CI**: 95% confidence interval
N: number of participants with gestational diabetes in each category of morbidity, age, ethnicity, and BMI
Cases: number of participants with gestational diabetes plus cardiovascular disease, in each category of morbidity, age, ethnicity, and BMI

Women with at least one birth, without pre-pregnancy diabetes, without pre-pregnancy CVD, and without pre-pregnancy hypertension and dyslipidaemia (n=216,278).

Cox proportional hazards models for risk of incident total CVD, by morbidity (incident diabetes, hypertension, dyslipidaemia), age group, ethnicity, and BMI group. Diabetes, hypertension and dyslipidaemia, all refer to incident cases after first birth. For the interaction analysis, diabetes, hypertension, and dyslipidaemia were not considered as present if their diagnosis or first reporting happened after developing CVD (i.e. if age of first diagnosis/reporting of diabetes, hypertension, dyslipidaemia was higher than the age of first diagnosis/reporting of CVD).

Hazard ratios were calculated using the fully adjusted model (Model 6), and likelihood ratio tests were calculated to determine Pheterogeneity without correction for multiple testing.

Not showing underweight and unknown for BMI, as only a few people included.

When exploring the association of GDM directly with each CVD risk factor, in the fully adjusted model (Model 6), women with GDM were 14 times more likely to develop diabetes later in life, compared to women without GDM. GDM was also associated with 49% and 30% increased risk for incident hypertension and dyslipidaemia respectively (**Table 2.4**). After excluding participants who developed each of these morbidities after pregnancy, but before enrolment into the UK Biobank in the sensitivity analysis, the risk of developing diabetes increased (almost 20-fold), the absolute risk decreased slightly for hypertension, and substantially for dyslipidaemia, although remained significant (**Appendix 2.8**).

Finally, in the time women were followed-up after pregnancy, those with a history of GDM had 44% increased risk for all-cause mortality in the fully adjusted model, with 95% CI 1.12 to 1.86 (Model 6, **Table 2.3**).

Table 2.4. Associations between GDM and incident diabetes, hypertension, and dyslipidaemia

Outcomes	Diabetes†	Hypertension§	Dyslipidaemia¶
Model 1: minimally adjusted (age underlying time covariate)			
GDM	20.38 (19.18-21.65)	1.76 (1.64-1.90)	1.48 (1.39-1.57)
Model 2: Model 1 + sociodemographics*			
GDM	17.74 (16.69-18.85)	1.70 (1.58-1.83)	1.44 (1.35-1.53)
Model 3: Model 2 + family history**			
GDM	16.22 (15.26-17.24)	1.65 (1.53-1.78)	1.41 (1.33-1.50)
Model 4: Model 3 + BMI			
GDM	14.44 (13.58-15.35)	1.52 (1.41-1.64)	1.39 (1.31-1.48)
Model 5: Model 4 + health behaviours††			
GDM	14.32 (13.47-15.22)	1.52 (1.41-1.64)	1.39 (1.31-1.48)
Model 6: Model 5 + pregnancy-related factors^‡			
GDM	14.37 (13.51-15.27)	1.49 (1.38-1.60)	1.30 (1.22-1.39)

GDM: gestational diabetes mellitus; **BMI:** body mass index

Adjusted hazard ratios and 95% confidence intervals of GDM obtained using Cox proportional hazard regression, and likelihood ratio tests. Age at risk adjusted for by using age as the underlying timescale variable for Cox regression.

† Women with at least one birth, without pre-pregnancy diabetes (N=220,726).
§ Women with at least one birth, without pre-pregnancy diabetes, and without pre-pregnancy hypertension (n=216,603).
¶ Women with at least one birth, without pre-pregnancy diabetes, and without pre-pregnancy dyslipidaemia (n=220,498).

* Sociodemographic characteristics: ethnicity, Townsend index of deprivation, education
** Family history: cardiovascular disease, diabetes, hypertension, where applicable
†† Behavioural risk factors: smoking, fruit & vegetable intake, saturated fat intake, physical activity, and alcohol intake
^ Pregnancy related factors: gestational hypertension/preeclampsia, number of live births, and menopausal status

‡ Full model adjusted for age, sociodemographics, family history (of diabetes for incident diabetes outcome; of diabetes and hypertension for incident hypertension outcome; of diabetes for incident dyslipidaemia outcome; and of cardiovascular disease, diabetes, and hypertension for all-cause mortality outcome), BMI, behavioural risk factors, and pregnancy-related factors (number of live births for incident diabetes outcome; number of live births, gestational hypertension/preeclampsia and menopause for incident hypertension outcome; number of live births and menopause for incident dyslipidaemia outcome; and all factors for all-cause mortality outcome).

2.5 Discussion

2.5.1 Main findings

In this retrospective cohort study utilising a large UK database, women with a history of GDM had a significantly greater risk of premature death, compared to women without GDM. Their risk of CVD

was increased, and incident common CVD risk factors (diabetes, hypertension, and dyslipidaemia) were all significantly increased later in life, though there was no evidence that these risk factors mediated CVD incidence. Sensitivity analysis excluding people who developed CVD and CVD risk factors after pregnancy, but before enrolment into the study, did not materially change the results. Exploratory interaction analyses suggested that GDM had greater adverse effect on CVD risk in women who did not develop diabetes, compared with those who did develop diabetes later in life. Other interaction analyses did not reach statistical significance, but they were suggestive of GDM having a greater impact on CVD outcomes among women with a more favourable CVD risk profile (no hypertension, no dyslipidaemia, younger age, lower BMI).

2.5.2 GDM increases the risk of incident CVD risk factors and CVD events

In recent years, a number of observational studies have reported an increased risk of CVD in women who develop GDM, compared with women who do not develop GDM (46). My study found that women with GDM had 50% increased risk of CVD compared with women without GDM, which is similar, but higher to the effect reported in the most recent systematic review available, reporting 45% increased risk (47). However, the latter was reported as a RR and not as a HR as in my study, which takes into account the time to event. Since publishing the protocol of this study, a similar analysis of the UK Biobank has been reported (263). This showed smaller increase in the risk of total CVD (HR 1.36, 95% CI 1.18 to 1.55), however, the definitions of the cases with GDM, CVD, and CVD risk factors, and time of follow-up differed from my study, and were less inclusive (263). More specifically, in the main analysis, the authors defined GDM only from women who developed GDM before enrolment in the UK Biobank, while I defined the exposed population based on whether they ever had GDM, including those who gave birth after enrolling into the UK Biobank, recognising that increasing maternal age is a risk factor for GDM (292). That said, participants were already at least 40 years old when they joined the UK Biobank, and thus, the majority of them had already given birth by the time point of enrolment. In addition, in the main analysis, this recent study defined the index date as the time of enrolment in the UK Biobank, whereas in my analysis, the index date was considered

the time point when the population became at risk, i.e. first pregnancy/birth. As a result, the follow-up period in my study was much larger for total CVD (40 years vs 10 years). In a secondary analysis, the authors of this study explored a longer-term risk for CVD for a sub-sample of participants for whom age at index pregnancy was available, defined as age at pregnancy affected by GDM for cases, or first pregnancy for non-cases (263), and reported that GDM was associated with a 2-fold risk of developing total CVD, similar to a previous systematic review (46). In contrast, as discussed in the limitations, I could not determine the age at which women had a pregnancy affected by GDM, due to the nature of questions asked about pregnancy, diabetes, and timings of these in the UK Biobank. As a result, for all women, I defined index pregnancy as the age when they give birth for the first time. However, despite some differences, the prevalence of GDM was similar in both studies, and both studies came to the same conclusion that GDM is associated with a significantly increased risk of CVD.

It is known that women who develop GDM, are also likely to display a cluster of CVD risk factors, such as high blood pressure, low levels of HDL-cholesterol, and increased levels of atherogenic cholesterol, some of which are explained by the presence of obesity (293, 294). Differences in the cardio-metabolic risk profile between women who develop GDM, and those who do not, may be present already before pregnancy, and become more pronounced after development of GDM (295). Several studies have shown evidence of increased CVD risk factors as early as 3 months post-partum (293, 294, 296), suggesting that women may have been exposed to increased risk for a long period of time (294, 297), and pregnancy, or a diagnosis of GDM, presented an opportunity where it was identified (298). In my cohort, mostly, women who developed GDM also developed one or more CVD risk factors later in life, including diabetes, hypertension, and dyslipidaemia. My analysis of these secondary outcomes is consistent with previous studies showing higher risk of later onset diabetes, hypertension, and dyslipidaemia, in women with history of GDM, compared with their peers who do not develop GDM, although the magnitude of the estimates varied between studies. For example, a retrospective cohort study using primary care data from the UK, found slightly larger risk for incident T2DM (incident risk ratio [IRR] 21.96, 95% CI 18.31 to 26.34), and substantially higher risk for

hypertension (IRR 1.85, 95% CI 1.59 to 2.16), over a period of 26 years follow-up (43). Longitudinal follow-up in the Nurses' Health Study from the US, showed a 26% increased risk of developing hypertension in women with a history of GDM, compared to those without a history of GDM, during a 16-year follow-up, independent of gestational hypertension or subsequent T2DM (262). What is more, GDM is an independent positive predictor of an atherogenic lipid profile post-partum, but there is paucity of evidence from cohort studies on its impact on the risk of subsequent dyslipidaemia. In my analysis, GDM was associated with 30% increased risk for dyslipidaemia, but a recent nationwide cohort study in Denmark, showed a more than 4-fold risk for dyslipidaemia after pregnancy affected with GDM (299).

I found no evidence of any mediation from incident diabetes, hypertension, or dyslipidaemia, in the association of GDM with incident total CVD. Previous studies have reached different conclusions, with some suggesting that the effect of GDM on later CVD is entirely mediated by diabetes (262, 273, 300), and some partially (43, 258, 274, 301). In the latest systematic review and meta-analysis, when the analysis was restricted to women who did not subsequently develop diabetes, the risk of CVD was attenuated, but remained significant (all GDM: RR 1.45, 95% CI 1.33 to 1.59, vs GDM without subsequent diabetes: RR 1.09, 95% CI 1.06 to 1.13), suggesting substantial mediation from subsequent diabetes (47). No previous studies have examined the potential mediating effect of other CVD risk factors, such as hypertension and dyslipidaemia, apart from the recent similar UK Biobank analysis which examined the contribution of diabetes, hypertension, and dyslipidaemia to the observed CVD risk, and suggested that these risk factors explained 23%, 11%, and 10% of the impact of GDM on total CVD respectively (263). However, the authors of this study captured these CVD risk factors from self-reports at enrolment into the UK Biobank, or diagnoses before enrolment, without specifying whether they pertained to time points after index pregnancy (i.e. incident cases), and also disregarding the fact that these morbidities would also develop after enrolment into the study as people get older. In my mediation analysis, I only considered the CVD risk factors that

developed after pregnancy, until any point up to the outcome of interest (total CVD), in line with the essence of mediation.

In interaction analyses, I found that after adjusting for confounders, the impact of GDM on CVD risk was much higher in women with GDM who did not develop diabetes in later life, compared to those women with GDM who subsequently developed diabetes. It is possible that the low prevalence of GDM in this study (<1%), and the small number of women with GDM in each interaction analysis, may suggest a lack of power to detect statistically significant interactions. Nevertheless, the totality of evidence is suggestive of a pattern where the impact of a GDM-affected pregnancy on CVD risk was particularly increased in women with a more favourable cardio-metabolic phenotype, specifically, those who did not later develop hypertension and dyslipidaemia, and those in younger age groups, and with lower BMI. These findings suggest that by the time women are older, or have developed comorbidities, including excess weight gain, these risk factors may supersede the independent effect of GDM on CVD. The fact that women who appear metabolically healthy still comprise an at-risk population for CVD following a diagnosis of GDM, is consistent with previous studies (46, 47). While it is known that diabetes, hypertension and dyslipidaemia share common pathophysiology with CVD, the main point of these data suggests that, regardless of whether they later develop CVD risk factors, women with a history of GDM have a higher risk of CVD than those who do not develop GDM. The implications of this finding is that a history of GDM should be considered as an independent risk factor for CVD, and women should receive advice, regular screening for known CVD risk factors (not just diabetes), and prompt intervention to mitigate risks as required. Indeed, some independent pathways in the association of GDM and CVD may exist. Exposure to hyperglycaemia during a pregnancy even for a short period of time, can have persistent effects on the cardiovascular system, for example, endothelial dysfunction (e.g. coronary artery calcification, left ventricular hypertrophy). This can be exacerbated in the presence of an adverse cardio-metabolic risk profile such as obesity, high blood pressure, or dyslipidaemia, eventually leading to development of CVD even without progression to diabetes (302-304). It is unclear if GDM actively causes this high-risk

vascular profile, or if this profile already existed before pregnancy in some women, and it just happened to be first identified during pregnancy, or both, but regardless, this evidence reinforces the suggested inclusion of GDM as a risk factor for CVD in women.

2.5.3 GDM is associated with increased risk of all-cause mortality

To my knowledge, this is the first cohort study exploring the longitudinal association of GDM with all-cause mortality in women, as cohort studies to date have focused on perinatal mortality only (305). A recent nationwide register cohort study in Denmark (299), reported that women with cardiovascular and metabolic morbidity (CVMM) with a history of GDM, did not have greater risk for all-cause mortality compared to women with CVMM but no history of GDM (adjusted OR 0.9, 95% CI 0.7 to 1.1), which however could be explained by the fact that women with previous GDM were more likely to be diagnosed earlier with CVMM due to recommended follow-ups following a GDM diagnosis, and could have received appropriate treatment. In the current analysis, I found that GDM was associated with a substantially increased risk by 44% for all-cause mortality, after adjustment for potential confounders. Death from any causes occurred on average within 44 years after giving birth for the first time, with a range of 9 to 61 years later. However, there may be residual confounding for which I was not able to adjust. Therefore, future studies should explore further the independent association between GDM and long-term risk for all-cause mortality adequately adjusting for confounders, and examining potential mediating pathways.

2.5.4 Limitations

2.5.4.1 Small prevalence of GDM

The prevalence of GDM in this population was less than 1%, while the current expected prevalence of GDM in the whole of UK population is around 16% (41). This small prevalence, however, is not surprising. The prevalence of GDM has increased in the UK in recent years, partly due to secular trends in population characteristics, such as an increasing proportion of women of non-White ethnicity and higher BMI, or increasing age of pregnancy. In addition, the majority of women in the UK Biobank cohort were pregnant before the late 1990s. Before that time, women would be tested for GDM only

if there was clinical indication from their medical history and assessment, and thus, reported GDM prevalence was small at 1-2% (306). Subsequently, screening for GDM in the UK remained selective, but was based on a broader range of risk factors, including obesity, previous macrosomic baby, previous GDM, family history of diabetes, and ethnicity greatly affected by diabetes (59). Based on the latter screening process, the current prevalence detected is around 10-20% (307). In addition, there have been different diagnostic criteria for GDM over the years, with hospitals in the UK choosing on their own which criteria to use prior to 2008 (308), while since 2010, the IADPSG criteria were widely adopted (87), and more recently the NICE criteria (59). These transitions introduced lower diagnostic criteria thresholds for fasting glucose, which led to an increase in the number of women identified as at risk of adverse outcomes, and in wider variation in GDM prevalence (up to 24%) (41). In view of the above, there has been differential classification of hyperglycaemia over the course of the past decades, resulting not only in different prevalence of GDM, but also different management strategies, which may impact on a woman's later health outcomes. These changes are likely to mean that many cases of GDM in my cohort may have been undiagnosed, leading to an underestimation of the impact of GDM on CVD and other outcomes of interest.

One more consequence of the small prevalence of GDM in this study, is that the numbers of women who had GDM and an outcome of interest were limited, which reduced the statistical power of the results, and may have affected the mediation and interaction analyses.

2.5.4.2 Definition of the exposure (history of GDM) in the current analysis

In the UK, GDM is recorded in the maternity services dataset, which typically informs the recording in primary care records. The present analysis however, did not have license access to primary care records or maternity services dataset, therefore, history of GDM was ascertained mainly from self-reported data in the Touchscreen questionnaire and verbal interviews, and some limited data on diagnoses from the HES records using ICD-10 coding. Self-reporting may have introduced recall bias in the definition of the exposure, although there is evidence of good agreement between self-reported and medical record data for GDM (309). In addition, if participants indicated in the questionnaire that

they had diabetes and they were female, they were asked if they only had diabetes during pregnancy. For those who answered yes, this was recorded as GDM in this analysis. However, some participants may have answered no to this question, but this does not necessarily mean that they did not have GDM. For example, women with pre-pregnancy diabetes, and women with GDM who later also developed other type of diabetes (e.g. T2DM), would have both answered no to this question, and were analysed as part of the comparator group. To distinguish between these two scenarios, I would ideally identify the pregnancy affected by GDM, and compare the age/date of GDM first diagnosis/reporting, with the age/date of other diabetes first diagnosis/reporting. However, I could not define the GDM-affected pregnancy, because participants were not asked in the questionnaire about age of GDM diagnosis, and only reported the age when they had their first and last live birth. In verbal interviews, only about a quarter of the GDM participants remembered the year of their diagnosis, and in the HES records, the dataset contained limited information on maternal age at delivery, and since GDM does not normally require hospitalisation, there were limited ICD-10 codes for GDM. To address the above issues, and to define GDM history and timing for my analysis, instead of excluding diabetes cases that happened before the actual GDM-affected pregnancy, I excluded diabetes cases that happened before or at the age of the mother at first birth, which was available for the majority of the cohort. As a result, the entry time point at which the participants become "at risk" for the survival analyses, was the maternal age at first birth both for women with and without GDM, while for women with GDM it should have been the pregnancy affected by GDM. This may have underestimated even further the number of people classified as having a history of GDM.

2.5.4.3 Outcomes, confounders, and mediators

For people who developed an outcome of interest, if the age at which it occurred was missing from all possible sources, instead of dropping them, I used the age of interview/questionnaire completion as the age of occurrence, which was the age at which participants attended the assessment centre, in order to keep them in the analysis. This may have biased the time-to-event estimations, as it would have biased my study's entry time point.

I assessed the risk of each outcome of interest at a time point after the time of first birth for all participants, not after the index pregnancy for women with GDM. It would have been more appropriate to evaluate the incidence of each outcome after the index pregnancy (first birth for women without GDM, and GDM-affected pregnancy for women with GDM), and adjust for variables collected at the time of index pregnancy. However, the UK Biobank enrolled participants of older age, collecting data from enrolment and at instances after enrolment, and as a result, many variables for which I adjusted my models, were collected at a time point closer to the outcome, rather than my study's entry point. However, the included variables in the adjusted models significantly affect the outcome and may explain some residual confounding. With the exception of sociodemographic factors and BMI, other variables did not materially change the effect estimates. To reduce the potential bias induced by the time point at which data were collected, I conducted a sensitivity analysis excluding participants who developed an outcome after first pregnancy but before enrolment into the study, which did not materially change the results, however, showed an even greater adverse effect of GDM on the risk of developing subsequent diabetes.

Additionally, the majority of data on variables used for adjustments, and potential mediators (incident diabetes, hypertension, and dyslipidaemia) came from self-reported data, subject to recall or social desirability bias. Lastly, pre-pregnancy BMI, which is a major confounder, is not available in the UK Biobank, therefore, I could only adjust models with the BMI of participants later in life. However, there is evidence that history of GDM might be a CVD risk marker independent of pre-pregnancy obesity (310).

2.5.4.4 Other limitations

Like with GDM, the prevalence of gestational hypertension/preeclampsia in this population was very small at around 1%, while evidence shows that up to 10% of pregnancies are affected by hypertensive disorders, with preeclampsia alone affecting 3-5%, and gestational hypertension alone affecting 5-10% of pregnancies (311, 312). This could be again attributed to the increasing prevalence of risk factors in the population (e.g. older age of pregnancy, obesity), as well as changes in the screening

and diagnostic processes and criteria throughout the decades. Although gestational hypertension and preeclampsia have some common risk factors and some similar clinical manifestations, they are distinct in terms of pathophysiology, symptoms, and severity (313). The effect of preeclampsia on CVD risk has been reported as higher than that of gestational hypertension, and the two diseases may affect the risk for different types of CVD differently (314). In the UK Biobank dataset the two conditions are provided as a combined variable, which may have biased the effect of the variable gestational hypertension/preeclampsia in the observed associations.

It was not possible to infer from the data the number of pregnancies affected by GDM, thus future research should evaluate the impact of recurrent GDM on maternal health. Moreover, I cannot exclude reverse causation affecting the results. However, the average length of time between births and each outcome was many years, and I excluded cases with the outcome of interest happening prior to first birth. Finally, the results of this study may not be generalisable to the whole UK population, because participants in the UK Biobank have lower rates of obesity, are less likely to smoke, and drink alcohol, and are less likely to live in deprivation (315). Therefore, further research using a nationwide representative cohort is required to validate my findings.

2.5.5 Strengths

To my knowledge, this is the first population-based cohort study with a very long-term follow-up time period, which apart from the risk of incident CVD and diabetes, also quantified the less well documented risk of hypertension, dyslipidaemia, and importantly, all-cause mortality, following GDM. Since the UK Biobank enrolled participants of older age, and the current entry date (age at risk) was determined retrospectively, I was able to follow the eligible cohort for many years to quantify the long-term effect of GDM after pregnancy. For example, women in this cohort were followed-up for CVD risk for up to 65 years after their first birth. This is much longer compared to 10-26 years follow-up reported in previous studies (46, 47, 263). The UK Biobank dataset also enabled me to adjust for a variety of demographic, socioeconomic, anthropometric, and lifestyle factors, compared to previous studies. Ascertainment of CVD risk factors from a variety of sources (self-reported and HES data), in

combination with the large follow-up time, allowed me to explore potential mediations underlying the associations.

2.5.6 Conclusions, and implications for practice, and for this thesis

This study showed that women diagnosed with GDM have substantially increased risk for premature death compared to women without a history of GDM. GDM was also associated with very high risk of developing subsequent diabetes, and a significantly increased risk for development of hypertension, dyslipidaemia, and CVD. However, there was no evidence that the risk of CVD was explained by development of CVD risk factors later in life (diabetes, hypertension, dyslipidaemia). The adverse impact of GDM on CVD risk was higher in women with GDM who did not progress to diabetes, compared to those who developed diabetes later in life, and data were suggestive (but not statistically significant), of GDM affecting CVD risk to a greater extent in women with a healthier cardio-metabolic phenotype, who did not develop subsequent hypertension and dyslipidaemia, and those who were of younger age, non-White ethnicity, and with lower BMI.

The current 2015 NICE guidelines recommend annual postpartum screening for diabetes and advice on weight, diet and exercise for all women diagnosed with GDM (59). However, there is no recommendation for postpartum monitoring of other CVD risk factors such as hypertension and dyslipidaemia in these women. Screening for diabetes alone may underestimate the health risks in this group of women who are at high risk of CVD, the leading cause of death among women. Thus, the diagnosis of GDM should be considered as an opportunity in routine care to inform women about their increased CVD risk (316), as well as screen, identify, and treat (including health behaviour interventions) CVD risk factors at an early point in a woman's life, when risk modification may have more chances of helping prevent CVD and improve long-term outcomes.

Considering the burden of the disease once it has developed, it is important to prevent GDM. Interventions applied early in women at risk of GDM, offer a potential opportunity to reduce the risk of GDM, and to help control other risk factors for later CVD. However, there is currently lack of evidence on which interventions can help reduce the chances of developing GDM. In the following

Chapters, I describe the development and testing of a novel dietary behavioural intervention designed to be delivered in women at high risk of developing GDM.

Chapter 3: The effectiveness of Motivational Interviewing in managing excess weight: a systematic review and meta-analysis

3.1 Summary

This Chapter presents a systematic review and meta-analysis of RCTs on the effectiveness of Motivational Interviewing (MI), a psychotherapeutic counselling style, as a tool in behavioural weight management programmes (BWMPs). I hypothesised that MI could help people with obesity to control their weight, and by extension be a useful component in BWMPs for women with obesity who are pregnant, to help them adhere to a dietary programme and control their weight gain, to lower their chances of developing GDM.

The aim of the review was to assess the independent contribution of MI as part of a BWMP, in controlling weight and improving psychological well-being, when used alone or alongside other behavioural components. Due to sparsity of studies using MI in the context of GDM, the review included RCTs delivering any BWMP in adults or adolescents, aiming at weight loss or maintenance, and comparing programmes incorporating MI versus interventions without MI. To isolate the effect of MI, studies with the following comparator arms were eligible: 1) trials with a control group that received no/minimal intervention for weight management; 2) trials that compared a BWMP incorporating MI versus a BWMP of similar intensity (in terms of content and amount of contact time) without MI; and 3) trials that compared a BWMP that included MI versus a lower-intensity BWMP (BWMP with less contact time than the MI intervention). The primary outcome was weight change. Changes in anxiety, depression, quality of life, or other aspects of psychological well-being, were also extracted as secondary outcomes, as they play an important role in the aetiology of excess weight. Pooled mean difference (MD) or standardised mean difference (SMD) of change in outcomes from baseline to follow-up between trial arms, were obtained using random- and fixed-effects meta-analyses.

Forty-six studies involving 11,077 participants, predominantly with obesity, were included. No included studies delivered MI during pregnancy. For adults, at 6 months follow-up, BWMPs using MI were more effective than no/minimal intervention (MD in weight change between groups from meta-analysis: -0.88 [95% CI, -1.27 to -0.48] kg; I^2= 0%), but were not statistically significantly more effective than lower-intensity (MD: -0.88 [95% CI, -2.39 to 0.62] kg; I^2= 55.8%), or similar-intensity BWMPs (MD: -1.36 [95% CI, -2.80 to 0.07] kg; I^2= 18.8%). At 1 year, data were too sparse to pool for comparisons with no/minimal intervention, but MI did not produce statistically significantly greater weight change compared with lower-intensity (MD: -1.16 [95% CI, -2.49 to 0.17] kg; I^2= 88.7%), or similar-intensity BWMPs without MI (MD: -0.18 [95% CI, -2.40 to 2.04] kg; I^2= 72.7%). At 18 months follow-up, MI did not produce statistically significant benefit in weight change in any of the comparator categories, but studies were also sparse. For adolescents, data interpretation was limited by sparsity in each comparator category by follow-up time point, but there was no consistent evidence of effectiveness with the addition of MI. There was no evidence of subgroup differences based on study, participant, or intervention characteristics. Too few studies assessed effects on psychological well-being to pool, but data did not suggest that MI was independently effective.

In conclusion, this review found that MI may independently slightly increase weight loss when compared to no/minimal intervention, but only in the short-term. There is no evidence that MI independently adds benefit to weight management compared to other lower- or similar-intensity BWMPs without MI. Moreover, there was no evidence that incorporating MI into BWMPs improved psychological well-being. Given the lack of clear benefit, and that MI typically requires intensive training and increased time for its delivery, I concluded that MI may not be a worthwhile addition to BWMPs, and by extension BWMPs in women with obesity during pregnancy.

Note: A version of this Chapter was published in the journal Annals of Internal Medicine (317).

3.2 Introduction to Motivational Interviewing (MI)

It is important that people with obesity who are pregnant, manage their diet and control the amount and rate of GWG, in order to reduce their risk for complications such as GDM (221, 318). However, the impact of dietary intervention trials to date aimed at limiting GWG in women with obesity during pregnancy, has been inconsistent (224, 233). These programmes included behavioural strategies such as goal setting, self-monitoring, structured advice, and feedback, to support women to change their dietary intake, and sometimes to increase physical activity. Interventions generally used intensive and frequent personalised counselling. Nevertheless, they yielded no or small to modest success in reducing GWG (e.g. mean between-group difference in GWG intervention vs control was -0.7 kg, with 95% CI -0.9 to -0.5 kg) (233). As a result, there is considerable interest in other strategies which might enhance women's engagement and adherence to BWMPs in pregnancy, and by extension possibly improve GWG control and clinical outcomes. Boosting intrinsic motivation for weight control is frequently recommended for enhancing adherence and supporting behaviour change in the context of obesity.

MI is a psychotherapeutic intervention, commonly promoted as key to engaging patients in behaviour change. MI should not be confused with behavioural change techniques. It is a complex communication approach during which multiple behavioural change techniques may be used. This section aims to present the concept of MI, its underlying spirit, its main processes, evidence on its use as a tool in BWMPs, and the rationale for conducting a systematic review.

3.2.1 What is MI?

The concept of MI was introduced for the first time in the early 1980's by clinical psychologists William Miller and Stephen Rollnick. It was initially proposed as a tool in the treatment of addictive behaviours (1991) (319), and progressed to addressing preparing people for change across a broad range of behaviours (2002) (320). A decade later, new knowledge emerged on the processes used in MI, research experience and outcomes in a variety of contexts, and how practitioners are trained in MI. This knowledge led to the third and most recent edition which describes how MI happens in practice

(2012) (321). There is no single definition of MI. Miller and Rollnick did not provide a definition in their first edition (1991), though subsequently, they have offered variations of it (320, 322, 323). In the latest edition, they offered 3 definitions as part of the response to 3 key questions: What is the purpose of MI? Why is MI a useful tool for practitioners/clinicians? How does MI work? (**Box 3.1**) (321).

Box 3.1. Three-fold definition of Motivational Interviewing (MI) (321)

Lay definition – What is the purpose of MI?

"MI is a collaborative conversation style for strengthening a person's own motivation and commitment to change. It can be brief or prolonged and it may occur in many different contexts, with individuals or groups, but is always a collaborative conversation, never a lecture or monologue."

Practitioner's definition – Why is MI a useful tool for practitioners/clinicians?

"MI is a person-centred counselling style for addressing the common problem of ambivalence about change."

Technical definition – How does MI work?

"MI is a collaborative, goal-oriented style of communication with particular attention to the language of change. It is designed to strengthen personal motivation for and commitment to a specific goal by eliciting and exploring the person's own reasons for change within an atmosphere of acceptance and compassion."

3.2.2 Spirit of MI

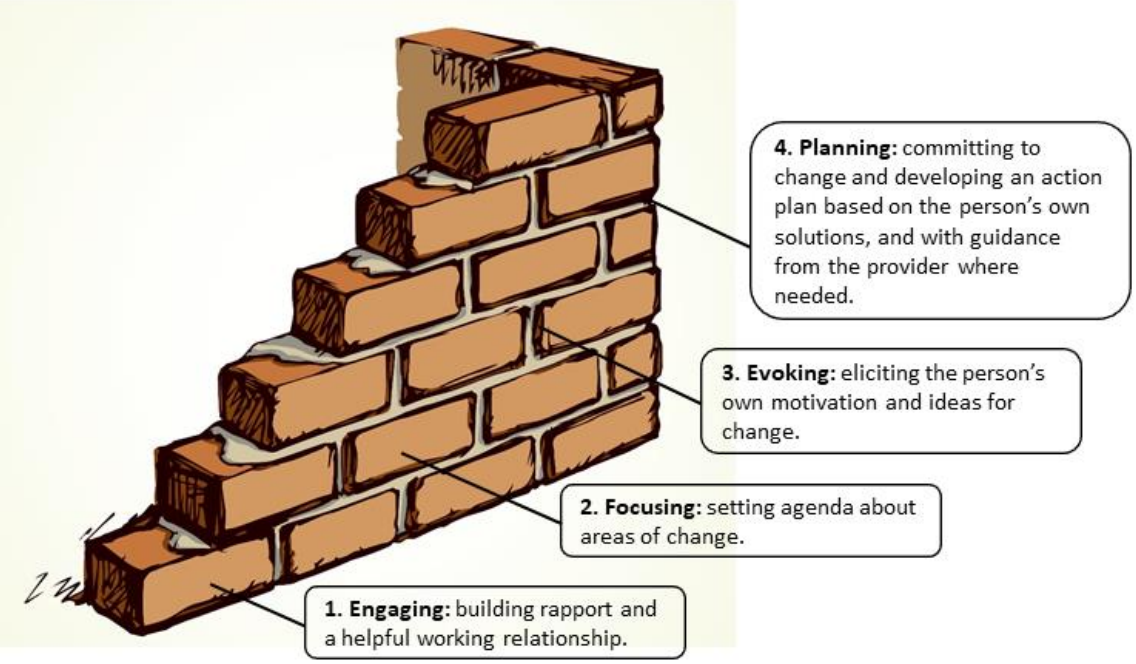
Despite the variations in definitions, what has not changed, is the spirit of MI. MI differs from most interventions in its strong emphasis on eliciting motivation for change from the individual, rather than seeking to motivate them by persuasion or other methods. Most people who need to change, experience some ambivalence about doing so (324). They recognise both reasons for and against it. MI is designed to make conversations about change more effective, in order to help a person move from ambivalence to commitment to change, by strengthening their intrinsic motivation for change. In doing so, MI establishes a collaborative conversation where the practitioner carefully listens to what the person has to say, assists them in clarifying their goals and values, and assess the consonance of

their current behaviour with these, and evokes certain forms of speech that could lead to behaviour change ("change talk"), as well as the person's belief in their ability to change. Eventually people talk themselves into change, rather than being persuaded to do so by an expert. Fundamental to MI is the development of a unique partnership where the practitioner does only a small part of the talking, accepts the person's perspectives, and their freedom to choose whether they want to change, affirms their efforts, and shows compassion by putting the person's needs first. MI is therefore a guiding, person-centred, but goal-oriented and non-judgemental conversation approach (321).

3.2.3 Processes and principles of MI

MI has been adapted to a range of settings, and has been delivered in various formats, including face-to-face, phone, and group consultations. Whilst delivery mode can vary, there are four common distinct processes in MI interventions, as explained in **Figure 3.1**. These usually happen in the order presented, as one is laid upon the progress of the other, but they may also recur (321). In practice, practitioners are trained in five main skills (principles) for applying MI (325), shown in **Table 3.1**.

Figure 3.1. The four processes of Motivational Interviewing (321)



1. **Engaging:** As a first step, the practitioner tries to get to know the person and their particular situation, and understand their perspectives through listening, asking open-ended questions, expressing empathy and being non-judgemental. This hopes to ensure the person feels that they are in a safe space to share their ambivalence, expectations, hopes and fears with regards to change, and that they are a team with the practitioner. As a result, the two parties build rapport and establish a helpful working relationship. Engaging is the foundation for all other processes that follow, as the person is more likely to keep attending appointments/consultations.
2. **Focusing (the "WHAT" of change):** The practitioner sets an agenda for the conversation. They first explore what the person came to talk about, and what their expectations are from the consultation. The practitioner then guides the person in focusing on an area where they are willing to make one or more changes according to what is most important to them. Throughout the conversation the practitioner maintains the direction. This process may typically lead to collaboratively agreeing on one or more goals for change so that the person feels they play a role in the decision making.
3. **Evoking (the "WHY" of change):** The practitioner explores the person's own reasons for change. Through open questions, affirmations, reflective listening and summarising, the practitioner can help the person uncover their own ideas and strategies about how they may go about achieving a change. When those solutions are voiced, the practitioner reinforces them by encouraging the person. This lays the foundation for the next process of planning, as people are more likely to stick with plans that they set out for themselves. If the person asks for guidance or they are struggling to come up with their own ideas, the practitioner can also ask the permission to offer some.
4. **Planning (the "HOW" of change):** The practitioner assesses the person's readiness to make a change and encourages them towards commitment. The practitioner then guides the person towards developing a specific plan based on their own solutions and, with permission, can add expertise where needed or when asked to do so.

Table 3.1. Principles of Motivational Interviewing (325)

Principle	Explanation
Expressing empathy	Showing interest and making effort to understand the person's perspectives through reflective listening. It hopes to build rapport, create a supportive environment, and start the foundation of a collaboration.
Developing discrepancy	Noting and increasing the person's awareness of the discrepancy between the person's goals and values, and their current behaviour. The hope is that the person will realise the disadvantages of the current behaviour, compared to what they want to achieve, and that they eventually voice arguments for change by themselves. The practitioner's role is again to be an effective reflective listener and offer the person's ideas back to them.
Avoiding argument and direct confrontation	Avoiding arguing with the person and imposing change and own ideas, as it can only make the person defensive, decrease the rapport and engagement, and thus counteract any progress made.
Respecting the person's autonomy	This was originally proposed as "rolling with resistance". Resistance was conceptualised in many forms such as being reluctant to change, interrupting the practitioner, not engaging, getting defensive, and arguing. In the latest edition from Miller and Rollnick, this concept was abandoned as it tends to put the blame on the person and disregards the complexity of ambivalence. The practitioner should respect the person's autonomy, affirm their freedom to choose whether and what they want to change, and not impose or become defensive.
Supporting self-efficacy	Boosting the person's belief that they are able to achieve their goal, which is a predictor for successful behaviour change (326). Reflective listening can help again the practitioner offer back to the person their ideas but in a way that affirms their strengths and acknowledges their progress.

3.2.4 MI and weight management

Motivation is a predictor for successful and sustained behavioural change in weight management programmes (327-331). Evidence from qualitative studies (detailed in Chapter 4) shows that pregnancy may be a teachable moment for women to improve their dietary intake and control their weight, in an effort to prevent maternal and neonatal complications (332). However, some women report barriers to changing their diet, which mainly relate to beliefs about pregnancy being an opportunity to avoid dieting and embrace a more positive body image, as well as to lack of self-efficacy with regards to managing their dietary intake and weight gain during pregnancy (332-335). Women have also emphasised the importance of structured, timely and accurate diet and weight management advice from their HCPs (336). They also emphasise need for HCPs to help boost their motivation for weight management during pregnancy, by addressing their personal circumstances, and delivering the advice in a sensitive and non-stigmatising way (332, 336). In turn, HCPs involved in routine maternity care such as midwives and nurses, recognise the importance of diet and GWG control during pregnancy, and that there is currently lack of appropriate support from their side (337, 338), but they perceive they have insufficient training and expertise in nutrition and weight management (339). Weight management is a sensitive issue not only for women who are pregnant, but also for HCPs to address, which may result in avoidance of doing so during antenatal visits, to reduce the risk of upsetting women or making them feel stigmatised (6, 337, 340-342).

Together this evidence suggests that boosting women's intrinsic motivation for diet and weight management could be an important component of BWMPs in pregnancy. MI could support behaviour change and GWG control, among women starting pregnancy with excess weight, by enabling them to understand and explore their own behaviours, enhance their motivation to manage their weight gain, and address ambivalence toward adopting healthier behaviours, such as diet and physical activity. Its non-confrontational empathetic style distinguishes it from other evidence-based behavioural strategies, and resonates with HCPs' concerns about hectoring patients with regards to weight and weight-related behaviours. In addition, there is growing interest in the psychological effect

of BWMPs, given the bi-directional association of mental health factors and excess weight (343). For example, there is evidence of a positive association between pre-pregnancy BMI, GWG, and anxiety and depression during pregnancy (344-346), but also women with high levels of stress and anxiety during pregnancy, tend to have dietary patterns characterised by higher sugar and fat intake (347). It has been proposed that the lack of effectiveness of some intervention studies aimed at reducing GWG in women with obesity, may be related to lack of strategies to address psychological factors (348). Exercises of MI applied worldwide in non-pregnant populations, show that people feel engaged, empowered and understood after conversations guided through MI (321). Moreover, a MI-based antenatal intervention for people with obesity during pregnancy, led to reductions in GWG and levels of anxiety (349). The psychological strategies used during MI and its patient-centred approach, may therefore be effective in enhancing psychological well-being during BWMPs in pregnancy. However, MI requires additional training for HCPs to develop the skills to enhance patient motivation toward behaviour change. Usually, it also requires prolonged contact time with patients in the form of extended or additional sessions with a therapist, to explore current behaviours and enable patients to identify and engage with potential solutions. In view of the above, it is important to analyse whether MI per se adds to the effectiveness of BWMPs.

There is a sparsity of studies testing MI-based BWMPs in pregnancy, as well as specifically in the context of GDM prevention or management (254, 349, 350), and no such studies to date have isolated the effect of MI from other intervention components. I sought to systematically review evidence on the independent effectiveness of MI as an addition to any BWMP, both in and outside of pregnancy. Most (351-355), but not all (356, 357) previous systematic reviews on the effectiveness of MI in weight management interventions have suggested weight benefits, but the difference in reported weight change has been modest. Many interventions have combined MI with other behavioural techniques typical in BWMPs, such as goal setting, self-monitoring, and feedback, rather than offering MI as a standalone intervention (355, 356). Only a few systematic reviews have isolated the effect of MI by comparing MI interventions with no/minimal interventions only or, in the case of

complex interventions, with the same intervention without MI. These reviews were older (351), or focused on outcomes for a specific group of patients (355). Consequently, evidence that MI is independently an effective intervention for weight control in routine care remains unclear. In addition, to my knowledge, no previous systematic review has explored the independent effect of MI on psychological well-being during weight management.

3.2.5 Research questions

First, does MI increase weight loss or enhance weight maintenance compared with no/minimal intervention? Second, does MI increase weight loss or enhance weight maintenance when used with weight management interventions, compared with a similar weight management intervention without MI? Third, does MI improve psychological well-being?

3.3 Methods

This is a systematic review of RCTs, with multiple meta-analyses. The protocol was registered prospectively on PROSPERO (CRD42020177259), and followed the Preferred Reporting Items for Systematic Reviews and Meta-analyses guidelines (358).

3.3.1 Study selection – Eligibility criteria

3.3.1.1 Population

Adolescents or adults (age ≥12 years) of all body weights, excluding studies specifically among people who were underweight, or selected because of the presence of eating disorders. Since I aimed to explore the effect of MI on both weight loss and maintenance as a primary or secondary goal of the intervention, I included studies that did not specifically select participants by BMI.

3.3.1.2 Intervention

Interventions providing MI in isolation or as part of a package of treatment, designed to help with weight loss or weight maintenance (maintenance of lost weight or prevention of weight gain), as a primary or secondary goal. This included interventions not explicitly identified as “weight loss” or “weight maintenance”, and interventions targeting either weight or multiple risk factors, but in which

I judged with the help of my co-investigators that there was adequate focus on weight. When the degree of focus on weight was uncertain, I discussed each study with all co-investigators, and I decided to include if weight was a pre-specified outcome, and the study population was in the overweight or obese BMI range (BMI ≥25 kg/m^2).

I started with the authors' assertion that their study includes MI or motivational strategies, including Motivational Enhancement Therapy, and checked each intervention individually. The final arbitration depended on the principles of counselling applied, matching the MI principles as defined by Miller and Rollnick, 2012 (321). Where unclear, I discussed with co-investigators to help me judge on a case by case basis, the extent to which an intervention appeared to comply with the MI principles. Behavioural interventions of any format, delivery mode, duration, length of follow-up, and delivery setting were eligible. Interventions using pharmacotherapy or bariatric surgery to support weight control were excluded.

3.3.1.3 Control

I included 3 comparisons:

(i) trials with a control group that received no/minimal intervention for weight management, such as a leaflet or one-off brief advice;

(ii) trials that compared a weight management intervention including MI to an otherwise similar-intensity programme without MI, i.e. a programme of similar content and amount of contact time received (minutes and/or days);

(iii) weight management interventions including MI compared to a lower-intensity behavioural programme, i.e. a behavioural programme with less contact time than the MI intervention (minutes and/or days).

Trials with intervention arms that included additional components for weight management alongside the MI that were not balanced in the comparator arm, and for which there is evidence that they can independently lead to weight change, such as food and/or activity diaries, pedometers, and weight monitoring, were excluded.

3.3.1.4 Outcomes

The primary outcome was weight change in kg. This could have been either a primary or secondary outcome in the included studies. Regardless of behavioural intervention type, weight loss programmes tend to lead to a nadir of weight at programme end, often 3 months, or up to 6 months, after which weight regain commonly occurs. Therefore, I examined weight change in reference to this, namely at 0-3 months, 4-7 months, 9-13 months and 18-24 months from baseline. There were no studies with measurement time points at 8 or 14-17 months from baseline. Changes in anxiety, depression, quality of life or other aspects of psychological well-being (secondary outcomes), were extracted if available from studies that included the primary outcome. Where available, data on fidelity in MI delivery, programme engagement or attendance, weight/diet/physical activity related-self-efficacy (an individual's perceived ability to perform a behaviour in spite of potential barriers), and motivation were extracted, and are reported narratively.

3.3.1.5 Type of studies

Only RCTs and cluster RCTs were included.

3.3.2 Data sources and searches

Searches were run without restrictions on language or publication date, from database inception on 7 February 2020 to 24 September 2021, by a research librarian. The search strategy included Boolean operators and a combination of the following terms: overweight/ obesity/ body mass index/ BMI/ weight loss/ weight reduction program/ diet, reducing/ body weight maintenance/ weight (loss, losing, lose, redu*, manage*, control*, maintain*, gain*) AND motivational interviewing/ motivational counselling/ motivate* (advice, session, practi*, behave*, enhance*, improve*, encourage&, facilitate*), and randomized control trial or controlled clinical trial. MeSH terms (Medical Subject Headings) were tailored to each database. Search strategies are presented in **Appendix 3.1**. Six electronic databases and 2 trial registries were searched: Cochrane Central Register of Controlled Trials; Cumulative Index to Nursing and Allied Health Literature; Embase; Medline; PsycINFO; Science Citation Index; Clinicaltrials.gov and World Health Organization International Clinical Trials Research

Platform. The reference lists of identified trials and relevant systematic reviews were also searched for potentially relevant trials. I excluded conference abstracts, thesis documents and studies where full-text was unavailable, despite efforts to obtain it by contacting the authors.

3.3.3 Data extraction

After de-duplication, a total of 6 reviewers (including myself) working in fixed pairs, independently screened titles, abstracts or both, of every record retrieved, using the pre-specified eligibility criteria, and a decision flow-chart that I developed (**Appendix 3.2**), and recorded the decisions via the Covidence screening software (Veritas Health Innovation). Each fixed pair of reviewers was then assigned to review full texts of potentially eligible articles, using another similar decision flow chart that I developed (**Appendix 3.3**). Discrepancies were resolved through discussion or recourse to a further reviewer or the main group.

Data were extracted independently by each fixed pair of reviewers, using a piloted extraction form and included information on: study setting; baseline characteristics of the population (age, proportion of females, baseline BMI); unique features of the population that stood out from the publication, such as whether they had a particular health condition; type of randomisation; MI and comparator group interventions described according to the Template for Intervention Description and Replication checklist (359), including intensity of counselling, interventionist information (training, qualifications), follow-up assessments and outcome data; weight; psychological well-being data, participant attendance; change in motivation; and change in self-efficacy. Discrepancies were resolved by discussion within the fixed pairs, or referral to the wider review team. Where the full text article could not be accessed or additional information was required, the author(s) were contacted on two occasions by email. When necessary information was not available or obtainable in the publication, I have reported these studies narratively.

3.3.4 Quality assessment

I assessed studies for risk of bias, using an adapted Cochrane Collaboration tool (Cochrane Handbook version 5.1.0) (360) from: random sequence generation; allocation concealment; blinding of outcome

assessment; incomplete outcome data; selective reporting; other bias. Guidance used for judgement of risk of bias in this review is presented in **Table 3.2**. As it is typically not possible to blind participants or interventionists to treatment group allocation in behavioural interventions, I did not assess this.

Table 3.2. Risk of bias guide used for included studies in the current review

Domain	Explanation	Specification for this review
Random sequence generation	Process in which participants were assigned to the trial arms on the basis of a random process (chance), characterised by unpredictability.	Assessed following the guidance set out in the Cochrane Handbook version 5.1.0, section 8.9.2 (360).
Allocation concealment	Process which shields those who enrol participants or recruit clusters into a trial from knowing their allocation into the trial arms. It aims to conceal the sequence before and until participants are allocated to groups or clusters are recruited. This is different from blinding, which aims to conceal the sequence after allocation or recruitment.	Assessed following the guidance set out in the Cochrane Handbook version 5.1.0, section 8.10.2 (360).
Detection bias	Refers to the outcomes being subject to biased reporting, either because they are self-reported, or the person assessing them is not blind to treatment allocation.	Detection bias is usually mitigated by objective outcome assessment (e.g. using electronic scales to measure weight). Also, in behavioural interventions it is impossible to blind participants and persnonnel. Therefore, I judged this risk as low, when an outcome of interest was measured through objective means, regardless of whether it was self-reported or measured by the study/clinical team, and regardless of whether the outcome assessor was blinded to treatment allocation.

Table 3.2. continued

Domain	Explanation	Specification for this review
Incomplete outcome data	Refers to risk of bias introduced due to attrition, i.e. that the number of participants not followed-up may have impacted the results.	Thresholds for follow-up rate are by nature arbitrary. I judged the risk as low when overall follow-up rate for the outcomes of interest (i.e. weight and psychological well-being) were ≥70%, and there was <20% difference in follow-up between arms.
Selective reporting	Refers to studies not reporting data for all the outcomes or not at all time points they said they would.	Apart from methods section of each paper, the reviewer team also checked protocol papers and/or trial registration pages for pre-specified outcomes. I only judged the risk about the outcomes of interest, i.e. weight and psychological well-being.
Other bias	Other risks of bias not included in the above.	Examples: contamination, baseline imbalances between the trial arms, discrepancies in reported data.

3.3.5 Data synthesis

I estimated the changes in outcomes for all relevant trial arms from baseline to follow-up. I extracted results as reported by authors; in the vast majority of included studies, this meant that I used complete case data (i.e. only data from participants with no missing data for the outcome of interest), or data imputed with last observation carried forward, where missing follow-up values are replaced by participants' previously observed values. In studies where two intervention arms received the same MI intervention but with different intensity (contact time), I combined these as one intervention arm as described in **Appendix 3.4.1**.

3.3.5.1 Mean difference

For weight outcomes, the difference in mean weight change between the trial arms from baseline to follow-up was extracted. Reporting of weight data varied across studies, and in **Appendix 3.4.2**, I describe the different approaches that I followed to obtain the MD in weight change. For psychological well-being, I used SMDs in score change between the trial arms, to overcome variability in reported scales. I inverted scales where needed so that higher scores represented improved well-being. This approach is in line with standard practice for meta-analyses as outlined within the Cochrane Handbook (version 6.3) (361). I initially extracted the mean score change in each arm, and calculated the SMD in score change between the arms using a following formula provided in **Appendix 3.4.3**.

3.3.5.2 Measures of spread

For weight outcomes, I used in the analysis the standard error (SE) of the difference in mean weight change between the trial arms. Reporting of spread of weight data again varied across studies, and in **Appendix 3.4.4**, I outline the different approaches I used to obtain this, based on available data. For psychological well-being outcomes, reporting of measures of spread from included studies followed a similar pattern. For this analysis, I used the Campbell Collaboration calculators which automatically calculate the variance (362). Then the SE of the SMD was calculated as per formulas in **Appendix 3.4.5**. I was conscious of cluster RCTs reporting analyses that did not account for clustering. In this particular study design, it is units that are randomised (e.g. GP practices, schools), rather than participants. The participants within a cluster, may often be similar or respond similarly, and if this is ignored in the analysis, it can result in narrow confidence intervals and falsely small P values. In addition, in a meta-analysis, studies in which clustering has been ignored in the analysis, will take up more weight. I used the method of inflating the SE (361), as outlined in **Appendix 3.4.6**.

3.3.6 Statistical analysis

I conducted meta-analyses to pool trial outcomes where at least 2 comparable groups were available. For 3-arm studies, I compared two comparable groups so that the only difference between them was the MI component. I used generic inverse variance random-effects models to pool effect estimates

(MD in weight change or SMD in psychological well-being), between individuals receiving MI and those in the comparator group, from baseline to follow-up time points. Random-effects models were considered appropriate as they take into account the heterogeneity within and between the studies with regards to study populations, interventions (e.g. aim, content, intensity, duration, frequency, mode of delivery), study methodology, and outcome assessment. As a result, the random-effects model reflects the fact that the true effect of MI is likely to differ across contexts and intervention types. Each meta-analysis was conducted per comparator category (no/minimal intervention vs lower-intensity BWMP vs similar-intensity BWMP), and resulted in few studies being pooled in each comparison. I therefore used the Hartnug-Knapp-Sidik-Jonkman approach applied to the DerSimonian-Laird simple method of moments estimator, to obtain less biased estimated effects and 95% CIs (363). Where most meta-analyses included fewer than 5 studies being pooled, I performed fixed-effect meta-analyses where the point estimates appeared similar, but refrained from pooling the studies where estimates appeared highly variable.

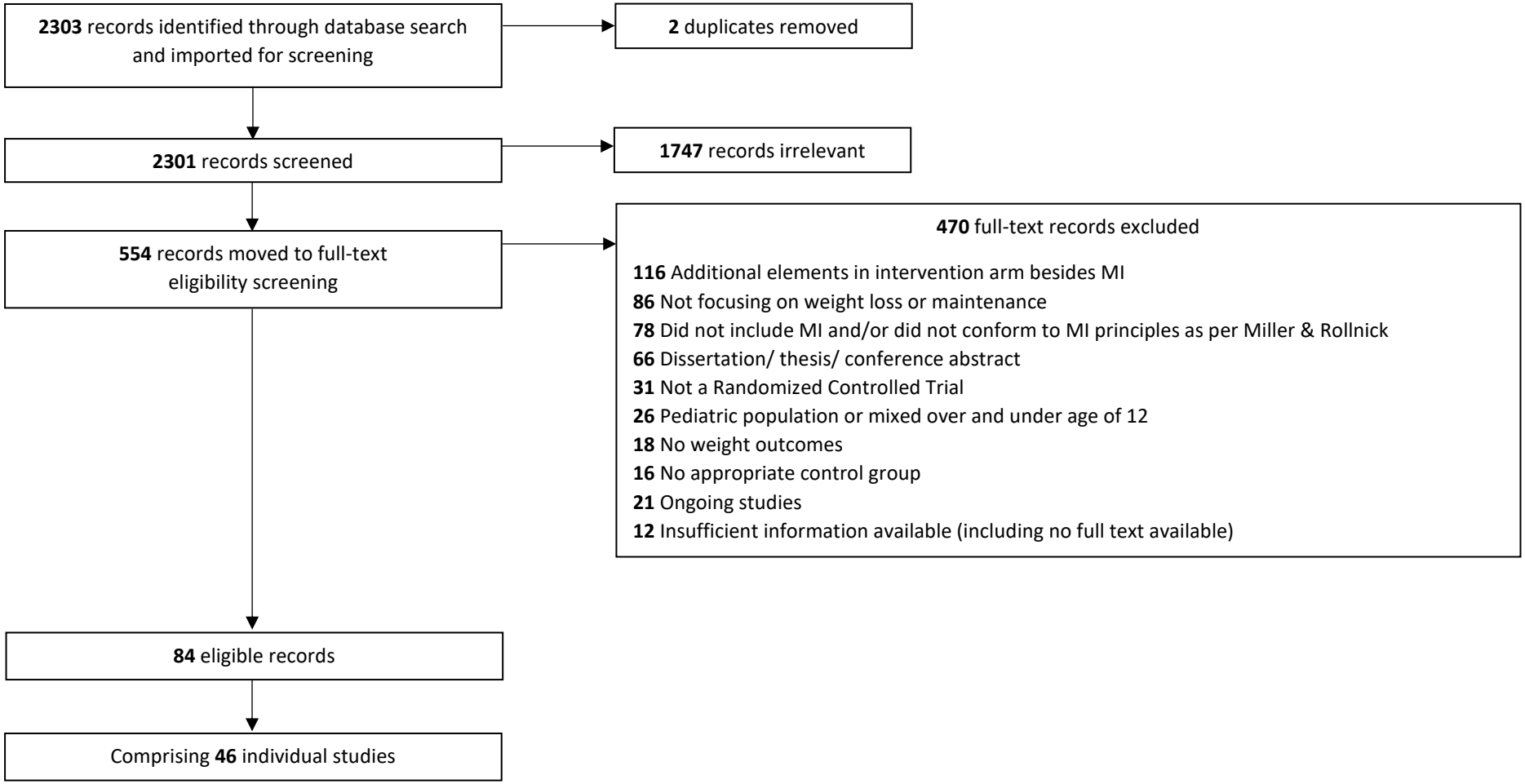
Separate sensitivity analyses excluded studies at high risk of bias and those in which it was questionable whether the independent effect of MI could be isolated, and included only studies which reported achieving overall satisfactory fidelity of MI delivery. I also ran exploratory analyses (some pre-specified and some additional), to explore evidence in effect sizes of MI based on population and study characteristics. These included: duration of intervention programme, age, BMI at recruitment, whether MI was delivered by a physician vs non-physician health professionals, mode of MI delivery (individual vs group vs mixed), degree of personal contact in MI delivery (text/email/online typed chat vs telephone/video call vs face-to-face vs face-to-face plus other), whether weight control was the main focus of the intervention vs secondary focus as a result of treating another condition. All meta-analyses were conducted in Stata version 14.0 (StataCorp), using metan, version 4.2.

3.4 Results

The search yielded 2,303 records, from which 554 full-text articles were assessed and 84 articles comprising 46 studies were included (364-409) (**Figure 3.2**). Five study authors provided additional

data. **Table 3.3** presents aggregate characteristics of included studies. **Appendix 3.5** presents detailed characteristics of each included study, including intervention content.

Figure 3.2. Evidence search and selection (312)



MI: motivational interviewing

Table 3.3. Aggregate characteristics of included studies (312)

Characteristic	Studies in adults	Studies in adolescents
Median age (IQR), years	48.1 (12.3)	15.4 (1.2)
Median body mass index (IQR), kg/m^2	33.3 (4.8)	33.4 (4.4)
Female, %	77.0	67.5
White, %	41.3*	24.4†
Median programme duration (IQR), months	6.0 (9.0)	2.5 (4.4)
Median maximum follow-up duration (IQR), months	12.0 (11.5)	6.0 (9.0)
Studies with 0-3 months of follow-up, n	10	4
Studies with 4-7 months of follow-up, n	16	5
Studies with 9-13 months of follow-up, n	19	3
Studies with 18-24 months of follow-up, n	10	0
Mode of delivery, n		
Individual	32	8
Group	5	0
Mixed	0	1
Personal contact in MI delivery, n		
Text/e-mail/online typed chat	2	0
Telephone/video call	3	1
Face-to-face	22	8
Face-to-face plus other	10	0
Setting, n		
Primary care	17	3
Hospital	3	3
Non-healthcare	9	2
Mixed	2	0
Unclear	7	1
Interventionist		
Physician	2	3
Healthcare professional‡	14	3
Psychologist	14	1
Researcher	0	2
Mixed	4	0
Unclear	2	0

IQR: interquartile range; **MI:** motivational interviewing

* Available from 27 of 37 adult studies.

† Available from 7 of 9 adolescent studies.

‡ Includes dietitians, nutritionists, exercise specialists, nurses, and health workers.

3.4.1 Study and participant characteristics

The included studies randomly assigned 11,077 participants, of whom three quarters were female. Thirty seven studies were conducted in adults (typically middle-aged adults), and 9 were conducted in adolescents (median age, 15 years), mainly with obesity. There were no studies delivering MI to women during pregnancy. One study recruited women who were pregnant, but delivered MI post-

partum (377). Twenty interventions were delivered in primary care, 6 were delivered in a hospital outpatient setting, 11 were delivered in a non–health care setting, 2 were delivered in more than 1 of these settings, and 8 were delivered in an unclear setting. Half of the included studies had unclear risk of bias, mainly because they did not fully describe randomisation procedures. About a quarter of the studies were at low risk of bias, and another quarter were at high risk of bias, primarily due to attrition (**Table 3.4**). **Appendix 3.6** presents the risk of bias assessments for each study with support for each judgment.

Table 3.4. Risk of bias in included studies

Risk of bias domain	Number of studies (n = 46)				
	Low risk		Unclear risk	High risk	
Overall	12 at 4-7 months follow-up	11 at 9-13 months follow-up	23	11 at 4-7 months follow-up	12 at 9-13 months follow-up
Selection bias – random sequence generation	30		16	0	
Selection bias – allocation concealment	21		25	0	
Detection bias	40		5	1	
Attrition bias	29 at 4-7 months follow-up	28 at 9-13 months follow-up	5	11 at 4-7 months follow-up	12 at 9-13 months follow-up
Reporting bias	41		1	4	
Other risk of bias	40		3	3	

3.4.2 Intervention characteristics

Two studies aimed to prevent weight gain, and 44 aimed to support weight loss. MI was used in counselling sessions about weight loss, healthy eating, and physical activity, which were either incorporated into existing BWMPs or routine care consultations or added as extra sessions. Thirty-five studies aimed to treat obesity through weight loss or weight maintenance, and 11 studies used weight management as one of several behavioural strategies to prevent or manage a chronic disease. No programmes tested MI alone; all incorporated behavioural strategies, such as goal setting, self-

monitoring, provision of feedback, and social support and planning. In the majority of studies, the MI group received more personalised advice than the control group. Participants in comparator groups with no/minimal intervention mainly received either standard medical care and/or information handouts or feedback with no additional input. Lower-intensity comparators comprised dietary, weight, and physical activity counselling as part of either an existing programme or routine care consultations but received fewer sessions than the MI group, or the MI group received additional support sessions. Comparators of similar intensity involved the same or similar advice and contact time but regular counselling that did not incorporate MI techniques. Most interventions provided written materials in addition to counselling to both groups. MI interventionists were mainly graduate or student psychologists or health care professionals, such as nurses, dietitians, or nutritionists. Two thirds of all studies reported information about MI training. Duration of MI training (available from 21 studies) ranged from 7 to 90 hours (median, 16 hours [IQR, 13.3 hours]), and in some cases involved supplemental training and ongoing supervision.

3.4.3 Fidelity, engagement, motivation, and self-efficacy

Twenty-six studies reported undertaking MI fidelity assessments through rating of the intervention delivery in recorded sessions, or through ongoing supervision. Fourteen studies published these data; all reported satisfactory fidelity based on MI-specific fidelity adherence scale scores and/or supervision or observation of key MI components delivered. Ten of 15 studies in which the 2 groups received interventions of similar intensity reported programme attendance or engagement data (364-373). Seven of 10 studies reported that participants allocated to MI had better attendance or engagement. One of 3 studies (366, 371, 374) reported higher self-efficacy for changing weight, diet, or physical activity. Three of 6 studies (365, 366, 369-372) reported that motivation for diet, physical activity, and/or weight change was higher in the MI groups; in 1 of the remaining 3 studies, motivation was similar between the groups (369), and in 1 other study, motivation increased more in the MI group at the end of the program but not in the longer follow-up (371).

3.4.4 Weight

3.4.4.1 Weight loss studies in adults

Ten studies with approximately 722 participants provided weight change data in adults at 0 to 3 months follow-up (median 3 months [IQR, 0.4 months]) (**Figure 3.3A**). Compared with the limited weight change noted in the control groups with no/minimal intervention (weighted mean change, 0.2; range, -0.1 to 1.1 kg), programmes incorporating MI led to about 1 kg greater weight loss. Data from one study showed that MI did not produce statistically significantly greater weight change compared with a lower-intensity programme (comparator weighted mean change, -1.2 kg). Point estimates for comparators of similar intensity without MI (weighted mean change, -1.4; range, -2.2 to -0.3 kg) were variable and could not be pooled with fixed-effects meta-analysis. Of the 5 studies, 3 favoured the control and 2 favoured MI. Effect sizes were similar compared with no/minimal intervention and crossed the null in all but 1 study.

Seventeen studies with approximately 4,003 participants provided weight change data in adults at 4 to 7 months follow-up (median 6 months [IQR, 1.8 months]) (**Figure 3.3B**). Compared with minimal intervention (weighted mean change, 0.6; range, -1.7 to 1 kg), programmes that incorporated MI led to an additional kilogram of weight loss. Compared with the weight change seen in programmes of lower intensity (weighted mean change in comparator group, -1.6; range, -5.5 to 0.4 kg) or similar intensity (weighted mean change, -1.8; range, -5.3 to -0.8 kg), incorporating MI led to differences of similar magnitude, but these estimates were very imprecise and not statistically significant.

Sixteen studies with approximately 4,918 participants provided weight change data in adults at 9 to 13months follow-up, with all but one study reporting data 12 months from baseline (**Figure 3.3C**). Only 2 studies compared MI with no/minimal intervention. Both tended to favour MI compared with the minimal weight change in the comparator groups (weighted mean change, 0.3; range, -0.2 to 0.5 kg); however, CIs crossed the null. There was no statistically significant benefit from incorporating MI into BWMPs compared with the modest weight loss achieved in either lower-intensity (weighted

mean change, -0.4; range, -1.5 to 2.4 kg) or similar-intensity (weighted mean change, -1.2; range, -3.3 to 1.7 kg) programmes; however, imprecision was high.

Nine studies with approximately 2,132 participants provided weight change data in adults at 18 to 24 months follow-up (median 18 months [IQR, 6 months]) (**Figure 3.3D**). Programmes incorporating MI did not outperform minimal interventions (weighted mean change, 0.8; range, 0.1 to 1 kg), lower-intensity BWMPs (weighted mean change, -1.1; range, -3.3 to 0.3 kg), or similar-intensity BWMPs (weighted mean change, 1.5; range, -1.7 to 3.7 kg), but data were sparse.

Sensitivity analyses excluding studies at high risk of bias (375-379) and studies in which it was unclear whether MI could be isolated (377, 378, 380-382) did not materially change the results (first and second footnotes of **Figure 3.3**). Analyses including only studies that reported good overall fidelity in MI delivery (371, 377, 378, 383-386) had sparse data, which precluded pooling, but did not show that intervention effects were clearly greater in studies with high fidelity (third footnote of **Figure 3.3**). There was no indication of a difference in the effect estimates of the main analyses according to duration of the intervention programme (**Figure 3.3**), age (**Appendix 3.7**), or BMI at recruitment (**Appendix 3.8**). The majority of MI interventions were delivered by non-physician health professionals. Most MI was delivered one-to-one, and very few studies delivered it in groups or in mixed formats, so pooling for this subgroup analysis was not possible. There was no observed pattern of a specific level of personal contact being effective (**Appendix 3.9**). In most studies, weight control was the main focus of the intervention, and there was no consistent indication that those led to greater weight loss than studies where weight control was a secondary focus (**Appendix 3.10**).

3.4.4.2 Weight loss studies in adolescents

All studies in adolescents aimed for weight loss. There were too few studies in each comparator category by follow-up time point to interpret the data, but there was no consistent evidence from these trials individually that programmes incorporating MI led to greater weight loss than minimal intervention or programmes of similar or lesser intensity (**Figure 3.4**).

3.4.4.2 Weight maintenance studies

One study aimed for maintenance of a healthy weight in adults in order to maintain good health, (387) and another aimed for weight maintenance after a weight loss programme in adults (388). Both studies compared a programme incorporating MI with a lower-intensity BWMP at 1 year after baseline. The first study showed no statistically significant benefit of incorporating MI on weight maintenance (-0.9 [95% CI, -1.76 to -0.04] kg), and in the second study, MI produced a statistically significant difference compared with a lower-intensity programme (-1.75 [95% CI, -3.40 to -0.10] kg).

Figure 3.3. Mean difference (in kg) in weight change in adults between MI and comparator (control) groups using fixed-effects (A and D) or random-effects (B and C) meta-analysis, by duration of intervention programme (312)

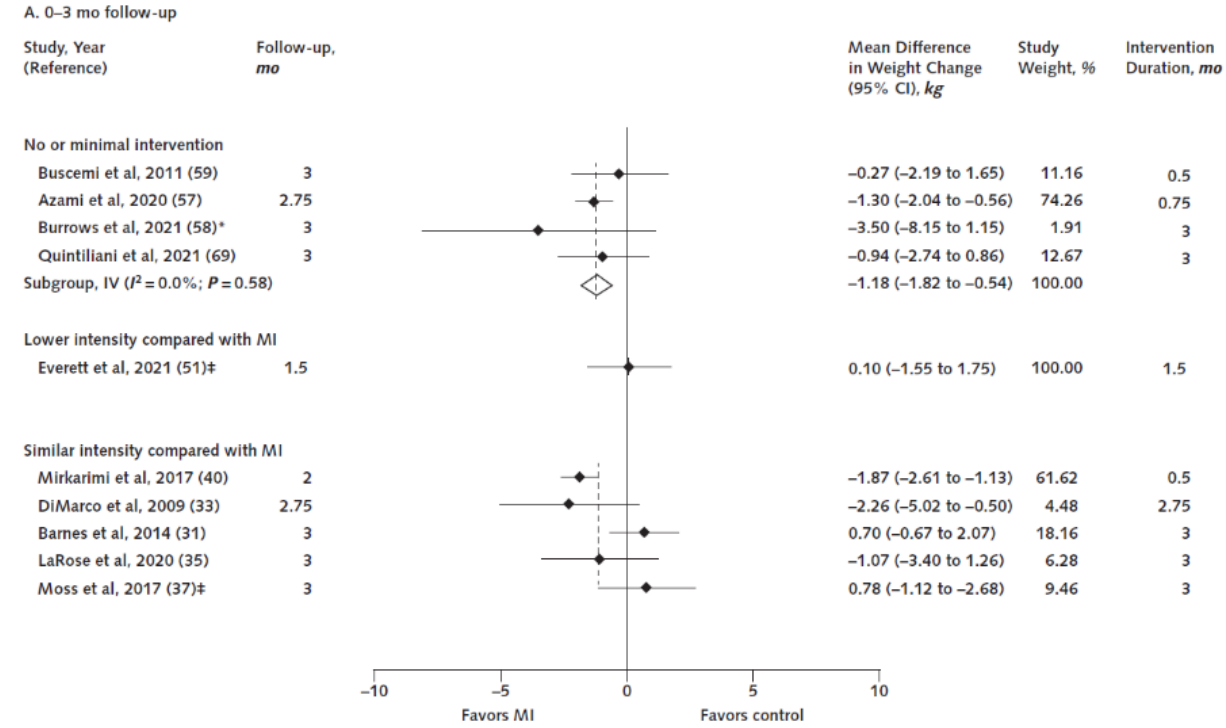


Figure 3.3. continued

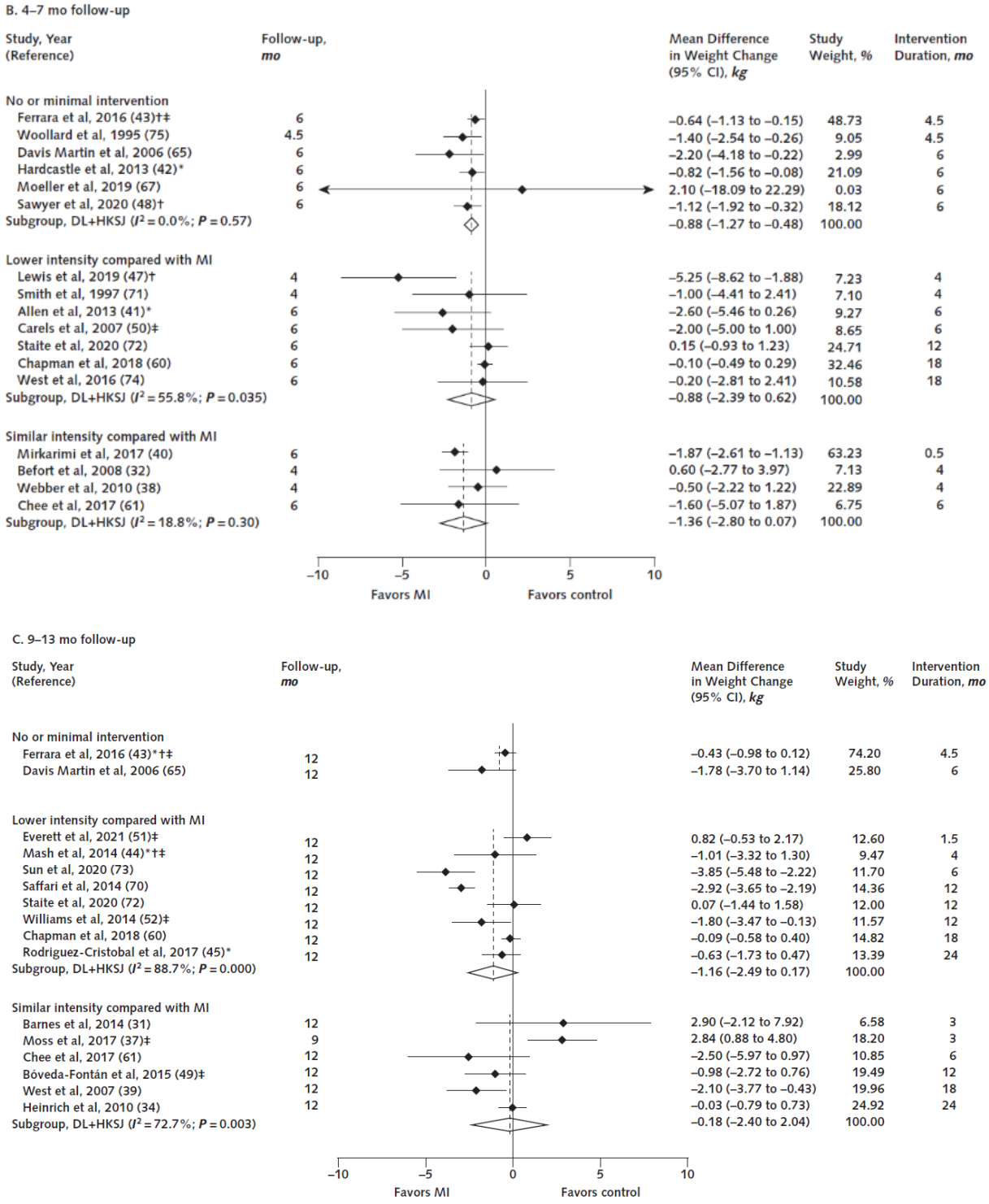
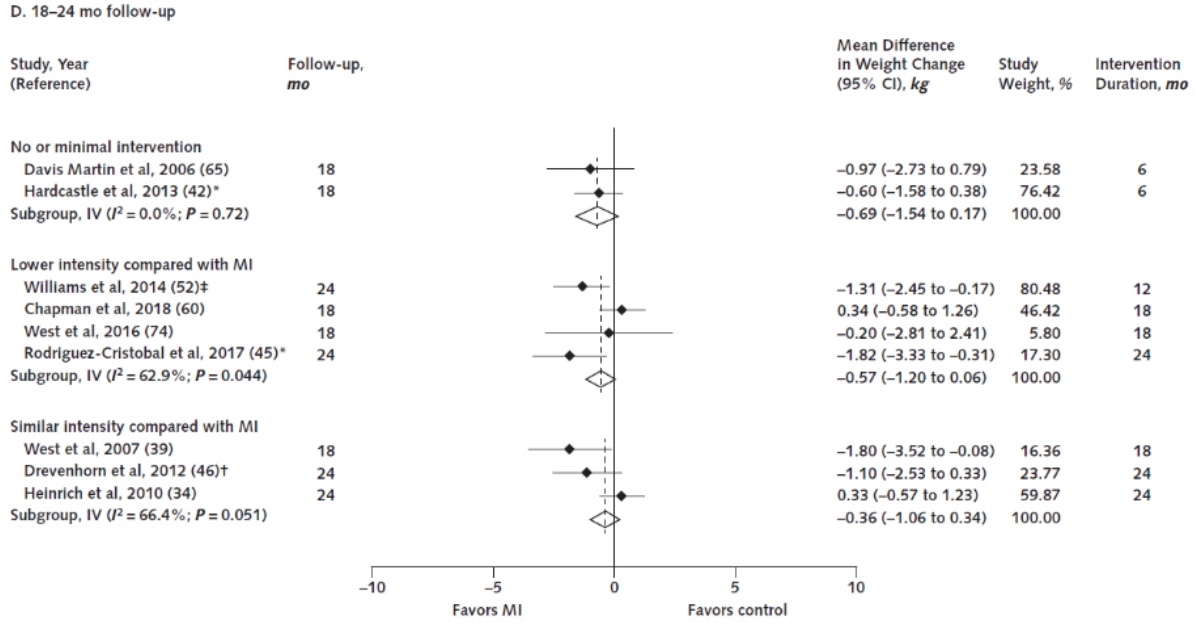


Figure 3.3 continued



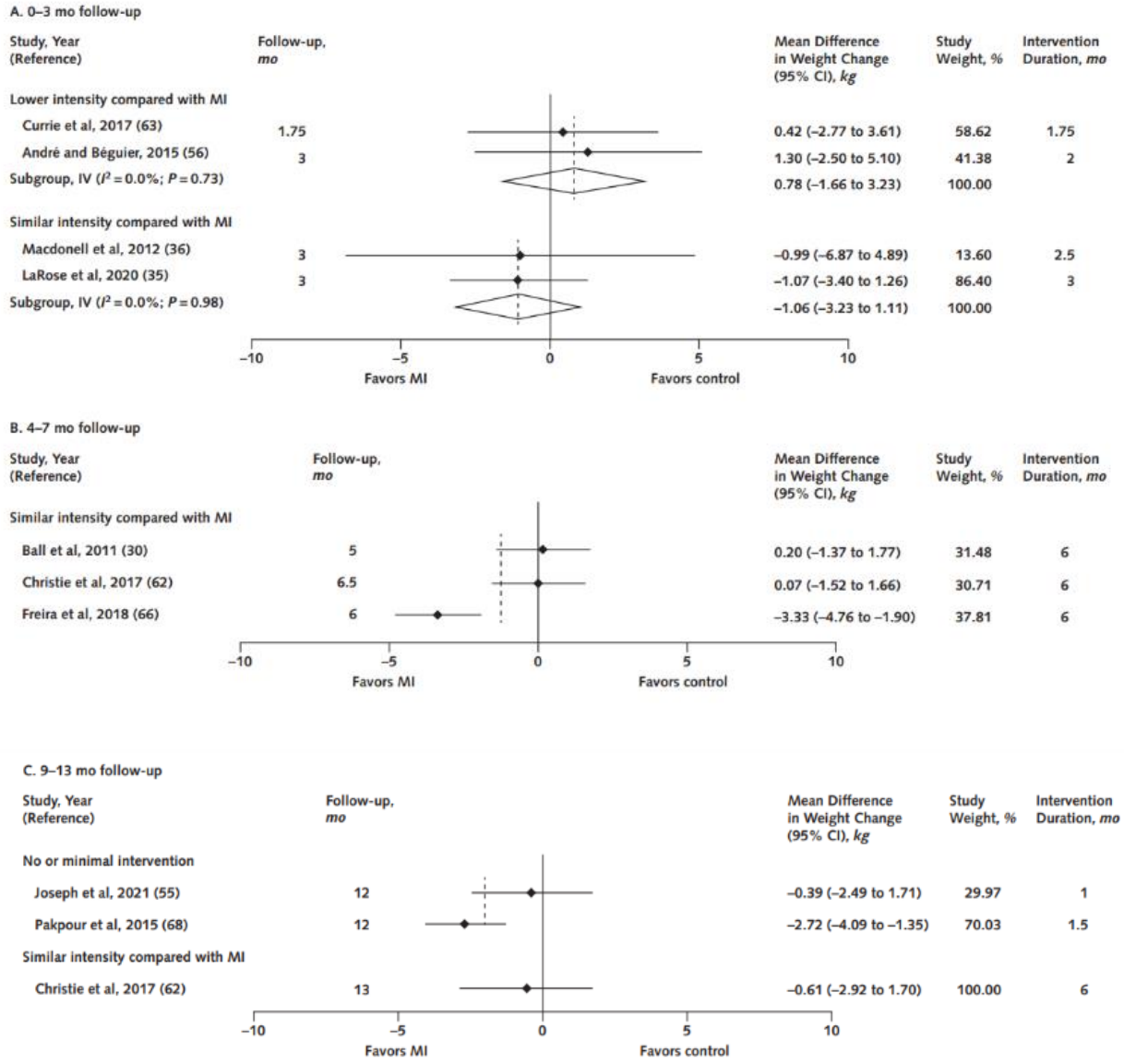
DL: DerSimonian–Laird; **HKSJ:** Hartung–Knapp–Sidik–Jonkman; **IV:** inverse variance; **MI:** motivational interviewing; **mo:** months

* Studies at high risk of bias. Summary estimates excluding these studies were as follows. A. No/minimal intervention: -1.14 (95% CI, -1.78 to -0.49) kg, subgroup IV (I^2= 0.0%; P= 0.60); lower and similar intensity: unchanged/not applicable. B. No/minimal intervention: -0.90 (95% CI, -1.43 to -0.36) kg, subgroup DL+HKSJ (I^2= 0.0%; P= 0.43); lower intensity: -0.66 (95% CI, -2.30 to 0.99) kg, subgroup DL+HKSJ (I^2= 0.0%; P= 0.055); similar intensity: unchanged/not applicable. C. No/minimal intervention: -1.78 (95% CI, -3.70 to 0.14) kg, data from only 1 study; lower intensity: -1.27 (95% CI, -3.21 to 0.66) kg, subgroup IV (I^2= 91.9%; P= 0.000); similar intensity: unchanged/not applicable. D. No/minimal intervention: -0.97 (95% CI, -2.73 to 0.79) kg, data from only 1 study; lower intensity: -0.31 (95% CI, -1.00 to 0.38) kg, subgroup IV (I^2= 59.1%; P= 0.087); similar intensity: unchanged/not applicable.

† Studies in which it was unclear whether MI was the only difference between groups. Summary estimates excluding these studies were as follows. A. Unchanged/not applicable. B. No/minimal intervention: -1.10 (95% CI, -1.91 to -0.29) kg, subgroup DL+HKSJ (I^2= 0.0%; P= 0.55); lower intensity: -0.15 (95% CI, -0.61 to 0.31) kg, subgroup DL+HKSJ (I^2= 0.0%; P= 0.43); similar intensity: unchanged/not applicable. C. No/minimal intervention: -1.78 (95% CI, -3.70 to 0.14) kg, data from only 1 study; lower intensity: -1.18 (95% CI, -2.74 to 0.39) kg, subgroup DL+HKSJ (I^2= 90.3%; P= 0.000); similar intensity: unchanged/not applicable. D. No/minimal intervention and lower intensity: unchanged/not applicable; similar intensity: data could not be pooled because only 2 studies with heterogeneous estimates were included.

‡ Studies that reported good overall fidelity in MI delivery. Summary estimates including only these studies were as follows. A. Data could not be pooled because only 2 studies (1 each in the lower- and similar-intensity subgroups) were included. B. Data could not be pooled because only 2 studies (1 each in the no/minimal intervention and lower-intensity subgroups) were included. C. No/minimal intervention: -0.43 (95% CI, -0.98 to 0.12) kg, data from only 1 study; lower and similar intensity: data could not be pooled because only a few studies with heterogeneous estimates were included. D. No/minimal intervention and similar intensity: unchanged/not applicable; lower intensity: -1.31 (95% CI, -2.45 to -0.17) kg, data from only 1 study.

Figure 3.4. Mean difference (in kg) in weight change in adolescents between MI and comparator (control) groups, by duration of intervention programme (312)



IV: inverse variance; **MI:** motivational interviewing; **mo:** months
All models used fixed-effects meta-analysis. The study by Joseph and colleagues (no/minimal intervention subgroup) did not report data at 6 months. No studies had 18- to 24-month follow-up.

3.4.5 Psychological well-being

Nineteen studies assessed psychological well-being, of which 17 provided data. Two studies in adults measured but did not report these outcomes (372, 379). There were too few studies in each follow-up time frame within the comparator categories to pool studies. Effect sizes from the remaining 11

adult weight loss studies were marginal (range of SMDs, -2.2 to 0.40), and in most cases, the 95% CIs crossed the null. Five of these 11 studies reported psychological score changes that favoured MI at all follow-up time points (range of SMDs, 0.26 to 0.40) (**Figure 3.5**). There were 2 studies in which interventions aimed to prevent weight gain. One year after baseline, 1 study reported a small improvement in well-being with MI (0.51 [95% CI, 0.27 to 0.75]) (387), whereas the second showed no difference (0.00 [95% CI, -0.35 to 0.35]) compared with a lower-intensity BWMP (388). All 4 adolescent interventions favoured MI with regard to psychological well-being, but effect sizes were similarly marginal (range of SMDs, 0.01 to 1.29) (**Figure 3.5**). Sensitivity or subgroup analyses could not be conducted because of sparse data.

Figure 3.5. Standardised mean difference in psychological well-being in adults and adolescents between MI and comparator (control) groups, by duration of intervention programme (312)

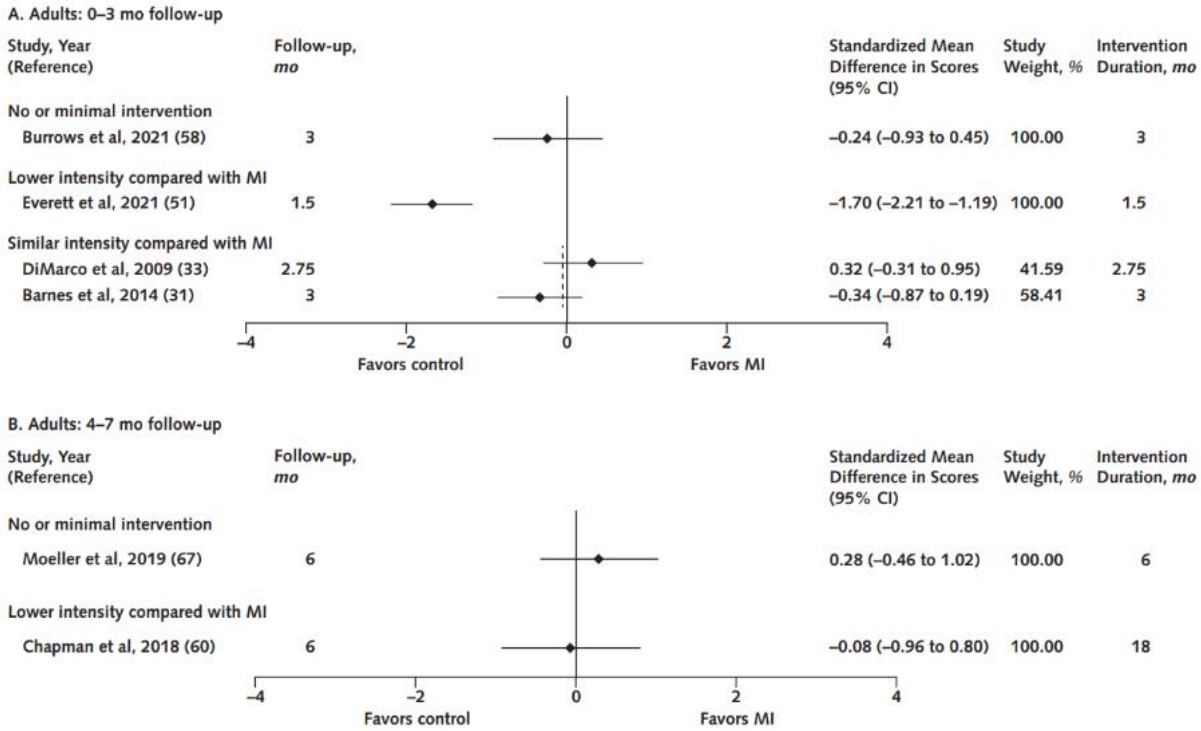
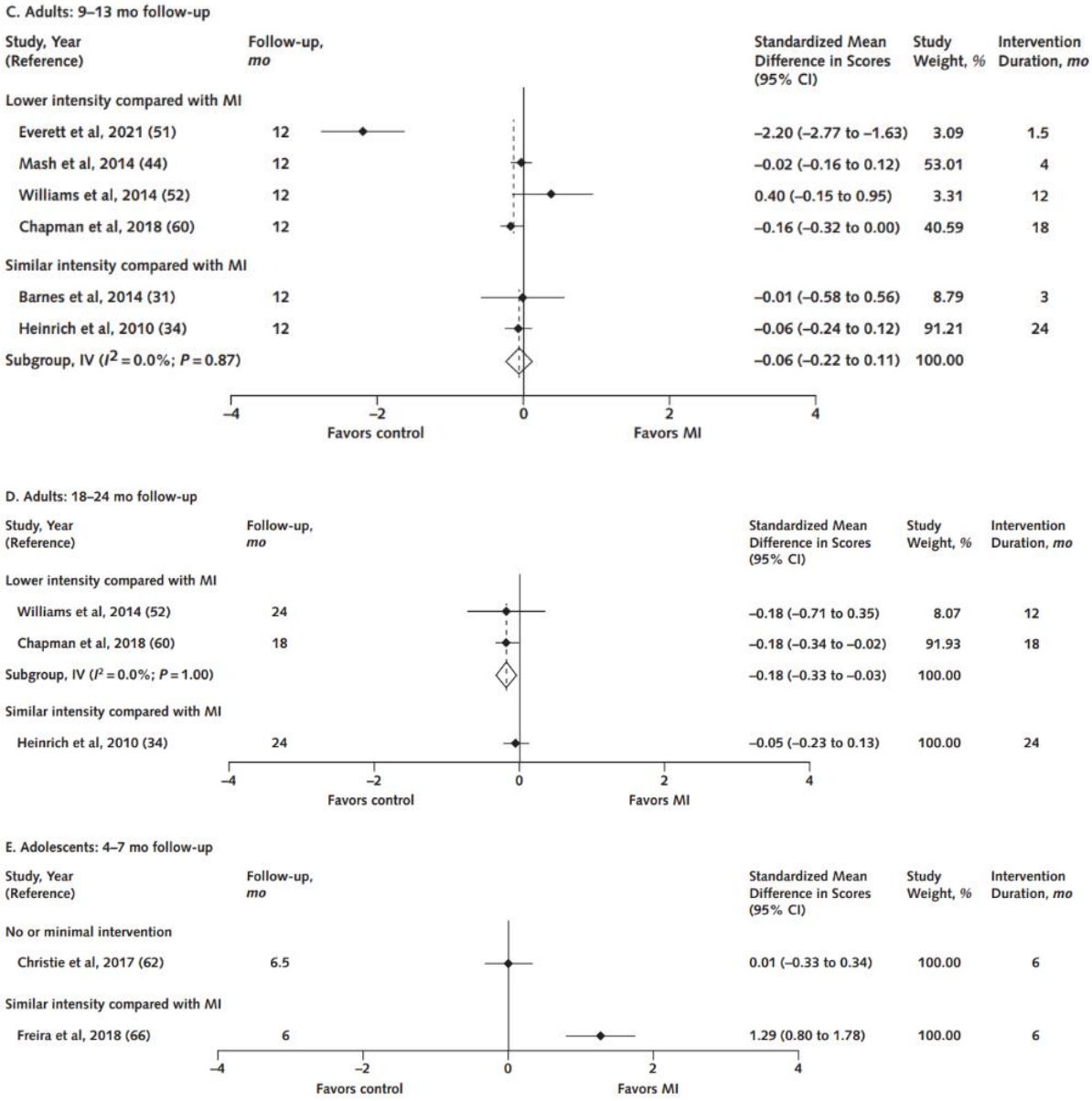


Figure 3.5. continued



IV: inverse variance; **MI:** motivational interviewing; **mo:** months

All models used fixed-effects meta-analysis.

Among adult studies, Ferrara and colleagues (no/minimal intervention subgroup) reported a reduction in the proportion of persons with depression in both groups at 6 and 12 months but a bigger reduction in the control group, and in the study by Sawyer and colleagues (no/minimal intervention subgroup), which reported the number of persons with a total wellness score >80 or <80 at 6 months, both groups showed an increase in the number of persons with a wellness score >80, but the increase was higher in the MI group.

Among adolescent studies, only the study by Andre and Beguier (lower intensity) had 0- to 3-month follow-up (standardised mean difference, 0.57 [95% CI, -0.43 to 1.57]), and only the study by Pakpour and colleagues (no/minimal intervention) had 9- to 13-month follow-up (standardised mean difference, 0.38 [95% CI, 0.13 to 0.63]); no studies had 18- to 24-mo follow-up.

3.5 Discussion

Compared with no/minimal intervention, programmes incorporating MI led to about 1 kg greater weight loss in adults at 3 and 6 months of follow-up, but only two studies provided data at 1 year, with no evidence of a sustained difference. There was no evidence that incorporating MI into a BWMP improved weight loss at any time point compared with either similar-intensity or lower-intensity BWMPs, but estimates were imprecise. Findings were generally unchanged in sensitivity analyses, and there was no consistent evidence of subgroup differences by a range of study, intervention, or participant characteristics. Data on adolescent or weight maintenance studies were too sparse to conduct meaningful meta-analyses, although individually, they provided no evidence of a benefit from MI. There was no data on women who were pregnant. There was no evidence that incorporating MI improved psychological well-being.

Previous systematic reviews reported that MI was associated with a small to moderate decrease in weight. Mean differences in weight change between groups were not always reported in these reviews, but the results in the publications suggested that effect estimates varied across studies, and reached higher than those shown in the current review (approximately -0.2 to -1.8 kg in favour of MI) (351-357). The majority of previous reviews pooled interventions that incorporated MI along with other elements and compared them against comparators that were usually of lower intensity or no intervention. Pooling these programmes would tend to overestimate the specific contribution of MI. I subdivided studies on the basis of the comparator to provide clearer insights into the potential value of MI, and when ambiguous descriptions created doubt, I conducted sensitivity analyses to exclude those studies. I also examined the effect of MI at specific time points from baseline, to reflect the typical trajectory of weight loss followed by weight regain.

There are concerns that BWMPs could have negative psychological effects given that many people do not achieve their weight loss goals (410, 411). Data were too sparse to conduct meta-analyses, but individual trials provided no evidence of benefit or harm from MI.

This review has several strengths. To limit bias and minimise confounding, I included only RCTs, did not exclude studies on the basis of year or language, and followed established Cochrane methods. Previous systematic reviews limited searches to populations with overweight or obesity (351-354, 356). Some focused their searches on a specific language (353-356), year of publication (354, 355), format (353, 354), setting of MI delivery (352), or intervention programme duration (354). I included studies regardless of participants' baseline BMI, but the typical study included mainly people with obesity. My searches were designed to be comprehensive and consequently included more studies than previous reviews of MI, with interventions of variable type, content, and duration from 14 countries, including both high- and middle-income regions. In addition, my review aimed to present a more realistic picture, by examining outcome change by time point of follow-up, reflecting the trajectory of weight with time, following a BWMP. It also aimed to assess effect modification by various participant or programme characteristics, on both weight and psychological well-being.

The review also has several limitations. Categorising studies by comparator, and analysing at distinct follow-up times, resulted in multiple analyses involving a small number of studies. Results were limited by high statistical heterogeneity for comparators of lower or similar intensity. Pooled interventions varied in intensity, duration, delivery, format, and contact time. Although I sought to identify the likely sources of heterogeneity, I was largely unable to explain the differences in the outcomes I observed. Most studies used interventionists other than the patients' usual physicians, although in four studies, interventionists who provided treatment were nurses and/or physicians responsible for delivering care for chronic disease (368, 379, 381, 389). It is unclear whether efficacy would be improved if MI were delivered by a physician or nurse known to the patient. One possible source of bias is that in two studies, comparing MI plus a BWMP with a similar-intensity BWMP, interventionists differed between groups, and in one study, it was unclear whether this was the case. In these small trials, imbalance in the skill of delivering non-specific aspects of therapy, could result in differences between groups that were caused by the therapist rather than the therapy, although this is unlikely to have played a large role in most of the included trials. Insufficient or inconsistent

reporting of interventions and outcomes made the review challenging and required several assumptions. For example, I used a predefined, though essentially arbitrary definition of programme end, as the end of the most active phase of an intervention. When interventions were incompletely described, the reviewer team attempted to check supplementary materials and trial protocols and contacted the authors. I sought to minimise outcome reporting bias by using standard formulas to calculate relevant outcome measures from extracted data, but these rely on assumptions. Less than two thirds of the included studies reported assessing MI treatment fidelity, and only half of these reported fidelity outcomes, which makes it difficult to draw conclusions about the quality of MI delivery. Relatively few studies followed up on participants at 1 year or later. Methods to handle missing data were often not sufficiently reported, and the variability may have introduced differences between studies. Seventeen percent of included studies were judged to be at high risk of bias, but removing these studies did not meaningfully affect the results.

3.6 Conclusion

BWMPs using MI may only have a small short-lived benefit on weight change, compared to no/minimal intervention, and there is no evidence of benefit compared to otherwise similar BWMPs without MI. Results were less clear for psychological well-being, due to sparsity of data, but there was no indication that MI improved outcomes. Given that MI requires intensive training and increased delivery time, there is little evidence that it makes a meaningful difference to weight control or well-being when added to a BWMP.

3.7 Implications for this thesis

Most data are available from studies in people seeking to lose weight. Data from studies aimed at weight maintenance might have been more relevant to women at risk of GDM whose aim is to attenuate their weight gain during pregnancy. However, only two studies aimed at weight maintenance (387), of which one aimed at prevention of weight gain to prevent ill health (387), and showed no benefit from incorporating MI compared to a lower-intensity BWMP. No included trials

delivered MI during pregnancy. Nevertheless, the results of this review are still applicable to women at risk of GDM, because a MI-based BWMP applied in this context, would still aim to boost intrinsic motivation for weight control, and enhance adherence to dietary and/or physical activity advice. Since in most studies, MI was tested as part of interventions for persons who were seeking help to manage their weight, this suggests that the participants were already motivated to take action. However, MI is typically advocated in contexts where people are less ready to change. Only four trials offered standard medical care adapted to include MI to address weight in people being treated for chronic diseases, such as T2DM, which may suggest that these participants were not specifically seeking help to control their weight (368, 380, 383, 389). In these trials, there was no evidence that MI increased weight loss. Likewise, a trial that aimed to test an MI-like intervention in primary care found no benefit across several behaviours (412). These data are perhaps the most relevant to my population of interest, women identified at high risk of GDM, even if they do not actually have the condition. However, MI was used not as a standalone intervention, but rather, in addition to components typical in BWMPs, such as goal setting, monitoring, and provision of feedback. These elements may be at odds with the spirit of MI and could have undermined the potential benefit on mental health outcomes.

Delivery of MI is resource-intensive with regards to patient contact and the interventionist training required for its delivery. It is unclear what is the appropriate quantity and delivery of MI within obesity care (356), but in the included studies, MI was typically delivered over 3 to 6 months, a window similar to that of interventions in pregnancy, with sessions usually lasting 45 minutes to 1 hour. In addition, MI is not just a technique that practitioners can easily learn. It requires a complex set of communication skills that need to be used strategically during the consultation to evoke motivation. As a result, although typically MI training lasted for 2 working days, in many cases it required top-up training, practice, coaching, and supervision (322, 413). Whilst it is possible for researcher interventionists to receive intensive training and supervision, and to have availability for increased patient contact time, it is unlikely that this would be practical if my intervention was to be delivered

in the routine antenatal service. The costs of the training of maternity HCPs would also be high, making routine MI delivery implausible in routine care, given workforce pressures. Accordingly, it seems implausible that the addition of MI to a standard BWMP (or similar intervention) in routine antenatal care would be cost-effective. Finally, although MI interventions led to greater weight loss than no/minimal interventions, the magnitude of the difference over 1 year was small, and similar to that of simple self-help interventions that do not require any interventionist time (414, 415).

Weighing the pros and cons of MI delivery, and taking into account the lack of evidence for its effectiveness in the context of a BWMP, I decided that it would not be worthwhile to add it as a specific component to my intervention. Instead, I aimed to use active listening, empathy, and enhancement of self-efficacy, but not MI specifically (Chapter 4).

Chapter 4: Developing a reduced-carbohydrate intervention for use in pregnancy

4.1 Summary

This Chapter presents the work I conducted to develop a novel intervention to help individuals at risk of GDM to reduce their carbohydrate intake. I developed the intervention by adapting the Behaviour Change Wheel (BCW) methodology. I first selected the target behaviour, and decided to focus on reducing the intake of total carbohydrate during early or mid-pregnancy. Second, I conducted a literature review to explore barriers and facilitators to changing dietary behaviours, and where available, carbohydrate intake during pregnancy. Barriers included pregnancy-induced physiological changes, lack of knowledge and information on GDM, diet, and weight management during pregnancy, competing priorities, the wider food environment, beliefs about diet during pregnancy, and psychosocial factors, including lack of self-efficacy, previous negative experience with dieting or weight stigma, social norms, and emotional eating. Conversely, wanting to have a healthy pregnancy and baby, behavioural strategies (e.g. goal setting, action planning, self-monitoring), clear guidance from a credible source, and social support were identified as facilitators to making healthier dietary changes during pregnancy. Third, I designed the intervention content, by selecting appropriate intervention functions from the BCW, choosing the behaviour change techniques (BCTs) through which to deliver each function, and translating BCTs into specific intervention components and materials. The aforementioned process was informed by consultations with an obstetrician, an obstetric physician, a research midwife, a diabetes dietitian, two academics, and a patient representative with previous GDM, as well as from a patient and public involvement (PPI) exercise with people affected by GDM. The resulting intervention included 6 intervention functions and 24 BCTs. The components of the intervention programme were:

- A face-to-face dietary consultation with a HCP

- Structured written information on GDM and appropriate food choices for a reduced-carbohydrate diet
- Written materials on behavioural control
- Remote telephone support sessions
- Self-monitoring of weight during pregnancy

Note: Sections of this Chapter have been published in the journal BMJ Open (416).

4.2 Introduction

Although some trials have been successful in attenuating GWG in women with overweight or obesity, through adherence to dietary and/or physical activity advice, the majority have failed to reduce GDM risk (223, 224). The interventions to date that have led to reduction in GDM incidence (225, 228, 232, 239, 240), had no or small effect on GWG, which may suggest that limiting GWG may not be sufficient in itself in reducing GWG, but other components of the intervention may have played a role in the success. The authors of these studies have proposed that implementation of the intervention at early stages of pregnancy was key to success, as was the change in dietary composition through manipulation of macronutrient content. However, most do not provide dietary intake data. For example, in the Mediterranean diet interventions, authors speculated that the increased unsaturated fat and polyphenol consumption through liberal consumption of olive oil and nuts, might have been beneficial with regards to insulin sensitivity and inflammation (228, 232). But what the authors may have overlooked, is that higher fat and protein consumption in contexts when energy intake remains similar, may have naturally resulted in reduction in dietary carbohydrate intake, which may have played a role in the observed effect on GDM, through for example, controlling blood glucose concentrations. In fact, all the successful interventions to date have included an element of carbohydrate reduction.

This suggests that there is considerable scope to explore the effect of dietary composition modification as a strategy to help reduce GDM risk. I hypothesised that an intervention which limited

carbohydrate at early stages of pregnancy, could help prevent GDM, though controlling glycaemia, and since carbohydrates comprise the biggest portion of total energy intake, reducing them without specific substitution, should also limit GWG. To my knowledge, only one previous RCT specifically aimed at moderately reducing total carbohydrate intake in women at risk of GDM, but did so as part of an intensive programme. This study, did not have a significant effect on GWG compared to control by the time of testing for GDM, and did not reduce GDM incidence, however, it only achieved a small reduction in carbohydrate intake (less than 1 portion of carbohydrate food/day) (254).

In this Chapter, I describe how I developed a dietary approach based on moderate carbohydrate reduction, suitable for use in pregnancy, combined with behavioural support, and structured written information. The intervention aims to improve participants' adherence to the diet through a behavioural support programme, delivered alongside routine antenatal care, including strategies such as goal setting, planning, and feedback. I developed the intervention based on a review of the literature, similar study protocols, qualitative data of similar interventions, and discussions with academics, HCPs working in maternity, and a patient representative with previous GDM. A group of women affected by GDM, also helped to shape the ideas for this research, and the dietary information and support they felt would be helpful.

4.3 Initial scoping and PPI

As part of an initial scoping for research in preventing GDM, members of my co-investigator team sought to identify whether it would be feasible to design and deliver a dietary intervention aimed at reducing the chances of developing the condition in women at high risk. Ten people affected by GDM in a current or previous pregnancy were recruited from a local antenatal clinic in Oxfordshire, a national GDM support website, and a social media forum. Two focus group discussions took place. Meetings were held at Oxford University Hospitals (OUH) NHS Foundation Trust, facilitated by a senior academic researcher and a diabetes specialist dietitian (members of the co-investigator team). The PPI members were initially asked about their knowledge around GDM, the treatment they received,

and their motivation for participating in diet-related research for the prevention, treatment or management of GDM. This helped prioritise and refine the research questions for a trial testing the feasibility of delivering alongside routine antenatal care, a dietary intervention to help prevent GDM (Chapter 5). The PPI members were also asked to provide their thoughts and comments specifically around reducing carbohydrate intake as a preventative strategy for GDM, by limiting the consumption of sugary foods and drinks, and reducing the amount of starchy foods in their diet.

A summary of quotations is presented in **Appendix 4.1**. Not all participants were aware of GDM before getting pregnant, and it was clear that they felt upset, shocked and anxious when they received their diagnosis. There was anxiety around the consequences on the baby, as well as frustration about recurring GDM despite all efforts. In addition, participants reported feeling overwhelmed with the amount of information they had to learn following GDM diagnosis. Information in leaflets or online was overwhelming or confusing, and they highlighted that they need clear, simple and specific messages about GDM. Most participants felt that pregnancy was a prompt for them to review their overall health, and those with a previous pregnancy complicated by GDM, reported that having experienced the consequences of having GDM, motivated them to take action to prevent it in a subsequent pregnancy. They were enthusiastic to hear about a preventative intervention that could be implemented early in pregnancy, rather than waiting until GDM was diagnosed before intervening. Aside from maternal outcomes, participants were keen to also know about neonatal outcomes. Although interested in taking part in clinical trials for the prevention, treatment or management of GDM, participants felt that attending extra appointments for study visits, and in particular, having to use the parking at the hospital, would be a major barrier to participation. With regards to diet and lifestyle, participants reported that the current advice delivered as part of routine antenatal care was too generic and they would welcome a more specific programme. They found the principles of a reduced-carbohydrate diet appropriate for pregnancy, in the context of a healthy balanced diet. They suggested that lowering carbohydrate intake would be easier with the support of their partner, family or friends.

Considering the feedback from this PPI scoping exercise, I aimed to develop a programme to be tested as a preventative strategy for GDM, including structured dietary information and advice, and behavioural strategies, to maximise adherence. I also sought to minimise the number and duration of additional study visits, by combining or replacing the usual clinical appointments, sharing information to the clinical care team to avoid duplication of visits and tests, and offering remote sessions for support with following the programme. In addition to the inconvenience allowance offered to participants, I also decided to use alternative facilities for the conduct of study visits, where parking is more readily available (more details in Chapter 5).

4.4 Dietary component

In selecting the appropriate level of carbohydrate consumption for my intervention, I considered the classification of diets based on carbohydrate content, proposed by Feinman and colleagues (**Table 4.1**) (417). Evidence from clinical trials of dietary interventions for diabetes management outside of pregnancy, shows that the lower the carbohydrate intake, the bigger the reduction on blood glucose levels, and that weight is reduced substantially (418, 419). Strict carbohydrate restriction may not however be appropriate in pregnancy. Concerns exist that if low carbohydrate intake is accompanied by higher maternal fat intake, this could lead to increased fetal lipid exposure and overgrowth (208, 420). In addition, since maternal glucose supports fetal growth and brain development, concerns have been expressed about adverse effects on the development of the fetus as a result of substantially low levels of carbohydrate intake (421), and/or induced maternal ketosis (422, 423). In extreme cases, a condition called ketoacidosis can be life-threatening, and requires immediate hospitalisation. Ketoacidosis is more common among people with T1DM, where it is known as diabetic ketoacidosis, although occasionally occurs in people with T2DM, and rarely in GDM (424, 425). However, the relationship between low carbohydrate intake and adverse perinatal outcomes is often confounded by inadequate energy intake (421). What is more, research in non-pregnant populations suggests that significant ketosis only occurs when carbohydrate intake is <50 g/day (417). Several other factors also often cause clinically severe ketosis or ketoacidosis in pregnancy, such as starvation, excessive

vomiting, infections, gastroparesis (425, 426). The above therefore leave considerable scope to adopt a moderately reduced-carbohydrate diet.

Table 4.1. Classification of diets based on carbohydrate content (417)

Type of diet	g total carbohydrate/day	% of total energy intake/day from carbohydrates
High-carbohydrate	>230	>45%
Medium-carbohydrate	130-230	26-45%
Low-carbohydrate	>50 to <130	<26%
Very low-carbohydrate	20-50	≤10%

Data from the UK's National Diet and Nutrition Survey (NDNS), reported that women's carbohydrate intake comprised on average 46% of their total daily energy intake (427). This is equivalent to 230 g of total carbohydrate/day for a recommended diet of 2000 kcal/day for women. My intervention was designed to encourage a substantial reduction in carbohydrate consumption compared to the population average, but to not be too restrictive, so as to avoid the risk of weight loss or ketosis. The diet aimed to provide 130-150 g of total carbohydrate/day (40g in each of three main meals, and snacks of no more than 10-15g), with healthy eating advice, and no additional energy restriction. This suggested level of carbohydrate consumption is in line with the dietary advice provided to individuals who receive a diagnosis of GDM as part of their routine antenatal care at OUH.

The IOM recommends that women during pregnancy consume a minimum of 175 g of total carbohydrate/day. This amount is based on the Recommended Dietary Allowance (RDA) for carbohydrates in adults (>130 g/day), adding extra 45 g for the estimated glucose consumed by the fetus during pregnancy (428). However, RDAs express the average daily dietary intake level sufficient to meet the nutrient requirements of nearly all healthy adults, and are based on expert opinion, rather than specific clinical trial evidence. I was confident that the level of carbohydrate reduction in my intervention was unlikely to cause high ketone levels, because previous trials of reducing carbohydrate

intake to similar levels during pregnancy (range of 95-180g of total carbohydrate/day), did not report adverse effects such as ketonuria, ketonaemia or ketoacidosis (201, 202, 429-431).

I named the intervention **"Reduced-carbohydrate intervention for the management of obesity and reduction of gestational diabetes" (RECORD)**. The dietary component of RECORD was designed around three core principles:

- **REFRAIN** from having sugary foods and drinks (e.g. biscuits, confectionary, juice, sugary fizzy drinks), with the exception of dairy and limited fruit intake;
- **REDUCE** the amount of starchy carbohydrates to a moderate level, by having smaller portions of foods such as rice, pasta, bread, grains, potato, yams, cassava, plantain, at main meals;
- **REPLACE** refined starchy carbohydrates with wholegrain, unrefined versions, and sugary foods and drinks, with lower-carbohydrate, and lower/no-sugar alternatives.

These principles were introduced in an initial consultation with the participants, along with information on the importance of controlling GWG (details in section 4.5.4).

4.5 Applying theory and the Behaviour Change Wheel (BCW)

Best available evidence recommends that behaviour change programmes are designed based on a theoretical model (432). Theory is a conceptual model derived from evidence, which helps us understand how various influences on a particular behaviour are related to, or predict behaviour. By identifying the influences of a behaviour, it is possible to identify appropriate targets for the intervention, as well as ways to change them (433). There are a multitude of behaviour change theories to draw on when designing a behavioural intervention (434), but they often do not consider the full range of potential options for intervention. In light of this, Michie and colleagues identified the need for a comprehensive model that can guide the design, implementation and evaluation of complex behaviour change interventions, which led to the development of the BCW (435). The BCW is a combination of 19 frameworks of behaviour change identified through a systematic literature review. The BCW has been used in the development of interventions in both pregnant and non-

pregnant populations, for a variety of health behaviours such as diet, physical activity, smoking (436-438).

The BCW approach recommends the following iterative stages in designing behavioural interventions:

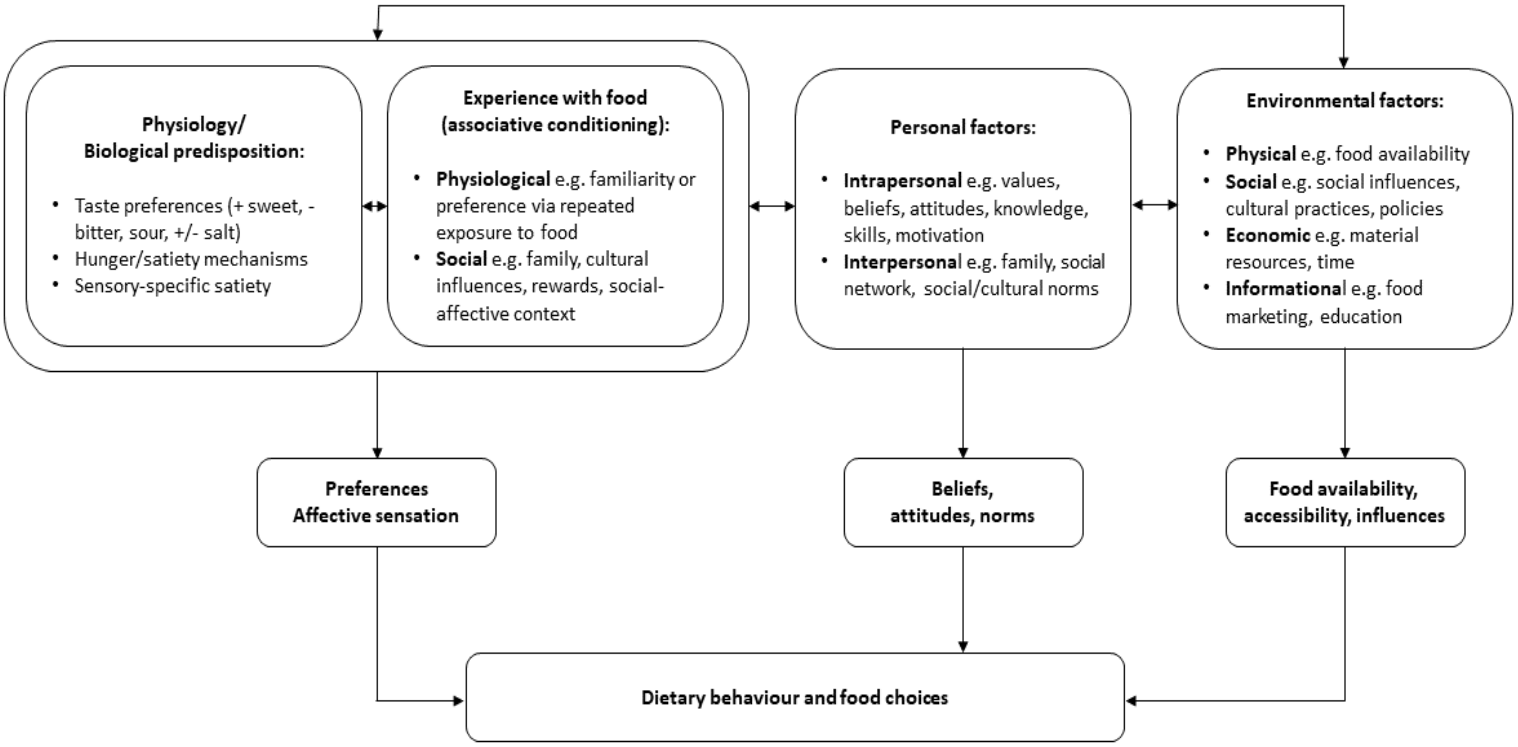
1. Specifying and characterising the target behaviour;
2. Identifying barriers and facilitators that prevent or encourage performance of the target behaviour respectively; and
3. Developing the intervention content and implementation strategy.

This is the ideal process for selecting behavioural targets and designing interventions. In practice, I knew my target behaviour would be reducing carbohydrate intake before I started the active intervention development, so rather than following the BCW as a step-by-step guide, I utilised it as a framework upon which I mapped my target behaviour and intervention components that I had already considered including, to help me identify gaps and issues with regards to the target behaviour, and to assist me with developing the intervention in a structured way.

4.5.1 Understanding the target behaviour

According to the BCW approach, the fundamental problem that the intervention aims to tackle needs to be described in behavioural terms, to understand the behavioural determinants of the problem that could be targets for intervention (435). Through my literature review, I already had identified that obesity is the strongest modifiable risk factor for GDM (439). A basic determinant of excess weight gain leading to obesity is overconsumption of calories, which in turn is the result of a complex interplay of physiologic, generic, personal, and environmental factors (**Figure 4.1**).

Figure 4.1. Factors influencing diet-related behaviours and food choices



Adapted from Contento 2008 (440).

Prioritising candidate behaviours enables to select the final behaviour that needs to change or promote. This can be facilitated by considering the likely **impact** of changing or promoting the behaviour(s) on the fundamental problem, the **feasibility** and ease of changing or promoting the behaviour(s), the likelihood of a positive or negative **impact** of changing or promoting the behaviour(s) **on other desirable behaviours**, and the **ease of measurement** of the behaviour(s). I decided *a priori* that for a behavioural intervention on an individual level, the appropriate target would be food choices during pregnancy, including the type, quantity, and frequency of foods consumed. Based on evidence from existing dietary interventions for the prevention and management of GDM, as well as interventions for the management of diabetes outside of pregnancy, I decided to focus my intervention on foods containing carbohydrates. Carbohydrates are the most important nutrient affecting blood glucose levels (441), as well as the major source of energy in the diet (442), and there is evidence from clinical trials in GDM management and T2DM, supporting the reduction of

carbohydrates for blood glucose and weight control (201, 202, 253). **Figure 4.2** shows how reducing carbohydrate intake meets the criteria as target behaviour in the BCW.

Figure 4.2. Criteria for choosing RECORD's target behaviour

Target behaviour: making healthy, low-to-moderate-carbohydrate food choices in pregnancy

☑ **Likely impact of changing the behaviour**

Individually targeted interventions to reduce total carbohydrate intake have been shown to be effective in managing blood glucose levels and weight in people with T2DM or GDM. Hyperglycaemia and excess weight are the underlying factors for the development of diabetes, and therefore intervening on both may reduce the risk for developing GDM.

☑ **Ease of changing the behaviour**

Reduced-carbohydrate advice is already provided as part of routine care to people with established GDM, and has been shown to help manage blood glucose levels. People at risk of GDM may be willing to take action to make reduced-carbohydrate food choices to reduce their risk of GDM, given that pregnancy is a teachable moment. People who are pregnant are in frequent contact with a primary and tertiary care health provider throughout pregnancy. The proposed dietary intervention is a variant of standard healthy eating advice during pregnancy, only more specifically focused on maintaining a moderate level of carbohydrate intake.

☑ **Likely spill-over effect**

An intervention targeting healthier and lower-carbohydrate food choices during pregnancy, may help reduce hyperglycaemia, as well as limit weight gain due to reduction in energy intake. The combination of the two effects may help improve maternal and neonatal outcomes, which also affect maternal and offspring health later in life. In addition, lower carbohydrate consumption may have positive spill-over effect on the consumption of other nutrients such as saturated fat, especially due to the focus of the intervention on minimising free sugars which often coexist with saturated fat in energy dense foods.

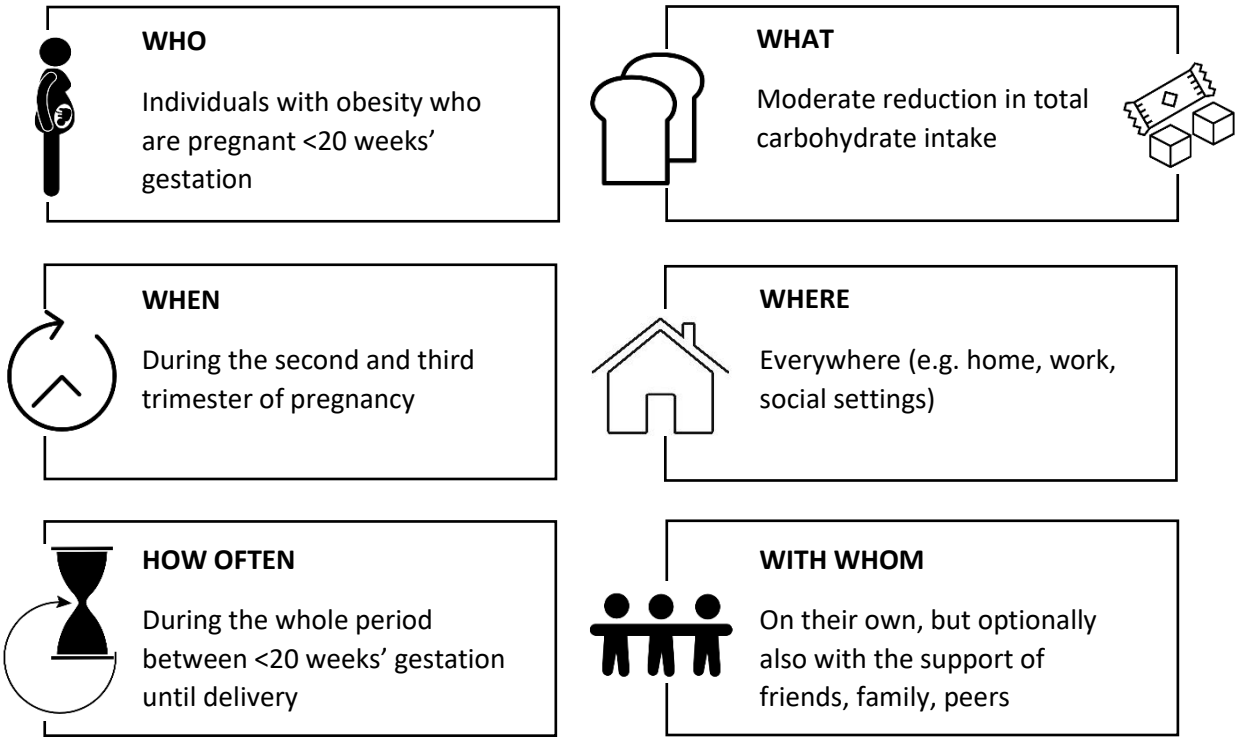
☑ **Ease of measurement**

Individual carbohydrate intake can be measured via 24-hour dietary recall questionnaires, either through interviews or self-completion, a method already used by the UK Government in the NDNS.

GDM: gestational diabetes mellitus; **T2DM:** type 2 diabetes; **NDNS:** National Diet and Nutrition Survey

Then the selected behaviour needs to be thoroughly described, which involves identifying the factors that explain or predict it, and identifying the specifics of "who needs to perform it, what they need to do differently to achieve the change, when, where, how often, and with whom they need to do it". I decided that among individuals with GDM risk factors, I would target those with obesity only, as they are more likely to benefit from an intervention that aims to attenuate GWG. As a result, RECORD's target behaviour is: "moderately reducing the consumption of carbohydrates among individuals who are pregnant with obesity, and at risk of developing GDM". I then specified further details of the target behaviour (**Figure 4.3**).

Figure 4.3. Specifying RECORD's target behaviour

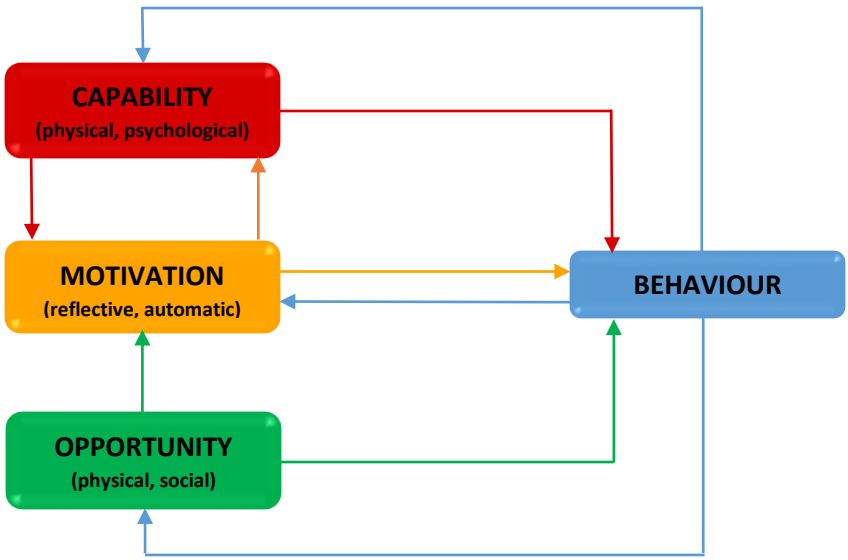


4.5.2 Identifying what needs to change for the target behaviour to occur

After specifying the target behaviour, the BCW recommends conducting a behavioural analysis of what needs to change in the individual or the environment to achieve the desired change (435). This can be done by identifying barriers and enablers that impede and facilitate the target behaviour

respectively. Specifically, the BCW recommends using the **Capability – Opportunity - Motivation (COM-B)** model, which suggests that to perform the desired behaviour, people need to have the capability, opportunity, and the motivation to do so (**Figure 4.4**).

Figure 4.4. The COM-B model interactions and influences. Adapted from Michie et al. (435)



While the COM-B may be a useful framework for analysing behaviour, it was not developed specifically to identify barriers and facilitators towards reducing carbohydrate intake in pregnancy. Thus, in identifying what needs to change in order for women at risk of GDM to moderately reduce their carbohydrate intake, I decided to adapt the BCW methodology. I drew upon qualitative evidence from studies in people at risk of, or with established GDM, as well as studies in HCPs working in antenatal care. I combined this evidence with insights from the scoping PPI exercise and discussions with stakeholders who are my co-investigators (an obstetrician, an obstetric physician, a diabetes dietitian, a research midwife, and a patient representative). This helped me draw evidence directly from patients and professionals involved in their care, which increases the chances that the RECORD intervention programme will be relevant and feasible to the people to whom it is intended to be delivered, and the people who are expected to deliver it, should it progress to alter stages of testing, or be delivered at scale. I then mapped the literature, PPI, and discussion findings onto the COM-B

components, to identify if there are any gaps in the type of information I sought to collect, or any areas of intervention focus that I had not considered.

4.5.2.1 Barriers and facilitators: qualitative evidence

My literature review of qualitative studies in pregnancy identified factors which might hinder or enable dietary change during pregnancy.

4.5.2.1.1 Capability

Pregnancy-related symptoms are known and expected to occur (**Box 4.1**), and dietary interventions need to provide people with the skills to manage diet-related symptoms while still following a healthy balanced diet, and need to be easy to follow, so as to not impose additional burden. There is lack of knowledge and advice around diet and weight during pregnancy (**Box 4.2**), therefore women tend to seek this by themselves from a range of others sources such as family and friends, but the majority refer to the internet and social media due to convenience and ease of access (335, 443, 444), where the information may be confusing and its accuracy is questionable (443).

Box 4.1. Pregnancy-related symptoms (physical capability)

- Common physical symptoms that occur during pregnancy, such as fatigue, pain, reduced sleep, may prevent people from following a healthy diet or being physically active (445).
- Experiencing nausea, vomiting, and food aversions may often lead people who are pregnant to limit certain foods, and have a preference for foods containing carbohydrates, although those symptoms usually subside in the beginning of the second trimester.
- Some people may also experience an increase in appetite, especially in the third trimester, or food cravings for specific foods such as fast food, crisps and confectionery (445, 446).
- Others, however, have reported that despite the body changes, they felt responsible for their eating behaviour to ultimately protect their health and the health of their baby (447).

Box 4.2. Knowledge (psychological capability)

- Some people are aware of their risk for GDM, or understand what it is and how it happens, but some lack this knowledge and, similar to findings from the PPI panel, report feeling shock, reduced control, frustration, sadness, guilt and/or confusion following a GDM diagnosis (339, 448, 449).

- With regards to nutrition, women who are pregnant, including those with overweight and obesity, report being generally aware that it plays an important role during and after pregnancy, for their own health and the growth and development of the baby, which makes them more conscious of their food intake (334, 445). Popular nutrition-related topics of interest include food safety, GWG, nutrient and energy content of foods, meal planning, vegetarian diets, and management of nausea and vomiting (445). Those with overweight and obesity have also expressed interest in energy restriction that would enable them to manage GWG (334).

- Information provided by HCPs has more impact on dietary changes during pregnancy than information obtained from other sources (450). However, as reflected also in the PPI exercise (451, 452), the amount, type, level and quality of information provided is conflicting, confusing, or inadequate (334, 445, 452-454).

- Knowledge around recommended GWG and risks of excessive GWG to maternal and fetal health is reported as typically low (332, 455). Advice on GWG during pregnancy is lacking, and when provided, it is vague, and addresses mainly standard healthy eating rather than weight management specifically.

- Even following a GDM diagnosis, people report lack of support in terms of what GDM could mean for them with regards to their health, weight and changes in dietary behaviours (334, 335, 456).

Enablers to making positive and sustainable dietary changes during pregnancy include credible sources of dietary advice, such as HCPs working in routine antenatal care, consistent contact with preferably the same HCP, tailored advice to individual circumstances and food preferences, clear messages about appropriate food choices, clear explanations about achieving recommended targets of GWG, and personalised feedback on behaviours and outcomes (**Box 4.3**) (332, 334, 445, 452-454, 457). Accompanying the advice with structured written resources, including meal plans, meal and snack ideas, advice on packing lunch, while incorporating cultural foods, has also been suggested as helpful by women who are pregnant, with or without GDM, to facilitate memory, attention, and decision making (332, 454, 458-460). Behavioural strategies, such as goal setting, action planning, and

self-monitoring may enable women with obesity who are pregnant, make lifestyle changes (Box 4.4). Importantly, if interventions involve self-monitoring of weight, which is a sensitive issue for these women, clear guidance on the amount and rate of GWG that is considered healthy for the BMI may help reduce feelings of anxiety (455).

Box 4.3. Memory, attention, decision making (psychological capability)

- Women make food-related decisions during pregnancy, based on personal food preferences, cravings, and beliefs they have about these (e.g. that cravings should be satisfied). If the dietary advice provided does not align or is not adjusted accordingly, women may not adhere to it (460).
- Some women report a memory of negative experiences of discussions with HCPs about their weight, or experiencing weight stigma (461), which have been reported as a barriers to weight management.
- For those with GDM, estimating the amount of carbohydrates in foods and meals is often challenging. The lack of knowledge and skills in label reading or carbohydrate counting, may limit food variety. Some people report feeling discouraged and stressed with regards to carbohydrate intake, especially after trials and errors and with experiencing how different foods affect their blood glucose differently (339, 460).

Box 4.4. Behavioural regulation (psychological capability)

- People starting pregnancy with overweight and obesity, acknowledge the importance and usefulness of setting realistic goals in terms of diet and weight management (334, 462).
- Action planning with the help of HCPs increases their self-efficacy towards making lifestyle changes (462).
- Women typically have positive experiences of self-monitoring of health behaviours such food intake and physical activity during pregnancy (336).
- Regular weighing at the clinic during pregnancy, may help to keep some people motivated and on track, but it may be a source of anxiety for others (455, 462). This complexity is reflected in evidence from studies of self-weighing. Some people may respond positively and use self-weighing as a motive towards action planning to avoid excess GWG, but some others may have negative emotional response, especially if self-weighing is not accompanied by guidance or feedback (455).

4.5.2.1.1 Opportunity

Competing priorities, including work or family commitment, and lack of time, as well as, the obesogenic environment, have been reported as major barriers to adopting healthy eating during pregnancy, which makes enhancing the physical opportunity for people with obesity at risk of GDM, to make lower-carbohydrate food choices, of paramount importance (**Box 4.5**).

Box 4.5. Competing priorities and food environment (physical opportunity)

- The challenges of balancing physical symptoms of pregnancy with demands of everyday life, such as work, caring for other children or the family, lack of time for meal planning, cooking or food preparation, and lack of transport, are represented throughout the qualitative literature as barriers to adherence to healthy eating and weight management (332, 335, 336).
- Some women also mention the pleasure and ease associated with fast food, take away, "unhealthy foods" such as foods high in sugar and fat, especially during experiencing fatigue or stress (332).
- Women with GDM, who need to make dietary changes to control both their GWG and blood glucose levels, report that it may be a challenge to fit the frequency of meals to their work schedules and lifestyles.
- Eating out may also pose a barrier as it may be hard to find lower-carbohydrate options, know the amount of carbohydrate in foods and meals, or control portion sizes (460).

Social norms around a specific behaviour refer to our perception of what other people do, and shared standards of acceptable behaviour (463). Social norms influence the amount and type of food consumed (464) (**Box 4.6**). This suggests that social norms may influence carbohydrate intake, and should be considered when developing a dietary intervention to prevent GDM. Women with overweight and obesity value social support from family and friends to help them change their diet, and control their GWG. Social support can also take the form of consistent interaction with HCPs, but an intervention programme and the HCPs delivering it, should adopt a supportive and empathetic approach, avoiding criticism if GWG goals are not met (462) (**Box 4.7**).

Box 4.6. Social norms (social opportunity)

- In the context of pregnancy, some women experience pressure from their family or peers to "eat for two" and gain a lot of weight, due to beliefs that weight gain will help grow a baby who is bigger, perceived to be healthier (332). This may be enhanced if dietary or weight advice from HCPs is insufficient (452).
- Women with GDM may find eating in social environments while trying to control their carbohydrate intake, challenging. For example, some report feeling uncomfortable measuring the amount of food while being in public or with friends or relatives, as they would expect them to eat "as normal".
- Even if partners generally recognise the importance of dietary changes for the management of GDM, some partners may support the belief that cravings should be satisfied, which may lead the patient to indulge in foods which should be limited for blood glucose control.
- While being involved in social events, the social environment of the partner posed at times specific eating norms and behaviours on some people (e.g. eating ice cream after a night out) (460).

Box 4.7. Social support (social opportunity)

- Women with overweight and obesity perceive that they would be better able to maintain a healthy diet and manage GWG when they have social support from their partners, family, or friends, as well as access to social environments that encourage nutritious food (332, 334-336, 456).
- Social support can be manifested in a variety of ways, such as enhancing motivation to eat healthily and control GWG, help with food preparation and grocery shopping, supervision of or just moral support with following the dietary advice (332, 457, 460). Being open with one's family about own needs has also been identified as a major enabler (462).
- Consistent and interactive engagement from HCPs to help maintain healthy eating and GWG control, is of paramount importance (332, 457).
- Receiving negative comments with regards to appearance or dietary habits during pregnancy, has been identified as a barrier towards behaviour change (332, 335).

Reflective motivation involves the internal conscious process happening before engaging in a behaviour. It is a major driver of intention formation and action-planning. It is influenced by beliefs about what behaviour is acceptable (e.g. social norms), the benefits or consequences of the behaviour, as well as confidence in oneself that they can achieve or control the behaviour (435). A number of

barriers and facilitators of reflective motivation reported in qualitative studies in women during pregnancy are in **Box 4.8**. Adapting this evidence to my intervention, women need to believe that GDM is worth trying to prevent, that nutrition plays an important role for maternal and fetal/neonatal outcomes, that reducing carbohydrate intake may be beneficial for blood glucose and GWG control, that it is socially acceptable to moderately reduce carbohydrate intake, that it is possible to fit the diet into their routine and social environments, and that they are capable of making the changes.

Automatic processes of emotional reactions, desires, needs, impulses, inhibitions, and habits, also affect diet-related behaviours. Barriers and facilitators of automatic motivation affecting adherence to diet and weight management advice during pregnancy, are given in **Box 4.9**.

Box 4.8. Reflective motivation

- For most women, pregnancy acts as a motivator to engage in positive health behaviours, including healthy eating. This intrinsic motivation is mainly driven from the perceived benefits of healthy eating for fetal and maternal health outcomes (332, 334, 335, 456, 462, 465, 466).
- Further motivators include the belief that dietary changes need to be short-term (460), and that they will facilitate weight loss postpartum (332).
- On the other hand, some women view pregnancy as a time to relax their eating, enjoy a more positive body image, and avoid negative comments and weight stigma (332-335).
- Other barriers include lack of self-confidence in controlling their eating and weight gain (335).
- For women who develop pregnancy complications such as GDM, the motivation to take action about their health may be even higher due to fear of associated consequences (460, 462). However, some women affected by GDM do not recognise that their condition may lead to long term health risks, beyond pregnancy (339).

Box 4.9. Automatic motivation

- Many women with overweight and obesity who are pregnant, present with low self-esteem and emotional eating (336).
- They often report feelings of guilt, shame, and despair when discussing weight-related matters with their HCPs, due to fear of judgement, negative comments, and stigmatisation that they may have experienced already before pregnancy, or during a previous pregnancy.
- When negative experiences relate to comments from HCPs, women reported losing trust towards them, and being less likely to follow weight management advice in pregnancy.
- Following a GDM diagnosis, some women report feeling "ill" or that their pregnancy is "abnormal", or that thinking of GDM and needing to be conscious of their actions every day, makes their pregnancy experience unpleasant. Some also feel scared to make mistakes in controlling their blood glucose levels through diet, or distressed if despite their efforts their blood glucose readings are still high, and a sense of failure if they need to resort to medication or insulin. Others however, report transitioning from the negative feelings and loss of control, towards feeling empowerment after gaining more knowledge of GDM, taking actions, and adjusting to the new habits (339).

4.5.2.2 Barriers and facilitators: input from HCPs

HCPs involved in routine maternity care such as midwives and nurses, recognise the need for discussion on diet and GWG during pregnancy, and they are aware of the importance of their role in promoting healthier behaviours (337, 338). However, HCPs consistently express concerns about the lack of sufficient training and expertise to provide appropriate advice (339). Midwives perceive that they should receive specialist training in diet and weight management for pregnancy, or this advice should be given by specialist HCPs (340, 467). Some studies report finding that weight management is a sensitive issue not only for the people who are pregnant, but also for their HCPs, who often avoid weight-related conversations during antenatal visits, to avoid upsetting their patients or making them feel stigmatised (6, 337, 340-342). Further challenges mentioned by HCPs include the limited time and availability of resources, and lack of appropriate referral options. For example, a typical antenatal visit may need to address a number of matters and as a result, nutrition and physical activity counselling may be the last priority (468). For women with established GDM, sometimes HCPs reported feeling helpless when there was too little that could be done to control the condition with diet and physical

activity (469). Accordingly, the design of dietary interventions and counselling during pregnancy, for women with overweight and obesity, should involve effective collaboration between HCPs working in routine antenatal care, with dietitians. Clear and specific messages accompanied with structured resources may not only help women follow the advice better, but also help HCPs deliver the advice more effectively, without requiring substantial additional training.

4.5.3 Developing RECORD's behavioural component

Taking into account knowledge from the literature, the PPI exercise and discussions with stakeholders on barriers and facilitators in changing dietary behaviour and controlling weight gain during pregnancy, I sought to develop the intervention content and identify how to deliver it. Following the BCW methodology, I first chose the intervention functions, i.e. the means through which the target behaviour can occur, the "how" of the behaviour change. The BCW identifies 9 possible intervention functions and outlines which are more likely to be effective in facilitating change related to the components of the COM-B model (435). I assessed the suitability of each function with the APEASE criteria of affordability, practicability, effectiveness, acceptability, safety and equity recommended in the BCW approach (**Table 4.2**) (435), and concluded that the intervention functions best suited to deliver the RECORD intervention were: **education** (increasing knowledge or understanding), **persuasion** (using communication to induce positive or negative feelings or stimulate action), **incentivisation** (creating an expectation of reward), **training** (imparting skills), **environmental restructuring** (changing the physical or social context), and **enablement** (increasing means or decreasing barriers to increase capability).

Table 4.2. Intervention functions and how they might address "what needs to change" to reduce carbohydrate intake in women at risk of GDM

BCW intervention function	Example for reducing carbohydrate intake	APEASE criteria
Education	Provide education on possible benefits of moderately reducing carbohydrate intake, and on how to moderately reduce carbohydrate intake.	**Suitable** Meets the criteria of affordability, practicability, and safety and there is evidence for effectiveness on blood glucose control both in pregnant and non-pregnant populations. It is also acceptable among people who are pregnant with established GDM.
Persuasion	Persuade people at risk of GDM that moderate carbohydrate intake is beneficial for their health, and that it is achievable.	**Suitable** Meets the criteria of affordability, practicability, acceptability and safety. Evidence for effectiveness is less clear as persuasion may be often combined with education/awareness.
Incentivisation	Creating a self-induced expectation of reward for adhering to the reduced-carbohydrate programme.	**Suitable** Meets the criteria of affordability, practicability, acceptability and safety, although there is no clear evidence of effectiveness.
Coercion	Create an expectation of punishment or cost for not adhering to the reduced-carbohydrate intervention.	**Not suitable** Unlikely to be acceptable to individuals.
Training	Training in food selection in line with a reduced-carbohydrate diet, and increasing skills to form and maintain new habits, or in meal planning.	**Suitable** Meets the criteria of affordability, practicability, acceptability and safety as it is already part of dietary consultations in routine care.
Restriction	Restrict access to sugary foods and drinks	**Not suitable** Not practicable.
Environmental restructuring	Restructure the home environment to have lower-carbohydrate/sugar options readily available. Encourage social support e.g. members of the household.	**Suitable** Meets the criteria of affordability, practicability, acceptability and safety, and there is evidence of effectiveness.
Modelling	Demonstrate examples of individuals choosing lower-carbohydrate/sugar options (e.g. success stories).	**Suitable, but not available** Meets the criteria of affordability, practicability, acceptability and safety, but I did not have available real success stories. Instead, I included fictional stories in written materials, but I did not address them in consultations.
Enablement	Making it easy to identify lower-carbohydrate/sugar alternatives, encouraging social support, personalised action planning, providing clear and structured written information.	**Suitable** Meets the criteria of affordability, practicability, acceptability and safety and there is evidence of effectiveness.

BCW: Behavioural Change Wheel**; APEASE:** Affordability, Practicability, Effectiveness, Acceptability, Safety and Equity; **GDM:** gestational diabetes mellitus

After identifying the intervention functions, I proceeded to identify BCTs, the active ingredients of the intervention that help bring about the change in the target behaviour (435). Michie and colleagues developed a taxonomy/set of definitions of commonly used BCTs and linked them to theoretical frameworks (BCT taxonomy v1) (470). I reviewed the full taxonomy of 93 BCTs to identify those that are more frequently used to deliver the intervention functions that I identified in the previous step, as judged by experts in behaviour change (435). I initially drew on the literature on BCTs that have shown effectiveness in dietary interventions, and identified goal setting, action planning, self-monitoring, provision of feedback, and social support (471-474). I also drew on the qualitative input from the PPI panel members and discussions with the key stakeholders. Both the PPI panel and previous qualitative work, showed that due to lack of adequate advice from HCPs on GDM, and the role of diet in managing glucose levels, women who are pregnant tend to rely on online sources of information which in certain cases are not credible (443). This led to the addition of the BCT "credible source". I finalised the list of identified BCTs considering those with a plausible rationale for reasonable use for the situation in which I am intervening (pregnancy, setting, resources, time, routine care processes). The selected BCTs included in the RECORD intervention are outlined in **Table 4.3**.

Table 4.3. Behavioural change techniques delivered through the RECORD intervention

BCT	Definition
Goal setting (behaviour) [1.1]	Set or agree on a goal defined in terms of the behaviour to be achieved.
Problem solving (incl. relapse prevention and coping planning) [1.2]	Analyse, or prompt the person to analyse, factors influencing the behaviour, and generate or select strategies that include overcoming barriers, and/or increasing facilitators.
Action planning [1.4]	Prompt detailed planning of performance of the behaviour (must include at least one of context, frequency, duration and intensity). Context may be environmental (physical or social) or internal (physical, emotional or cognitive).
Review behaviour goal(s) [1.5]	Review behaviour goal(s) jointly with the person, and consider modifying goal(s) or behaviour change strategy, in light of achievement. This may lead to re-setting the same goal, a small change in that goal, or setting a new goal instead of (or in addition to) the first, or no change.
Review outcome goal(s) [1.7]	Review outcome goal(s) jointly with the person and consider modifying goal(s) in light of achievement. This may lead to re-setting the same goal, a small change in that goal, or setting a new goal instead of (or in addition to) the first.
Feedback on behaviour [2.2]	Monitor and provide informative, or evaluative feedback on performance of the behaviour.
Self-monitoring of behaviour [2.3]	Establish a method for the person to monitor and record their behaviour(s) as part of a behaviour change strategy.
Self-monitoring of outcome(s) of behaviour [2.4]	Establish a method for the person to monitor and record the outcome(s) of their behaviour as part of a behaviour change strategy.
Feedback on outcome(s) of behaviour [2.7]	Monitor and provide feedback on the outcome of performance of the behaviour.
Social support (un-specified) [3.1]	Advise on, arrange, or provide social support (e.g. from friends, relatives, colleagues, buddies or staff), or non-contingent praise, or reward for performance of the behaviour. It includes encouragement and counselling, but only when it is directed at the behaviour.
Social support (practical) [3.2]	Advise on, arrange, or provide social support (e.g. from friends, relatives, colleagues, buddies or staff), or non-contingent praise, or reward for performance of the behaviour.

Table 4.3. continued

Social support (emotional) [3.3]	Advise on, arrange, or provide emotional social support (e.g. from friends, relatives, colleagues, buddies or staff) or non-contingent praise or reward for performance of the behaviour.
Instruction to perform behaviour [4.1]	Advise or agree on how to perform the behaviour.
Information about health consequences [5.1]	Provide information (e.g. written, verbal, visual) about health consequences of performing the behaviour.
Demonstration of the behaviour [6.1]	Provide an observable sample of the performance of the behaviour, directly in person or indirectly, e.g. via film, pictures, for the person to aspire to or imitate.
Behaviour substitution [8.2]	Prompt substitution of the unwanted behaviour with a wanted or neutral behaviour.
Habit formation [8.3]	Prompt rehearsal and repetition of the behaviour in the same context repeatedly so that the context elicits the behaviour.
Credible source [9.1]	Present verbal or visual communication from a credible source in favour of, or against the behaviour.
Pros and cons [9.2]	Advise the person to identify and compare reasons for wanting (pros), and not wanting to (cons) change the behaviour.
Self-incentive [10.7]	Plan to reward self in future, if and only if there has been effort and/or progress in performing the behaviour.
Self-reward [10.9]	Plan self-praise or self-reward, if and only if there has been effort, and/or progress in performing the behaviour.
Conserving mental resources [11.3]	Advise on ways of minimising demands on mental resources to facilitate behaviour change.
Restructuring the physical environment [12.1]	Change, or advise to change, the physical environment in order to facilitate performance of the wanted behaviour, or create barriers to unwanted behaviour (other than prompts/cues, rewards and punishments).
Verbal persuasion about capability [15.1]	Tell the person that they can successfully perform the wanted behaviour, arguing against self-doubts, and asserting that they can and will succeed.

BCTs: behaviour change techniques; [Bracketed numbers] refer to the Behaviour Change Technique Taxonomy (v1) (470).

I translated the selected BCTs into concrete intervention components (section 4.5.4). These were refined and finalised after discussions with the key stakeholders (co-investigators and patient representative). As a final step, I considered how best to deliver the intervention, for the identified functions and BCTs. Taking into account the feedback from the PPI panel about practical barriers to participation (e.g. time availability, parking), and following discussions with the patient representative and HCP co-investigators, I decided that, in order to deliver the intervention alongside routine antenatal care, it would need to be an-individual-level intervention, delivered preferably during one or more antenatal visits, or remotely via telephone. Due to the clinical outcomes I wished to get out of the study, and wanting to exclude people with pre-existing or early hyperglycaemia, I decided to ask participants to attend an extra hospital visit at baseline, which was outside of the routine antenatal appointments (details in Chapter 5). This visit offered the opportunity of conducting a one-off face-to-face dietary consultation combined with information from written materials. I then decided that any extra support offered, could be done via the telephone, but that I could also offer the flexibility of face-to-face support sessions if participants preferred them. Being a dietitian, delivering the intervention programme is within my job role and skill set, without the need for additional training.

4.5.4 The resulting RECORD intervention package, and implementation

The RECORD intervention was a multicomponent programme including 6 intervention functions and 24 BCTs. The full logic model for the RECORD intervention is visualised in **Figure 4.5**. Each of the intervention components (**Figure 4.6**) is described in detail below.

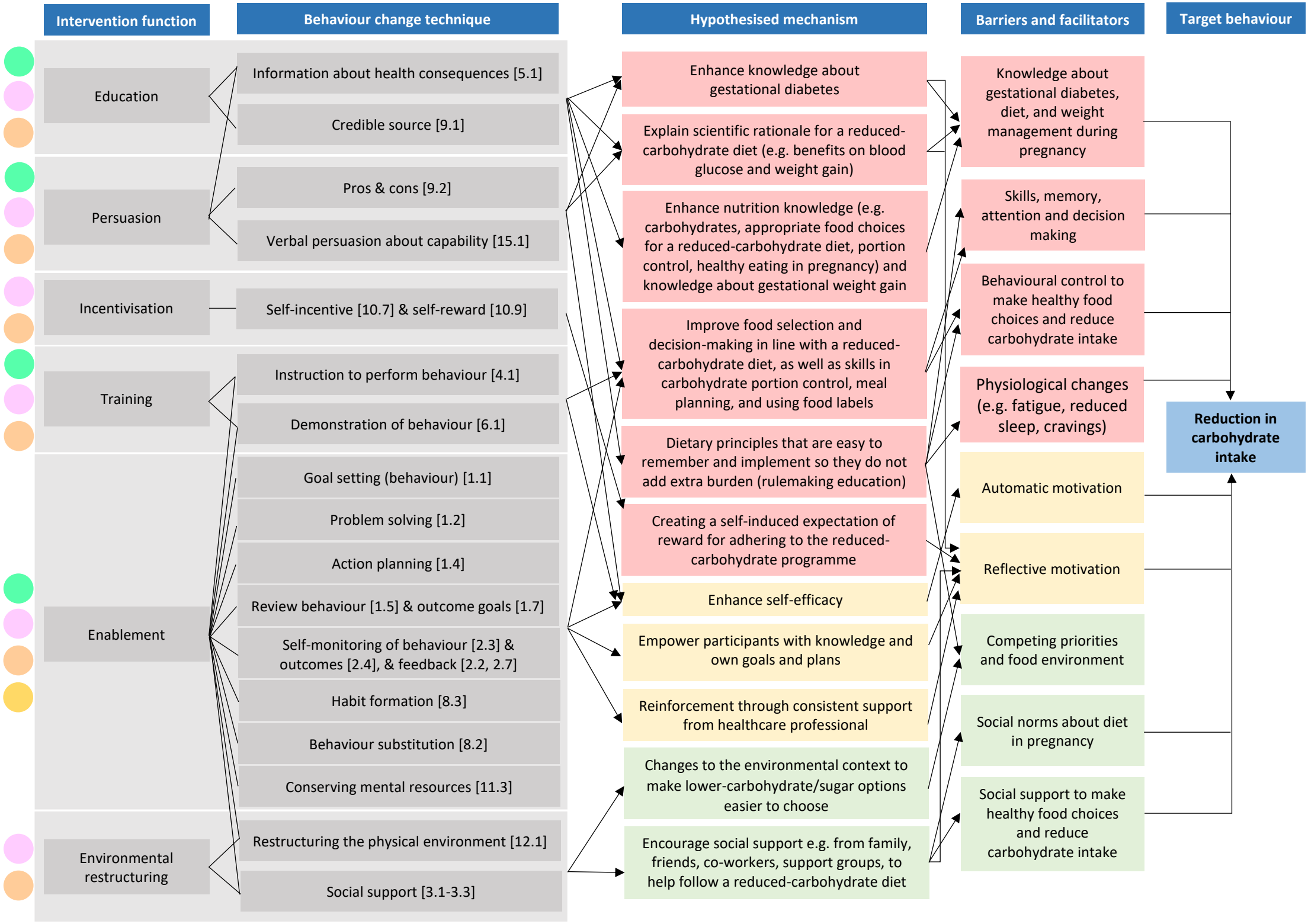

Intervention function
Behaviour change technique
Hypothesised mechanism
Barriers and facilitators
Target behaviour
Education
Persuasion
Incentivisation
Training
Enablement
Environmental restructuring
Information about health consequences [5.1]
Credible source [9.1]
Pros & cons [9.2]
Verbal persuasion about capability [15.1]
Self-incentive [10.7] & self-reward [10.9]
Instruction to perform behaviour [4.1]
Demonstration of behaviour [6.1]
Goal setting (behaviour) [1.1]
Problem solving [1.2]
Action planning [1.4]
Review behaviour [1.5] & outcome goals [1.7]
Self-monitoring of behaviour [2.3] & outcomes [2.4], & feedback [2.2, 2.7]
Habit formation [8.3]
Behaviour substitution [8.2]
Conserving mental resources [11.3]
Restructuring the physical environment [12.1]
Social support [3.1-3.3]
Enhance knowledge about gestational diabetes
Explain scientific rationale for a reduced-carbohydrate diet (e.g. benefits on blood glucose and weight gain)
Enhance nutrition knowledge (e.g. carbohydrates, appropriate food choices for a reduced-carbohydrate diet, portion control, healthy eating in pregnancy) and knowledge about gestational weight gain
Improve food selection and decision-making in line with a reduced-carbohydrate diet, as well as skills in carbohydrate portion control, meal planning, and using food labels
Dietary principles that are easy to remember and implement so they do not add extra burden (rulemaking education)
Creating a self-induced expectation of reward for adhering to the reduced-carbohydrate programme
Enhance self-efficacy
Empower participants with knowledge and own goals and plans
Reinforcement through consistent support from healthcare professional
Changes to the environmental context to make lower-carbohydrate/sugar options easier to choose
Encourage social support e.g. from family, friends, co-workers, support groups, to help follow a reduced-carbohydrate diet
Knowledge about gestational diabetes, diet, and weight management during pregnancy
Skills, memory, attention and decision making
Behavioural control to make healthy food choices and reduce carbohydrate intake
Physiological changes (e.g. fatigue, reduced sleep, cravings)
Automatic motivation
Reflective motivation
Competing priorities and food environment
Social norms about diet in pregnancy
Social support to make healthy food choices and reduce carbohydrate intake
Reduction in carbohydrate intake

Figure 4.5. Logic model

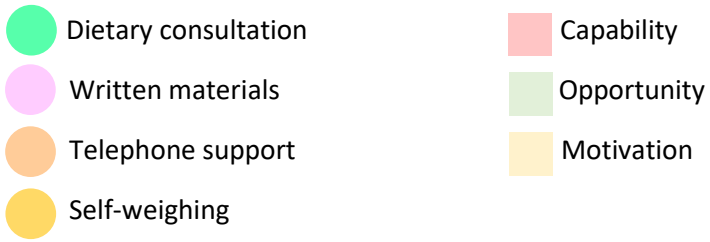
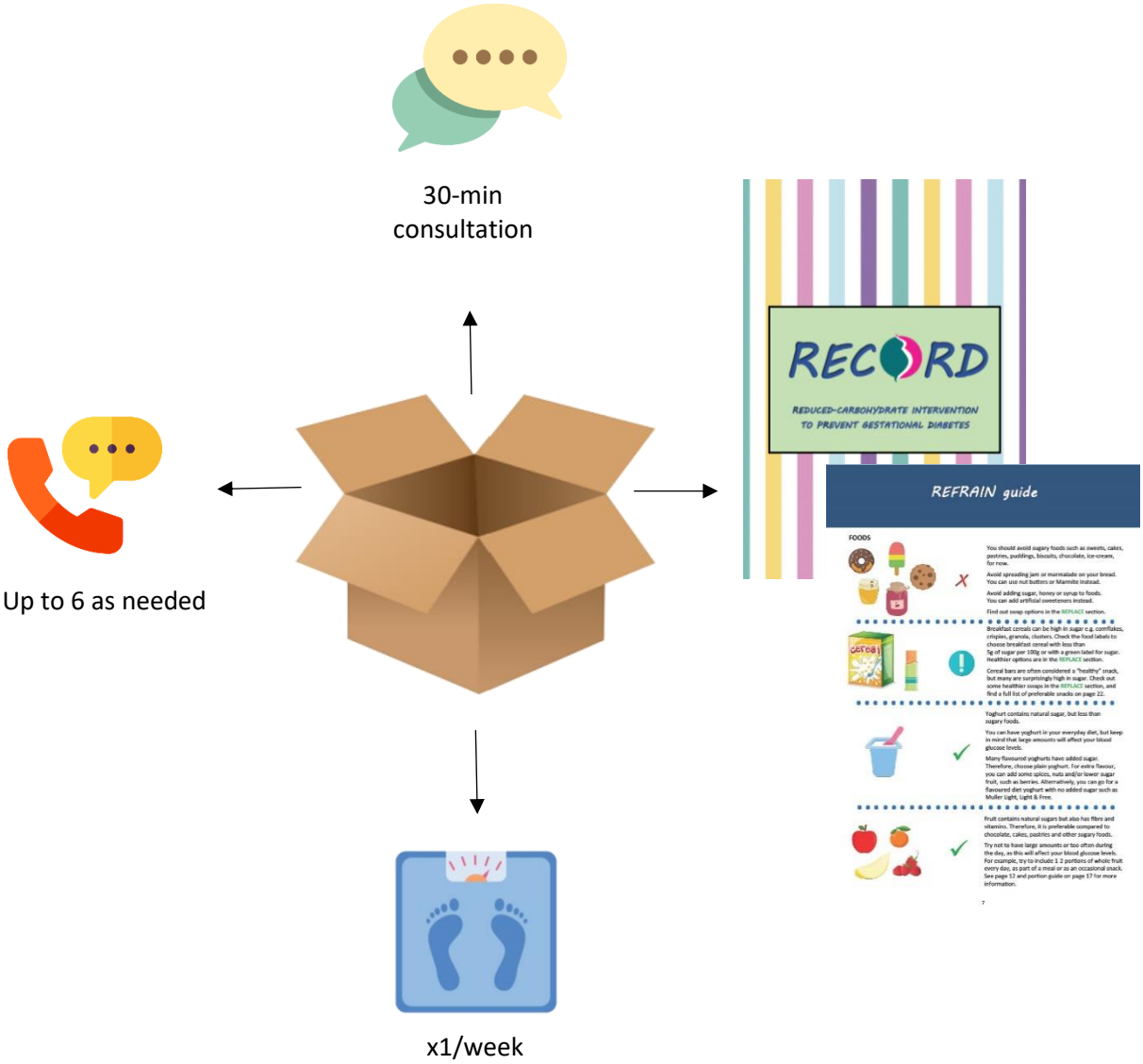


Figure 4.6. The RECORD intervention package



4.5.4.1 Initial dietary consultation

The initial consultation session aimed to:

- Increase knowledge about GDM, its associated health consequences, the rationale behind the reduced-carbohydrate intervention, the types and food sources of carbohydrates.
- Introduce participants to the main principles of the dietary programme.
- Motivate participants to decrease their carbohydrate intake.

- Initiate the behaviour change process by helping participants to set goals, and make an action plan for reducing their carbohydrate intake.

Due to the limited time, the initial consultation focused primarily on how to achieve the 3 core diet principles (3R's). If participants wished to also discuss or ask about standard healthy eating advice during pregnancy, opportunity was given at the end of this session, or during subsequent telephone support sessions. The consultation was supported by the main intervention booklet (section 4.5.4.3), which included structured, specific messages about GDM, the 3 R's, food choices, portion sizes, food labels, meal and snack suggestions. Although the session was delivered by myself, a trained dietitian, the clear messages and brief design of the session, would allow other HCPs involved in routine antenatal care, to receive brief training on the theory behind the intervention and the content, and deliver it alongside routine appointments. The outline of the initial consultation is in **Table 4.4**.

Table 4.4. Components of the initial RECORD consultation

Component	Description
1. Agenda setting	Participant is welcomed and asked if they have any questions or concerns about reducing their carbohydrate intake, before going into detail about the content of the intervention. This gives the opportunity of finding out what is most important to the individual, and reassure them from the start. At the end of this stage, the HCP presents the main intervention booklet, and informs that the session and programme will work through it.
2. Information about GDM	The HCP provides information about what GDM is, why it is a problem, how it happens, who is at risk, what the health consequences are for the mother and the baby during pregnancy and post-partum.
3. Rationale behind the intervention	The HCP asks the participant to suggest what foods contain carbohydrates, and supplements their response if needed. Then the HCP provides information on types of carbohydrates (e.g. sugars vs complex carbohydrates), and explains how the body reacts to ingestion of carbohydrates (insulin production), as well as how dysregulation of glucose control happens in GDM.
4. Personal motives	The HCP prompts the participant to voice their personal reasons for trying to change their diet, and what is most important for them to achieve. The HCP also presents the personal action plan booklet (details in section 4.5.4.3), explaining that participant has the option to use this throughout the programme to write down other benefits or challenges they may think of from trying to follow the dietary advice, as well as use it for their goal setting which will be discussed later in the session.
5. Guide to the RECORD diet	The HCP presents the 3 R's in summary, and then in more detail for each. During this, the HCP asks the participant to identify the type of foods they prefer to currently consume from the ones mentioned in the guide, and tries to explore the pattern of participant's eating behaviours e.g. quantity, frequency, preferences, occasions/context, and triggers, with open-ended questions.

Table 4.4. continued

Component	Description
6. Goal setting and action planning	HCP and participant collaborate in finding ways to modify current food choices to help them align with a reduced-carbohydrate diet, and ways to easily control carbohydrate portion sizes, and find lower-carbohydrate/lower-sugar alternatives. After each principle has been explained and discussed, the HCP prompts the participant to choose no more than 1 or 2 changes from each principle that they feel comfortable changing first, and give a try for the next couple of weeks. HCP asks participant to suggest steps on how to achieve a change, and suggests that participant can choose to write down these in the personal action plan booklet. HCP highlights the importance of small, measurable, achievable, relevant and time-specific goals (e.g. Can you think of specific steps you can take every day? How can it fit into your routine? Do you need to buy or prepare anything?), as well as the importance of consistency and repeating the changes until they become more automatic. If participants report barriers, HCP tries to use problem solving to encourage change in the areas that participants will benefit most from (e.g. empathise and acknowledge, ask participant to remember why a particular change is suggested, think whether the benefits are worth changing for, how they would feel if they achieved it, prompting participant to think of solutions, and supplementing ideas if needed, prompt participant to weigh up the options and what might work best for them, as well as prompt participant to think of an "if then" scenario, and what social support they can get).
7. Standard healthy eating	The HCP informs participant that in the rest of the booklet, they will find standard healthy eating advice for pregnancy from all food groups, portion size information, advice on food labels, meal and snack ideas, as well as answers to frequently asked questions. Participants can choose to read the rest of the booklet in their own time, and are encouraged to ask if they have questions, in the subsequent support sessions or reach out anytime via phone, text or email. HCP also informs of the option to use a recipe book, and sample meal planner.

Table 4.4. continued

Component	Description
8. Self-monitoring	The HCP highlights the importance of self-monitoring of behaviour and outcomes, and suggests that participant has the option to use monitoring charts for the progress of their changes (details in section 4.5.4.3), but otherwise, informs that telephone support sessions will also give them the chance to reflect on the changes they make, should they find, using extra materials overwhelming. HCP also provides information on recommended GWG, and prompts participant to record this once a week as part of the intervention for the following reasons: to ensure the diet does not induce significant weight loss, to explore how what they eat affects their weight gain, to help them keep on track, and facilitate the advice provided during the programme, as it can help spot any problems and receive advice early.
9. Wrap-up	At the end of the session, the HCP summarises the 3R's and mutually agreed changes, checks if participant has any last questions, and arranges a support session within the next couple of weeks for a brief telephone call. As a last step, HCP asks the participant what they think about the changes, and if they would be willing to give the programme a go.

GDM: gestational diabetes mellitus; **HCP:** healthcare professional; **GWG:** gestational weight gain

4.5.4.2 Self-monitoring of weight

Regular self-monitoring of weight has been consistently associated with successful weight gain prevention (475). Self-weighing can enhance self-regulation processes whereby it provides individuals with feedback on weight change, and allows them to compare it with their weight goals, and adjust their behaviour (e.g. dietary intake) to prevent excessive weight gain (476, 477). However, previous research in weight loss interventions, suggests that self-weighing on its own may not be sufficient to prevent excessive weight gain in everyone, and individuals may need to be guided through the self-regulation process (478). Previous trials testing the effectiveness of self-weighing to control GWG in pregnancy, failed to engage participants in regular self-weighing, but the reasons behind reduced adherence were not explored (479, 480). Recent qualitative evidence from people who self-weighed themselves in their first half of pregnancy, suggested that most participants found self-weighing useful, and that it prompted self-regulation. Negative responses were related to lack of guidance on the appropriate levels for weight or other worries about pregnancy (455). In view of these, as part of the RECORD intervention package, I asked participants to weigh themselves once a week until delivery, and guided them through provision of feedback on their weight changes compared to the total and weekly GWG IOM guidelines (127), to support them in evaluating their dietary behaviours, and prompt them to take action with regards to reducing their carbohydrate intake.

4.5.4.3 Written resources

All written resources provided as part of the RECORD programme, are described in **Table 4.5**. Before developing the dietary resources (**Appendices 4.2-4.4**), I gathered information from other materials provided to people with GDM or diabetes outside of pregnancy, either in the NHS, or by major organisations and charities in the area of pregnancy and/or diabetes. I also reviewed published protocols and materials of other GDM prevention and management clinical trials. The outline and content of the materials was finalised after discussions with the key stakeholders. The dietary resources serve to increase women's skills and confidence for meal planning, and to help reduce the burden of behaviour change, by preserving their mental reserves.

Accordingly, drawing evidence from theory-based dietary interventions outside, as well as during pregnancy, I hypothesised that in terms of behavioural control, participants could achieve the target behaviour (reduction in carbohydrate intake), by setting personalised realistic goals, self-monitoring their progress, and making adjustments when necessary, or forming coping and action plans when a discrepancy between behaviour and goal is noticed (476). Drawing from qualitative feedback from the literature and PPI panel discussions, due to the physical and mental changes and burdens associated with pregnancy, I decided that it may be useful to provide resources for goal setting and self-monitoring in the RECORD intervention, so that participants can have a record of their plan and their progress (**Appendices 4.5-4.7**). However, given the vast amount of resources that people receive in pregnancy, which can feel overwhelming, I prioritised addressing the principles and content of these resources verbally, during the initial and subsequent support sessions, and make the actual print materials optional for participants to use.

Table 4.5. Written intervention materials provided as part of the RECORD intervention

Resource	Description
Main intervention booklet	The inclusion of a main booklet is driven by the qualitative literature review and PPI panel discussions which identified the need for increase in knowledge about GDM and the role of nutrition, to facilitate decision making through clear specific messages about healthy food choices, and to increase skills in controlling carbohydrate portions. This booklet concentrates all of this information in one resource that the participants can refer to throughout pregnancy. • The most important information on GDM, the rationale of the intervention, and the 3R's guide are presented first, with clear and specific messages on food choices, and visual representations where needed (e.g. portion control, "plate model"), thus ensuring that key messages are delivered from the very start and individuals are not lost in the information • Alternative food choices and products, as well as easy meal and snack suggestions are available to facilitate decision making. • Additional information includes simple education on food label reading, focused on total and sugary carbohydrate content, food safety during pregnancy, and answers to frequently asked questions, such as guidance on when eating out, or how to deal with challenging environmental triggers, or lapses. • Standard healthy eating advice during pregnancy is also included, which simply and briefly summarises appropriate food choices from each food group. This advice includes high intake of vegetables, moderate intake of lean protein and dairy, broadly aligning with the principles of a Mediterranean-style diet.
Recipe booklet	The recipe booklet supplements the main intervention booklet's meal suggestions, adapting common, and culturally diverse recipes to a lower-carbohydrate content.
Example meal planner	This shows how the various suggested meals and recipes can be mixed and matched, to provide variety in the diet.

Table 4.5. continued

Resource	Description
Personal action plan booklet	This was designed to guide participants through behavioural regulation, by prompting them to think of reasons to change, set personalised achievable goals and steps they will take to achieve them, and reflect on their progress.
Behavioural goal monitoring cards	Daily cards were provided for the first 2 weeks, and then weekly ones thereafter. These were developed to prompt participants to take 5 minutes at a time, to track the progress of their behavioural goals, to reinforce the changes. Participants could tick boxes if they felt they met a goal on a particular day of the week. At the end of each week, participants could have an overview of their progress. Space for notes was available to write down what helps or halts achieving a particular goal, and how participants felt about their progress. At the end, they could also choose to set a reward after setting a new goal for the coming week, which may increase chances of achieving it.
Home monitoring booklet	This was developed to guide participants on recording their blood glucose and ketones, and for the intervention group, also the weight (IOM guidelines). It included brief information and instructions on why and how to take these measurements, what they should expect, how to share the results with the study team, and what needs to be done in case of abnormal values. It also included useful contact information for clinical support should it be needed.

GDM: gestational diabetes mellitus; **IOM:** Institute of Medicine

4.5.4.4 Telephone support sessions

The telephone support sessions were designed to help participants reflect and receive support and reinforcement at regular time points throughout pregnancy, at a convenient day and time for them, attending extra visits, thus preserving time and mental resources as much as possible. During these sessions, the HCP (myself) was able to provide feedback to participants about the progress of their behaviour as well as outcomes (e.g. blood glucose, ketones, weight), help participants re-evaluate their goals if necessary, provide support, contingency planning, problem solving, planning of social support, help with environmental or emotional triggers, as well as enhance self-efficacy. The intervention was designed so that the support sessions were delivered at 2, 4, 8, 12, 16 and 20 weeks after the initial session, providing closer support in the beginning while participant is still attempting to follow the new programme. However, it was expected from the start that people progress at their own pace, therefore, the amount and frequency of the support sessions was adjusted according to participant need. For example, some participants' sessions may be brought forward for a couple of weeks if they are struggling to follow the programme, or some participants may not receive all 6 sessions if they feel, or the HCP judges, that they are able to stick to their changes, and there is no more changes to introduce, or if their due date has been brought forward for some weeks. Nevertheless, in all cases, the HCP gets in touch with the participant via phone, text or email to check whether further support is needed.

4.6 Discussion

In this Chapter I outlined how I developed the RECORD intervention to help women who are pregnant and at risk of GDM, to reduce their carbohydrate intake, and control their GWG and blood glucose. RECORD is a multi-component intervention combining a dietary consultation with written structured information, self-weighing, and remote telephone sessions for support with adherence as needed. The development of RECORD was informed by the BCW framework, insights from qualitative literature in people who are pregnant, a PPI exercise, and discussions with HCPs working in maternity, academics, and a patient representative.

First, literature review enabled me to select the target behaviour, and the BCW framework helped me to clearly define it, as well as identify barriers and facilitators preventing or enabling dietary changes during pregnancy, and tailor the intervention content to tackle these barriers, and promote the facilitators in order to enhance capability, opportunity and motivation. Second, literature review, previous experience with delivering diet and weight management interventions, as well as feedback from PPI and discussions with stakeholders, enabled me to select intervention components that successfully contribute to dietary changes, as shown in previous interventions both outside of, and during pregnancy, increasing the chances to deliver impact. Further, consultations with the stakeholders helped me make decisions about issues for which there was no clear evidence or theory, such as for how long to deliver the intervention, or what specific content to include. Especially the feedback from a patient representative, enhanced the possibility that each intervention component was relevant, engaging, and understandable to women who are pregnant. RECORD's logic model hypothesised that the intervention would impact through the functions of education, persuasion, incentivisation, training, environmental restructuring, and enablement, delivered through 24 BCTs, mainly including goal setting, self-monitoring, feedback, and action planning.

4.6.1 Strengths

To my knowledge, this is the first intervention designed to be delivered alongside routine antenatal appointments, to specifically attempt a substantial reduction in carbohydrate intake in women at increased risk of GDM, delivered through the aforementioned combination of intervention components. A small number of previous programmes that were effective in reducing the incidence of GDM, included intensive dietary interventions or provided key foods, which may not be feasible in routine maternity care. I spent a considerable time developing the RECORD programme and used a systematic approach, undertaking a rigorous behavioural analysis, drawing on evidence from the literature, focus groups, and discussions with key stakeholders, to make the programme suitable for the population whom it is intended to serve. The programme was designed to deliver simple, specific and clear messages on food choices, supported by structured written resources which people can

access constantly and look through in their own time outside clinical appointments. Although the resulting intervention was delivered by myself, a trained dietitian, the comprehensive messages and resources make it plausible for the skills required for intervention delivery to be easily transferable to other HCPs involved in antenatal care, without needing extensive training or detailed nutritional knowledge.

It was evident from the literature, the focus groups and discussions with HCPs working in maternity, that time allocation for consultations, amount of appointments, staff training and availability of resources, remain challenges which compete with other components of maternity care, and prevent people from receiving appropriate dietary advice in pregnancy. The initial consultation is more time consuming (30 minutes), but the follow-up support sessions last as long as routine primary care consultations (10-15 minutes). The RECORD intervention was designed to address challenges by offering the flexibility of delivery of the initial and subsequent sessions both in person, and remotely (e.g. via telephone).

4.6.2 Challenges and limitations

Despite the strengths, I faced numerous challenges throughout the intervention development. Applying the BCW methodology to undertake the behavioural analysis, review the literature, and conduct discussions with stakeholders in order to identify suitable functions, BCTs, and content, was time consuming. What is more, the BCW leaves some gaps between behavioural analysis and final delivery (the actual "how" of delivery), which required extra thinking and discussions. The BCW also requires comprehensive training to be applied properly, to maximise the benefit of applying theory and have impact, which I did not undertake, but rather, I used mostly my previous experience in delivering dietary and weight management interventions, and self-completed reading of the BCW methodology. It was challenging to include the BCTs in a concise manner. This resulted in creating additional written resources, making it unclear whether they would be used by the participants, given the amount of information and written resources they already receive during pregnancy. As a result,

I decided that I would emphasise that the behavioural materials were optional for anyone who may find them helpful, and that I would go through them as part of my counselling during the sessions, with uncertainty as to whether BCTs would be implemented to the core. I also decided to deliver the materials in print form. Further research may need to explore if it would be preferable to adapt this intervention to online form.

Importantly, the focus groups which informed the intervention development were conducted with women who had experience of GDM, and thus, the intervention may not be straight applicable to women at risk of GDM, which is the intended population to receive this intervention. Women with GDM have already experienced the consequences of the disease, and may have higher understanding of the risks associated with GDM, as well as different attitudes towards a preventative intervention. Lastly, it is established that environmental factors largely influence food choices. The RECORD intervention and support sessions were designed to provide advice on how to deal with environmental triggers that can be managed by the individual, such as changing the food environment at home so that there are no sugary foods available, however, they did not include any discussion about the counter-influence that commercial marketing of carbohydrate-rich foods could have on food choices (481).

4.7 Looking ahead

The RECORD intervention package was tested in a feasibility trial, with embedded qualitative analysis, discussed in Chapter 5.

Chapter 5: REduced-Carbohydrate intervention for managing Obesity and Reduction of gestational Diabetes (RECORD): A randomised controlled feasibility trial

5.1 Summary

In this Chapter, I report results from a feasibility RCT, testing if it is possible to deliver the moderately reduced-carbohydrate intervention programme (RECORD), which I developed in Chapter 4, alongside routine antenatal appointments, and how successful women with obesity were in following it during the second and third trimester of pregnancy. I recruited 51 women who were pregnant <20 weeks' gestation, with BMI ≥30 kg/m^2, and a negative baseline OGTT, and randomised them 2:1 to the RECORD intervention or control (usual care). The dietary plan aimed to provide 130-150 g of total carbohydrate/day. The feasibility outcomes were: 1) adoption of the reduced-carbohydrate advice by the intervention group at 24-28 weeks' gestation (mean carbohydrate intake and 95% CI around it), and 2) retention of all participants, assessed by completion of a second OGTT at 24-28 weeks' gestation (proportion of completion and 95% CI around it). Secondary outcomes included incidence of GDM, change in markers of glycaemic control, GWG, total carbohydrate and energy intake. Process outcomes examined resources and management issues. Exploratory outcomes included further dietary changes, quality of life, maternal and neonatal outcomes, and qualitative measures.

Forty-nine of 51 participants attended the 24-28-week OGTT, a retention rate of 96% (95% CI 86.8% to 98.9%) (retention criterion). In the intervention group, total carbohydrate intake at follow-up was 190.4 (95% CI 162.5 to 215.6) g/day (adoption criterion), an absolute reduction of -19.5 (95% CI -47.6 to 8.7) g/day, and an adjusted reduction of -24.6 (95% CI -51.5 to 2.4) g/day, from baseline. Between the groups (intervention vs control), the adjusted difference in total carbohydrate intake at follow-up was -15.3 (95% CI -61.3 to 30.7) g/day. I also observed some potentially favourable effects of the intervention on glucose control, GWG, and blood pressure, however, the study was not powered to detect significant differences in these. In qualitative interviews, participants found the

intervention acceptable, and were content with the study processes, but some women reported barriers to sustained adherence, mainly pertaining to competing priorities. In conclusion, retention was high, suggesting the study processes are feasible, but the reduction in carbohydrate intake in the intervention group was small, and did not meet pre-specified progression criteria, limiting the likelihood of achieving the desired goal to prevent GDM.

Note: Sections of this Chapter have been published in the journal BMJ Open (416).

5.2 Introduction

As discussed in Chapter 1, previous studies in women with obesity during pregnancy aiming to prevent GDM, have encouraged women to change their diet and/or increase their physical activity. While some interventions have helped to limit GWG, they have been largely unable to reduce GDM incidence (224, 233). The small number of successful preventative trials, included intensive dietetic support and/or provision of key foods to study participants, with no indication of how these strategies could be part of routine practice (225, 231, 232, 239, 240, 482). In addition, the mechanism behind the success of some dietary interventions over others in preventing GDM remains unclear. Implementation at earlier stages of pregnancy was a common characteristic of successful interventions, but the optimum dietary composition to help prevent GDM is unknown. Carbohydrates represent the major energy-providing nutrient in the diet (442), so reductions may help attenuate GWG, as well as lower blood glucose levels, as shown in people with T2DM and established GDM (201, 202, 253). All successful interventions to date have included some advice around reducing carbohydrate intake, through limiting sugar consumption, and/or moderating starchy food intake (225, 231, 232, 239, 240, 482), but in none of these, carbohydrate reduction has been a specific focus. Carbohydrate reduction was specifically targeted in one previous trial, which was intense, did not achieve substantial reduction, and was not powered to detect effectiveness on GDM prevention (254). Thus, it is worth exploring whether a reduced-carbohydrate approach may reduce the risk of GDM by attenuating GWG and reducing hyperglycaemia.

A full-scale RCT to demonstrate that such dietary intervention is effective in reducing risk of developing GDM and improving maternal and neonatal outcomes, would require considerable investment (432). Before this is justified, it is important to address uncertainties around recruitment, whether the study processes and research methods run as planned, as well as acceptability of the intervention, and follow-up rate. The aim of the current study was to assess if it is possible to deliver the RECORD programme detailed in Chapter 4, alongside routine antenatal appointments at a single site, and whether women with obesity would follow it for the second and third trimester of pregnancy. Other objectives included: to assess the study procedures to inform the design of a full RCT; to assess the potential effect of the intervention on markers of glycaemic control, incidence of GDM, GWG, dietary intake, quality of life, and maternal and neonatal outcomes; and to qualitatively analyse participant experiences of the intervention.

5.3 Methods

5.3.1 Study design, participants, and recruitment

This was a two-arm parallel group individually randomised controlled feasibility trial, examining the use of a moderately reduced-carbohydrate dietary behavioural intervention, in women who were pregnant <20 weeks' gestation, and at increased risk of GDM, due to having BMI ≥30 kg/m^2. Participation lasted approximately 6 months per participant, from early or mid-pregnancy (no more than 19 weeks plus 6 days' gestation), until delivery. The protocol was reviewed and approved by the South-Central Oxford B Research Ethics Committee NHS National Research Ethics Committee and the Health Research Authority (Reference: 20/SC/0442), and prospectively registered (ISRCTN16235884), as well as published following peer review (416).

With the contribution of a research assistant, I recruited participants from the Women's Centre at OUH, where women who are pregnant attend their ultrasound appointments. In this Trust, all women who are pregnant are informed that they may be approached to take part in research studies, unless they specifically opt out. Women attending their dating or nuchal scan (typically

between 8 and 14 weeks' gestation), were usually approached directly to take part. Alternatively, sonographers provided a flyer summarising the study, to all women attending their nuchal scan, inviting them to contact us (**Appendix 5.1**). We summarised the study (purpose and procedures), and asked permission to look up their BMI from their booking appointment with their midwife. If there was time, we assessed eligibility according to the wider list of inclusion and exclusion criteria (**Table 5.1**), but otherwise provided all women with eligible BMI, with the participant information sheet, study flowchart, and directions to the assessment centre (**Appendices 5.2-5.4**). Women who were interested in taking part were invited to give their contact details. I then contacted those women via phone/text/email, to discuss the study, and assess self-reported eligibility to participate (if not already assessed at first approach).

I arranged a face-to-face baseline visit before 20 weeks' gestation with the initially eligible women who wished to participate, in order to conduct a baseline OGTT to rule out pre-pregnancy hyperglycaemia, and to complete baseline study assessments (details in section 5.3.2), and I tried to arrange this as early as possible (e.g. within 2 weeks after the nuchal scan). This allowed at least a month to practise the dietary changes.

Box 5.1. Note 1
Initially, only women who were <15 weeks' gestation (no more than 14 weeks and 6 days' gestation) at baseline were eligible. However, it was challenging for many women to attend the extra appointment at such short notice, due to family and work commitments. I therefore amended the inclusion criteria to allow women to attend their baseline visit up to 20 weeks' gestation.

Due to the nature of the OGTT, and exclusion of women with hyperglycaemia at the baseline test, full eligibility could only be confirmed after the baseline visit, and thus, after randomisation. While there is controversy over whether GDM can be diagnosed prior to 24 weeks' gestation with existing criteria (483), the clinical care team advised that women meeting the NICE diagnostic thresholds for GDM (439) at the baseline visit, should enter the standard GDM care pathway. Therefore, women with abnormal OGTT at baseline were discontinued after randomisation, and referred to the diabetes team for standard treatment.

For women who declined to participate, I sought to record the barriers to participation. I did not approach any woman whose pregnancy was deemed non-viable, or there were serious problems identified during the nuchal scan.

Table 5.1. RECORD trial eligibility criteria

Inclusion criteria	Exclusion criteria
• Pregnant women <20 weeks' gestation • Aged ≥18 years • BMI ≥30 kg/m^2, measured at booking appointment • Planned antenatal care and delivery at the study setting (Oxfordshire)	• Severe congenital fetal anomaly (confirmed by ultrasound) • Planned termination of pregnancy or ectopic pregnancy • Pre-pregnancy diagnosis of diabetes or impaired glucose tolerance or taking metformin • Renal disease • Severe liver disease • Organ transplant • Cardiac failure (grade II New York Heart Association, and more severe) (484) • Severe neurological disorder (including epilepsy) • Severe psychiatric disease requiring in-patient admission • GDM diagnosis at the baseline study visit according to NICE diagnostic criteria: a fasting plasma glucose level of 5.6 mmol/L or above, or a 2-hour plasma glucose level of 7.8 mmol/L and above (59) • History or presence of eating disorder • Hyperemesis gravidarum • Unable to understand spoken and written English • Previous bariatric surgery • Women participating in other intervention research studies • Any other significant disease or disorder which may either put the participants at risk because of participation in the trial, or may influence the result of the study, or the participant's ability to participate in the study

BMI: body mass index; **NICE:** National Institute for Health and Care Excellence

5.3.2 Study procedures

The baseline visit took place at the Oxford Centre for Diabetes Endocrinology and Metabolism, and lasted approximately 2 hours and 30 minutes. All women were asked to attend this visit in the morning, after an overnight fast, and to have not smoked, vaped, used nicotine replacement therapy or chewed sugary gum for at least 8 hours before, in line with the Trust's guidance. On arrival, I

summarised again the study aim and procedures, formally assessed inclusion and exclusion criteria, and collected written informed consent (**Appendix 5.5**), as declared by dated signature. All participants completed the following baseline assessments: blood pressure, weight and height measurements, a 2-hour 75 g OGTT, a quality of life questionnaire, demographic characteristics, and measurement of their carbohydrate intake as part of a broader assessment of their dietary intake via an online questionnaire. All assessments were completed with my help, apart from the blood pressure measurements and the OGTT, which were conducted by a research nurse. I also demonstrated to participants how to monitor their fasting capillary blood glucose and ketones at home for the duration of the study, and provided them with supplies to do so (details in section 5.3.7.3), before randomising them to one of the two trial arms. Participants in the intervention group proceeded to receive the dietary consultation, which advised them to reduce their carbohydrate intake until delivery, while participants in the control group, just waited until the last blood sample collection. All participants were invited to attend a follow-up visit at 24-28 weeks' gestation, where all baseline measures (except height) were repeated. This visit replaced the routine visit for an OGTT that all participants would have been invited to attend as part of antenatal care (59). Participants received text reminders for the study visits from the day before, reminding them of the appointment and the preparation for the OGTT.

After the follow-up assessments at 24-28 weeks' gestation, participants in the intervention group were advised to keep following the diet, and kept receiving telephone support sessions, until delivery as needed. They were also invited to take part in qualitative interviews (details in section 5.3.11). After delivery, I extracted maternal and neonatal outcomes from the electronic medical records. **Figure 5.1** shows the study processes.

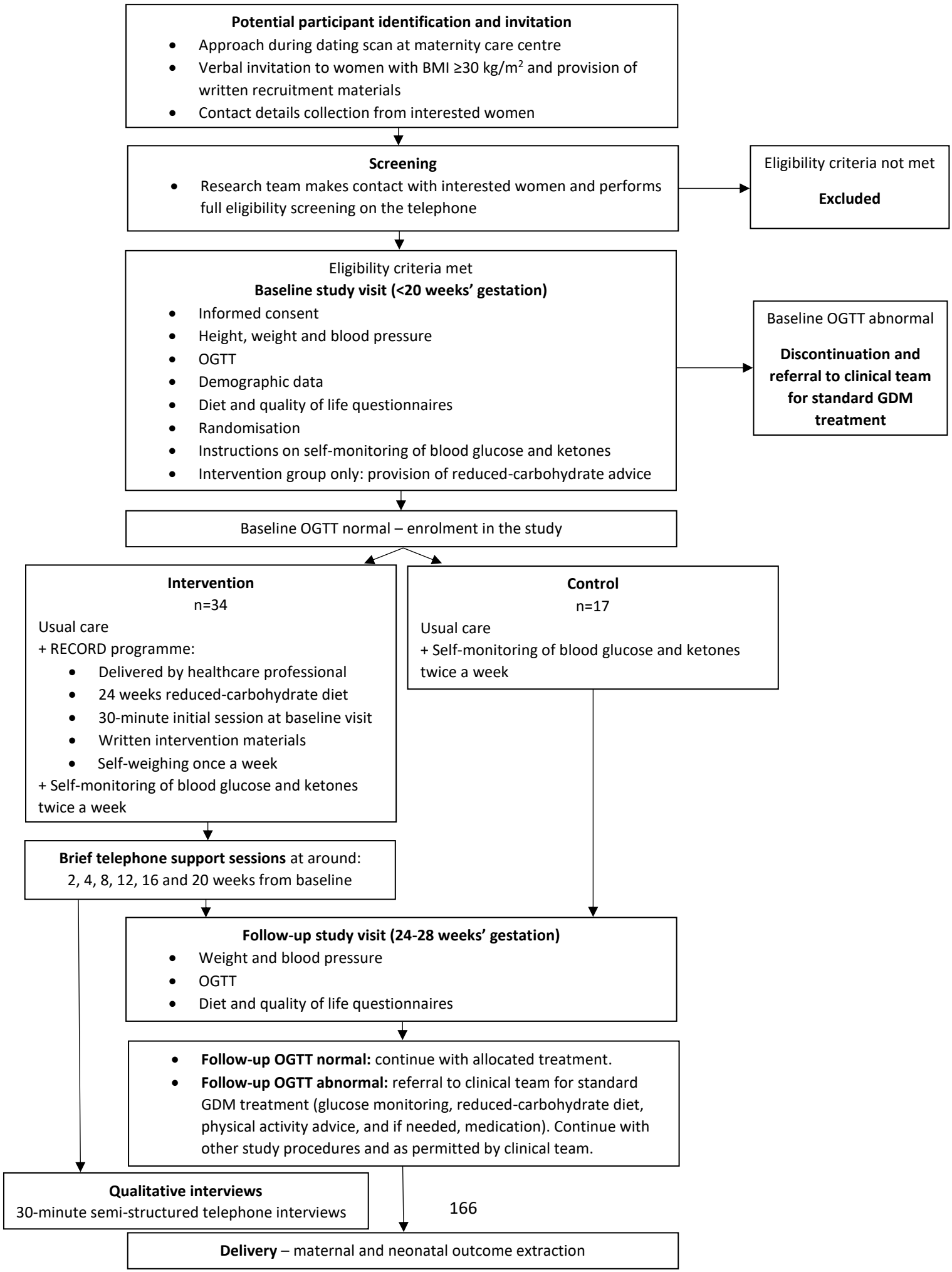
Box 5.2. Note 2
Women with GDM in a previous pregnancy were offered an earlier extra OGTT at around 16 weeks' gestation, on top of the one at 24-28 weeks' gestation, in line with NICE guidance. I offered these women the option to either complete this early OGTT with their clinical care team as originally planned, or to have it with the study team. All of these women chose to complete the early OGTT with their clinical team, so once it was confirmed to be within the normal ranges, these women consented via email, and completed the study assessments via email. I asked them to weigh themselves at home (as per measurement standards in section 5.3.7.2), I accessed their height from their booking appointment, and asked them to send me the most recent blood pressure measurement taken during a midwife or hospital appointment. Upon receiving the completed assessments, I randomised them, and for those in the intervention group, I posted the intervention materials, and completed the dietary consultation on the telephone. At 24-28 weeks' gestation, they completed another OGTT with their clinical team, so repeated all follow-up assessments remotely too. Importantly, for these participants, some measurements for the study were not available, as they are not measured as part of routine OGTT visits (details in section 5.3.7.3).

5.3.3 Sample size

This feasibility study is not powered to detect a statistically significant difference in clinical effectiveness between the trial arms. Instead, I tested what are the uncertainties around the adoption of the reduced-carbohydrate intervention and retention rate, as indicators of feasibility. The average total carbohydrate intake in women who are not pregnant is about 230 g/day (427). I set the sample size to be able to detect a target intake at 130–150 g/day, that is, approximately 140 g of total carbohydrate/day at follow-up, with 95% CI that does not cross 170 g/day. Progression criteria to a full trial, also included adequate retention of participants as a measure of feasibility. I considered that a minimum of 80% of participants needed to complete an OGTT at 24–28 weeks' gestation, similar to previous trials (143, 485), with 95% CI that doesn't cross 70%. Both progression criteria thresholds could be satisfied with a sample size of 60 participants allocated in 2:1 ratio, intervention: control. Unequal randomisation allowed me to have sufficient participants in the intervention arm for a qualitative study. Details of the sample size calculations are in **Appendix 5.6**.

However, due to disruptions and delays in governance and ethical approvals, which delayed the start of the study, as well as difficulties in recruiting, together with my supervisors, I made the decision to stop recruitment at 51 enrolled participants. As shown in **Appendix 5.6**, I revisited my progression criteria for a total sample of 51 participants, and these were still satisfied. Dietary data at follow-up were available for 28 intervention participants, but the adoption progression criterion was also still satisfied.

Figure 5.1. Study processes. BMI: body mass index; **OGTT:** oral glucose tolerance test; **GDM:** gestational diabetes



5.3.4 Randomisation and blinding

I randomised eligible participants during the baseline study visit to one of the two treatment groups, at a ratio 2:1 intervention: control, using permuted block randomisation with random block sizes of 3 and 6. An independent researcher generated the allocation sequence, and assignment was revealed once eligibility had been confirmed, using an online software (Study Randomizer) to ensure allocation concealment (486). Due to the nature of this study, it was not possible to blind participants, clinicians, myself, or any member of the study team to the treatment allocation beyond this point.

To reduce the potential risk of social desirability bias in participants' dietary and other questionnaires, as well as telephone support sessions and qualitative interviews, I reminded participants that there were no right or wrong answers, that all data collected were anonymised, that their clinical care would not be affected by their responses or degree of engagement with the study and the intervention where relevant, and that it was important to collect accurate data for the analysis. I conducted all the data coding and entry, but most data collected in this study were obtained through objective means such as online software, electronic machines, and medical records, which minimised the risk of bias during data coding and entry.

5.3.5 Intervention and control

Details of the intervention development are described in Chapter 4. The dietary advice aimed to provide 130-150 g of total carbohydrate/day, based on 3 main principles (3R's): Refrain from sugary foods and drinks, Reduce portions of starchy carbohydrates, and Replace refined starchy carbohydrates with unrefined varieties, and sugary foods/drinks, with low/no-sugar alternatives. The intervention package combined a dietary consultation from a HCP (myself), with structured written materials (both dietary and behavioural), remote telephone support until delivery, and weekly self-monitoring of weight. The control group received usual antenatal care.

5.3.6 Outcomes

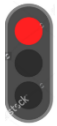
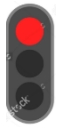
5.3.6.1 Primary

The primary objective of this study was to test whether the RECORD programme is feasible and leads to a reduced-carbohydrate intake in women with obesity who are pregnant and at risk of GDM. These feasibility measures would further determine whether to progress to a full RCT. Progression criteria were based on a traffic light system to decide whether to proceed to a full RCT (green), proceed with amendments for remediable issues (amber), or to not proceed (red) (**Figure 5.2**) (487).

5.3.6.2 Secondary, process, and exploratory outcomes

Secondary outcomes offered the opportunity to collect some pilot data which could be used to power a definitive RCT in the future. Process outcomes explored procedures, resources, and management issues, to aid the design of a future RCT. Exploratory outcomes examined further dietary changes, the potential effect of the intervention on maternal and neonatal outcomes, and sought feedback on the acceptability of the intervention and the study (**Table 5.2**).

Figure 5.2. RECORD trial feasibility progression criteria

Criteria	How it will be assessed?	Indication of success	
Adoption of the diet from the intervention group	Mean total carbohydrate consumption via 24-hour recall online diet questionnaire at follow-up (24-28 weeks' gestation)		Mean intake <170 g/day and 95% CI that includes 140 g/day, but does not include 170 g/day
			Mean intake ≤170 g/day and 95% CI that includes both 140 g/day and 170 g/day
			Mean intake >170 g/day and 95% CI that does not include 140 g/day or 170 g/day
Retention rate	Mean proportion of all enrolled participants who complete an OGTT at follow-up (24-28 weeks' gestation)		Retention of ≥80% of recruited participants, with estimated 95% CI that does not include 70%
			Retention of ≥70% of recruited participants, with estimated 95% CI that includes both 70% and 80%
			Retention of <70% of recruited participants, with estimated 95% CI that does not include 70% or 80%

OGTT: oral glucose tolerance test; **CI:** confidence interval

Table 5.2. Secondary, process, and exploratory outcomes in the RECORD trial

	Outcomes	Assessment time point(s)
Secondary	Change in fasting plasma glucose, 1-hour, and 2-hour glucose	OGTT at baseline and follow-up visits
	Change in HbA1c, fasting plasma insulin, and insulin resistance (HOMA-IR)	Blood samples collected as part of OGTT at baseline and follow-up visits
	Proportion of participants who are diagnosed with GDM	Documentation at baseline and follow-up visits
	GWG	Weight change from baseline until before delivery. If pre-delivery weight would not be available, I would use weight at 36 weeks' gestation collected as part of routine practice.
	Proportion of participants meeting the IOM recommendations for GWG (127)*	Weight change from baseline until before delivery. If pre-delivery weight would not be available, I would use weight at 36 weeks' gestation collected as part of routine practice.
	Dietary intake: total carbohydrate intake (g/day) and total energy intake (MJ/day), percentage of daily total energy intake from carbohydrates	Dietary composition analysis at baseline and follow-up visits
	Fasting capillary blood glucose and ketone levels in each group, and comparison between the groups	Across gestational age from baseline until before delivery
Process	Number of eligible women who are approached and enrolled into the study per month	Documentation per recruitment month
	Percentage of intervention participants who complete the initial and support sessions	Documentation at each relevant time point
	Percentage of participants in each group who attend the follow-up visit	Documentation at follow-up visit
	Percentage of participants for whom weight at 36 weeks' gestation is available	Usually measured as part of a routine hospital/midwife appointment at 36 weeks' gestation
	Proportion of participants who record their blood glucose and ketones every week	Documentation from baseline until before delivery
	Proportion of participants in the intervention group who self-monitor their weight every week	Documentation from baseline until before delivery
	Proportion of participants in the control group who, after randomisation, follow a reduced-carbohydrate diet (contamination of the control group)	Dietary composition analysis at baseline and follow-up visits
	Proportion of essential elements included in the intervention delivery (fidelity)**	Evaluation of audio-recorded consultations against a checklist

Table 5.2. continued

	Outcomes	Assessment time point(s)
Exploratory	Further dietary changes: fibre intake, percentage of daily total energy intake from total fat, saturated fat and protein	Dietary composition analysis at baseline and follow-up visits
	Changes in systolic and diastolic blood pressure	Blood pressure measurements at baseline and follow-up visits
	Pregnancy-related outcomes: - Gestational hypertension and preeclampsia - Requirement for insulin or oral diabetic medication - Mode of delivery - Induction of labour - Gestational age at delivery - Birth weight - Sex of baby - Rates of macrosomia (>4500 g) (488), LGA (birth weight >90th percentile) and SGA infant (birth weight <10th percentile) (488) - Neonatal intensive care unit admission - Shoulder dystocia/birth trauma - Neonatal hypoglycaemia requiring intravenous glucose - Neonatal hyper bilirubinaemia requiring phototherapy	Extraction from medical records following delivery
	Change in maternal quality of life	Quality of life questionnaire at baseline and follow-up visits
	Participant acceptability of the intervention and the materials, overall experience of the intervention, and the study, and barriers and facilitators of adherence	Qualitative interviews at some point between the follow-up visit and before delivery

OGTT: oral glucose tolerance test; **IOM:** Institute of Medicine; **HOMA-IR:** Homeostatic Model Assessment of Insulin Resistance; **GDM:** gestational diabetes mellitus; **GWG:** gestational weight gain; **LGA:** large-for-gestational-age; **SGA:** small-for-gestational-age

*Pre-pregnancy weight was not available, therefore, this outcome was estimated according to how much weight women would be expected to gain from enrolment, until delivery/36 weeks' gestation (whichever is available), if meeting the IOM guidelines.

** Fidelity was assessed by an independent researcher, assessing whether the initial dietary consultation addressed the following components: (i) information about GDM, (ii) 3R's (Refrain, Reduce, Replace), (iii) goal setting, and (iv) self-monitoring of weight.

5.3.7 Measurements

A schedule of measurements can be found in **Figure 5.3**.

5.3.7.1 Sociodemographic characteristics

I accessed participants' age and address from their medical records. At the baseline visit, participants were asked to self-report their highest education level (none, GCSE or equivalent, A-levels or equivalent, University undergraduate, University postgraduate, still studying, or prefer not to say), current employment status (employed, unemployed, looking after home or family, student, retired, long-term sick or disabled, other, or prefer not to say), and ethnic background (White, Mixed/Multiple ethnic groups, Asian/Asian British, Black/African/Caribbean/Black British, or prefer not to say).

5.3.7.2 Physical measurements

I measured height by asking participants to remove their shoes, using a stadiometer, to the nearest 0.1 cm at baseline only. I weighed participants to the nearest 0.1 kg using a digital scale (Active Era, BS-03S) at each study visit. I placed the scales on a level and stable surface, asked participants to remove all outdoor clothing and shoes, and empty their pockets, I offered them to visit the toilet before the measurement, and asked them to step with both feet. For participants completing assessments remotely, I accessed their measured height from their booking appointment, and I asked them to measure their weight using their own digital scales, or digital scales provided as part of the trial, if they did not currently own a set. I asked these participants to measure the baseline weight on a morning before eating or drinking anything, and after having gone to the toilet, in the same way that I would have measured it if they attended their baseline visit with the study team (described above). For the weekly self-weighing at home, I included similar written instructions in the Home Monitoring Booklet (to use a solid surface, calibrate the scales each time they are moved, and weigh themselves at a fasting state after visiting the toilet, and wearing light clothes), but also highlighted these verbally. Participants received reminder texts early in the morning on the day they were expected to weigh themselves, and either texted the measurements to me, or logged them manually onto a mobile

application. At 36 weeks' gestation, women should be weighed during a routine antenatal midwife/hospital appointment as per routine practice, and digital scales are used for this. If pre-delivery weight would be available, digital scales are also used for this. Blood pressure was measured in duplicate by a research nurse, using a digital blood pressure machine (Omron, M3) after a 5-minute seated rest, with at least 1 minute between each measurements. For remote participants, I used the most recent blood pressure measurements taken at a midwife/hospital visit, where digital blood pressure monitors are used, but the procedure may have varied (e.g. rest time), and only one measurement was taken at a time.

5.3.7.3 OGTT and remote glucose and ketone monitoring

Participants attended the study visits after an overnight fast, refraining from smoking, vaping, using nicotine replacement therapy or chewing sugary gum for at least 8 hours before. A fasting venous blood sample was collected for the determination of glucose, HbA1c, insulin concentrations. Participants were then provided with a 75g glucose load (Polycal, Nutricia). Further venous blood samples were collected at 1 hour and 2 hours post-drink, for the determination of glucose concentrations. The results of OGTTs were available on the electronic medical records and the clinical team could view them, but I also posted them to their GP. Insulin, HbA1c, and 1-hour glucose are not routinely measured during OGTTs in the UK, therefore, for participants who completed their OGTTs with their clinical team, these measurements are missing.

All participants were provided with a Bluetooth-enabled capillary blood glucose and ketone monitoring kit (4SURE Smart Duo, Nipro Diagnostics). I provided all participants with a short demonstration and information flyer on how to collect and record the measurements, and I advised them to take a fasting capillary glucose and ketone measurement twice a week. For participants not completing their study assessments in person with the study team, I posted the information flyer and supplies for self-monitoring of blood glucose and ketones along with detailed written instructions on how to take a measurement, including link to a video demonstration on the supplier's website. The

blood glucose and ketone monitor was connected remotely to a mobile application (Diabetes: M, Sirma Medical Systems), allowing me to monitor the readings remotely and escalate concerns to the clinical team. I did not provide cut-offs to participants for fasting capillary glucose and ketone levels, due to lack of level references specific to pregnancy and before GDM diagnosis. An obstetrician and an obstetric physician from my study team who are also members of the clinical care team at the hospital, interpreted the measurements on an individual basis and/or based on evidence from non-pregnant populations. Participants received reminder texts early in the morning on the day they were supposed to do their finger-pricks. The collection of this data during the feasibility study can guide thresholds that can be set for any future trial.

5.3.7.4 Dietary intake, including carbohydrate consumption

Participants completed at baseline (<20 weeks' gestation) and follow-up (24-28 weeks' gestation), an online multiple-pass 24-hour recall for their dietary intake on the day before, which has been validated against interviewer-led multiple-pass recalls in adolescents and adults (Intake 24, Newcastle University) (489, 490). By the time participants enrolled in the study (mid-pregnancy), their dietary intake was likely to have stabilised compared with the fluctuations usually observed in the first trimester due to pregnancy symptoms. The outcomes recorded with the online 24-hour recall tool can be affected by errors during the recording process. For example, during completion of the recall, errors might occur due to participants' difficulties estimating portion sizes, difficulty in recalling all foods and drinks that they had, and social desirability bias. Despite this, collecting dietary intake data using a self-administered web-based 24-hour recall is efficient, it greatly reduces the burden on the study team, standardises the questions, and offers the responded the ability to choose from a list of UK products and adjust the portion size they actually had through visuals (491-494). As a result, food and nutrient estimates are generally consistent between interviewer-led and web-based 24-hour recalls (495-497).

To protect the accuracy in participant responses, I showed participants a demonstration video of how the recall should be completed the first time, although no one felt that they needed to watch it again at follow-up as they felt confident that they remembered how to do it. I was also present most of the time while participants were completing their recall and helped with any questions they had, for example if they could not find the exact food that they had. However, this was not possible for participants who completed all study assessments remotely. After completion, I went through each recall and asked participants clarifications where they could not find or had forgotten to provide details on foods and meals. I then created a dummy participant, and entered the correct foods and meals and updated the original recall outputs accordingly

5.3.7.5 Quality of life

Participants filled in a questionnaire about their quality of life, via the European Quality of Life Five Dimension (EQ-5D) questionnaire and visual analogue scale (VAS) (498).

5.3.8 Retention and withdrawal

This study was designed to run alongside routine antenatal appointments with remote support, to minimise the burden associated with attending extra visits. The brief telephone support sessions with myself acted as prompts for the participants to engage with the intervention and self-monitoring. To compensate for the time and inconvenience in taking part, I offered participants financial incentives for their participation, more specifically, the option to choose between a voucher and a bank transfer for each study visit, and I paid for their parking or a taxi to come to the study visits, and for a light breakfast after each OGTT, on top of this. I used reminder text messages to increase commitment to self-monitoring and attendance to the two study visits.

Participants were informed that they had the right to withdraw from the study at any time, and that the Chief Investigator or I had the right to discontinue them from the study if they became ineligible and/or the clinical care team advised so. For example, women with stillbirth would be discontinued from the study due to clinical decision. If women had preterm neonates, they would not

be discontinued from the study given that they met the eligibility criteria until the point of delivery. Participants were asked at the point of withdrawal if they would prefer to also withdraw their collected data or not, apart from withdrawing their active participation. If participants chose to withdraw, I asked them for the reason, which may help refine the study processes or intervention, but providing a reason was optional. Withdrawn eligible enrolled participants were not replaced in this feasibility study. I only replaced participants whose baseline OGTT was abnormal, as they had already consented and been randomised before OGTT results became available, but they essentially had failed the full screening. Withdrawal or discontinuation of participants from the study was communicated to their GP and clinical team via letter and electronic medical record notes.

Figure 5.3. Schedule of study measurements (412)

	STUDY PERIOD								
	Enrolment	**Allocation**			**Study visits/sessions**				**Delivery**
TIMEPOINT	Baseline = Week 0 (<20 weeks' gestation)	Week 0	Week 2	Week 4	~Week 8	Follow-up visit = ~Week 12 (24-28 weeks' gestation)	~Week 16	~Week 20	Week 24
ENROLMENT:									
Eligibility screening	X								
Informed consent	X								
Randomisation	X								
TRIAL ARMS:									
RECORD programme	X	X				X			X
+ telephone support			X	X	X	X	X	X	
Usual care	X	X				X			X
ASSESSMENTS:									
Demographics	X								
Weight	X					X			
Height	X								
Blood pressure	X					X			
OGTT	X					X			
EQ-5D	X					X			
Self-completed 24-hour online dietary recall	X					X			
Fasting plasma insulin	X					X			
HbA1c	X					X			
Self-monitoring of fasting capillary glucose		Twice a week for the study duration							
Self-monitoring of fasting capillary ketones		Twice a week for the study duration							
Self-weighing (intervention group)		Once a week for the study duration							
SAEs									
Maternal and neonatal outcomes									X

EQ-5D: EuroQol – 5 Dimensions questionnaire; **OGTT:** oral glucose tolerance test; **HbA1c:** glycated haemoglobin; **SAEs:** serious adverse events

5.3.8 GDM diagnosis

I referred participants who were diagnosed with GDM at 24-28 weeks' gestation, to the diabetes team at the hospital, who offered the current standard medical treatment (59). In addition, participants diagnosed with GDM, were advised to moderately reduce their carbohydrate intake (120-150 g/day), choose lower-GI foods, limit their weight gain, and do 150 minutes of moderate-intensity activity/week, as per local practice in this hospital. Therefore, I advised those from the intervention group to keep following the RECORD diet until delivery (at the discretion of their clinical team), since the principles were very similar. Women from the control group received reduced-carbohydrate advice at this stage, as per routine GDM care.

Box 5.3. Note 3
The diabetes team uses different monitoring device and mobile application to monitor glycaemic control, to which I had access, so I could obtain fasting capillary glucose data twice a week. However, the monitor provided by the diabetes team does not measure ketones. I encouraged participants to continue monitoring ketones for the study after GDM diagnosis, using the study's monitor if it was not an inconvenience, and documented how many people did that.

5.3.10 Statistical analysis

5.3.10.1 Descriptive statistics

I used descriptive statistics to characterise the sample in terms of baseline age, ethnicity, socioeconomic status (highest level of formal education and index of multiple deprivation [IMD] (499)), clinical characteristics, dietary intake, and quality of life. I reported continuous variables as mean and SD, apart from IMD which is reported as median (IQR). I reported categorical variables using count and percentages.

5.3.10.2 Definition of population for analysis

One participant was recorded by mistake by myself as belonging to the control group, although was randomised to the intervention. They received the initial dietary consultation, but none of the support sessions. Nevertheless, the statistical analysis was carried out following the intention-to-treat approach, where participants were analysed according to their allocated trial arm, irrespective of the

treatment they actually received. The analysis was based on available data only. Women who were initially randomised but excluded due to abnormal OGTT at the baseline visit, were not included in any analysis.

5.3.10.3 Statistical analysis of progression criteria

The progression criteria are presented as descriptive summary statistics with 95% CIs, calculated using the OpenEpi calculator with Wilson score corrected for small population size (500).

5.3.10.4 Statistical analysis of secondary and exploratory outcomes

I used linear regression models to determine the within- and between-group differences at follow-up, to explore the effect of the intervention on secondary and exploratory continuous outcomes. I presented both unadjusted and adjusted models. In most analyses, outcome was the change score, and models were adjusted for baseline maternal age, ethnicity, IMD, baseline BMI, and the baseline value of the outcome, to help adjust for the fact that not everybody started the trial with the same baseline levels. For weight change, which was measured at baseline, and at two follow-up time points (24-28 weeks and 36 weeks' gestation), I used the mean weight measurement at follow-up as an outcome, I used repeated measures linear regression models, where I included as fixed effect the interaction between visit and randomised group, and instead of baseline BMI, I adjusted for baseline mean weight. Before running linear regression models, I checked main assumptions: linear relationship between variables in the model using visual matrices; no high correlation between independent variables using correlation matrices and variance inflation factor statistic; and that the residuals exhibited a normal distribution and the same variance across levels of the independent variables, using residuals plots, skewness and kurtosis, Q-Q plots, and heteroscedasticity tests (Breush-Pagan and White's tests).The regression models tested the null hypothesis that there was no intervention effect on each outcome. The null hypothesis was tested against a two-tailed P value of alpha=0.05. I reported all within- and between-group differences as mean and 95% CI. Binary

outcomes (e.g. GDM, and other maternal and neonatal outcomes) are reported descriptively for each group as count and percentages. All statistical analyses were conducted using Stata 16.0.

5.3.11 Qualitative study

I embedded a qualitative sub-study within the trial to explore participants' experiences of the intervention, as well as the study as a whole. The specific aims of the qualitative sub-study were to explore participants': (i) experience of attempting to follow the dietary programme, (ii) opinion on the intervention components (initial dietary consultation, written materials, remote support sessions), and (iii) experience of study processes.

5.3.11.1 Recruitment and sampling strategy

I invited participants who received the intervention, to take part. I strived to invite a purposive sample of participants with a breadth of GWG and glycaemic control levels, age, education level, ethnicity and socioeconomic status. During the follow-up visit at 24-28 weeks' gestation, I provided participants with a separate participant information sheet about the qualitative interviews. For participants who did not complete their follow-up with the study team, I sent the information in the post or via email (**Appendix 5.7**). Participants were given as much time as they wished, from the time point of follow-up until before delivery, to decide if they would like to take part in this sub-study. Prior to commencing the interview, I reminded participants that it would be audio-recorded and transcribed, that the results would be included in a PhD thesis and published in academic journals and communications, and that anonymous quotes might be used in those. I reassured participants that not taking part in the qualitative interviews would not affect their participation in the main RECORD trial, or any care they receive, and gave them the opportunity to ask questions. For two interviews that took place face-to-face, participants gave their written consent form. For telephone interviews, I read out the conditions of the consent form to the participants, who gave their verbal informed consent. I recorded this verbal consent in writing on the consent form, dated, and signed it, and I posted a copy to each participant (**Appendix 5.8**).

5.3.11.2 Sample size for qualitative interviews

I intended to recruit and interview a sufficient amount of participants to reach data saturation. Previous qualitative studies suggest this is likely at about 20 participants. Data saturation was reached after 14 participants, and I interviewed an additional 2 participants to ensure that no new themes were emerging during the interview process, which confirmed saturation. Only one of the total of 17 participants that I had approached by the time of data saturation, refused, due to limited time availability.

5.3.11.3 Interviews

One-off qualitative interviews took place between the follow-up visit for the main RECORD trial and before delivery. Interviews took between 20 and 30 minutes, and explored participants' experiences of the RECORD diet programme and taking part in the RECORD feasibility trial. I followed a semi-structured interview topic guide, which provided structure to the interview, whilst allowing me to explore any themes that naturally emerged during the interview process (**Appendix 5.9**). The topic guide consisted of open-ended questions to allow participants to elaborate without leading them. Where necessary, I used prompts to elicit additional information.

5.3.11.4 Data collection and analysis

All interviews were audio-recorded and transcribed verbatim. I checked each transcription file for accuracy against the recording, and filled in gaps where the transcriber was unsure or could not understand what was spoken. None of the transcriptions contained identifiable information as the audio-recording started after having addressed the participant with their name. The aim of the analysis was to explore the participants' subjective views of the RECORD intervention and trial. I therefore followed a descriptive qualitative analytic approach, which is designed to help understand and describe a phenomenon, e.g. how participants experienced the intervention and study, how they coped with the programme, and what were the barriers and facilitators towards adherence. I sought to stay as close to the surface of the data as possible, so as to reflect the participant experiences, and

refrained from generating new theories. This approach is appropriate for my research, as it is unknown how participants may experience this novel dietary programme, and the information required is obtained directly from them (501). My ontological position was relativism, and my epistemology was based on subjectivism.

I used thematic analysis to code, categorise, and identify patterns of meaning in the data, following the 6 steps proposed by Braun and Clarke (501) (**Box 5.4**). In practice, I went back and forth between the steps. Due to practical constrains of this DPhil, all interviews and the analysis were conducted by me, however, I discussed each step and the findings throughout the process with my supervisors, who have experience of conducting and analysing qualitative interviews in the context of weight management interventions. Throughout the analysis, I kept a coding record of how and why new codes were created, as well as thoughts when reading each transcript. During supervision meetings, I discussed this record with my supervisors to reach a consensus. I also kept a reflexivity log of my personal beliefs and experiences in order to be aware of them and of how they may have impacted the analysis, and raised these with my supervisors. I coded my data using NVivo version 12. Anonymous quotes are presented in the results.

Box 5.4. Steps followed during descriptive thematic analysis; OGTT: oral glucose tolerance test	
Step 1	I read all transcribed interviews to familiarise myself with the data, and kept a record of initial thoughts about potential codes and patterns. Most of my thoughts were based on themes that I had identified from previous similar qualitative interviews.
Step 2	I coded each transcript, using initially a deductive approach to identify data reflecting each of the RECORD intervention components (dietary consultation, written materials, support sessions, weight monitoring), and study processes (e.g. recruitment, OGTTs, data collection, self-monitoring of blood glucose and ketones). Within this framework, I then coded each transcript line-by-line, developing my coding frame.
Step 3	I grouped codes into broader categories, based on purely what participants reported, without generating new theories (501, 502). I summarised the categories using the One Sheet of Paper approach (503), to identify patterns in the data, leading to broader analytic themes.
Step 4	I refined the thematic analysis by checking the consistency between the data, the codes, the categories, and the themes, which led to developing new themes, discarding others, or merging some existing ones.
Step 5	I named the themes so that they accurately reflect their essence.
Step 6	I wrote-up the analysis.

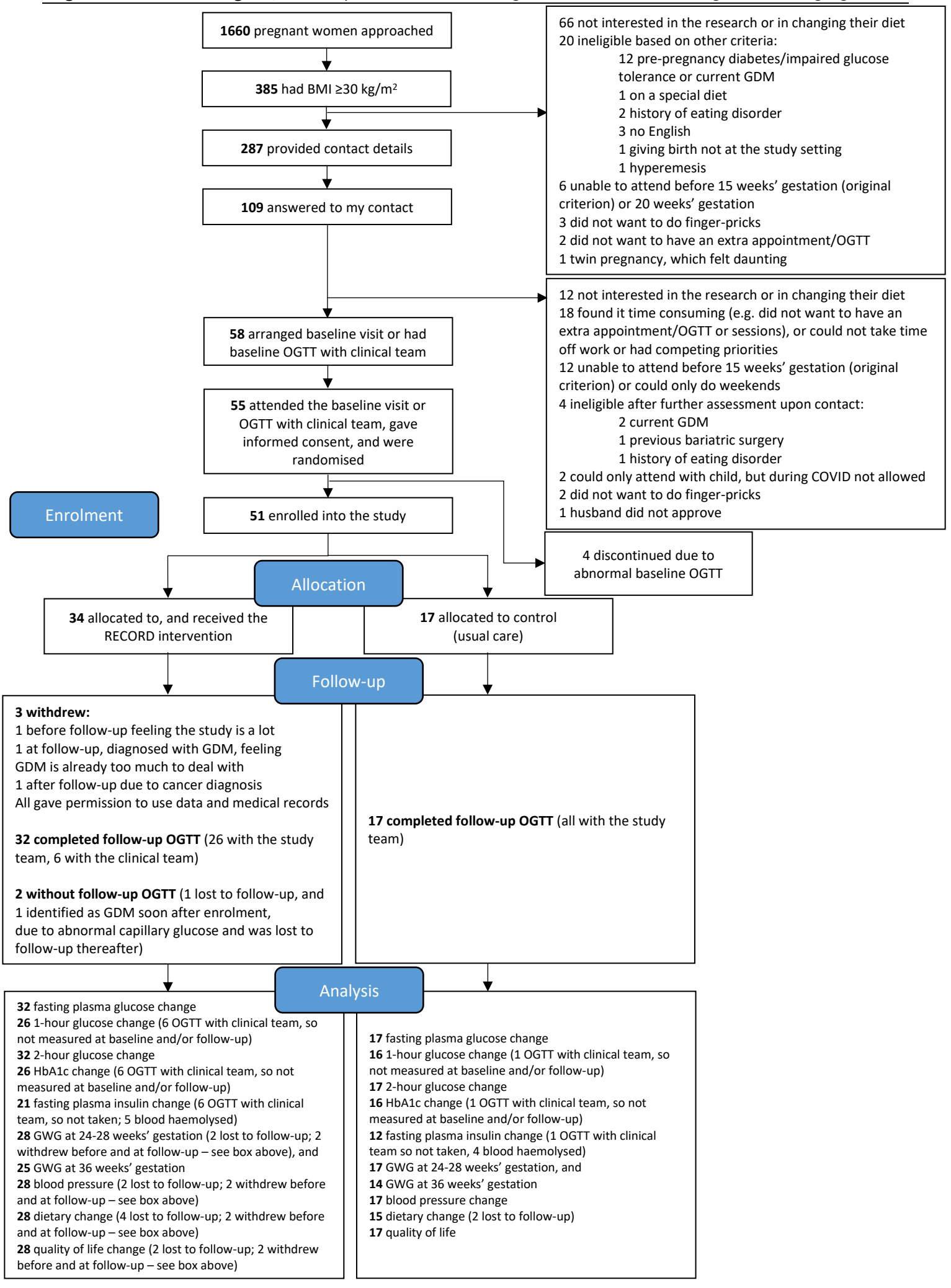
5.4 Results

The trial started one year later than originally planned, due to delays in obtaining ethical and regulatory approvals caused by the COVID-19 pandemic.

5.4.1 Recruitment and participant characteristics

Recruitment was challenging, and took much longer than expected (10 months). From May 14th, 2021, to March 31 2022, 1660 women were approached and assessed for inclusion based at least on BMI. Fifty-five women gave informed consent to participate and were randomised. Of those, 51 were confirmed as fully eligible after the baseline OGTT, with 34 comprising the intervention group, and 17 the control group (**Figure 5.4**).

Figure 5.4. Trial flow diagram, BMI: body mass index; OGTT: oral glucose tolerance test; GWG: gestational weight gain



Six participants were offered as part of their routine care, an early OGTT (5 due to previous GDM, and one deemed at high risk by their team, due to comorbidities and older age, despite no history of GDM). These 6 participants chose to have both OGTTs with their clinical team, and therefore completed all study assessments remotely. At follow-up (24-28 weeks' gestation), two more participants had their OGTT with their clinical team. In total, 49 of 51 enrolled participants completed an OGTT at 24-28 weeks' gestation, 42 with the study team, and 7 with their clinical team. One participant was lost to follow-up, both from the study and the clinical team, and one participant did not have a follow-up OGTT, because she entered the GDM care pathway shortly after joining the study, as judged by her clinical team, due to consistently high fasting capillary glucose measurements taken as part of this study.

Dietary data at follow-up were available from 43 of 51 participants (6 lost to follow-up, e.g. were sent the dietary questionnaire via email, but did not complete it, and 2 withdrew before and at follow-up). All participants had live births, and their clinical outcomes were extracted after delivery from their medical records. Follow-up for pre-specified outcomes was completed immediately after delivery for each participant, with the latest delivery time point being September 15th, 2022. The study closed on December 31st 2022, and serious adverse events were recorded up to that point.

All pregnancies were singleton. Participants were mainly in their thirties, predominantly of White ethnic background, and highly educated. BMI was similar between the groups at baseline, with the median (IQR) being in the obesity class I category (34.3 kg/m^2, IQR=5.1), and the mean (±SD) belonging in the obesity class II category (35.5±4.6 kg/m^2). Participants' baseline characteristics are displayed in **Table 5.3**.

Table 5.3. Baseline characteristics of participants assigned to the RECORD programme or usual care

	Control (n=17)	Intervention (n=34)	All (N=51)
Maternal age, years*	34.1 (±5.5)	33.2 (±3.5)	33.5 (±4.2)
BMI (kg/m^2)*	35.5 (±4.6)	35.6 (±4.7)	35.5 (±4.6)
Gestational age at baseline*			
Weeks	14.5 (±1.9)	15.1 (±1.7)	14.9 (±1.8)
Days	3.3 (±2.0)	3.4 (±1.9)	3.4 (±1.9)
Ethnicity^			
White	13 (76.4)	28 (82.3)	41 (80.4)
Black or Asian	1 (5.9)	4 (11.8)	5 (9.8)
Mixed or Other	3 (17.7)	2 (5.9)	5 (9.8)
Education^			
No formal education	0 (0.0)	0 (0.0)	0 (0.0)
Secondary education	8 (47.1)	4 (11.8)	12 (23.5)
Higher education	9 (52.9)	30 (88.2)	39 (76.5)
Index of Multiple Deprivation 10th †	9.0 (3.0)	9.0 (4.0)	9.0 (3.0)
Previous GDM^	0 (0.0)	5 (14.7)	5 (9.8)

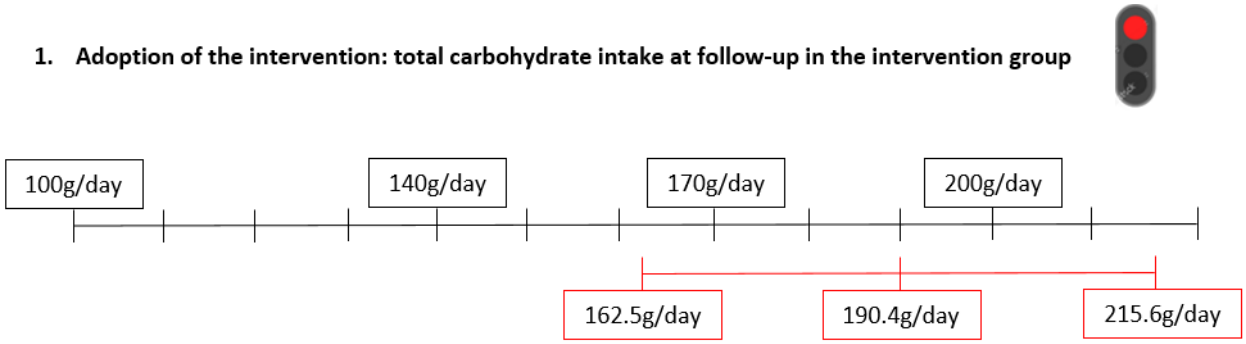
BMI: body mass index; **GDM:** gestational diabetes mellitus
* Values are means (± standard deviations).
^ Values are count (proportion).
† Indicator of deprivation, with first decile being most deprived, and fifth decile, least deprived. Values are median (interquartile range).

5.4.2 Progression criteria

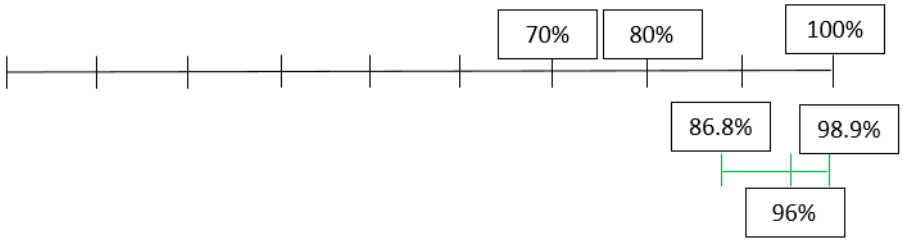
Mean total carbohydrate intake in the intervention group at follow-up was 190.4 (95% CI 162.5 to 215.6) g/day, an absolute reduction of -19.5 (95% CI -47.6 to 8.7) g/day, and an adjusted reduction of -24.6 (95% CI -51.5 to 2.4) g/day, since baseline in this group. Therefore, the adoption criterion was not satisfied (red light – **Figure 5.5**). The retention rate (49/51 attended follow-up OGTT) was 96 (95% CI 86.8 to 98.9) %. Therefore, the retention criterion was satisfied (green light – **Figure 5.5**). Since one participant was not required to have the second OGTT, the retention rate among women who were expected to have a second OGTT was 98% (i.e. 49/50), and the retention rate for women who were expected to complete a follow-up OGTT with the study team, was 93% (i.e. 42/45).

Figure 5.5. Primary outcomes

1. **Adoption of the intervention: total carbohydrate intake at follow-up in the intervention group**



2. **Retention rate: proportion of all participants completing an OGTT at 24-28 weeks' gestation**



OGTT: oral glucose tolerance test

5.4.3 Secondary and exploratory measurements

Within- and between-group changes in measurements of glycaemic markers, weight, blood pressure, dietary intake, and quality of life, are presented in detail in **Table 5.4**, and some are also presented visually in **Figure 5.6**.

5.4.3.1 Glycaemic control and insulin sensitivity

Glucose levels were similar between groups at baseline. Fasting glucose increased significantly at 24-28 weeks' gestation in the intervention group; 0.2 (95% CI 0.1 to 0.3) mmol/L. One-hour glucose levels post-drink increased significantly in both groups, with adjusted within-group differences of 1.0 (95% CI 0.5 to 1.5) mmol/L and 1.1 (95% CI 0.5 to 1.7) mmol/L in the intervention and control group respectively. Two-hour glucose post-drink increased significantly in the control group, with within-group adjusted difference of 0.7 (95%CI 0.1 to 1.4) mmol/L. The glucose at 1 and 2 hours increased

less in the intervention group, compared to the control group, but the differences did not reach statistical significance; adjusted difference of -0.3 (95%CI -1.1 to 0.5) mmol/L and -0.1 (95% CI -0.9 to 0.7) mmol/L respectively. There were no statistically significant differences between groups in change in HbA1c or markers of insulin control, but data showed that HbA1c decreased more in the control than the intervention group, whereas fasting insulin and HOMA-IR increased less in the intervention group.

5.4.3.2 Self-monitoring of glucose and ketones

Average fasting capillary glucose and ketone levels during pregnancy were similar in both groups. Ketone levels remained low throughout pregnancy in both groups. Only one participant (intervention group) developed high ketone levels above 4 mmol/L on 3 days, indicative of ketoacidosis, but the clinical team advised this was likely due to liver dysfunction and preeclampsia on top of GDM, that this participant developed which were unrelated to the study (see section 5.4.6).

5.4.3.3 Weight

At 24-28 weeks' gestation, the intervention group gained less weight (2.4 [95% CI 1.1. to 3.6] kg), compared to control (4.2 [95% CI 2.7 to 5.8] kg), with adjusted between-group difference of -2.0 (95% CI -4.8 to 0.8) kg, which did not reach statistical significance. At 36 weeks' gestation, GWG was also lower in the intervention group compared to control (7.3 [95% CI 4.9 to 9.6] kg, and 8.8 [95% CI 5.6 to 11.9] kg, respectively), with adjusted between-group difference of -1.4 (95% CI -4.5 to 1.6) kg, which was not statistically significant. According to the IOM guidelines, in the second and third trimester of pregnancy (~total of 28 weeks duration), women with obesity should gain approximately 4-7 kg (127). This would translate to about 3-5 kg recommended weight gain from the point that participants enrolled in the study, at around 15 weeks' gestation, until 36 weeks' gestation that I have data for weight (~total of 21 weeks duration). Of the 25 participants in the intervention and 14 participants in the control group, for whom weight at 36 weeks' gestation was available, 24% of the former as opposed to 7% of the latter, gained weight within this range. GWG above this range was observed in

52% of intervention and 78.5% of control participants, while rates of GWG below this range were similar between the groups (12% intervention; 14% control).

5.4.3.4 Blood pressure

Changes in systolic and diastolic blood pressure, both within and between groups, did not reach statistical significance, but they decreased to a greater extent in the intervention group, compared to the control.

5.4.3.5 Dietary intake

None of the dietary changes within or between groups were statistically significant at follow-up. Both groups reported decreased energy intake, with larger absolute decrease in the control (-152 kcal/day) compared to the intervention group (-41 kcal/day). However, the adjusted within-group change was larger in the intervention group, and the adjusted mean difference in change in energy intake between the groups (intervention vs control) was -90 (95% CI -500 to 320) kcal/day. Both groups reduced their average total, starchy, and sugary carbohydrate intake at follow-up. These decreases were greater in the intervention compared to the control group (adjusted between-group differences: -15.3 [95% CI -61.3 to 30.7] g/day; -12.5 [95% CI -45.4 to 20.4] g/day; and -8.9 [95% CI -29.9 to 12.1] g/day, respectively), but were not statistically significant. The percentage of energy from carbohydrates slightly similarly decreased in both groups. Mean fibre intake was similar between the groups at baseline, and slightly decreased in both at follow-up. The control group reported substantially lower total fat intake at follow-up, while the intervention group, reported similar levels to those at baseline, but after adjustment for confounders, there was similar level of small reduction within each group. However, non-statistically significant adjusted analyses showed that the intervention group reduced their saturated fat intake, while the control group maintained this intake at follow-up (adjusted between-group difference: -3.2 [95% CI -15.9 to 9.4] g/day). Finally, the intervention group reported higher, while the control group reported lower mean protein intake compared to their baseline intake,

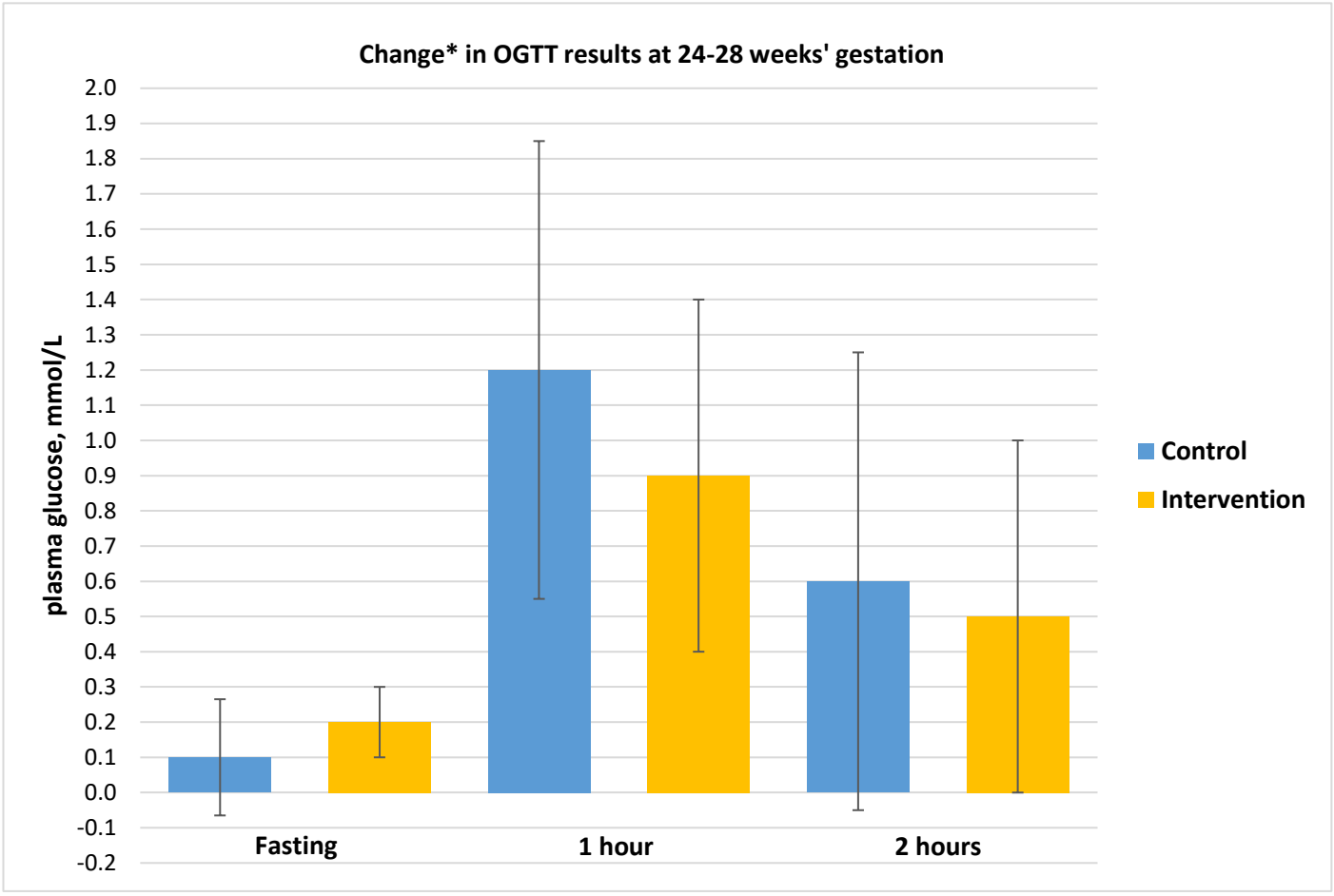
and the adjusted mean difference between the groups, though not statistically significant, favoured the intervention group.

5.4.3.4 Quality of life

The EQ-5D Index Score was similar at baseline between the groups and remained practically unchanged at follow-up. The VAS score significantly decreased in the control group at follow-up. The between-group adjusted difference in VAS score favoured the intervention compared to control, but did not reach statistical significance; 4.0 (95% CI -2.0 to 9.9).

Figure 5.6. Secondary and exploratory outcomes

A. Glycaemic markers



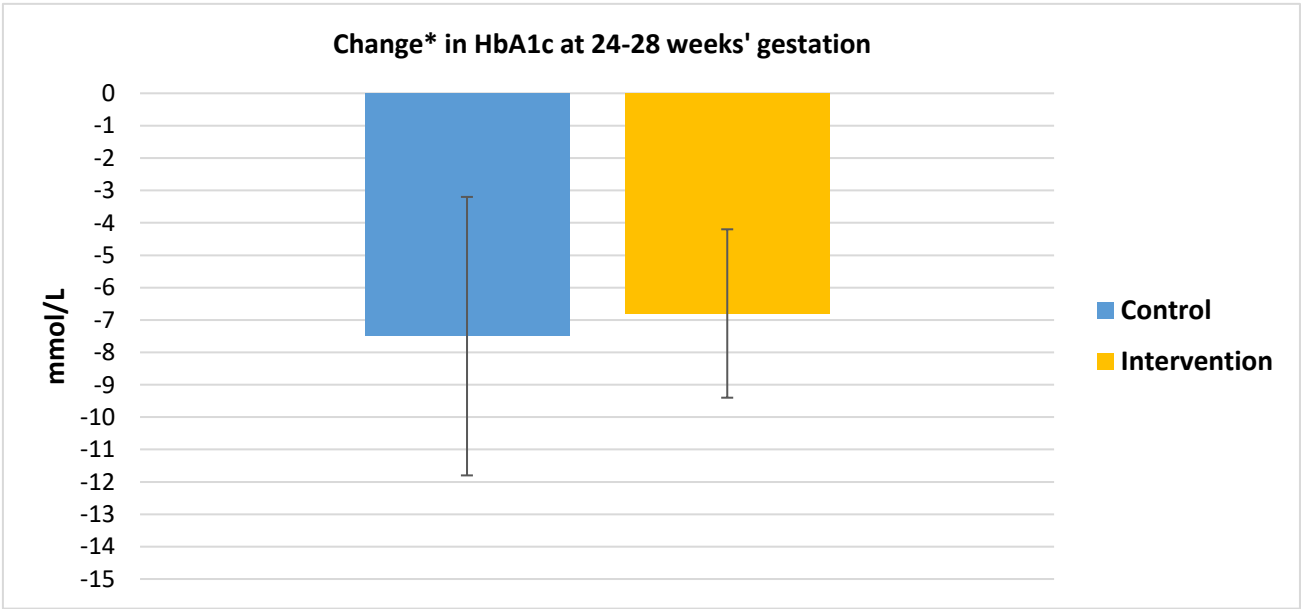
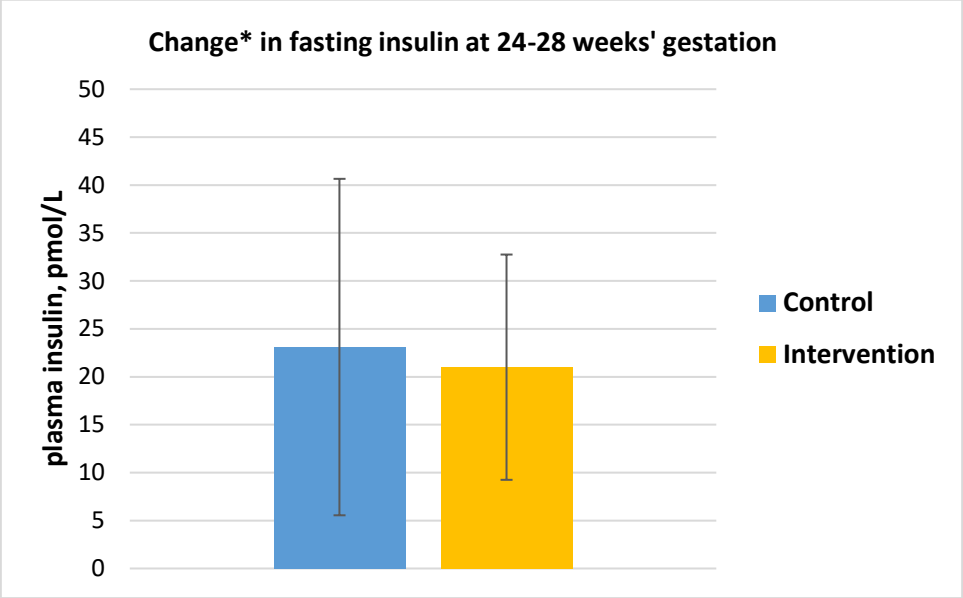


Figure 5.6. continued



B. Weight

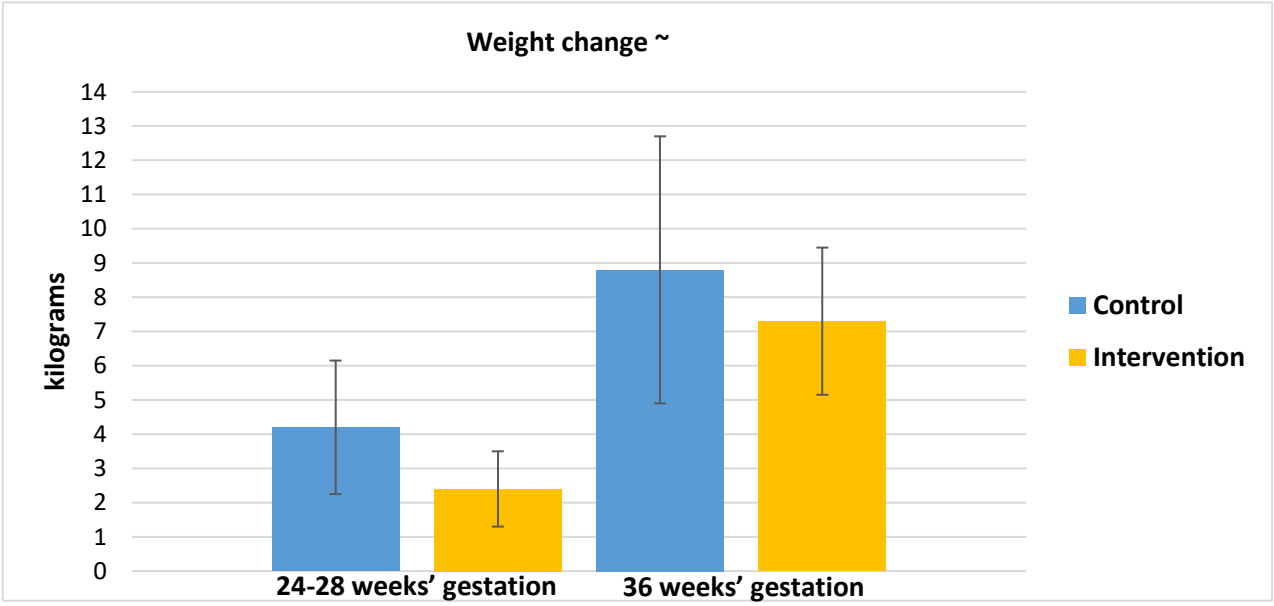
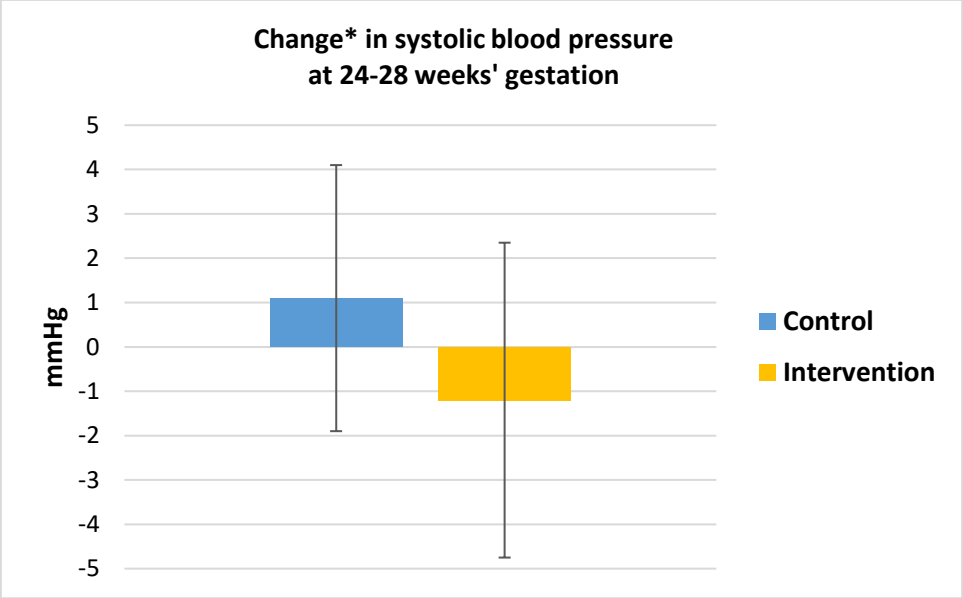


Figure 5.6. continued

C. Blood pressure



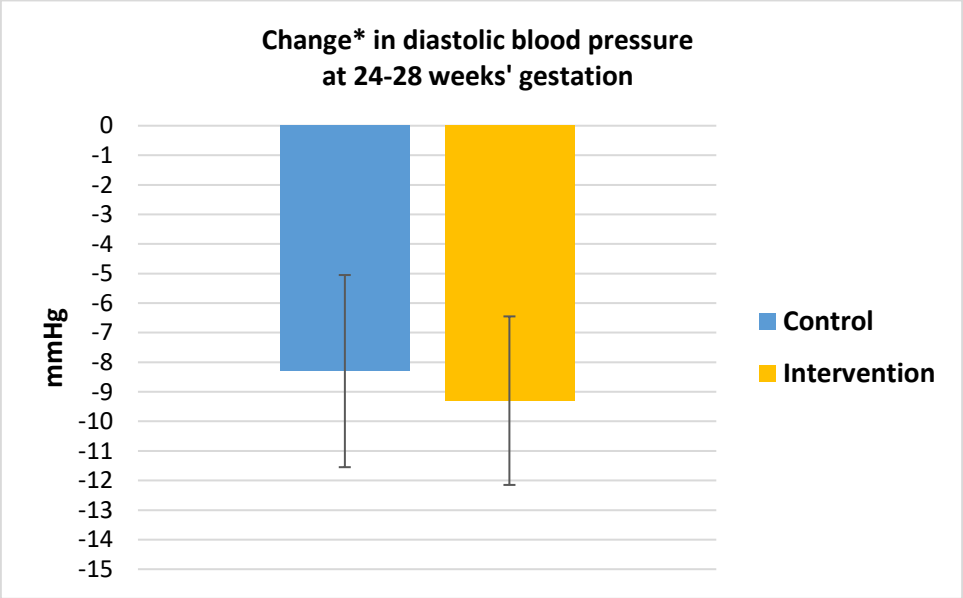


Figure 5.6. continued

D. Energy intake

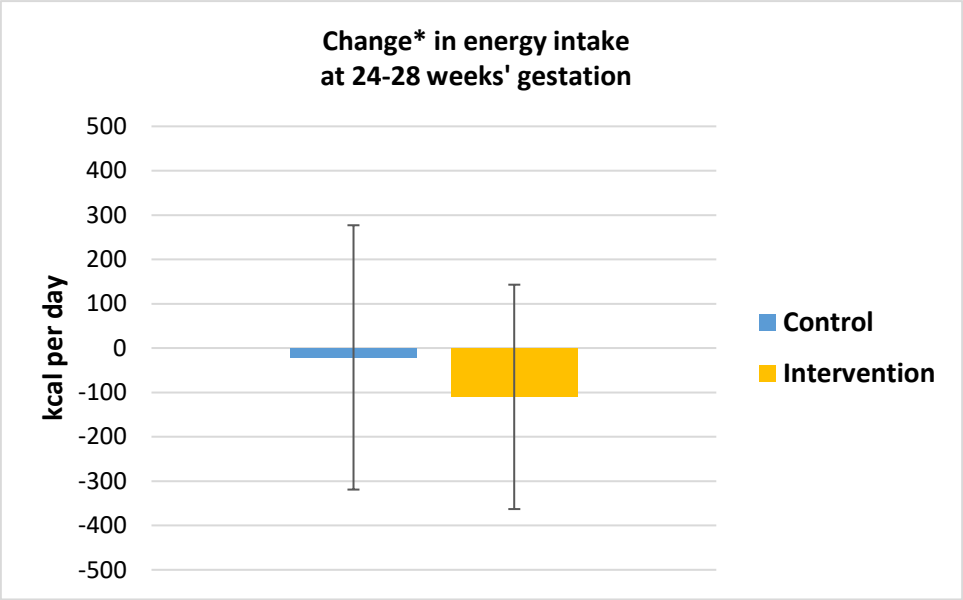
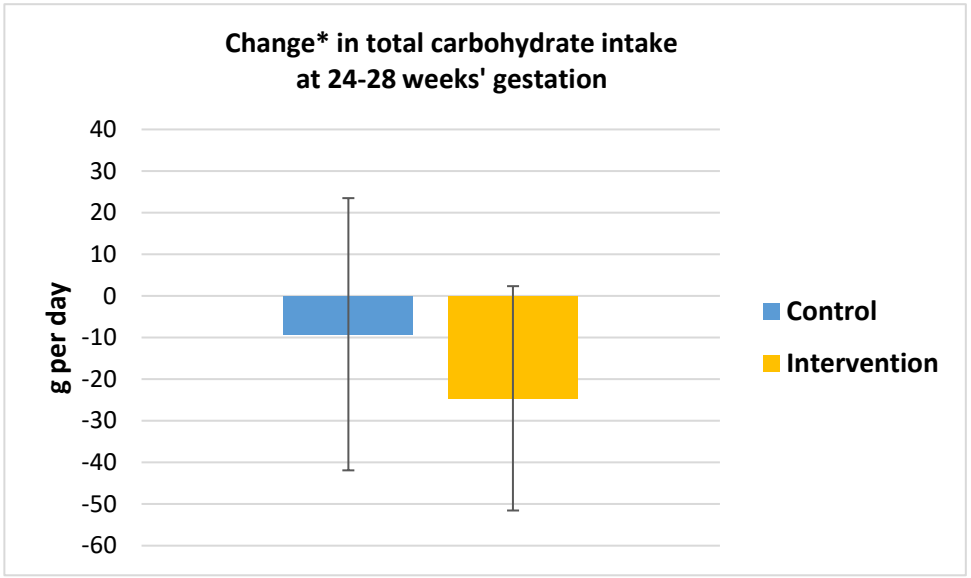
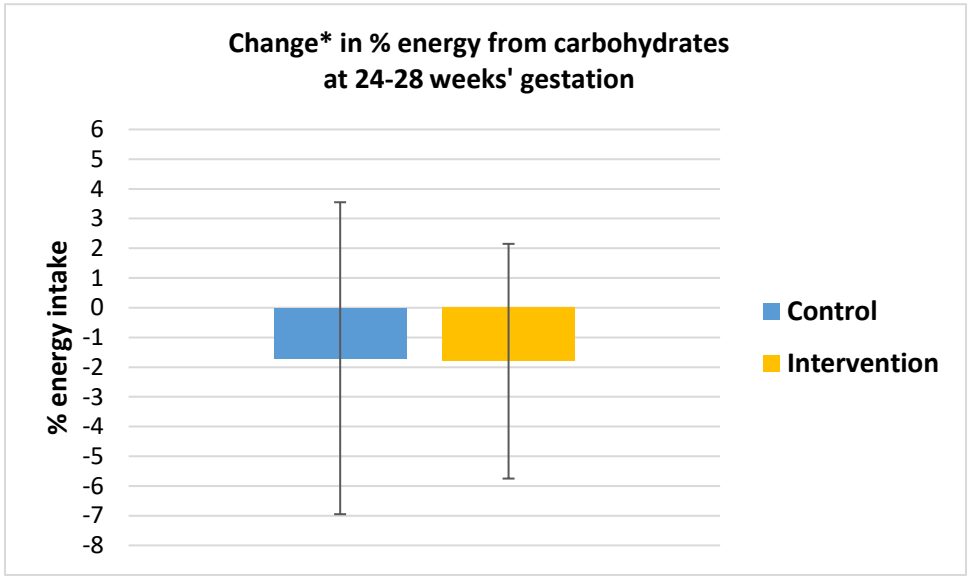
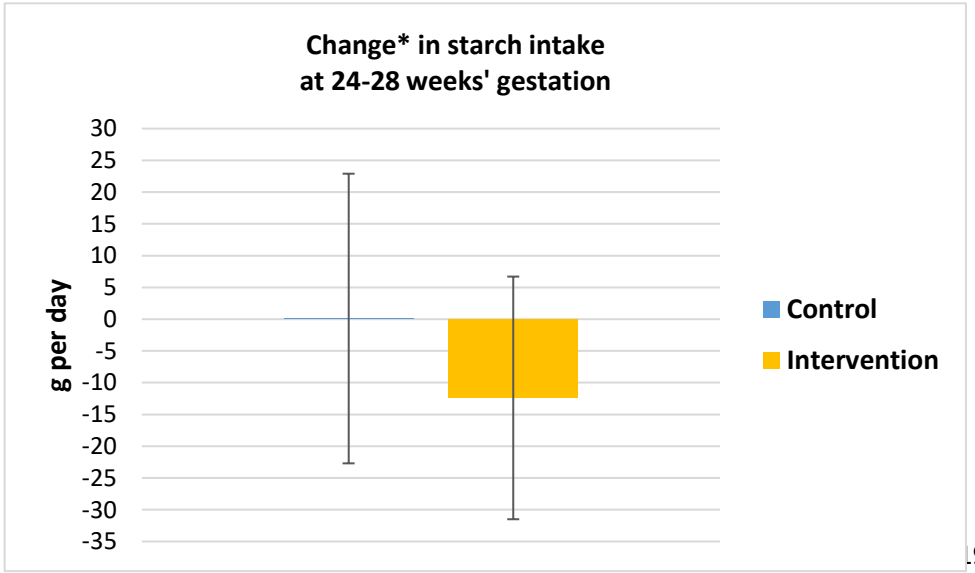


Figure 5.6. continued

E. Carbohydrate intake







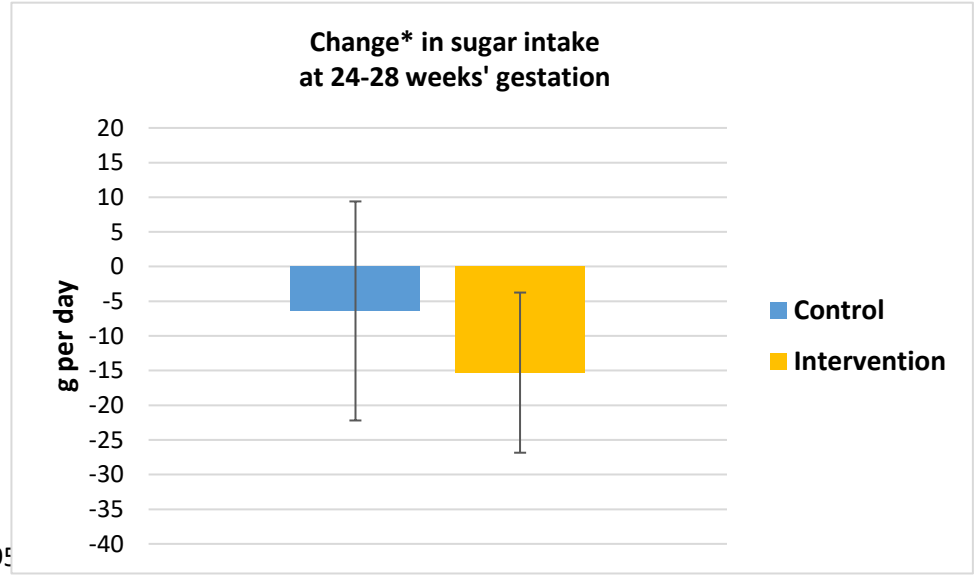
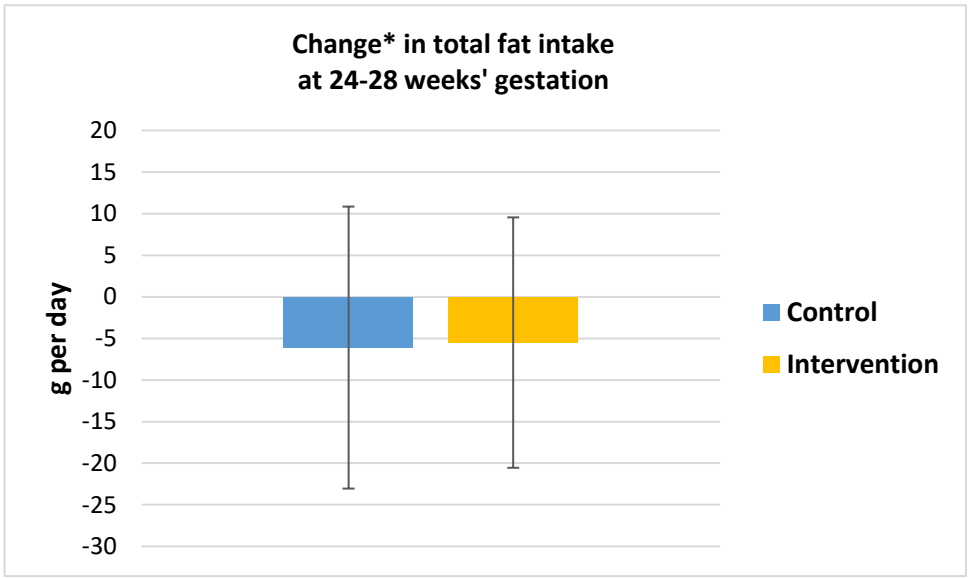
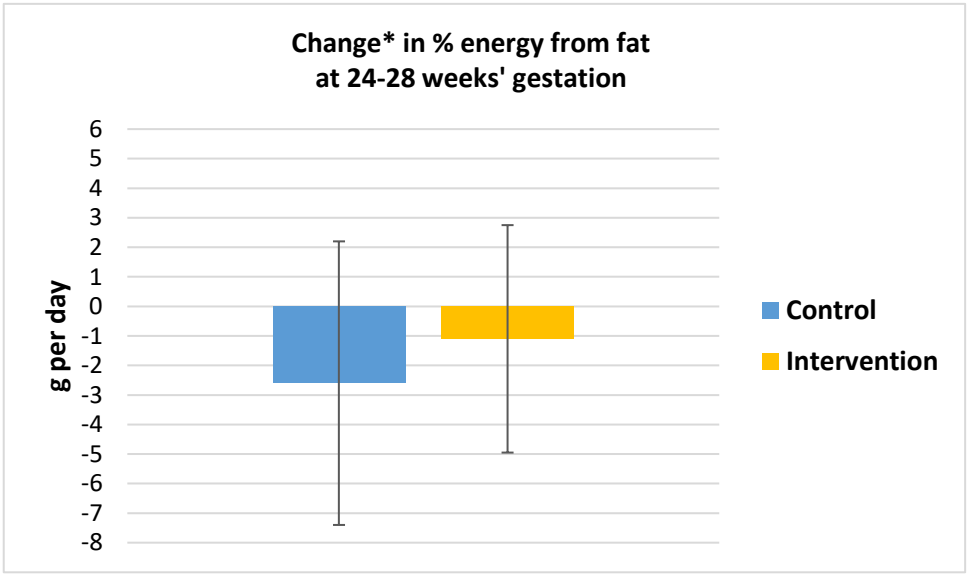


Figure 5.6. continued

F. Fat intake





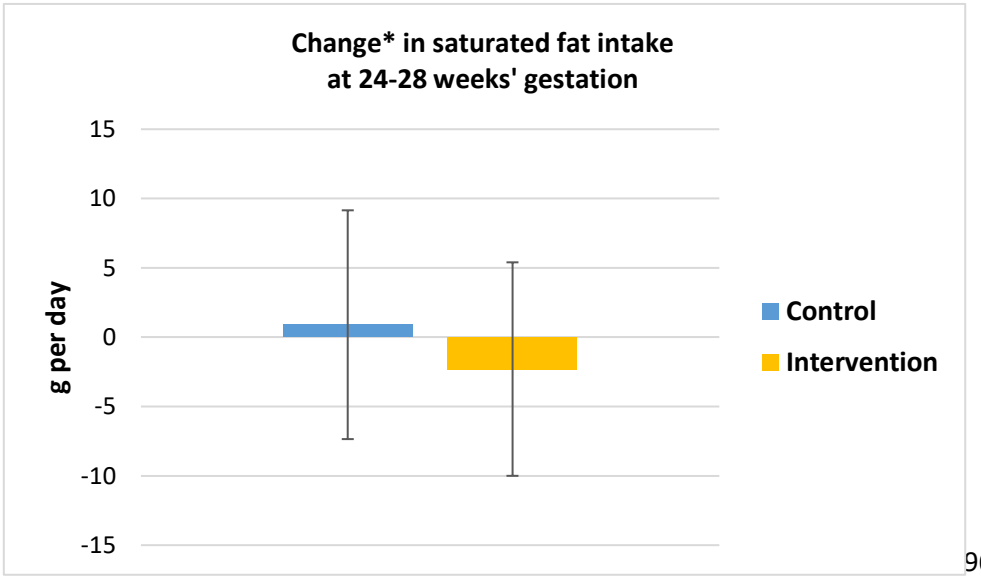
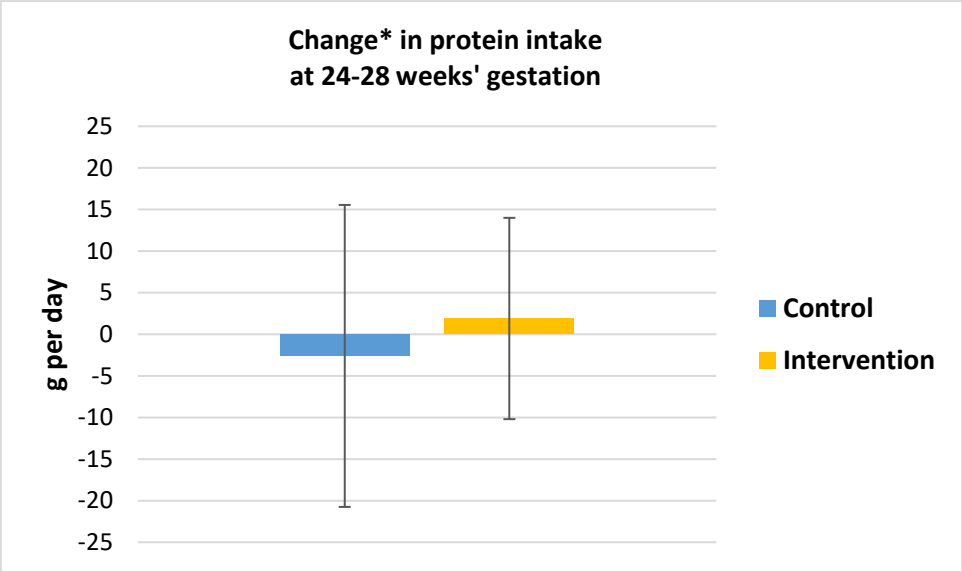
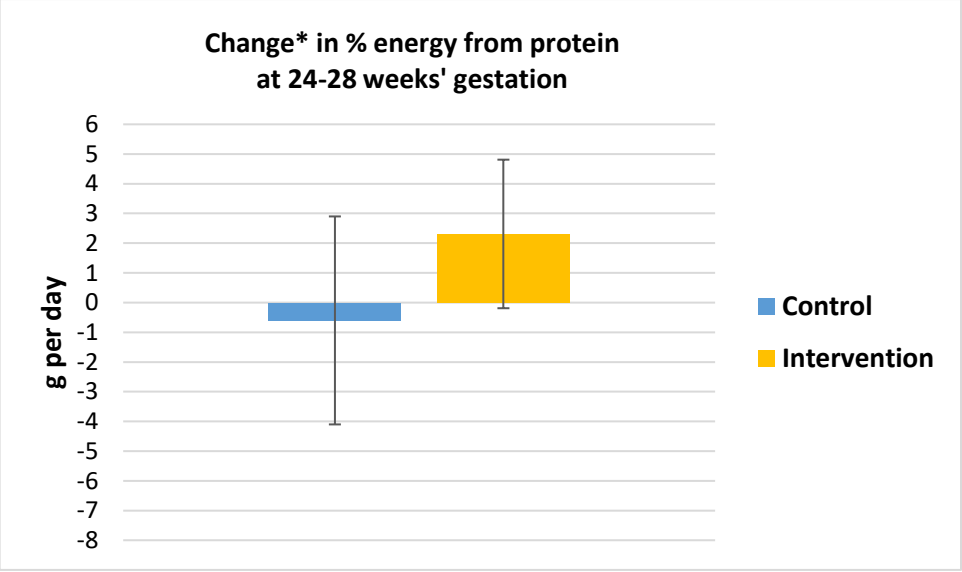


Figure 5.6. continued

G. Protein intake





OGTT: oral glucose tolerance test; **HbA1c:** glycated haemoglobin

*Adjusted for: age, ethnicity, Index of Multiple Deprivation, baseline BMI, and baseline value of the outcome.

~Adjusted for: age, ethnicity, Index of Multiple Deprivation, and baseline weight.

Table 5.4. Secondary and exploratory maternal measurements by period of gestation and group allocation

	Baseline <20 weeks' gestation	Follow-up 24-28 weeks' gestation	36 weeks' gestation	Change at follow-up	Change at 36 weeks' gestation	Change adjusted* at follow-up	Change adjusted* at 36 weeks' gestation		Adjusted* between group difference in change, intervention vs control	
	Mean (±SD)	Mean (±SD)	Mean (±SD)	Mean (95% CI)	Mean (95% CI)	Mean (95% CI)	Mean (95% CI)		Mean (95% CI)	P value
Glycaemic markers										
Fasting plasma glucose, mmol/L										
Intervention	4.4 (±0.4), n=34	4.6 (±0.4), n=32**	-	0.2 (0.1 to 0.3), n=32**	-	0.2 (0.1 to 0.3), n=32**	-		0.1 (-0.1 to 0.3)	0.409
Control	4.4 (±0.4), n=17	4.5 (±0.5), n=17	-	0.1 (-0.02 to 0.3), n=17	-	0.1 (-0.03 to 0.3), n=17	-		-	-
1-hour glucose, mmol/L										
Intervention	6.7 (±1.4), n=27†	7.6 (±1.6), n=26**	-	1.0 (0.5 to 1.5), n=26**	-	0.9 (0.4 to 1.4), n=26**	-		-0.3 (-1.1 to 0.5)	0.460
Control	6.6 (±1.5), n=17	7.9 (±1.6), n=16	-	1.1 (0.5 to 1.7), n=16	-	1.2 (0.6 to 1.9), n=16	-		-	-
2-hour glucose, mmol/L										
Intervention	5.5 (±1.2), n=33†	5.9 (±1.3), n=32**	-	0.4 (-0.1 to 0.9), n=32**	-	0.5 (0.0 to 1.0), n=32**	-		-0.1 (-0.9 to 0.7)	0.866
Control	5.0 (±1.0), n=17	5.7 (±1.3), n=17	-	0.7 (0.1 to 1.4), n=17	-	0.6 (-0.1 to 1.2), n=17	-		-	-

Table 5.4. continued

	Baseline <20 weeks' gestation	Follow-up 24-28 weeks' gestation	36 weeks' gestation	Change at follow-up	Change at 36 weeks' gestation	Change adjusted* at follow-up	Change adjusted* at 36 weeks' gestation		Adjusted* between group difference in change, intervention vs control	
	Mean (±SD)	Mean (±SD)	Mean (±SD)	Mean (95% CI)	Mean (95% CI)	Mean (95% CI)	Mean (95% CI)		Mean (95% CI)	P value
HbA1c, mmol/L [#]										
Intervention	42.6 (±56.4), n=28	31.6 (±4.0), n=30	-	-12.6 (-31.5 to 6.2), n=26	-	-6.8 (-9.3 to -4.2), n=26	-		0.7 (-4.8 to 6.2)	0.789
Control	30.9 (±2.9), n=17	33.1 (±14.9), n=16	-	2.1 (-21.9 to 26.1), n=16	-	-7.5 (-11.8 to -3.2), n=16	-		-	-
Fasting plasma insulin, [#^] pmol/L										
Intervention	76.9 (±32.4), n=25	94.7 (±48.6), n=23	-	22.0 (10.7 to 33.3), n=21	-	21.0 (9.2 to 32.7), n=21	-		-2.1 (-23.5 to 19.2)	0.840
Control	66.9 (±29.8), n=16	95.1 (±30.2), n=13	-	21.3 (6.4 to 36.1), n=12	-	23.1 (5.5 to 40.6), n=12	-		-	-
HOMA-IR [#^]										
Intervention	2.5 (±1.1), n=25	3.2 (±1.8), n=323	-	0.9 (0.4 to 1.4), n=21	-	0.9 (0.4 to 1.4), n=21	-		-0.1 (-0.9 to 0.8)	0.858
Control	2.2 (±1.1), n=16	3.3 (±1.3), n=13	-	0.9 (0.3 to 1.5), n=12	-	0.9 (0.2 to 1.6), n=12	-		-	-
Fasting capillary glucose, mmol/L										
Intervention	4.8 (±0.5), n=33								0.05 (-0.2 to 0.3)	0.730
Control	4.8 (±0.5), n=17								-	-

Table 5.4. continued

	Baseline <20 weeks' gestation	Follow-up 24-28 weeks' gestation	36 weeks' gestation	Change at follow-up	Change at 36 weeks' gestation	Change adjusted* at follow-up	Change adjusted* at 36 weeks' gestation		Adjusted* between group difference in change, intervention vs control	
	Mean (±SD)	Mean (±SD)	Mean (±SD)	Mean (95% CI)	Mean (95% CI)	Mean (95% CI)	Mean (95% CI)		Mean (95% CI)	P value
Fasting capillary ketones, mmol/L										
Intervention	0.1 (±0.1), n=33								0.03 (-0.01 to 0.1)	0.191
Control	0.1(±0.01), n=17								-	-
Clinical measurements										
Weight, kg										
Intervention	98.2 (±16.0), n=34	99.9 (±16.8), n=28	106.4(±16.2), n=25	2.4 (1.1 to 3.6), n=28	7.3 (4.9 to 9.6), n=25	2.3 (1.2 to 3.4) ~, n=28	7.3 (5.1 to 9.4) ~, n=25		24-28 weeks' gestation: -2.0 (-4.8 to 0.8) ~ 36 weeks' gestation: -1.4 (-4.5 to 1.6) ~	0.159 0.252
Control	95.5 (±14.6), n=17	99.7 (±14.0), n=17	105.1(±11.0), n=14	4.2 (2.7 to 5.8), n=17	8.8 (5.6 to 11.9), n=14	4.3 (2.3 to 6.2) ~, n=17	8.8 (4.9 to 12.7) ~, n=14		-	-
BMI, kg/m^2										
Intervention	35.6 (±4.7), n=34	36.3 (±5.0), n=28	-	-	-	-	-		-	-
Control	35.5 (±4.6), n=17	36.9 (±4.4), n=17	-	-	-	-	-		-	-

Table 5.4. continued

	Baseline <20 weeks' gestation	Follow-up 24-28 weeks' gestation	36 weeks' gestation	Change at follow-up	Change at 36 weeks' gestation	Change adjusted* at follow-up	Change adjusted* at 36 weeks' gestation		Adjusted* between group difference in change, intervention vs control	
	Mean (±SD)	Mean (±SD)	Mean (±SD)	Mean (95% CI)	Mean (95% CI)	Mean (95% CI)	Mean (95% CI)		Mean (95% CI)	P value
Systolic blood pressure, mmHg										
Intervention	118.5 (±9.9), n=34	118.0(±11.8), n=28	-	-0.9 (-4.5 to 2.8), n=28	-	-1.2 (-4.7 to 2.4), n=28	-		-2.3 (-7.4 to 2.9)	0.374
Control	119.3(±15.7), n=17	119.9(±12.7), n=17	-	0.6 (-4.1 to 5.3), n=17	-	1.1 (-1.9 to 4.1), n=17	-		-	-
Diastolic blood pressure, mmHg										
Intervention	74.5 (±8.1), n=34	73.0 (±7.7), n=28	-	-1.3 (-21.8 to 19.3), n=28	-	-9.3 (-12.1 to -6.4), n=28	-		-1.0 (-5.5 to 3.6)	0.665
Control	94.9 (±86.9), n=17	73.3 (±6.7), n=17	-	-21.5 (-47.8 to 4.8), n=17	-	-8.3 (-11.6 to -5.1), n=17	-		-	-
Dietary intake										
Energy, kcal/day and MJ/day										
Intervention	1723 (±486) 7.2 (±2.0), n=34	1643 (±613) 6.9 (±2.6), n=28	-	-41 (-279 to 198) -0.2 (-1.2 to 0.8), n=28	-	-110 (-364 to 142) -0.5 (-1.5 to 0.6), n=28	-		-90 (-500 to 320) -0.4 (-2.1 to 1.3)	0.659
Control	1918 (±400) 8.0 (±1.7), n=17	1740 (±638) 7.3 (±2.7), n=15	-	-152 (-477 to 171) -0.6 (-2.0 to 0.7), n=15	-	-21 (-319 to 277) -0.1 (-1.3 to 1.2), n=15	-		-	-

Table 5.4. continued

	Baseline <20 weeks' gestation	Follow-up 24-28 weeks' gestation	36 weeks' gestation	Change at follow-up	Change at 36 weeks' gestation	Change adjusted* at follow-up	Change adjusted* at 36 weeks' gestation		Adjusted* between group difference in change, intervention vs control	
	Mean (±SD)	Mean (±SD)	Mean (±SD)	Mean (95% CI)	Mean (95% CI)	Mean (95% CI)	Mean (95% CI)		Mean (95% CI)	P value
Total carbohydrates, g/day										
Intervention	216.9 (±68.0), n=34	190.4 (±72.3), n=28	-	-19.5 (-47.6 to 8.7), n=28	-	-24.6 (-51.5 to 2.4), n=28	-		-15.3 (-61.3 to 30.7)	0.503
Control	220.8 (±49.2), n=17	199.9 (±72.0), n=15	-	-18.7 (-57.2 to 19.7), n=15	-	-9.2 (-41.9 to 23.5), n=15	-		-	-
% energy from carbohydrates										
Intervention	47.3 (±7.1), n=34	44.2 (±9.7), n=28	-	-2.6 (-7.7 to 2.5), n=28	-	-1.8 (-5.7 to 2.2), n=28	-		-0.1 (-6.9 to 6.8)	0.979
Control	43.9 (±8.6), n=17	44.1 (±9.1), n=15	-	-0.1 (-7.1 to 6.9), n=15	-	-1.7 (-6.9 to 3.6), n=15	-		-	-
Starchy carbohydrates, g/day										
Intervention	129.4 (±48.2), n=34	117.6 (±49.7), n=28	-	-4.9 (-25.8 to 14.7), n=28	-	-12.4 (-31.5 to 6.7), n=28	-		-12.5 (-45.4 to 20.4)	0.446
Control	139.9 (±30.6), n=17	123.5 (±48.3), n=15	-	-13.8 (-42.3 to 14.7), n=15	-	0.1 (-22.7 to 22.9), n=15	-		-	-

Table 5.4. continued

	Baseline <20 weeks' gestation	Follow-up 24-28 weeks' gestation	36 weeks' gestation	Change at follow-up	Change at 36 weeks' gestation	Change adjusted* at follow-up	Change adjusted* at 36 weeks' gestation		Adjusted* between group difference in change, intervention vs control	
	Mean (±SD)	Mean (±SD)	Mean (±SD)	Mean (95% CI)	Mean (95% CI)	Mean (95% CI)	Mean (95% CI)		Mean (95% CI)	P value
Total sugars, g/day										
Intervention	87.5 (±36.6), n=34	71.1 (±36.7), n=28	-	-16.2 (-29.2 to -3.1), n=28	-	-15.3 (-26.9 to -3.8), n=28	-		-8.9 (-29.9 to 12.1)	0.394
Control	80.8 (±29.5), n=17	76.4 (±32.7), n=15	-	-4.9 (-22.7 to 12.9), n=15	-	-6.4 (-22.2 to 9.4), n=15	-		-	-
AOAC fibre, g/day										
Intervention	20.9 (±6.6), n=34	19.1 (±8.1), n=28	-	-1.2 (-4.6 to 2.2), n=28	-	-1.4 (-4.5 to 1.7), n=28	-		0.4 (-5.3 to 6.2)	0.876
Control	20.6 (±7.5), n=17	18.7 (±9.7), n=15	-	-2.3 (-6.9 to 2.4), n=15	-	-1.9 (-7.1 to 3.4), n=15	-		-	-
Total fat, g/day										
Intervention	70.6 (±26.8), n=34	69.7 (±36.1), n=28	-	0.6 (-14.1 to 15.3), n=28	-	-5.5 (-20.5 to 9.6), n=28	-		0.7 (-24.8 to 26.2)	0.957
Control	88.8 (±26.5), n=17	70.4 (±32.8), n=15	-	-17.5 (-37.6 to 2.6), n=15	-	-6.1 (-23.1 to 10.8), n=15	-		-	-

Table 5.4. continued

	Baseline <20 weeks' gestation	Follow-up 24-28 weeks' gestation	36 weeks' gestation	Change at follow-up	Change at 36 weeks' gestation	Change adjusted* at follow-up	Change adjusted* at 36 weeks' gestation		Adjusted* between group difference in change, intervention vs control	
	Mean (±SD)	Mean (±SD)	Mean (±SD)	Mean (95% CI)	Mean (95% CI)	Mean (95% CI)	Mean (95% CI)		Mean (95% CI)	P value
% energy from fat										
Intervention	36.3 (±7.5), n=34	36.9 (±9.3), n=28	-	0.5 (-3.7 to 4.7), n=28	-	-1.1 (-4.9 to 2.8), n=28	-		1.57 (-5.0 to 8.2)	0.630
Control	41.3 (±8.4), n=17	35.9 (±7.7), n=15	-	-5.5 (-11.2 to 0.3), n=15	-	-2.6 (-7.4 to 2.2), n=15	-		-	-
Saturated fat, g/day										
Intervention	24.8 (±10.7), n=34	25.9 (±18.5), n=28	-	0.8 (-6.7 to 8.4), n=28	-	-2.3 (-10.0 to 5.4), n=28	-		-3.2 (-15.9 to 9.4)	0.606
Control	32.8 (±10.4), n=17	27.5 (±14.3), n=15	-	-4.8 (-15.2 to 5.4), n=15	-	0.9 (-7.3 to 9.2), n=15	-		-	-
Protein, g/day										
Intervention	68.3 (±22.2), n=34	75.2 (±29.3), n=28	-	6.7 (-7.2 to 20.5), n=28	-	1.9 (-10.2 to 14.0), n=28	-		4.5 (-16.2 to 25.1)	0.663
Control	85.4 (±26.6), n=17	73.6 (±31.3), n=15	-	-11.4 (-30.2 to 7.5), n=15	-	-2.6 (-20.7 to 15.6), n=15	-		-	-

Table 5.4. continued

	Baseline <20 weeks' gestation	Follow-up 24-28 weeks' gestation	36 weeks' gestation	Change at follow-up	Change at 36 weeks' gestation	Change adjusted* at follow-up	Change adjusted* at 36 weeks' gestation		Adjusted* between group difference in change, intervention vs control	
	Mean (±SD)	Mean (±SD)	Mean (±SD)	Mean (95% CI)	Mean (95% CI)	Mean (95% CI)	Mean (95% CI)		Mean (95% CI)	P value
% energy from protein										
Intervention	16.3 (±4.3), n=34	18.8 (±6.3), n=28	-	2.1 (-0.6 to 4.9), n=28	-	2.31 (-0.4 to 4.6), n=28	-		2.8 (-1.3 to 6.8)	0.178
Control	18.1 (±4.9), n=17	17.6 (±5.8), n=15	-	-0.7 (-4.5 to 3.1), n=15	-	-0.6 (-4.1 to 2.9), n=15	-		-	-
Quality of life										
EQ-5D index score										
Intervention	1.0 (±0.1), n=34	0.9 (±0.1), n=28	-	-0.01 (-0.03 to 0.01), n=28	-	-0.01 (-0.03 to 0.01), n=28	-		-0.01 (-0.05 to 0.02)	0.296
Control	0.9 (±0.1), n=17	0.9 (±0.1), n=17	-	0.01 (-0.0 to 0.03), n=17	-	0.01 (-0.0 to 0.03), n=17	-		-	-
Visual analogue scale score										
Intervention	81.2 (±12.7), n=34	80.8 (±10.9), n=28	-	-0.9 (-4.6 to 2.9), n=28	-	-1.1 (-4.8 to 2.5), n=28	-		4.0 (-2.0 to 9.9)	0.185
Control	80.3 (±8.9), n=17	74.7 (±13.6), n=17	-	-5.5 (-10.4 to -0.8), n=17	-	-5.1 (-10.0 to -0.2), n=17)	-		-	-

Table 5.4. continued

HbA1c: glycated haemoglobin; **HOMA-IR:** homeostatic model assessment – insulin resistance; **BMI:** body mass index; **AOAC:** association of analytical chemists; IOM: Institute of Medicine

*Adjusted for: age, ethnicity, Index of Multiple Deprivation, baseline BMI, and baseline value of the outcome, unless otherwise specified.

~Adjusted for: age, ethnicity, Index of Multiple Deprivation, and baseline weight.

**One participant from the intervention group did not complete an oral glucose tolerance test (OGTT) at 24-28 weeks' gestation with neither the study nor clinical care team. One participant from the intervention group was diagnosed with GDM before 24-28 weeks' gestation due to consistently high fasting capillary glucose measurements taken as part of the study. Therefore, this participant did not have an OGTT at 24-28 weeks' gestation.

#For participants who completed their OGTTs with their clinical care team, 1-hour glucose, fasting insulin and HOMA-IR are missing, as they are not measured in routine care. HbA1c is also not measured in routine care, however, for some participants, their clinical care team measured this at follow-up.

†Baseline 1-hour and 2-hour glucose for one participant in the intervention group cannot be trusted because participant vomited a small amount after drinking the glucose drink, therefore these two measurements were kept blank. However, it was clinical decision that this participant could still enrol into the study.

^For some participants, insulin levels may be missing because the blood was haemolysed.

5.4.4 Process outcomes

Process outcomes are summarised in **Table 5.5**, and for some (*), more details are presented in **Appendix 5.10**.

Table 5.5. Summary of results on study processes from the RECORD feasibility trial

Process outcome	Result
Monthly enrolment*	~5 participants per month
Completion rate of initial and support intervention sessions*	All 34 intervention participants completed the initial dietary consultation. On average, I offered 4 support sessions, of which, an average of 3 were completed. About a third completed all support sessions that they were offered.
Attendance of follow-up visit in each group* (since some participants completed assessments remotely, I judged this based on completion of 24-hour recalls as a proxy)	82.4% in the intervention group, and 88.2% in the control group completed a dietary recall at follow-up
Availability of weight at 36 weeks' gestation (± 2 weeks)	Available for 39 of 51 participants (76.5%), however, it was measured at the midwife appointment for 37 participants, while 2 participants self-reported this weight from measuring it at home with digital scales, as their midwife did not measure it.
Proportion of participants who record their blood glucose and ketones every week*	Almost a third of participants monitored their fasting capillary glucose and ketones at least once, on all weeks from enrolment until before delivery. Average completion rate for glucose monitoring was 87%, and for ketone monitoring, 78.3% (number of completed measurements out of number of required measurements for duration of participation).
Proportion of participants in the intervention group who self-monitor their weight every week^†# **	Weight data were received for an average of 12.4 weeks (range 0-23), equivalent to 55% of expected measurements. All but one intervention participants (97.1%) reported their self-measured weight at least once.
Contamination of the control group‡	5 of the 15 participants in the control group for whom I had both baseline and follow-up dietary data, substantially decreased their carbohydrate intake over the course of the study, suggesting a potential contamination rate of 33.3%.
Fidelity§	All of initial dietary consultations were audio-recorded and available for assessment of fidelity. Six of them were checked by an independent researcher, and all (100%) addressed each of the 4 pre-specified essential criteria.

Table 5.5. continued

*Further details in **Appendix 5.10**.

^ The time period each participant in the intervention group was required to weigh themselves varied, depending on the gestational age of the participant at baseline, and the gestational age at delivery, as well as whether participants withdrew or not from the study. On average, participants were required to provide self-weighing measurements for 22.5 weeks (range 3-28).

† Some intervention participants tended to not weigh themselves on the week of their follow-up visit, since they mentioned that they were going to be weighed at the visit anyway.

Intervention participants would generally not weigh themselves on the week of their delivery.

** One participant was recorded by mistake by myself as belonging to the control group although was randomised to the intervention, which resulted in missing weekly weights for this person.

‡ I did not apply a specific rule here to define what would substantial reduction be in the control group. Almost all control participants increased or maintained their carbohydrate intake at follow-up, or the decrease was really small, but in these 5 participants, the follow-up carbohydrate intake was very obviously much lower than at baseline.

§ Due to time constrains of this DPhil, it was not possible to assess more intervention audio-recordings, therefore stopped at the first 6 since they all seemed consistent.

5.4.5 Clinical outcomes

Incidence of GDM was 17.6% in the intervention and 5.9% in the control group, based on the NICE criteria (59). However, some women had elevated 1-hour glucose levels at their 24-28-week OGTT (≥10 mmol/L), which was judged by the diabetes team to require treatment, and these women entered the GDM care pathway at this point. As a result, 20.5% of participants in the intervention group, and 17.6% of the control group, were treated as having GDM. Women who developed gestational hypertension and preeclampsia all belonged to the intervention group. Proportionately, more women from the control group required caesarean section, but more women from the intervention group required induction of labour. There were no preterm babies, but the few babies requiring NICU admission all belonged to the intervention group. The proportion of macrosomia was similar between the groups, the proportion of LGA babies was higher in women from the intervention group, while these women had no SGA babies. One baby in each group had neonatal hyperbilirubinemia, with the one from the intervention group requiring phototherapy (**Table 5.6**).

Table 5.6. Clinical outcomes by group allocation. Values are count (%) unless otherwise specified.

	Intervention (n=34)	**Control** (n=17)
GDM at 24-28 weeks' gestation		
NICE criteria	6 (17.6), n=33	1 (5.9), n=17
Actual treatment (NICE criteria and/or 1-hour glucose of 10 mmol/L and above)	7 (20.5), n=33	3 (17.6), n=17
Gestational hypertension	5 (14.7)	0 (0.0)
Preeclampsia	2 (5.9)	0 (0.0)
GDM treatment		
Insulin only	1 (2.9)	0 (0.0)
Metformin only	3 (8.8)	0 (0.0)
Both	1 (2.9)	1 (5.9)
Mode of delivery		
Unassisted vaginal delivery	16 (47.1)	5 (29.4)
Assisted vaginal delivery	3 (8.8)	2 (11.8)
Caesarean section	16 (47.1)	10 (58.8)
Elective caesarean section	6 (17.6)	4 (23.5)
Emergency caesarean section	10 (29.4)	6 (35.3)
Induction of labour	10 (29.4)	3 (17.6)
Gestational age at delivery		
Weeks	39.4 (±1.3)	38.9 (±1.4)
Days	3.4 (±2.4)	2.2 (±1.9)
Birth weight, kg	3.7 (±0.4)	3.4 (±0.5)
Sex of baby		
Male	17	6
Female	17	11
Macrosomia	2 (5.9)	1 (5.9)
Large-for-gestational-age infant	11 (32.4)	2 (11.8)
Small-for-gestational-age infant	0 (0.0)	2 (11.8)
NICU admission	3 (8.8)	0 (0.0)
Shoulder dystocia	0 (0.0)	1 (5.9)
Neonatal hypoglycaemia	0 (0.0)	0 (0.0)
Neonatal hyper bilirubinaemia	1 (2.9)	1 (5.9)
requiring phototherapy	1 (2.9)	0 (0.0)

GDM: gestational diabetes mellitus; **NICE:** National Institute for Health and Care Excellence; **NICU:** neonatal intensive care unit

5.4.6 Serious adverse events (SAEs)

There were a total of 4 SAEs from the start until the closing of the study. One participant in the intervention group was hospitalised for preeclampsia and obstetric cholestasis, and her child was born with undiagnosed cardiac abnormality, and required heart surgery immediately after birth. One

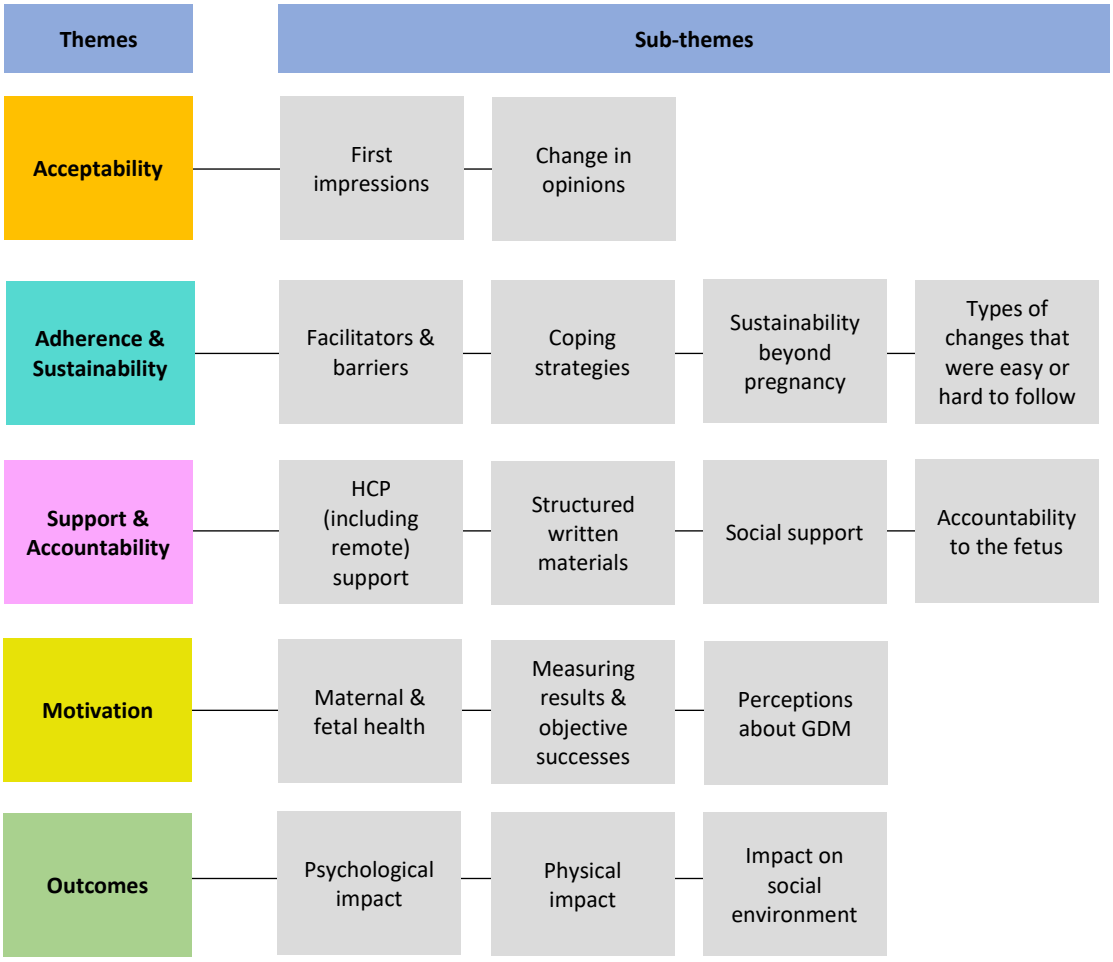
participant in the intervention group developed metastatic thyroid cancer. One participant in the control group suffered bleeding around 17 weeks' gestation, and was hospitalised for monitoring for one night. All were judged by the Chief and Principal Investigators, an obstetric physician, and the central study team, as not related to the study.

5.4.6 Qualitative findings

5.4.6.1 Experiences of the intervention

Five themes emerged from the thematic analysis of the participants' experiences of the intervention (**Figure 5.7**); "acceptability", "adherence and sustainability", "support and accountability", "motivation", and "outcomes". These were interlinked, and contained a number of subthemes.

Figure 5.7. Themes and sub-themes emerging from the thematic analysis of participants' experiences of the RECORD intervention



GDM: gestational diabetes mellitus; **HCP:** healthcare professional

5.4.6.1.1 Acceptability

Most interviewed participants found the intervention content and delivery acceptable and positive. First perceptions of the diet varied, from doubt, through to acceptance and enthusiasm. More specifically, some participants viewed the dietary changes positively from the beginning, which stemmed from their motivation for a healthy pregnancy, for avoiding GDM, and feeling reassured that they were taking control over their pregnancy. Making small gradual changes enhanced acceptability. As the trial progressed, these participants remained positive about following the diet, and reported increasing confidence, knowledge and enthusiasm (Quotes 1 & 2). A notable subgroup reported that changing their diet and reducing their carbohydrate intake during pregnancy, was initially perceived as a big undertaking, because of a sudden transition to a different than usual diet, restricting favourite foods, or trying to cognitively process the volume of provided information. However, they stated that with time, and as they continued with the intervention, things became easier and they appreciated being in the programme. The HCP (myself) facilitated this process by advising participants to make small gradual changes (Quotes 3 & 4). One of the participants, although making some dietary changes, reported that they did not find it enjoyable (last sentence of Quote 4).



Quote 1: *"So that really helped me feel like I could take control of the chances I had of getting gestational diabetes and just a chance to sort of make sure my pregnancy was really healthy and my diet was really healthy in my pregnancy. It was really good to have some guidance on that, and I know that is the best thing for the baby."* (participant 25, age 30)

Quote 2: *"It wasn't overwhelming or it didn't feel like it was too much because when we did the exercise [goal setting], there's a way that you put it, you're very mindful of keeping it to a level that doesn't feel like it's a lot. So we picked the ones that we thought could be more important. We start with those ones. I can't remember the number but probably maybe three or four changes maximum. It didn't feel like the first pregnancy […] This time I was ready."* (participant 20, age 39)

Quote 3: *"It can be a little bit like…you know, to change your diet without a lot of notice. Was like a bit of a challenge. But then at the same time you did suggest just trying to change one or two things at a time, so it didn't feel completely drastic either […] For me I probably was unprepared for that but kind of good in the end that I've been able to think a bit more about my diet in pregnancy."* (participant 5, age 30)

Quote 4: *"It wasn't something I wanted to do. I like my food, and it wasn't something that I was excited about. It felt quite daunting at first when I'd just read all the material. But then after we had our consultation and you explained that it was just sort of doing little steps to get towards the ultimate goal and that you weren't expecting sort of massive changes overnight, that made me feel a bit more like I could do it; and it wasn't as intimidating as it originally felt like it might be. But yeah, I still wasn't…I'm not going to say I was excited about reducing [Laughs] my sugar and carbohydrate intake. That would be a lie."* (participant 17, age 33)

5.4.6.1.2 Adherence and sustainability

The RECORD diet programme as a whole, as well as pregnancy in itself, made participants mindful and cautious of their eating. Most interviewed participants reported being able to follow the majority of the RECORD dietary recommendations and adjust them to their individual circumstances and needs. A few participants were challenged towards the late stages of pregnancy, and a couple of participants reported struggling to follow the advice. Nevertheless, all participants reported having made at least one dietary change (Quotes 5 & 6).



Quote 5: *"Like obviously being pregnant, it's just made me a little bit more conscious that it's not just myself I'm looking after. I need to make better choices, obviously for the benefit of my child. It's something I was paying a lot more attention to. And making conscious mental notes about, 'Well, these are the things I know I can easily substitute'."* (participant 43, age 32)

Quote 6: *"[…] I really want to be careful with regards to my diet. And I think I'd have been a bit careful, but I have not taken everything on board. Like it's been really hard for me to follow everything. I've definitely taken on something and I'm definitely limiting myself here and there, but not completely."* (participant 44, age 32)

Participants talked in more detail about factors that helped or challenged sustained adherence to the RECORD diet. The use of behavioural strategies facilitated acceptability and engagement with the programme. Examples included setting small measurable, achievable, and relevant goals, and attempting a few changes at a time (Quote 7), action planning (Quote 8), forming habits through consistent practice (Quote 9), and self-monitoring (Quote 10). Many participants reported coping behavioural strategies they used during challenging situations, such as using the written materials to find alternative snack options when feeling like indulging, having higher-carbohydrate foods (e.g. sugary snacks or crisps) less often and in smaller amounts, or sharing them with someone, avoiding environmental triggers (e.g. avoiding having sugary foods in the house), as well as effectively dealing with lapses (e.g. Quotes 11 & 12). Receiving clear and specific information and guidance about the dietary changes, were found to be important in knowledge transfer and education, acceptability of the programme, behavioural control, and ultimately sustained adherence to the programme. Participants praised the dietary programme for its simplicity and practical

guidance, which enabled many of them to tailor the advice to their own requirements (Quote 13). Participants also highlighted the importance of support in their ability to adhere to and maintain the dietary changes, detailed in section 5.4.6.3 below, as it was also identified as a theme in itself.



Quote 7: *"I didn't find it [following the diet] really difficult because […] I didn't feel like I was going on a diet you know, where every part of my diet as such is changing. I made kind of, I think it was suggested one or two smaller changes every few weeks. So I didn't find it to be particularly difficult."* (participant 31, age 38).

Quote 8: *"I made a list of things that I was going to get and I went to the shops and I swapped things out and I was going to work so I could prepare my lunch box and have all the swaps and all things like that."* (participant 24, age 33)

Quote 9: *"[…] I found like two or three weeks of not having it [chocolate] constantly, it was a lot easier*." (participant 10, age 31)

Quote 10: *"I've probably been weighing myself more than I would normally for it. I don't think I would weigh myself once a week. I think it's made me a bit more mindful in some ways. For example, a couple of weeks ago we went on holiday and it was reflected in my weight, which if I hadn't weighed myself I wouldn't have known that. That kind of put me back on track quite quickly I think, because obviously I don't want to gain loads of weight really quickly, or at all really."* (participant 11, age 31)

Quote 11: *"[…] I just, again, stopped buying as many sugary snacks as well. We never had cupboards full of biscuits and stuff; but rather than buy that one pack of biscuits a week, I wouldn't buy them. So, I'd almost have to actively go seek out a sugary snack if I wanted it."* (participant 17, age 33)

Quote 12: *"[…] I'm quite sure that one of the conversations we had about if I've had a bad day and stuff like, if I've had a takeaway, is making sure that I'm just back on plan the next day, really. Not to just be too panicky about it and I haven't missed out, but just to make sure on average I'm being very good about it rather than being awful about it. But then, I'm not getting punished for having a bad day, if that makes any sense."* (participant 22, age 37)

Quote 13: *"It's [the advice] very well explained in the book, and you've been brilliant as well, sort of explaining everything. So, I've always felt very well informed with everything. So, it's been easy to follow. For me anyway, it just seems quite effortless, really, because you've made it so easy."* (participant 28, age 32)"

On the other hand, competing priorities often acted as inhibitors to adherence with the diet. Family and work commitments, lack of time, physical or mental health problems, were examples of reported reasons for being unable to sustain the dietary changes, especially towards the later stages of pregnancy, even for participants who had been able to stick to the diet up to that point (Quote 14). About a third of participants mentioned physical symptoms of pregnancy as challenges to adhering to the dietary programme, especially as the pregnancy progressed. These included feeling tired, hungry, or having cravings, pelvic, or back pains. Participants tended to crave carbohydrates, such as sugary

foods. They often viewed satisfying a craving as necessary treat to “pick them up” or “feel good” (Quotes 15 & 16). When the principles of the diet aligned with participants’ existing dietary habits and food preferences, this increased acceptability of the intervention and facilitated sustained adherence. Conversely, one participant reported struggling with reducing the carbohydrate portion sizes at main meals, as the advice provided in the programme did not align with her preferred meals (Quote 17). A few participants reported using sugary foods to deal with negative emotions, like stress, which made it challenging to refrain from them at times. But generally, participants tried effective coping mechanisms, including having them less often, practising avoidance, finding replacements, having a smaller portion (Quote 18). One participant reported extensive history of dieting, and a disrupted relationship with food. Being on yet another dietary programme, even if it is not aimed at weight loss, pushed her towards eating more sugary foods than before the study (Quote 19).



Quote 14: *"I think I have definitely mentally hit a point with this where it's like I've got so much else going on. I've got the impending baby arrival, getting away for Christmas. I've got my toddler. I'm suffering with my pelvic pain, so I've got the exercises I'm supposed to be doing with that. This [the diet] is at the bottom of my list of priorities, so I will go a couple of days where I've not thought about it […] I think it was probably around like the time of my second glucose tolerance test. That was when I was starting to get a bit like, 'Hmm, yeah. This is quite a lot of mental effort.' […] I let myself off the hook a bit more; and then as I've gone on since that point, I have given myself a break a bit more with it I think."* (participant 17, age 33)

Quote 15: *"Sometimes, you really feel like you just want some carbohydrates, and you're thinking, 'I need to think of something else to have, really, than having that all the time.' Obviously, the fruits are a good alternative, but then, you're also thinking about, 'Right, I need to make sure I don't have too many because they'll all have sugars in there as well', so kind of thinking about how many portions of fruit you're eating as well. That can be a bit of a challenge as well."* (participant 22, age 37)

Quote 16: *"As time went on throughout the pregnancy, I think it became harder as I became more tired. […] And towards the end of the night, especially now, feels a bit fed up with the pregnancy. Having a bit of something nice at the moment is one of the only real treats that you have."* (participant 24, age 33)

Quote 17: *"I think I found it difficult to just generally reduce my carbohydrate intake in my meals […] I don't tend to eat a meat and two veg sort of plate of food. I will cook a meal for my husband and I that is like a pasta bake or a stir fry or…something where all of your foods are mixed in together. So, it's not like I can cook meat, potatoes, vegetables and just take less of the potatoes. It's all sort of in one pot, so I did try and sort of pick meals that were bulked out with veg. But generally, I did find it quite difficult to sort of reduce the percentage of carbohydrates on my plate because of just, I guess, probably the foods that we tend to eat and cook as a family. I didn't find it simple."* (participant 17, age 33)

Quote 18: *"[…] for me if I'm stressed or whatever, my go to would be to have some sugary treat or something. Like in general before pregnancy that would be how I'd probably deal with stress at times. Obviously like in pregnancy you can't drink, or you're not smoking, and neither of those things would be things I would go to automatically if I was stressed. To have that taken away of like the… you know trying to avoid sugary things… haven't always been able to refrain as such. But I've been conscious of trying to limit it or sharing a portion or just having less than I would normally."* (participant 5, age 30)

Quote 19: *"I found diets in the past really hard anyway, so that part of it has almost pushed me more the other way, which is awful. I have probably been eating a lot more chocolate cake, mainly chocolate cake, and sweets, than I would of if I had not heard of the study and not heard of anything. You know when somebody says you cannot do something, you sort of want to do it more. […] My relationship with food it very weird. […] I do not think there are going to be any lasting changes because I do not think I have learnt anything that I did not know before. I think I just need to, I do not know, think about my relationship with food. It is more the psychological aspects of it that I need to work on."* (participant 54, age 36)

The majority of participants reported intentions to keep the dietary changes beyond pregnancy. Some of these intentions stemmed from positive experience of making the changes, reinforcement from have seen positive outcomes during the study, wanting to be healthy, and lose the pregnancy weight. Having practised the dietary changes for a long time, helped participants form new habits which was reported as a facilitator for keeping up the changes after pregnancy (Quote 20). A few participants felt that it may be more challenging to sustain the changes after delivery when the

motivation for the protecting the fetus's health is gone (Quote 21). One participant who, despite following some changes during the course of the study, did not particularly enjoy reducing her carbohydrate intake, reported that she would not continue with the changes. Competing priorities, such as family commitments, was also another reason for this participant to not keep up (Quote 22). One participant also reported perceived adverse effects on mental health, pertaining to her relationship with food (Quote 23).



Quote 20: *"I can keep those changes for the long term and it won't be so difficult for me to lose the weight after the birth, so that's another that compared to my first pregnancy I was kind of more lost on what to do and because I've been already doing the changes and sticking to them for weeks, or months, I know I can keep it."* (participant 20, age 39)

Quote 21: *"I'm hoping to maintain it and keep going with it. I'm sure that… at the moment obviously the motivation is that the baby is inside me and I am trying to be as healthy as possible. I guess like after I've had the baby, I might think now I can kind of relax a bit more. Yeah, that will probably be like the bigger transition. Of course, when I'm due it will be like Christmas time, so… Yeah, I'm sure we'll have people bring meals, dinners that sort of thing. Again, I'll just have to try and like remember the [principles]."* (participant 5, age 30)

Quote 22: *"I have to say I don't think I'll be carrying it on once the baby has arrived mostly because I've had a baby, and I know that I'm going to be a bit out of it and starving from breastfeeding. And then, I'm going to be so preoccupied with that and a toddler that I can't imagine that I'll be thinking about what I'm eating a huge amount."* (participant 17, age 33)

Quote 23: *"[…] I do not think there are going to be any lasting changes because I do not think I have learned anything that I did not know before. I think I just need to, I do not know, think about my relationship with food. It is more the psychological aspects of it that I need to work on. Because I know what to do, it is just putting it into place."* (participant 54, age 36)

Participants described which of the recommended changes they found easy or challenging to follow. There was high heterogeneity in participants' responses, reflecting the unique experience of each individual. Avoiding sugary drinks appeared to be the change that participants found the easiest. For example, choosing diet versions of fizzy drinks, and avoiding sugar in tea or coffee (Quote 24). Participants also reported that they easily swapped refined starchy foods with wholegrain varieties (Quote 25). One participant reported feeling bloated, possibly due to increasing wholegrain foods, but this was short-lived. Participants valued the availability of snack swaps and for most, this was a key solution to help them reduce sugary snacks or crisps (Quote 26). Some people were able to apply

coping techniques, but some did not manage to reduce them (Quotes 27 & 28), and a similar variable pattern was observed in efforts to reduce starchy food portions in main meals (Quotes 17 & 29).



Quote 24: *"I found cutting out the sugary drinks really easy, and cutting out sweeteners and sugars from things like tea and coffee."* (participant 10, age 31)

Quote 25: *"[…] the easiest thing for me was swapping for whole grain bread, rice, pasta. That was just an easy swap once I finished what I had in the cupboard; and when I went to the supermarket, I bought whole grains. So, I think that was the absolute easiest thing to do."* (participant 17, age 33)

Quote 26: *"In general, I managed to keep to having just two bits of fruit a day. Then either some popcorn or like… I think for a while I had some peppers with humus. And they were quite easy swaps to have from having additional sweets and crisps and things like that. Those replacement things for snacks have been quite straightforward."* (participant 5, age 30)

Quote 27: *"I think reducing sugary snacks is an easy one. If you're someone that has one or two sugary snacks a day, it's easy to sort of go, 'Right, next week, I'm going to have one sugary snack a day, and then, two weeks after that, I'm going to cut down to four'."* (participant 17, age 33)

Quote 28: *"For me, I just love chocolate. And I know I have a sweet tooth like. It's just way too…way too difficult for me to just say no completely to like sugar stuff […] I think even though inside of me I was like 'No, I shouldn't, I shouldn't'. I know I have had a lot of it like compared to maybe what the diet requires me not to have."* (participant 44, age 32)

Quote 29: *"[…] That saying about the fist size, that's a really easy way of remembering. So like if I'm making spaghetti Bolognese, I know that in terms of my pasta, I'm not going to more than like my fist size. And if I'm having mashed potato, again, I'm not going to have more than my fist size. So, I'm not missing out on what everybody else is having, but I'm reducing how much I'm having of it to help myself, if that makes any sense."* (participant 20, age 39)

5.4.6.1.3 Support and accountability

- HCP support

According to the interviews, the initial dietary consultation worked mainly through education and knowledge transfer. Some participants obtained new nutritional information, while some were already familiar with most of it, due to previous experience of dieting, and for them the dietary consultation served more as a refresher and introduced little novel information, which, however, they still appreciated (e.g. Quote 30). One participant with GDM in a previous pregnancy, reported having practised a reduced-carbohydrate diet before, but still learnt some useful new information with regards to carbohydrate foods. None of the participants was aware of the guidelines for appropriate GWG, and they found the study's advice useful (Quote 31). All participants were able to understand,

remember, and summarise the majority of the 3R's, which might suggest that organising the information into a few basic rules, facilitates cognitive processing (Quote 32). Participants reported lack of, or limited, dietary advice from their clinical team during routine appointments. When provided, this was mainly during their booking appointment with their midwife, was generic, and mainly focused on unsafe foods to avoid during pregnancy (Quote 33). One interviewed participant who developed GDM, attended a session with a dietitian as part of the routine GDM care pathway, where principles similar to the RECORD diet were discussed, offering her reassurance. In their majority, participants received no advice about GWG. Weight and BMI were brought up during the booking appointment, pertaining to their risk for GDM and/or need for more specialised medical care, but no further. One participant was reassured by their midwife that the weight issue was not something to be concerned about. Some participants who were particularly concerned about GWG due to their increased BMI, raised the issue with their midwife, but received no or generic advice, especially if the weight gain had not been excessive (Quotes 34 & 35). A few participants perceived that HCPs might have been influenced by their taking part in the study, in that they might have been reassured that they had received advice on diet and weight, and they were self-monitoring their blood glucose and weight. Participants also commented on the timing of the consultation, highlighting the need for education about diet and GDM at earlier stages of pregnancy (Quotes 36 & 37).



Quote 30: *"Really, really useful [the dietary consultation]. I felt like sometimes that you go into pregnancy – especially with my first pregnancy – and no one advises you not to eat for two […] This time it was like you're having the right guidance of - this is what you should really eat and shouldn't eat."* (participant 10, age 31)

Quote 31: *"[…] it was helpful to sort of have an indication of what's normal to gain because I didn't really have much of information on how much they expect you to gain, and stuff that I never talked about it in my last pregnancy so I didn't know."* (participant 25, age 30)

Quote 32: *"I remember cut out the sugary snacks and make reasonable adjustments to what we were eating. Rather than having a plate full of carbs, you change that so that you'd have like a quarter of carbs, but you would bulk it out with salads, vegetables, and have maybe a bit more meat. The same with things like sugary drinks and snacks – just changing snacks from maybe not having that orange, but having something like nuts and things like that."* (participant 10, age 31)

Quote 33: *"I think I only remember at booking appointment which I think I was about eight weeks, six to eight weeks, they just went over some foods to avoid in pregnancy. Things like some of the cheeses and raw and that sort of thing. So, it was more just a brief conversation about things to avoid eating. It was kind of generic."* (participant 5, age 30)

Quote 34: *"Just at my booking appointment my midwife spoke to me about my weight because I had to be referred to a consultant because of my weight. But she more spoke to me about it in a 'It's nothing too much to worry about' kind of way. No, nobody's given me any advice."* (participant 10, age 31)

Quote 35: *"I think I had raised it before because of my BMI at the booking appointment. I just said that I was not happy with my BMI and was worried about gestation diabetes. She just said that I could eat healthily, basically."* (participant 54, age 36)

Quote 36: *"[…] from the beginning learning the study and being educated on the foods that will benefit you, how does it work, you know how it actually helps you in this situation has made a big difference."* (participant 20, age 39)

Quote 37: "*Maybe it would be helpful, for the healthcare provider, the midwife, and things, to actually talk to you about the risks of gestational diabetes and what that means for you and your baby early on. Not to sort of scare you, but to make you think about it more seriously."* (participant 54, age 36)

- Structured written materials

Participants used the written dietary materials, i.e. the main dietary booklet and the recipe booklet, as the "main" resource. None of the participants reported using the behavioural materials. For some, the dietary booklet provided new knowledge on how GDM happens and its consequences, the role of diet in controlling blood glucose levels, as well as appropriate food choices for a reduced-carbohydrate diet (Quote 38). On the other hand, some participants felt that the booklet did not add directly to their pre-existing knowledge (Quote 39). Participants often found the dietary booklet helpful when they needed to refresh their memory about the main principles of the diet and appropriate food choices, or when they were unsure of whether they should choose particular foods (Quote 40). Participants

valued the dietary booklet for the clear and specific guidance it provided on what foods to choose, and reported that this enhanced their understanding of the dietary information (Quote 41). Conversely, some participants expressed their need for more detailed guidance with regards to the recommended amount of carbohydrate (Quote 42).



Quote 38: *"I think just the general information on the gestational diabetes and how the trial with doing sort of the diet, having the diet alongside monitoring the blood glucose, how that actually works because it can be a bit confusing sometimes when it's all quite medical and all the medical jobs, but I feel like it was explained very well in the leaflets and things."* (participant 28, 32)

Quote 39: *"I found the information okay. It was a bit too generic in terms of I've seen that kind of information before. There was nothing there to me that was particularly new […] I think the new bit was considering it from a pregnancy frame of mind."* (participant 43, 32)

Quote 40: *"Just the little reminders of what you can swap things for, I think, was quite good at the beginning as well, just to kind of remind me of that mantra, I guess you kind of call it, don't you? Just what you can change and stuff and how to change it, so I think that was probably a bit of…It was good to look at as well, especially when we had that first chat, and you said about looking back at that bit."* (participant 22, 37)

Quote 41: *"I think it's [the dietary booklet] very straightforward, it's in a very simple way. I don't think there was anything missing from there. It's very simplistic, the way it's proposed, so there's no difficulty of understanding it."* (participant 32, 34)

Quote 42:
Interviewer: *"So, you would have liked, if I understand correctly…So if you eat this much, then you get about 40 grams, let's say, of carb. Then, have another 40 grams at lunch and another 40 grams at dinner, something like that."*
Respondent: *"Yeah, something like that I would find quite helpful to sort of guide me. I like to know if I'm hitting the spot or not."* (participant 17, 33)

- Social support

Participants placed high value on the role of social support in their motivation and ability to adopt the dietary changes. For example, participants found it easier to follow the diet when their family was on board (Quote 43), while making separate arrangements for themselves when that was not possible, was a challenge (Quote 44). Keeping on track was easier when participants had control over the food that was available and prepared. Many participants found it challenging to control their eating during social occasions, such as holidays, or eating out, or in other people's homes, due to the food availability and social norms. However, participants recognised that social situations were not happening every day, and therefore were able to go back to their newly formed dietary habits (Quotes 45 & 46). Having

coping strategies also facilitated this process (Quote 47). One participant felt her engagement could have been improved with peer support (Quote 48).



Quote 43: *"My partner kind of joined me because he needs to lose weight. Like all of us in the family did it, rather than just me [...] It was like a household change, so that's why I think it wasn't as hard to implement or as difficult […] Even like my mum and dad, they were really keen to read all the information and take things away from that because they felt like they could make their diet healthier."* (participant 10, age 31)

Quote 44: *"I think maybe the hardest one is sort of breakfast. I just sort of had the same breakfast at the start of this, it was just like bran flakes and cereal. I know there are some nice recipes in the booklet but because we've got a two-year-old it's just...having to be quick in the morning. So I think if this was my first pregnancy I probably would have been able to explore, like the tofu scramble and stuff like that, I just didn't have time for that in the morning."* (participant 25, age 30)

Quote 45: *"[…] eating out can be difficult, and kind of socialising. If you're eating at other people's houses, if things are put on a plate for you – for me, personally, I feel quite rude if I don't eat everything. I think that's just the way I was brought up […] if you go to a restaurant or something like that can be really difficult. Some places don't really offer anything, which is not really very helpful. That's kind of my biggest challenge at the moment. […] But then sometimes if I go out I think, 'Oh, I'm out with my friends, just have a nice time' kind of thing. Or for example, we went on holiday a couple of weeks ago. I went a bit with the attitude, 'Well, we're on holiday. We haven't been on holiday for ages; just enjoy yourself' kind of thing."* (participant 11, age 31)

Quote 46: *"Christmas was the worst because obviously there's chocolate and sweets everywhere and you're given loads of chocolate and sweets everywhere, so I did pig out a bit over Christmas. I'm not going to lie. [Laughs] But then, we've kind of got back into a routine again […]"* (participant 22, age 37)

Quote 47: *"You gave me two good tips. Which were don't go anywhere hungry, which is actually really good and really useful. You told me that, then a few days later I was going out for dinner with my friends and I was starving. I ate an apple before we went, which I wouldn't normally do because I think, 'Oh I'm just going out for dinner, you don't need to eat anything.' I had an apple and then just ended up having a main course, whereas I think I probably would have had either a starter or dessert because I was so hungry. That was really useful. Then another thing, which is helpful for barbecues or things where you're serving yourself, was trying a little bit of everything rather than restricting yourself. Having lots of salads or filling half your plate with that sort of thing, then a little bit of everything else, was useful."* (participant 11, age 31)

Quote 48: *"[…] an active group where it is not just that you meet once a week. It is the chat every day, whether that is a WhatsApp group or a Facebook group or something. It can kind of have that support. Or buddy up with somebody and do it together."* (participant 54, age 36)

- Accountability

Being pregnant made participants more conscious of their health behaviour practices, including their dietary choices, due to the potential impact of those on the health of the fetus and the pregnancy overall. In some cases, accountability to the unborn baby facilitated adherence to the diet (Quote 5). However, some participants who struggled to adhere to the diet principles overall or at times, reported feelings of guilt and worry from knowing the potential consequences of not following the

programme or gaining excessive weight, for the health of the baby and the pregnancy (Quote 49). Another participant also reported feeling guilty for not fully adhering, as she perceived this study was important for medical science (Quote 50).



Quote 49: *"But I think as a person myself, and I'm…I take full responsibility for this…because I remember saying to you that, you know, I really want to be careful with regards to my diet […] After a point I have to stop [eating biscuits] because I get scared. The fear is that it is going to affect my baby."* (participant 44, age 32)

Quote 50: *"[…] I have to say it [following the diet] does go to the bottom of my list, but then, I feel guilty because I feel like it's a good thing to do for medical science. And I feel like a bad person for not giving it my all."* (participant 17, age 33)

5.4.6.1.4 Motivation

Participants described how internal motivation impacted on their liking of the intervention programme and their ability to adhere to it. All participants reported that their baby's health was a major driver of motivation. Some participants' motivation also stemmed from their concerns to avoid GDM or other complications during pregnancy, or to improve their longer-term health (Quotes 2, 51-53). Measuring results and objective successes (e.g. limited GWG) helped to sustain motivation (Quotes 54). However, in a few cases, participants struggled with motivation (Quote 55). From the messages that participants reported for other women who are at risk of GDM, I identified some patterns with regards to participants' perceptions of, and attitude towards GDM. Participants would advise other women to not panic about GDM but still to take action against it, while a few seemed to not have fully realised their increased risk of GDM and its consequences (Quotes 56 & 57).



Quote 51: *"I think a friend of mine is also pregnant and she's not on your study and she's probably not as high a risk as me but she has developed gestational diabetes and I think her quality of life compared to my quality of life at the moment is quite different and it's really worth trying to keep on top of it before you develop it. Because if you do develop it, it really does change your daily life. Weighing things out, being careful. We've been out for dinner and she's had to be really careful what she's had to eat, things like that."* (participant 24, age 33)

Quote 52: *"[…] it's just a matter of getting used to it [the dietary advice] really, especially if you are pregnant and if you are worried about getting much more weight than you already have, I don't think it's… I think it's probably a good motivation for you to follow this kind of diet as much as you can."* (participant 32, age 34)

Quote 53: *"I think the biggest thing I'll probably take away from this is my sugar. The changes that I've already made I'm likely to stick with, just because I know it's good for me anyway in general."* (participant 43, age 32)

Quote 54: *"[…] I'm weighing myself regularly every week, and so actually, it's quite nice to see, "Oh, I'm actually not putting on as much weight as I thought I might be." And actually, that makes me feel better, like I'm actually managing my diet and doing something good."* (participant 17, age 33)

Quote 55: *"[…] I think it really comes down to me as a person and what my motivation is because I feel like the way I behaved […] I just gave in you know like I cannot blame it on, and I cannot say 'oh, no, the baby'. I gave in. I know what I'm craving. I know what I want."* (participant 44, age 32)

Quote 56: *"Don't panic but invest the time in investigating yourself and look for support. Don't try to manage it blindly by yourself. It's much more common than it looks like."* (participant 20, age 39)

Quote 57: *"I would say try not to worry about it too much because it might not happen. In my first pregnancy, I was at high-risk, and I never had any issues with it at all. And, I wasn't following the dietary advice, and it never happened. This time round, I've been following the dietary advice. It hasn't happened."* (participant 17, age 33)

5.4.6.1.5 Outcomes

Participants reported intrinsic feelings of well-being and reassurance, as well as perceived improvements in physical measures, and a positive impact of the RECORD diet on their social network and household (Quotes 58 & 59). Most participants viewed the self-weighing component of the intervention positively, especially because they were content with the limited GWG rate (Quote 60), however, a subset of participants did not enjoy the regular weighing, despite knowing that weight gain during pregnancy was expected, because of negative perception of their body image and history of dieting, which made them feel uncomfortable (Quote 61). A few participants mentioned worrying about weight gain above the recommendations, particularly as to how this could affect the pregnancy (Quote 62).

Quote 58: *"[…] my husband has noticed this difference as well. We just both feel a bit healthier. It's been a good effect on the family."* (participant 28, age 32)

Quote 59: *"[…] when the midwife first mentioned [risk of] gestational diabetes [at the booking appointment], I sort of freaked out a little bit and thought, oh my God, I've done this myself. It's because I'm overweight. But getting onto the diet, I don't know, it helps calm me down a little bit."* (participant 28, age 32)

Quote 60: *"Weighing myself, it's been quite good because I didn't weight myself for the last pregnancy, so I didn't really know if I was gaining weight more or less than I should be. Whereas this time, I'm weighing myself regularly every week, and so actually, it's quite nice to see, "Oh, I'm actually not putting on as much weight as I thought I might be." And actually, that makes me feel better, like I'm actually managing my diet and doing something good."* (participant 17, age 33)

Quote 61: *"[…] I think it's just from being overweight my whole life so...always sort of getting on the scale and logging the number and then try to sort of come to terms with that in my last pregnancy. Because I knew it was OK to gain weight, it was natural and normal. But it's still sort of like a bit of a mental barrier, to be like ok I know I'm going to weigh more this time, I'm currently at the heaviest that I've ever been. But I know that's fine because I'm incredibly pregnant. It's just...as soon as you see that thing on your head... on the scale, it's kind of sad I guess." (participant 25, age 30)*

Quote 62: *"Earlier on, it was reassuring that it [the weight] was not going up as much, and then recently, especially with my holiday as well, it has really rocketed so now I am a bit worried about it."* (participant 54, age 36)

5.4.6.2 Experiences of the study

Apart from the experiences of the intervention, participants also reported their experiences of taking part in the trial itself (**Table 5.7**), including:

- their experience of being approached to take part in the study,
- their reasons for enrolling into the study,
- how they experienced attending an extra hospital appointment, and undergoing OGTTs, and
- their experience of self-monitoring their blood glucose and ketone levels.

Table 5.7. Experiences of the RECORD study processes

First approach at nuchal scan	• The viability of the pregnancy was the predominant thought of participants at the nuchal scan, however, most felt it was appropriate being approached at this stage (Quote 63), and they valued having time to think about the study before making a decision (Quote 64).	**Quote 63:** *"[…] you are waiting for a scan or sometimes for a medical procedure, so you are dealing with challenges in general and you are obviously looking to take more care about your baby and yourself, so I think it was kind of appropriate. Don't think anything wrong with it."* (participant 32, age 34) **Quote 64:** *"Yeah, that was absolutely fine. You were really friendly, and sort of gave me the information, but didn't make me make a decision then and there. So yeah, I think it was really well-positioned, the way I was approached about it."* (participant 17, age 33)
	• One participant noticed that when the waiting area is too busy, it might be preferable to use a more silent space to talk to people (Quote 65).	**Quote 65:** *"You might be benefitted if they give you like a little side corner somewhere that's nice and quiet to talk to people really rather than trying to do your best just trying to pull them to one side. If they could give you a little bit more space to actually talk to people in the first place because we weren't too bad because obviously we just went to one side, didn't we? And, it was very quiet there that day; but the other day I've been there, it was absolutely rammed."* (participant 22, age 37)
	• One participant, however, reported feeling an initial shock for being approached at an early stage, before the viability of the pregnancy was known (Quote 66). For another participant, being approached for the study revealed some negative thoughts about body image, which were however alleviated by motivation for a healthy pregnancy (Quote 67).	**Quote 66:** *"[…] for us, we got sent for an urgent scan. So we literally had a phone call the day before saying you must come for a scan tomorrow […] So that's all you're expecting. You're not expecting anyone else to approach you. Not that it was unpleasant at all. I mean, it was okay, and you were very nice and all these things. But at that time, I suppose you feel like the only thing that matters is going to have that scan at that point […] Because at that point, you don't really truly even know if there's a living baby inside you."* (participant 24, age 33) **Quote 67:** *"Part of me was like, you know when you feel like you're being identified because you're like the big girl? So there was like that kind of 'Oh' moment. But actually, it felt like it was the right thing. It was a good opportunity and that people were actually interested in my pregnancy. I wasn't just going to be sent away and left to kind of muddle through on my own."* (participant 10, age 31)

Table 5.8. continued

Reasons for enrolling	**3 main drivers** for participants to take part in the study were: 1. **Being specifically concerned about GDM**: These participants were generally aware of the risk factors they had for developing GDM, and they were also aware that GDM has consequences for their health and quality of life, especially if they had experienced GDM in a previous pregnancy (Quotes 68 & 69), or were aware of the experience of others. A few participants reported feeling shocked after hearing they were at increased GDM risk, which motivated them to enrol into the study (Quote 70). 2. **Wanting a healthy pregnancy overal**l: These participants found the idea of receiving additional advice or close monitoring of their pregnancy appealing, and some of them were particularly motivated by health complications in previous pregnancies (Quotes 2, 71 & 72). 3. **Wanting to contribute to scientific progress, and/or give back to the health system, and/or were interested in nutrition or health topics in general.** One participant was also motivated to help increase the representation of their ethnic background in research (Quotes 73-75).	**Quote 68:** *"Mostly because gestational diabetes was something I was a little bit concerned about. My dad is a diabetic and I'm obviously overweight, so I was just a little bit concerned about it. So, kind of any way to maybe avoid it would be of benefit, in my mind anyway." (participant 11, age 31)* **Quote 69:** *"So I knew I was at high risk of gestational diabetes. I was a high-risk in my last pregnancy so I knew I would be again this time, because of my weight. So I thought it was probably a good thing to try and intervene if I could so that I wouldn't develop it but my friend developed it in her pregnancy and it was literally hell for her, so I wanted to avoid that."* (participant 25, age 30) **Quote 70:** *"I think I was a bit shocked when I initially went to the GP to report the pregnancy and they said, 'oh you are on the cusp of…being obese'. And then, in the middle of [the appointment], they mentioned about diabetes and things, and I got really worried about it. When I was approached, my first scan for the study, it just felt like a really good idea […]."* (participant 54, age 36) **Quote 71:** *"I had a very bad pregnancy last time, and the opportunity to reduce any problems with this one was greatly appreciated."* (participant 22, age 37) **Quote 72:** *"When you first approached me when we were waiting for a scan, it was such a shock to find out that I was pregnant, to begin with. And I was such a wuss about everything and I thought, oh, no, I can't do any extra. But once I thought about it, my husband said, if anything, you're going to have more monitoring. You're going to see more people have your glucose checks and all those kinds of things. You might as well go for it."* (participant 24, age 33) **Quote 73:** *"I decided to take part in the study because I think it's a really interesting topic, and it felt like a good thing to do to sort of help in medical research and a good thing to help the NHS […] It felt good to be able to do something helpful because I have a high-risk pregnancy, I feel like the NHS needs to support me throughout my pregnancy more than a straightforward pregnancy, so it felt nice that I could do something helpful to almost like give back, sort of repay the extra burden I guess I am on the NHS when I'm pregnant. So, it felt like a nice thing to do."* (participant 10, age 31)

Table 5.8. continued

Reasons for enrolling continued		**Quote 74:** *"I think it's good to take part in research and studies and things when you can, just because that's how we find out things about medical research and things. So I had no reason not to. It didn't appear like it would take lots of time or effort on my part so I thought why not?"* (participant 31, age 38) **Quote 75:** *"One reason was because my diet before was very high in sugar. I've always been aware of that, but I wasn't particularly afraid of developing diabetes or anything like that. I wanted to learn more about what the impact is in terms of mental health, like everybody, especially during this time. Secondly, it's that someone who's of Black African descent, I know that diabetes and gestational diabetes is quite high within the community. I know that we're not necessarily the most engaged group when it comes to this type of research, so it's something that I wanted to provide some data on."* (participant 43, age 32)
Extra visit and OGTT	• Participants appreciated attending the visits at a less busy setting than the antenatal clinics with comfortable atmosphere and attentive staff (Quotes 76 & 77), paying for their parking or for a taxi to and from the centre, and arranging visits at a convenient day and time (Quote 78), though there were some concerns about additional time off work (Quote 79).	**Quote 76:** *"There was no problem because it was in the research centre rather than the main hospital. I was fine because I had a room to myself for the whole time. I remember in my first pregnancy when I had a glucose tolerance test, you'd have the first blood test; and then you had to go sit in the waiting room for two hours. So, I couldn't do anything, whereas because it was in a nice setup, I worked whilst I was there. So, it didn't really affect me, having to come in for an extra visit, because I was made to feel comfortable. You got me some lunch for afterwards, so you made it as easy as possible for me to come in, and it was not as disruptive as it could have been. So yeah, that was no problem."* (participant 17, age 33) **Quote 77:** *"Everyone is so kind. This is probably a really awful thing to say, but when you are in the main hospital and you go in to have bloods, you're kind of rushed in. Everything's a rush and rushed out. Whereas I felt like everyone took the time, wanted to talk, and was just really kind. Like you matter, rather than you're just a number and a ticket."* (participant 10, age 31) **Quote 78:** *"It was helpful having a taxi to take me there because it was obviously early in the morning. It was nice not having to drive and sort packing and things like that [..]."* (participant 31, age 38) **Quote 79:** *"Visit was kind of soon after the 12 weeks. Just like fitting that in. But I think my work is quite understanding about it so I was able to participate […] and I think because I had an understanding employer, like that was good. But I could imagine that obviously you're entitled to have your antenatal appointments when you work. But I don't know for other people, their employers might find it frustrating if they're out for more appointments than normal. But mine's been fine."* (participant 5, age 30)

Table 5.8. continued

Extra visit and OGTT continued	• Some participants were motivated to attend an extra OGTT, as they found it reassuring to know their blood glucose levels from early on in the pregnancy (Quote 80) and for one participant, appeared to have affected their behavioural control from that point on (Quote 81).	**Quote 80:** *"[…] I did think it was kind of good, positive, for me to have both of those [OGTTs] because I had family members with diabetes during pregnancy, so you never know if you're going to have that too, so for me to not have anything at all, just really positive to have both, so it was fine."* (participant 32, age 34) **Quote 81:** *"That was quite sort of helpful in a way to see where I was at early to see if I... because I think my results came back quite borderline on that so it's good to know that anything that I do from now will actually potentially have an impact. So it's quite helpful to have an indication earlier in the pregnancy."* (participant 25, age 30)
Self-monitoring	• None of the participants expressed concerns with monitoring their blood glucose and ketones. For some participants it took time to get used to the process, but it became part of the routine (Quote 82). Participants appreciated the equipment as it was designed to make the finger-pricks as less painful as possible (Quote 83). • Reasons for not being always consistent with finger-prick testing were mainly time, family or work commitments, but these were usually short-lived, and for most part of the study, participants remembered, and were keen to self-monitor these markers. Receiving text reminders, as well as the automatic transfer of the measurements into a mobile application, or simply texting them back, were helpful (Quote 84). • Participants felt reassured about receiving the extra monitoring with the blood markers (Quotes 85 & 86). Some felt that it made them more conscious about their food choices, especially if the measurements were higher on some days than others, but a few mentioned that they used the finger-pricks as a kind of reassurance that, despite eating higher amounts of carbohydrates or gaining excessive weight, their fasting glucose levels were still within normal	**Quote 82:** *"The first time…I'd watched you do it when I was in the hospital, and I've messed up a few times with some of the strips and stuff, like 'Ahhhh'. Eventually, I got there in the end, but yeah, it's actually really quick to do now. I just don't even think about it. I go, 'Oh, it's Sunday night. Right, I've got to do my tests in the morning'. I put the kit there by the kettle. Again, on a Tuesday, 'Right, so tonight I'll put the kit by the kettle'."* (participant 22, age 37) **Quote 83:** *"[…] really easy erm it doesn't hurt erm the needle is really thin so could barely feel it, I always got blood as well and never had any problems or had to prick myself again, there was plenty of equipment to be able to do it, and the monitor was really easy to use."* (participant 30, age 30) **Quote 84:** *"It helped a lot to get the text message in the morning. That was really helpful […] because I take my phone every morning and I know what I have to do, so that was very easy to do […] But the test, it's also easy because I didn't really have to submit any form or like really go on my computer every day because I can do it from the phone, so that makes a lot of… yeah, that's definitely easier."* (participant 20, age 39) **Quote 85:** *"I think I was happy to have more monitoring in pregnancy than not. I think there was one friend of mine had developed diabetes in pregnancy and I think she missed her 24-week glucose test. I think it was just like an error. I was more reassured having a bit of extra monitoring, like someone checking those results during the weeks gone by."* (participant 5, age 30) **Quote 86:** *"You're not kind of left for weeks where no one is checking anything. It's your responsibility to obviously do your blood sugars and your ketones, but you know then that you're healthy. I feel like a lot of pregnant women probably don't monitor their weight and things like that. I think it just was really beneficial for me to not worry."* (participant 10, age 31)

Table 5.8. continued

	range (Quote 87), and despite that I had highlighted to them that normal fasting capillary glucose levels do not necessarily that someone would not develop GDM, but they are just taken for research purposes, for ensuring the intervention has no adverse health effects compared to control, and for feedback with regards to the observed pattern throughout pregnancy. • As explained in section 5.4.6.1.5 above, most participants found regular self-weighing acceptable and useful, apart from a few who expressed feeling uncomfortable due to body image issues (e.g. Quote 61). Most of the participants who struggled with self-weighing, though not consistently, still provided some weight data, because they knew these data were needed for the study.	**Quote 88:** *"And I do not know whether I have, with the finger prick testing, almost used that as reassurance in some way. Like, I test my blood sugar and I had a lot of sugar the day before, but then in the morning, the finger prick test is like, oh, that looks okay. I can carry on. Just using that as reassurance that I can carry on as I am doing."* (participant 54, age 36)

GDM: gestational diabetes mellitus

5.5 Discussion

5.5.1 Principal findings

This randomised feasibility trial met the retention, but not the diet adoption progression criteria. The secondary and exploratory outcomes between the groups, indicative of early effectiveness, did not reach statistical significance in this small feasibility study, but indicated a potential improvement in 1-hour and 2-hour glucose levels of the OGTT, blood pressure at 24-28 weeks' gestation, as well as in GWG at both 24-28 and 36 weeks' gestation in the intervention compared to the control group. Participants reported varied experiences of attempting to adhere to the dietary programme, but most reported overall acceptance and a positive experience. All interviewed participants reported being content with the study processes, including regular monitoring of blood glucose, ketones, and weight.

5.5.2 Comparison with previous studies

5.5.2.1 Early identification of diabetes in pregnancy

My study is among the small number of prevention trials which provided early OGTT testing to exclude people with early or undiagnosed hyperglycaemia (144, 225, 239, 254). In my study, the rate was 7.3%, while in previous studies, it ranged from 11.6-27.5%, with the exception of Petrella et al.(240), who identified no early hyperglycaemia.

5.5.2.1 Intervention content and characteristics

Similar to RECORD, previous dietary interventions to prevent GDM (224), were mainly delivered by trained HCPs (e.g. nurses, dietitians). However, the dietary advice of previous programmes focused on general healthy eating principles (224), while a few studies promoted a Mediterranean style diet (227). Some studies set specific energy intake goals so that participants did not gain excessive weight (225, 239), while others, like RECORD, did not necessarily advise on energy restriction (143, 228). All programmes intervened in one way or another on carbohydrate intake, for example, by encouraging reduction in sugary foods and drinks, or switching to lower-GI foods. RECORD differs from previous interventions in that it specifically focused on reducing the total amount of carbohydrate in the diet.

Only one previous preventative study delivered similar dietary principles to those of RECORD (e.g. replace sugary drinks with sugar-free alternatives, and reduce potatoes, pasta, rice), but did so as part of an intensive healthy eating intervention (146). Some dietary interventions combined dietary advice with advice on physical activity, but this was based on keeping to levels of national recommendations (e.g. for walking), rather than engaging to exercise programmes (143, 225, 239).

Like in RECORD, previous interventions so far have supplemented consultations with written materials and supporting tools, like handbooks, the plate model, goal sheets, and pedometers. A study of Mediterranean diet also offered foods essential to the intervention to participants, namely olive oil and nuts, for the duration of the study (228). However, not all interventions to date have described their behavioural theoretical basis. Those which did, used behavioural strategies, such as goal setting, self-monitoring of goals, problem solving, and social support (143, 144, 229, 230, 254). As described in Chapter 4, RECORD followed a similar paradigm and behavioural strategies with other intervention packages, however, it was among the few interventions to also incorporate regular self-monitoring of weight from early or mid-pregnancy until delivery. A previous trial by McCarthy et al., followed similar process with RECORD, by delivering brief initial healthy eating advice, and requesting participants to engage into weekly self-weighing for the duration of pregnancy, with discussion of GWG with the clinical team at routine antenatal appointments (480). One other trial (239) collected weight measurements at regular visits, and asked participants to weigh themselves every 2-3 days in the last month of pregnancy. Importantly though, interventions to date (224) have been more intensive compared to RECORD in terms of frequency and personal contact, without indication on how they could be delivered as part of routine practice. Even in the simpler intervention by McCarthy et al., some women accessed extra consultations with a dietitian, as this was available as an option (480). More recent interventions (228-231, 504), have tended to combine face-to-face visits with remote delivery and/or follow-up, but were still more intense than RECORD, involving, overall, more visits, and more frequent interaction with HCPs.

5.5.2.2 Effects on dietary intake

The RECORD intervention, although focused specifically on reducing carbohydrate intake, resulted in only a small absolute reduction in the intervention group at follow-up, equivalent to -1.3 portions of carbohydrate foods/day, with adjusted, non-statistically significant within-intervention-group reduction being -1.6 portions/day. Between-group differences did not reach statistical significance, but indicated that, compared to control, women in the RECORD diet group consumed 1 portion of carbohydrate food less per day. In the UPBEAT, a way more intense intervention than RECORD, which did not focus on reducing the amount of carbohydrate, but encouraging a low-GI diet, the intervention group reduced their total carbohydrate intake by approximately 30 g/day (i.e. by about 2 portions/day), after 8 weeks of dietetic sessions, but the between-group difference was similar to the one of RECORD (-1.2 portions/day) (143). In the DALI trial which had a specific focus on total carbohydrate reduction, women reduced significantly their total carbohydrate intake compared to the control group, but the degree of reduction was less than 1 carbohydrate portion/day (-4.8 portions/week compared to usual care) at 24-28 weeks' gestation, and about 1 portion/day (-7 portions/week compared to usual care) at 35-37 weeks' gestation (254). Baseline levels of carbohydrate intake for each group were not published for this study, therefore, the within-intervention-group change, i.e. intervention adoption, is unknown. In addition, I would expect that dietary interventions in women with established GDM would have yielded greater reductions in carbohydrate intake given that women have the disease and may be motivated to control it, however, even studies in GDM management, have not yielded substantial reductions in carbohydrate intake. For example, Mijatovic et al. (429), delivered a modestly reduced-carbohydrate diet in women with GDM aiming for 135 g total carbohydrate/day, but only 20% of intervention participants met the target intake, and the within-intervention-group difference was null at follow-up, while the between-group difference was -25 g/day and statistically significant. However, it was noted that this population already consumed a moderate-carbohydrate diet since baseline (~165 g/day). With regards to types of carbohydrates, in the RECORD trial, the average starch intake was already within the recommended

levels since baseline in both groups, therefore, it was mainly the sugars that participants did not manage to substantially decrease, and this was reflected in qualitative interviews. What is more, the RECORD intervention recorded no increase in fibre intake, although during dietary consultations and qualitative interviews, participants mentioned that one of the easiest changes was to switch from white varieties to wholegrain. However, this was mainly mentioned for bread or breakfast cereal, and participants were less likely to make the swap for other foods, like rice or pasta. But it is notable, that even in the UPBEAT trial which primarily promoted a lower-GI diet, fibre increased only slightly in the control group compared to the control group (between-group adjusted mean difference: 0.83 g/day, 95% CI 0.17 to 1.48). On the contrary, Zhang et al. (504), assisted participants in choosing lower-GI foods with a mobile app, and showed a significant increase in daily fibre intake in the intervention compared to control group (difference of 3.9 g/day). The above data suggest that it is unclear whether substantial reduction in total carbohydrate intake is feasible in women with overweight or obesity during pregnancy, that there is space for improvement in emphasising messages around higher fibre intake, and my study particularly suggests that any future interventions should pay special attention on finding effective ways to reduce sugary foods. Other dietary changes observed as a result of the RECORD intervention compared to usual care, were increase in protein intake, and slight decrease in saturated fat intake, similar to or more than some previous prevention studies (143, 254, 505), though not statistically significant in my study.

With the available dietary data to date, it is not possible to conclude whether changing the diet composition can independently reduce GDM, and if it does, it is still unclear which is the optimal dietary composition for preventing GDM, because successful interventions have not reported details on the effect of the intervention on macronutrient intake (225, 228, 231, 232, 239, 240). From these studies, only Ding et al. (231), reported such detail, showing that an intensive smartphone-based intervention for healthy eating and physical activity, reduced the incidence of GDM compared to control, although all comparisons were unadjusted. In this study, total carbohydrate intake was high in both groups, and all macronutrient intakes increased by 25 weeks' gestation, but physical activity

increased more, and energy intake increased less in the intervention group, and as a result, the intervention group gained less weight. The authors attributed the reduction in GDM to the increased frequency of intervention delivery, the early intervention at 8-12 weeks' gestation, and the significant attenuation of GWG. Accordingly, whether specifically reducing carbohydrates from early or mid-pregnancy works as a preventative strategy, and whether it is worth exploring it further, is also unclear. All successful interventions intervened in some way on carbohydrate intake, especially in reducing sugar intake (225, 228, 231, 232, 239, 240), but with the largely unavailable dietary details we cannot know if this can drive effects, and even interventions which specifically focused on carbohydrate reduction (254), including RECORD, had suboptimal adherence.

5.5.2.3 Effects on markers of glycaemic control

The RECORD trial was not powered to detect significant differences in markers of glycaemic control between intervention and control, however I observed some potential benefits in 1-hour and 2-hour blood glucose levels from the OGTT, in favour of the intervention. Compared to the small number of studies which have published blood glucose data (143, 225, 254), participants in the RECORD trial had similar levels of fasting blood glucose at baseline, but the RECORD intervention group had a slight increase in it at follow-up compared to what was observed in other studies (e.g. 0.1 mmol/L in RECORD vs -0.1 mmol/L in other studies). However, RECORD showed a slightly greater reduction of 1-hour glucose at follow-up (e.g. -0.3 mmol/L vs -0.1 mmol/L), even from studies that prevented GDM, and similar levels of reduction difference in 2-hour glucose at follow-up (e.g. -0.1 mmol/L). Only a few other studies have provided data on the effect of an intervention on fasting insulin levels. In the UPBEAT trial for example (143), there was a non-statistically significant increase in insulin compared to usual care, while in RECORD I observed a non-statistically significant highly variable between-group difference of -2.1 (95% CI -23.5 to 19.2) pmol/L. Although the collection time and context was not fully controlled, ketone levels were generally low and similar in both groups in RECORD throughout pregnancy, which was reassuring that the reduced-carbohydrate advice did not put pregnant women

at risk. Similar ketone levels were observed in a recent reduced-carbohydrate intervention trial in women with established GDM (429).

5.5.2.4 Effect on GWG

Although the RECORD trial was not powered to detect a statistically significant difference in GWG between the groups, the intervention group gained less weight during the relatively short period from enrolment <20 weeks' gestation, until 24-28 weeks' gestation (-2 kg between-group difference in GWG), with a difference between the groups still apparent at 36 weeks' gestation (-1.4 kg). In previous, more intensive interventions of diet and/or physical activity in women with obesity during pregnancy, intervention groups, also gained less weight compared to control groups, but the effects were variable, with between-group differences ranging from -1.2 to -0.4kg, from pre-pregnancy or enrolment in the second trimester until 28 weeks' gestation, and from -3.4 to -0.2kg, from pre-pregnancy or enrolment in second trimester till 36 weeks' gestation (143, 146, 225, 228, 232, 239, 240, 485, 505-509). In view of the above, the effect of my lower-intensity intervention on GWG, is considerable, despite the apparent limits in the adoption of the reduced-carbohydrate component of the diet.

Previous trials testing the effectiveness of self-weighing on limiting GWG have been unsuccessful in engaging women in regularly measuring their weight during pregnancy (e.g. 11-33.2% provided any self-recordings) (455, 510), probably due to negative emotional responses elicited by regular weighing, especially in the absence of appropriate support and guidance. Exception is the intervention by McCarthy et al. (480), achieving good engagement in the majority of women (82% of intervention participants completing at least 5 measurements), and RECORD (55% completion of all, and 65% completion of half of required measurements, over 6 months). However, as opposed these previous trials RECORD had greater success in limiting GWG compared to the control group, which may be attributed to self-regulatory processes that may have been triggered, during which participants contextualised their weight with previous measurements, reflected on their eating

behaviour, and planned and performed actions to change their dietary intake to achieve weight control (476). Previous qualitative research has suggested that self-regulation does not occur automatically when people self-monitor their weight, and the full iterative process of self-regulation occurs only rarely without support and further instruction (478). In the RECORD trial, I did not assess if participants went through all self-regulation steps, however, I made the effort during the support sessions to provide feedback on the progress of GWG in the context of the IOM guidelines (127), as well as support with action plans to adhering to the dietary principles, to maximise the opportunity of harnessing the full potential of self-regulation. Whether participants employed reduced-carbohydrate strategies, or simply improved their overall diet as a result of the self-regulation processes, is not certain, but their dietary reports at follow-up showed their energy intake decreased because of slight decrease in total carbohydrate intake, while protein intake increased, and fat intake remained almost unchanged. In qualitative interviews, RECORD participants reported that measurable successes, such as observed gradual weight gain, helped keep them on track with the RECORD dietary advice.

5.5.2.5 Effect on blood pressure

Previous GDM dietary prevention trials have not explored effects on blood pressure. In the RECORD trial, there was substantial, albeit non-statistically significant decrease in mean diastolic blood pressure in both groups from baseline to follow-up, with the adjusted between-group difference (intervention vs. control) favouring the intervention (-1.0 mmHg). The adjusted between-group difference in systolic blood pressure also favoured the intervention (-2.3 mmHg), although was not statistically significant. These data are however notable, because even small changes in blood pressure on the individual level, can largely protect health outcomes in the population.

5.5.2.5 Effect on clinical outcomes

The incidence of GDM, gestational hypertension, preeclampsia, LGA, and induction of labour, was higher in the intervention group, which partly may be expected due to the ratio 2:1 of randomisation.

However, the frequency of caesarean section was higher in the control group. Meaningful effects on these outcomes would need to be investigated in a definitive trial.

5.5.2.6 Effect on quality of life

Women's quality of life during pregnancy depends on socioeconomic, medical and psychological factors, but at least the physical aspect of it has been shown to generally decline as pregnancy progresses, mainly due to decreased physical activity and functional limitations (511). A healthier lifestyle (e.g. being physically active) has been associated with improved quality of life in pregnancy (511), but data are lacking specifically on the effect of diet. Previous lifestyle GDM prevention trials have rarely examined effects on quality of life. The study by Bruno et al., of serial self-weighing and simple dietary advice, showed no significant between-group differences in physical (-0.43), psychological (0.12), social (-2.62), environmental (-0.96) domains of the WHO Quality of Life Subscale (512). On the contrary, Bogaerts et al. (349) demonstrated a significant reduction in anxiety with a MI-based lifestyle intervention. In RECORD, the EQ-5D index score combining aspects of mobility, self-care, ability to do usual activities, pain/discomfort, and anxiety/depression, was unchanged in both groups at follow-up. The absolute VAS score, decreased in both groups, but less in the intervention group, without reaching statistical significance. This finding however is not very informative as VAS, which reflects participants' view of their overall health-related quality of life, is complementary to the EQ-5D index, and it could be a chance finding, since the 95% CI was very wide.

5.5.3 Participant experiences

Qualitative interviews confirmed that the RECORD intervention affected all domains of the COM-B model that I had hypothesised in my logic model in Chapter 4. With regards to physical capability, pregnancy-related physiological changes posed challenges in adhering to the RECORD diet, however, the majority of interviewed participants felt that, because the dietary principles were easy to remember and implement, attempting to follow the diet did not add extra burden, and that they had alternative options available, so they were able to find coping strategies. With regards to psychological

capability, women felt that they enhanced or refreshed their knowledge around GDM, diet and weight, through the RECORD consultation and written materials. The RECORD programme enabled women to make healthier food choices mainly through its clear specific messages and structured materials, as I had hypothesised. In adhering to the diet, as well as increasing their confidence, and not feeling overwhelmed about making dietary changes during pregnancy, women found useful to set small realistic goals, seeing measurable successes, and obtaining feedback on these, as well as planning actions. However, I should note that, though not mentioned in the interviews, during telephone support sessions, I identified that participants were not keen to act through creating a self-induced expectation of reward for adhering to the diet (incentivisation), as I had originally hypothesised, because they did not feel there was need for this.

As originally planned, the intervention also acted through physical opportunity for participants to make lower-carbohydrate food choices. For example, they mentioned changing the food availability in their house, or coping strategies that they learnt through our discussions for social situations involving food or holidays. Previous research shows that holidays for example, are linked with weight gain, and social circumstances involving food, can put someone off track from their healthy eating efforts (513). In these cases, I proposed realistic plans around meeting their eating goals, emphasised the short duration of these circumstances compared to commitment to the programme for the majority of the time, and I encouraged the use of the plate method, and having variety on the plate. On the other hand, demands of everyday life, such as work and family commitments, or lack of time for meal planning and preparation, and fitting the type and frequency of meals to their work schedules (e.g. when working shifts, travelling to and from work, or teaching), were major barriers towards sustaining changes, and despite solutions during support sessions (e.g. meal planning), and tailoring advice to individual circumstances, a sub-sample of participants still found it hard or impossible to keep up. With regards to social opportunity, social norms were not reported as a significant barrier, because generally, participants' social environment was encouraging in their efforts, which facilitated adherence. I found through consultations that I did not need to

directly encourage social support because participants utilised it by themselves anyway, however, from qualitative interviews, the easily adjusted dietary principles of the RECORD intervention, seemed to have facilitated their ability to utilise social support, which adds another indirect pathway in the logic model which I had not considered.

For most participants, wanting a healthy pregnancy and/or to avoid GDM, feeling accountable to the unborn baby, seeing measurable successes (e.g. GWG) through self-monitoring and feedback, and having social support from their immediate environment and from the HCP, increased participants' reflective motivation to sustain change, confirming original hypotheses. Importantly though, it became apparent from a few interviews that although participants knew that they had risk of GDM and were further informed about it in our consultation, some participants did not actually realise the severity of the condition, especially if they did not develop it in a previous or the current pregnancy, which could have hindered their motivation in sustaining the dietary changes. With regards to automatic motivation, participants generally reported feeling reassured by being in the intervention group and having extra information and monitoring during pregnancy, and that this alleviated feelings of anxiety around the health of the pregnancy. Negative emotions, such as stress were major barriers for adherence. When facing some of the above situations, participants often needed sugary foods, due to the pleasure and ease they offer. The RECORD intervention was able to help some, but not all of these participants, through an array of alternative food options offered, and through the support sessions which enhanced self-efficacy.

In view of the above, I have updated the RECORD logic model to reflect the potential mechanisms through which the intervention delivered impact, in **Figure 5.8**. Combining the quantitative and qualitative data above, and seeing them in the context of existing interventions, also helped me to identify opportunities for improvement of the current intervention and of routine dietetic practice in pregnancy, discussed in Chapter 6.

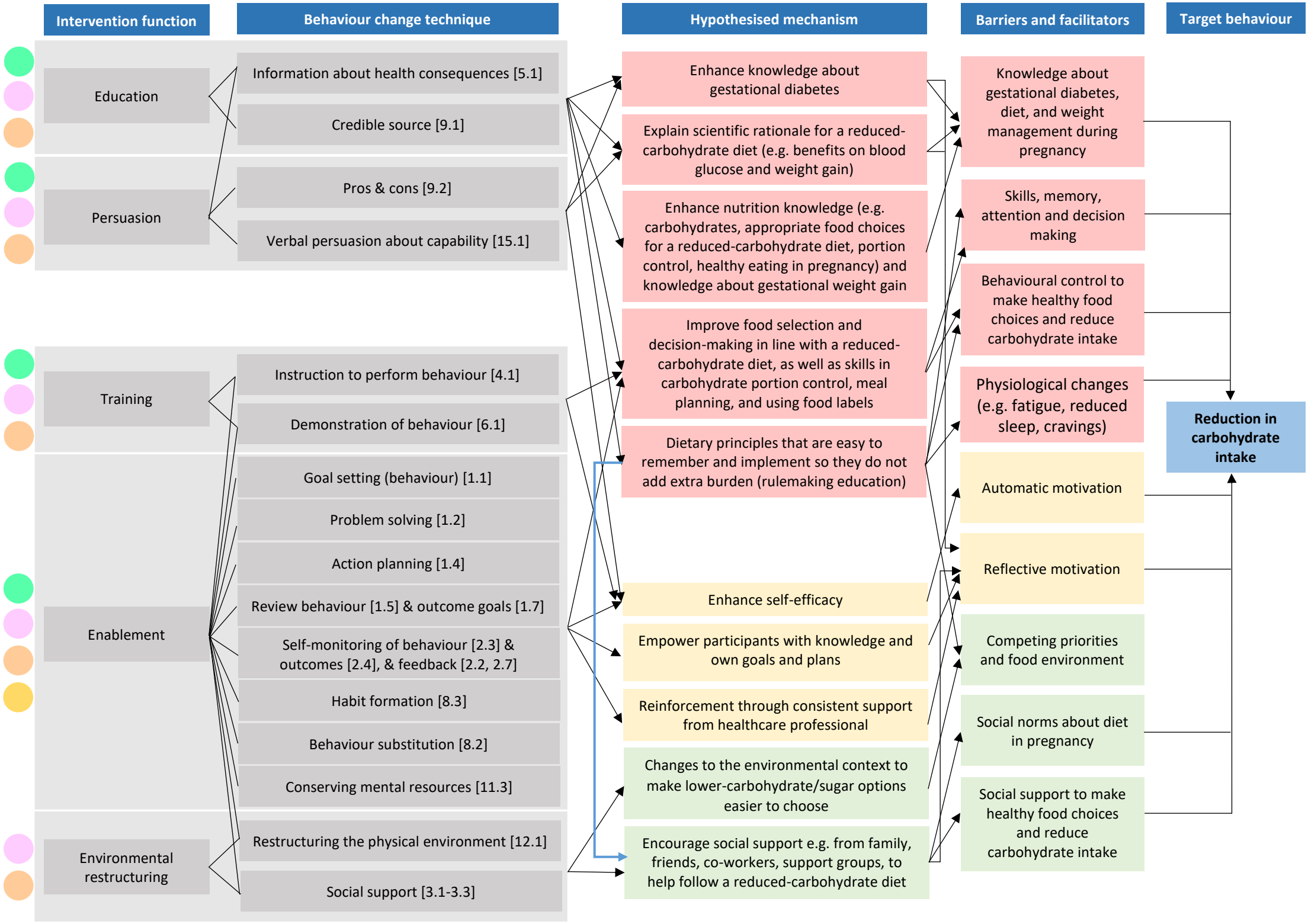
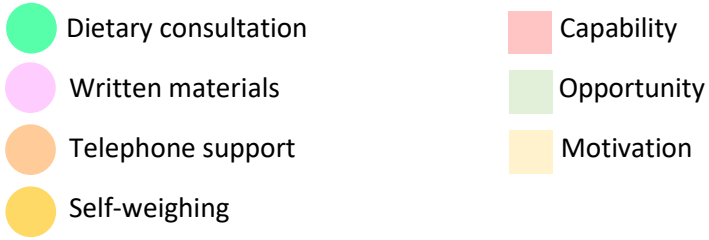

Intervention function
Behaviour change technique
Hypothesised mechanism
Barriers and facilitators
Target behaviour
Education
Persuasion
Training
Enablement
Environmental restructuring
Information about health consequences [5.1]
Credible source [9.1]
Pros & cons [9.2]
Verbal persuasion about capability [15.1]
Instruction to perform behaviour [4.1]
Demonstration of behaviour [6.1]
Goal setting (behaviour) [1.1]
Problem solving [1.2]
Action planning [1.4]
Review behaviour [1.5] & outcome goals [1.7]
Self-monitoring of behaviour [2.3] & outcomes [2.4], & feedback [2.2, 2.7]
Habit formation [8.3]
Behaviour substitution [8.2]
Conserving mental resources [11.3]
Restructuring the physical environment [12.1]
Social support [3.1-3.3]
Enhance knowledge about gestational diabetes
Explain scientific rationale for a reduced-carbohydrate diet (e.g. benefits on blood glucose and weight gain)
Enhance nutrition knowledge (e.g. carbohydrates, appropriate food choices for a reduced-carbohydrate diet, portion control, healthy eating in pregnancy) and knowledge about gestational weight gain
Improve food selection and decision-making in line with a reduced-carbohydrate diet, as well as skills in carbohydrate portion control, meal planning, and using food labels
Dietary principles that are easy to remember and implement so they do not add extra burden (rulemaking education)
Enhance self-efficacy
Empower participants with knowledge and own goals and plans
Reinforcement through consistent support from healthcare professional
Changes to the environmental context to make lower-carbohydrate/sugar options easier to choose
Encourage social support e.g. from family, friends, co-workers, support groups, to help follow a reduced-carbohydrate diet
Knowledge about gestational diabetes, diet, and weight management during pregnancy
Skills, memory, attention and decision making
Behavioural control to make healthy food choices and reduce carbohydrate intake
Physiological changes (e.g. fatigue, reduced sleep, cravings)
Automatic motivation
Reflective motivation
Competing priorities and food environment
Social norms about diet in pregnancy
Social support to make healthy food choices and reduce carbohydrate intake
Reduction in carbohydrate intake

Figure 5.8. Updated logic model



Incentivisation pathway has been removed, and the updated pathway has been added in coloured arrow.

5.5.4 Strengths

To my knowledge, this is only the second RCT that has specifically aimed to reduce total carbohydrate intake in women with obesity from early or mid-pregnancy, with the aim to help prevent GDM. A key strength is that this was a theoretically informed intervention, developed with input from academics, obstetric clinicians, midwives, a diabetes specialist dietitian, and a patient representative. The practitioner input ensured it was suitable for delivery alongside routine antenatal appointments, and PPI input ensured it added the minimum additional burden. In addition, the fact that some participants completed all assessments and dietary consultations remotely with no issues reported, shows that the intervention programme and study procedures can be flexible. Accordingly, if the feasibility trial had shown promising results, it would be relatively easy to scale up the intervention and embed in routine care. Although there was large variability in the extent to which participants were able to adhere to the dietary principles, the programme was overall acceptable, and most interviewed participants were keen to attempt to keep the changes they made beyond pregnancy. Some of these also reported that the main dietary booklet acted as a point of reference for them to look through when they needed answers. This suggests that the intervention could be delivered by any HCP without detailed nutritional knowledge.

Attendance at the intervention delivery sessions was good, as almost two thirds of participants completed at least half of the sessions, and the overall follow-up/retention rate based on rates of OGTT completion at follow-up was excellent, and higher than some previous UK trials (143, 228). Conducting study assessments during the waiting times of the two OGTTs, also enabled me to obtain dietary information a large proportion of participants (84%), which is lower but comparable to some prevention trials (87-99%) (225, 230, 231, 254), and higher than others (39-68%) (143, 228, 239).

Intervention participants in this study had better engagement in regular self-monitoring of weight than previous studies, and for a long time, and this is the first study to report regular blood

glucose and ketone levels from early or mid-pregnancy through to delivery, which provides clinicians with insight on expected values for pregnancy.

Finally, my qualitative work had several methodological strengths. The semi-structure nature of the interviews allowed participants to elaborate on their thoughts, and allowed me to explore themes naturally emerging during the data collection process. I interviewed most participants towards the final stages of pregnancy, and only a few at the time of follow-up. I did this so that participants could give me a more realistic experience of the intervention until the third trimester of pregnancy, when pregnancy may have more effect on participants' life and ability to follow the diet, as well as the initial enthusiasm may have phased out. This enabled me to get a rich account of their thoughts and feelings. Conducting interviews individually allowed participants to elaborate on their experiences independently without being influenced by a collective group think. I recruited a large sample (47% of intervention participants), which might have contributed towards identifying a wide range of experiences, and I specifically sought to recruit the people who did not have the best experience of the intervention. All interviews were audio-recorded and transcribed verbatim, which facilitated an in-depth and iterative analysis.

5.5.5 Limitations

On the other hand, this study has several limitations. The study took place in one hospital site in Oxfordshire, UK, with low ethnic diversity and socioeconomic deprivation. The majority of women screened for this study did not meet the BMI inclusion criteria, and the majority of participants were highly educated, and only a few women were of non-White ethnic backgrounds, which echoes previous experience that women with higher education, and of White ethnicity, are more likely to take part in research (514). As a result, the findings of this study may not be generalisable to other ethnicities and socioeconomic groups who have higher risk of obesity and GDM than participants in this study.

In addition, similar to some previous studies (143, 228), large numbers of women had to be approached to recruit the sample, and I had to end recruitment at 51 of the originally planned 60 participants. Slower recruitment could be due to a number of factors, such as recruitment from only one hospital site, and lower rates of obesity in the study setting, however, the reluctance of women with obesity to take part in complex behavioural interventions during pregnancy is also previously known and was expected (515). The exact reason why most women declined participation was unknown, because the majority did not respond to my contact, or did not specify the reasons for not being interested, but some eligible women who declined, reported competing priorities, making it difficult to commit to an extra 3-hour study visit, on top of making dietary changes and self-monitoring. Qualitative reports suggest that women are more likely to take part in lifestyle interventions if approached directly by their immediate clinical care team (515). Although I did involve sonographers into encouraging women to speak to me about the study, they were not part of women's immediate clinical team, and not everyone was able to do this, due to time constraints or reluctance to recommend a dietary intervention or discuss about weight. Thus, the extent to which involving other HCPs actually helped with recruitment is unknown. With these practical limitations in mind, I also sought help from a qualitative researcher to improve my conversation with potential participants. More specifically, after a month of very low recruitment around Christmas time, I amended my "recruitment script" to make it a more flexible conversation around what people already knew and what they wanted to know, rather than bombarding them with information. I emphasised collaboration, by explaining how they could help the study and other women in the future, as well as what the benefit for themselves would be by taking part. This shift seemed to make conversation more engaging and seemed to have made women think more carefully about the study, but it is unclear to what extent it helped recruitment rates. Future trials would need to pay more careful attention to recruitment rates.

The small sample size in this study benefited a feasibility trial, however, this also meant that I was unable to assess any subgroup effect of background dietary intake prior to the study, or whether

attendance, ethnic origin, or socioeconomic factors affected the adoption of the diet, or if biomarkers of glucose control and insulin resistance at the study could predict the subgroup of women in whom the intervention could show clinical benefit.

The dietary data suggested that women in the intervention group overall did not adopt the diet, despite the mostly positive experiences they reported. However, I only assessed their dietary intake on 2 days (baseline and follow-up visits), which may have induced a large amount of random error in estimates, and may not have reflected habitual intake over time (516, 517). Ideally, I would account for the effect of within-subject variability in intake by administering a larger number of 24-hour recalls, would assess intake both on weekdays and weekends, but I chose to not burden participants further with study assessments, as they were already required to commit to weekly self-monitoring of biomarkers, with intervention also needing to self-weigh each week and change their diet. Alternatively, I could have used a Food Frequency Questionnaire to assess habitual dietary intake, like in most previous trials, but at the time, I thought that an online 24-hour recall would help more accurately choose the portions consumed, and that carbohydrate foods are present in the diet on a daily basis, therefore, any recall would be a good representation of habitual intake. Weight measurements indicated that women in the intervention group gained less weight than those in the control group, despite the study not being powered to detect statistically significant differences, and although this was a lower-intensity intervention than previous ones, it led to greater attenuation of GWG. Thus, I cannot preclude that women in the intervention group indeed had better adherence to the diet than reflected in the data. An additional limitation is that I was unable to reliably determine (e.g. Goldberg cut off method (518)), which participants may have under-reported their dietary intake, due to the small sample size.

Error may have affected weight measurements that participants in the intervention group completed at home, but I tried to mitigate this through providing clear instructions on taking a measurement, and use of digital scales. Error variance might also have affected biomarkers measured

at home. Although I asked participants to take these measurements in a fasting state first thing in the morning, I did not ask them to fast for specific amount of hours before taking measurement, so the length of time in a fasting state would have varied according to each person's circumstances and lifestyle. However, I asked all participants about the usual time that they ate or drank something before bed, and when the first time they ate or drank the next day was, and for all participants, this was at least an 8-hour interval. Error variance is less likely to have affected OGTT results, because all participants were sent the same instructions about preparing for the OGTT from the night before, and the time of attendance was similar among participants. Random error was also introduced in measuring blood pressure because sometimes we could only get one measurement if the participant's arm diameter was large, as well as in measuring insulin levels, because sometimes the blood was haemolysed. What is more, in some participants, it was impossible to get some measurements. For example, those completing OGTT results with their clinical care team, are missing 1-hour glucose and markers of insulin resistance, and for them, only one blood pressure measurement was available from their most recent midwife appointment. A last source of measurement error might have occurred through data entry. All data was manually inserted in a bespoke database, apart from the dietary data which were automatically available from the software. This task involved transcribing a large number of data points and is likely to have introduced some human error. To mitigate these errors, I used range checks and other diagnostic tests before locking the database.

It is inherently impossible to blind participants to behavioural interventions. This means that some of the effect achieved could be the result of the novelty of the intervention, which may fade over time. In addition, there was a potential contamination rate of 33% in the control group. This could be the result of non-blinding and being prompted by the information about the study, which indicated that a reduced-carbohydrate diet was being tested. However, there could be plenty of reasons for contamination, which are largely unknown because I did not ask participants in the control group directly if they changed their diet because of enrolling into the study, although a few mentioned by

themselves that they became more mindful of their eating just by taking part in the study, and monitoring their blood glucose.

Another limitation is that I ran and managed the whole study by myself. I was the only person to be in touch with participants throughout the study, which might have created an increased sense of accountability. Indeed, in the qualitative interviews, some participants expressed that they wanted to do well for the research and for me. Although I took measures to mitigate this, for example by asking participants' honest feedback, asking open ended questions, and avoiding questions of evaluative nature, it would have been ideal to let an independent researcher conduct qualitative interviews. However, this was not possible within the constraints of my DPhil. Another issue created by being the sole researcher conducting the study was that I was not blinded during the quantitative analysis.

My qualitative study was also subject to some methodological limitations. For example, I did not pilot the interview topic guide with other people before commencing this study, which may have been useful in checking whether the questions made sense to interviewees and were able to raise a range of insights. This may have led to instrumentation bias (519, 520). In addition, my qualitative analysis may have been affected by biases introduced by my subjective perceptions. For example, I was both the interventionist and the interviewer, which may have led me to seek positive feedback on the intervention, or be influenced by my pre-existing hypotheses about potential themes and about how the intervention might have affected the participants. However, I was aware of this, and kept a reflexivity log which I discussed with my supervisors, and I actively tried to recruit participants who I knew had difficulty in adhering to the intervention (521). A key limitation, is that I made the pragmatic decision to analyse the interviews by myself, without a second researcher duplicating my work. As a result, I could not compare my coding frame and analysis with a second researcher, which may have compromised the validity of my results. To mitigate this, I endeavoured to check the consistency between the data and the codes, categories and themes, and iteratively update my analysis to better

reflect the essence of the data (501). My personal capability and interpretation might also have influenced the results of the qualitative study. My training before this DPhil was solely quantitative, and this was the first type of qualitative work I ever did. I read textbooks on qualitative research, completed a 5-day qualitative course, and after the first few interviews, an experienced qualitative researcher assessed the audio-recordings, in order to help me improve the quality of my interviewing skills (e.g. how to not ask composite or suggestive questions). I received good feedback however, about my ability to be patient, and allowing time to answer. I found that with time and practice, I overcame initial difficulties, however, at the point of analysis, I realised I should have prompted more on certain issues, and asked some questions differently to elicit the information I needed. In a future study, I would ideally conduct some preliminary analysis alongside running interviews. Moreover, although the interviews captured a range of experiences, they were not designed to estimate how prevalent these experiences were in the sample. As a result, I cannot preclude the possibility that some of the themes I identified, only represent the experiences of a small sub-sample of intervention participants. Nevertheless, it was not the purpose of this qualitative study to generate a detailed account of the prevalence of experiences, but rather to explore ways through which the intervention might have worked, and aspects I could refine. Another limitation of this sub-study was that I needed to complete data collection for the main trial earlier than planned to allow me to analyse the data in time for writing up my thesis. This may have compromised the purposeful sampling strategy I originally planned, as I ended up interviewing the first 16 participants that completed the intervention. Although I reached information saturation, those who agreed to be interviewed, might have done so because they felt particularly positively about the intervention or they might have been systematically different from those who were not given the opportunity for an interview in respect to other characteristics. Finally, like with the results of the main study, the qualitative findings are not necessarily generalisable, because the sub-sample of participants being interviewed were primarily White and well-educated volunteers residing in Oxfordshire. People from other social or cultural backgrounds may have perceived the intervention differently.

5.5.6 Conclusions and implications

This study had excellent retention rate, but according to the pre-specified criteria, did not succeed in significantly reducing total carbohydrate intake overall in women with obesity at risk of GDM. It was clear from the quantitative and qualitative analyses, that adherence to the intervention varied. Although most participants made dietary change, they could not all sustain them towards later stages of pregnancy, or alongside competing priorities. While this evidence alone is insufficient to progress to a definitive trial, the secondary and exploratory analyses suggest that this intervention may be worth refining and retesting in a feasibility trial. In such a trial, I would want to apply some opportunities for improvements that I identified throughout the discussion (detailed in Chapter 6), as well as find new ways to improve recruitment rate, and reinforce adherence to the diet. In a future such trial I could also explore the value of self-weighing independent of the dietary advice.

Chapter 6: Discussion

6.1 Summary of thesis findings

In the introduction chapter (Chapter 1), I presented an overview on knowledge to date around GDM, the most common pregnancy complication. I identified that the full burden of the disease is not known. GDM is an established risk factor for future T2DM in the mother, but there is also increasing evidence that it increases the risk of future CVD. However, the magnitude of the long-term effect of GDM on CVD events remains unclear due to heterogeneity in findings from large observational cohort studies, and inadequate exploration of confounding and mediating pathways explaining the observed associations. In addition, the association of GDM with future development of other CVD risk factors, such as hypertension and dyslipidaemia, is less well documented, while I could not identify any literature on the longitudinal association of GDM with maternal all-cause mortality. My analysis of data from the UK Biobank in Chapter 2, is the first to show that women with a history of GDM had a substantially increased risk for premature death, compared to women without GDM. My analysis confirmed existing literature that GDM increases the risk of subsequent CVD (47), and incident common CVD risk factors (diabetes, hypertension, dyslipidaemia) (43, 44, 252), but showed no evidence that these mediate the CVD incidence. Importantly, the impact of GDM on CVD risk was higher in women with a more favourable cardio-metabolic phenotype (e.g. those who did not subsequently develop diabetes, hypertension, or dyslipidaemia, of younger age groups, and with lower BMI). These findings made me think that all women with GDM should be considered to be at risk of cardio-metabolic disease later in life, and should be regularly monitored. It is also imperative to find effective ways to prevent GDM in the first place. This led to the idea of developing an intervention to help women with obesity who are pregnant, to control their GWG and glycaemia during pregnancy, to reduce their chances of developing GDM. Since diet affects both weight and blood glucose levels, and given that physical activity may decline as pregnancy progresses (ref)(255),

I opted for a dietary only intervention to start with, though if effective, it could in due course be combined with any intervention shown to increase physical activity.

In designing the intervention programme, I thought about how I could increase participant engagement and adherence to the programme, to support dietary behaviour change and GWG control. Qualitative evidence from the field of obesity, both in and outside of pregnancy, suggests that boosting intrinsic motivation is an effective strategy to help people change their diet and manage their weight (327-331). I therefore systematically reviewed evidence on the effectiveness of MI as a counselling style, in the management of excess weight, to eventually assess if it could be a potential component in my intervention. I also looked at whether this style of counselling might improve psychological well-being, such as anxiety, depression, and quality of life, given the bidirectional association with obesity (343). I found that MI is not a worthwhile addition to BWMPs, as it only leads to a very small additional weight loss benefit when compared to no/minimal intervention, and no difference when compared to other BWMPs without MI. Moreover, it requires extensive interventionist training, and increased contact time, which make it impractical for adoption in routine antenatal care, where there are already workforce shortages, and many competing demands on the time available to spend with each woman.

From the literature review, I also identified that dietary and weight management advice offered in current antenatal care, is limited. Clinical trials of interventions to limit GWG in women with overweight and obesity during pregnancy, have mostly failed to reduce GDM incidence (224, 234). I presented a small number of trials which showed effectiveness in GDM prevention, but these included intensive face-to-face dietetic support, and in some cases provision of key foods to participants, which would not be feasible in the current routine antenatal care (225, 228, 232, 239, 240). My DPhil sought to address the need for effective dietary interventions to help prevent GDM which are easy to follow, and can be delivered as part of, or alongside routine appointments, and without major training and resources required. I chose to intervene on reducing total carbohydrate intake, because it is the

nutrient primarily determining energy intake and blood glucose levels, and reduced consumption has been shown to help people with T2DM and established GDM in controlling their weight and glucose levels at least on the short-term (201, 202, 253). In Chapter 4, I presented the detailed design of a moderately reduced-carbohydrate intervention (RECORD), suitable for use in pregnancy, to avoid the risk of weight loss and ketosis, as well as how I developed the behavioural component using behavioural mapping on the BCW (522), evidence from qualitative research, and feedback from a PPI exercise. The diet was based on three easy principles (the 3R's: Refrain, Reduce, Replace), and the intervention package combined an one-off dietary consultation from a HCP (myself), with structured written materials for dietary and behavioural control, remote support for engagement as required, and weekly self-monitoring of weight.

In Chapter 5, I described the protocol and running of a small trial testing the feasibility of delivering the RECORD intervention from early- or mid-pregnancy until delivery, in women with obesity at risk of GDM, alongside routine antenatal appointments. The trial did not meet pre-specified progression criteria for a full RCT, with regards to adoption of the diet, as the reduction in carbohydrate intake in the intervention group at follow-up was highly variable, and on average, small. The study was not powered to detect effectiveness in other outcomes, however, there were encouraging results with regards to potential effects on secondary and exploratory outcomes, including GWG, blood glucose from OGTTs, and blood pressure. Retention of participants was excellent, but there were practical issues with recruitment, as a disproportionately large number of women needed to be approached to recruit a small sample size, echoing previous UK prevention trials (143, 228).

I also present qualitative interviews exploring participants' experiences of the RECORD programme and study. Participants generally reported a positive experience from attempting to follow the diet, and were content with the study processes, especially self-monitoring of biomarkers and weight. However, some women reported some barriers in their ability to adopt the diet, mainly

competing priorities and psychological relationship, which should be taken into account in the design of better future interventions.

Drawing on quantitative and qualitative data, I discuss potential opportunities for improvement in section 6.4.

6.2 Strengths and limitations

6.2.1 Strengths

Before setting out the aims and objectives of this thesis, and the individual studies, I conducted a comprehensive literature review, synthesising the vast amount of conflicting and inconclusive evidence available around diet, weight, and GDM. I identified important research gaps (section 6.2), which make my DPhil research novel.

In addition, while it is not clear whether theory-based interventions are actually more effective than non-theory based interventions, the research community is calling for more theory-based interventions (432). However, many health behaviour interventions are not theory-based (523), and of those which are, many to not fully apply it, do not describe how they used it, or add components to the intervention that do not align with the theory (523). A strength of my work is that I developed the RECORD intervention by drawing upon the BCW, which incorporates many behavioural theories, and offers a systematic way of considering aspects of the intervention from the participant and interventionist perspective, and practical considerations. RECORD was mainly based on principles of self-regulation theory, supporting participants in changing their diet and managing their weight during pregnancy, despite the obesogenic environment and demands of pregnancy. Although I did not specifically explore whether participants went through the whole self-regulation process, I used all self-regulation-related BCTs during dietary consultations, keeping unrelated BCTs to a minimum.

Another strength of this work is the use of mixed methods. Across my studies, I drew from insights generated through a big data project, a systematic review of clinical trial evidence, behaviour

change theories, PPI, a feasibility RCT, and semi-structured qualitative interviews. Drawing insights from these sources enabled me to better understand the determinants of dietary intake during pregnancy, and the mechanisms through which behavioural interventions could help women reduce their carbohydrate intake specifically, or eat healthier in general. For example, combining the findings from my RCT and qualitative interviews, allowed me to better understand how RECORD delivered impact, and where opportunities for refinement of the intervention and the study processes lie.

6.2.2 Limitations

A general limitation of both the UK Biobank analysis and the RECORD trial, is that the generalisability of the results is restricted. Both studies overrepresented women of White ethnic background, highly educated, with high socioeconomic status. The obesity and GDM prevalence is higher in people of non-White ethnicities and of lower socioeconomic status (5, 524), and these groups are less likely to receive or access BWMPs in the first place (525, 526). Even though the UK Biobank analysis covered a big sample, the small prevalence of GDM in this cohort meant that the analysis was not adequately powered to detect interactions between history of GDM and participant characteristics, including ethnicity and socioeconomic status, with small number of cases in each category. Accordingly, in the RECORD trial, due to the small sample size, I could not examine differences in effects by ethnicity or socioeconomic status, although, a previous weight management self-regulatory intervention, showed no evidence of difference in effects based on education (527). Even the theories I used to structure my research and develop my intervention, were informed by highly educated academics and HCPs, and the PPI feedback I obtained came from well-educated White women. However, the small number of non-White women who took part in the RECORD trial, were able to adjust the dietary principles to their cultural preferences, which suggests that the RECORD diet is versatile. Nevertheless, these women did express that they would find it helpful to see more tailored suggestions of meals in the handbook and recipe book, and so if the RECORD diet were to be tested again in a refined version, promoting it in lower socioeconomic settings, and in a more culturally diverse version would be a priority.

6.3 Implications for research, policy, and practice

6.3.1 Timing of intervention

The lack of effective scalable interventions in pregnancy for the prevention of GDM, suggests that such interventions may be more successful if delivered before pregnancy, so that women can adjust to the changes while still not facing the demands of pregnancy. For example, there is evidence that interventions of lifestyle and metformin in people with overweight outside of pregnancy, are effective in reducing the risk of diabetes development, with lifestyle interventions being more effective than metformin (528). Accordingly, substantial weight loss has been shown to reverse diabetes (419). Therefore, future research could evaluate the effect of interventions in the pre-conception period in women with obesity, on GDM risk (529). Such interventions could follow the example of RECORD by addressing weight and glycaemia through a reduced-carbohydrate intervention, although the aim would be to induce weight loss. Nevertheless, the pre-conception period is not always easily determined, and some pregnancies are unplanned, thus, the next best available opportunity to prevent GDM would be as early in pregnancy as possible, like all successful prevention trials to date have shown. If the intervention is delivered by the immediate clinical team (e.g. midwives), application could be possible from as early as the booking appointment.

6.3.2 Recruitment

Challenges to recruitment for my feasibility trial were bigger than anticipated, despite taking a number of measures, including planning the approach and recruitment to coincide with a routine scan, asking sonographers to briefly introduce the study, requiring only one extra visit, offering flexibility to complete consultations and assessments remotely, offering remote support with the diet throughout pregnancy, improving my recruitment script, and providing reimbursement and transport. The vast majority of approached women who did not take part, did not respond to my contacts, therefore, the exact reasons of reluctance to take part in this dietary intervention are unknown. Some women reported feeling overwhelmed already by demands of everyday life and pregnancy, and felt they could

not commit to the increased number of tasks required for this study. Some qualitative reports also showed that some participants were primarily preoccupied with the viability of pregnancy at the time point of approach, or that changing their diet seemed at first as a big undertaking and transition. The above, in combination with my feeling while approaching women, and data from literature of successful recruitment approaches, helped me identify potential improvements to recruitment for any future trials of early lifestyle intervention in women with obesity.

- **Recruitment should be from multiple sites** with higher numbers of women at risk of GDM.

- **Building trust with the research team is imperative**. This could involve improving the visibility of the research conducted, and research team (e.g. through advertisements, leaflets and videos in waiting areas), testimonials from previous participants, advertising the study safety, and approaching hard-to-reach communities through gate-keepers (530).

- **The immediate clinical care team** (e.g. midwives) that women are in frequent contact and have developed rapport with from the start of pregnancy, **could promote the study** (531). This may be even more effective if the immediate team is the one delivering an intervention.

- Research can explore **effective ways to engage family or friends in the recruitment process** (531).

- Allowing study **visits** to take place **over the weekend**, or offering **home visits**, adapting the intervention and study processes to be conducted **remotely** (phone/mobile applications/video), or **offering child care**, may ease the burden of having to make special arrangements (531).

6.3.3 Intervention content

Although my findings do not support the usage of the RECORD intervention in its current form, I gathered some potential ideas for its refinement, which can permit further testing in another feasibility trial. These considerations, could also be taken into account while designing dietary interventions in women during pregnancy in general.

- **Small, gradual goal setting** should be an integral part.

- **Dietary principles which are easy to remember,** accompanied by **clear, specific messages** around food choices, are needed, instead of general healthy eating information. Also, more work needs to be done on tailoring set principles according to an individual's circumstances and preferences (e.g. shift work), cultural background, and preferences. Specifically dedicated sections in handbooks could address these.

- **Available list of strategies, may support women in dealing with challenges:**

  Most participants reported some effective strategies which helped them stick to the diet (e.g. having sugary treats less often and in smaller amounts, snack swaps, sharing a dessert), but the extent to which these were adequate to avoid relapse is unclear. The qualitative interviews indicated that participants like having options, therefore, this strategy could be extended, not only to more appealing meal and snack ideas, but also to options for actions that each individual could choose on a daily basis to help them ultimately form their own diet and weight management plan. For example, a previous weight management self-regulatory intervention in a non-pregnant population with obesity, showed that planning daily actions for weight management enhanced the self-regulation process into identifying effective and sustainable action plans (527). Accordingly, the independent role of self-weighing, on top of dietary changes, on GDM risk, could be explored in future studies.

- **Interventions should be mindful of and sensitive to weight stigma:**

  During the consultations, all participants mentioned past experience with dieting. In the qualitative interviews, some participants reported feeling uncomfortable with their body size, or being identified as “the big person in the room”. In addition, it is known from the literature (although participants did not explicitly state it), that some women have memory of negative experiences of discussions with HCPs about their weight or experiencing weight stigma, which have been reported as a barriers to weight management (461). None of the women in this study reported feeling stigmatised from this intervention or from the interventionist HCP (myself), which could be because I kept reminding participants that obesity is not personal responsibility, and that weight gain is normal during pregnancy. I was also mindful of using non-stigmatising person-first language (e.g. people living in larger bodies). When participants gained more weight than expected, I avoided blaming them for it, and instead I discussed potential solutions on how participant could best, but at the same time realistically, adhere to their dietary goals, and reassured them that weight would be controlled by doing so. Future studies could investigate how women with obesity who are pregnant would best like to discuss about weight with their HCPs, similarly to what has been done before for the general population (532). Attention may need to be given to specific training for HCPs to minimise weight bias. What is more, using food to deal with emotions was also common among participants, and my intervention tips did not help to completely avoid this.

- **Interventions need to tackle deeper psychological determinants of obesity**, rather than just implementing sole behaviour change strategies, such as using cognitive behavioural therapy (533).

- **Social support may need to be more effectively utilised:**

  Women in the RECORD diet group placed high importance in the value of social support in their efforts to follow the diet. Having understanding from family and friends, or having them on board following the same programme was a major facilitator. Indeed, when individuals attempt weight management programmes together with others (known or strangers), they find it easier to adhere to a programme, as they share a common goal and feel accountable to each other (534-536). Future interventions could explore how to make more extensive and effective use of social networks, especially during challenges.

- **Effective ways to motivate women to take preventative action towards GDM, and to frame and communicate prevention messages are needed:**

  Through qualitative interviews, it was evident that drop in motivation for sustaining dietary changes as pregnancy progresses was a barrier towards adherence to the RECORD diet. At the intervention development stage, I had considered incorporating specific motivation components, such as MI, but decided against this, because my systematic review showed no evidence of independent effectiveness of MI in BWMPs, and besides, it could increase the burden of the intervention, which was already considerable given the number of tasks participants were asked to complete. As a result, I just addressed motivation by asking participants to list the reasons why they wanted to change their diet, and by reminding them of those reasons during support sessions. During telephone sessions, I also used encouragement, enhancement of self-efficacy, constructive feedback, and problem solving. Even though none of the intervention components specifically addressed motivation, participants following the RECORD diet expressed a number of components which drove their motivation to engage, namely measurable successes, perceived physical and psychological benefits for them and their family, and social support, on top of already existing factors such as feeling accountable to the unborn baby, and wanting a healthy pregnancy. The verbal

feedback I provided in support sessions might also have had such a motivational impact, as discussed in Chapter 5. However, for a sub-sample of participants, these factors were not enough to help them keep up the changes. Indeed, there is evidence that, despite strong motivation and intentions, individuals may fail to apply action plans during the self-regulation process, when they feel overwhelmed by constantly practising self-control and in response to triggers, such as temptations (537).

An option could be to make the dietary changes as effortless as possible, by encouraging the formation of habits, by repeating changes consistently and in the same context, so they become ingrained in people's routine without requiring mental effort or motivation (538). In the RECORD trial, I prompted participants to identify actions that work for them and practise them on a daily basis, but I did not go much into the consistent context required as I had originally planned, because during the brief support sessions, participants reported doing either really well, with small help from me required, or were resistant in changing (e.g. we addressed what to eat in from of the TV which comprises a consistent context, but they were attached to their habit of having sugary snacks or crisps), or were unresponsive to my contacts. Those who were successful in changing, did mention that the changes had become a routine after a few weeks of practising them, but I am unsure whether participants fully applied habit formation, and therefore there is scope to further explore its specific role in future pregnancy interventions. Habit formation could also facilitate sustained adherence until later stages of pregnancy, when women get tired of being pregnant, as well as beyond pregnancy.

Finally, while some women feared GDM and were ready to take any action to avoid it, a few expressed beliefs showing that they did not realise the severity of GDM and the importance of preventing it. Interestingly, one participant who did not follow the intervention due to emotional relationship with food, mentioned that she may have been committed to reduce her carbohydrate intake if her clinician or midwife, had talked to her about the risks of

GDM and what it means for her and the baby since early on, and advised her to reduce carbohydrate-rich foods. In past qualitative interviews, HCPs working in maternity reported perceptions that due to differences in communication strategies among HCPs some women perceive the severity and demands of GDM, while others perceived GDM as insignificant (539). The above potentially confirm my earlier suggestions, that although the advice was given by a credible HCP (myself), receiving the advice from the immediate clinical care team and as part of the whole pregnancy plan, rather than something that is offered on the side, may be an effective strategy.

- **Practical considerations:**

  There were a few easily fixable practical downsides to the intervention that participants mentioned during their qualitative interviews. For example, participants with specific dietary requirements (e.g. coeliac, vegan), would welcome materials and meal ideas that are specifically tailored to them. Some women identified as "foodies", and were particularly attached to their favourite recipes, and wanted more ideas on how to adapt the meals they usually choose. Others would welcome more practical strategies around portion control such as dry weight of carbohydrate foods that make a recommended portion of cooked food. A useful strategy for future interventions might therefore be to involve participants and PPI into sharing success stories or recipes to inform the content of the intervention, so that it is relevant and appropriate across a wider range of people. Finally, none of the participants used the written behavioural materials on goal setting, monitoring and action planning, partly because progress and clear plans were discussed during the support sessions, but also because they already receive a lot of information and materials, which felt overwhelming. In a future intervention, I would continue to ensure behavioural support is mostly offered during sessions with the HCP.

6.3.4 Personal reflections

Lastly, there are some personal random experiences of conducting this DPhil, that although are not necessarily reflected in data, I feel are important to report, as they complement my findings, and help future research. For example, some participants tended to rush through support sessions. It felt like they were not particularly engaging, but completed them just because they had committed to do so by taking part in the study. In addition, some participants tended to report during the support sessions, that they felt they had made some changes they were happy with, and there is nothing else they could improve, therefore, I felt there was nothing else I could offer them. These participants were among those who did not substantially reduce their carbohydrate intake at follow-up. I feel that the fact that I was not a member of participants' immediate clinical team may have played a role in this, aside from challenges that participants faced in adhering to the diet. I had excellent relationship with all participants, but from some conversations, it seemed that it was their midwife who they talked to the most during pregnancy. Also, the fact that I am a young academic female researcher with a normal BMI, and no experience of pregnancy, may have created some distance between us, which may have been accentuated by the fact that I am also a dietitian, and participants may have had negative experiences with dietitians in previous weight loss attempts. It is conceivable, that these may have affected the impact I had on persuading participants, and on how comfortable they felt opening up to me. I tried to overcome these challenges, through my empathetic approach and non-judgemental counselling, but if the intervention were to be re-tested, I would have attempted to recruit participants' midwives to deliver it. Finally, women in the intervention group who found it challenging to follow the diet principles, if diagnosed with GDM, tended to then be extra mindful of their carbohydrate intake. I noticed this from dietary reports they submitted through a blood glucose monitoring application that the diabetes team provided. Seeing out of range glucose measurements after high carbohydrate intake, seemed to trigger in itself self-regulation processes and made them realise the importance of carbohydrate control. It seemed that having the disease made these

participants actually realise their risk. This further supports my suggestion above about need of effective ways to make women aware of the importance of preventing GDM.

6.4 Conclusion

Taken together, the research presented in this thesis has helped to advance the field of GDM research in the context of its long-term consequences, and behavioural interventions for its prevention. I conclude that women with obesity need to be informed of, and better understand their risk of GDM and what the short- and long-term consequences are for them and their children. Once GDM has developed, it is crucial that women are followed-up in the years post-partum for T2DM as well as CVD risk detection, and effective interventions should be offered as early as possible. Most importantly, efforts should still be made to prevent GDM in the first place.

Running a feasibility trial in women with obesity at risk of GDM, and delivering a reduced-carbohydrate intervention aiming to achieve GWG and blood glucose control from early or mid-pregnancy, to help reduce GDM risk, was challenging in terms of recruitment, and the adoption of the diet was variable, but on average poor. However, I identified a number of opportunities to achieve better recruitment rate, and reinforce motivation and adherence to the diet. Although the diet in its current form was not feasible, potential benefits on GWG were encouraging, and participants' experiences showed that the diet was overall acceptable, and they were happy to engage to the study's processes, such as regular self-weighing. Therefore, I believe that the intervention and processes could be refined and explored in another feasibility trial, in particular to dissect the effects of self-weighing from the dietary advice.

My research combined findings using different methods, samples, and settings, which strengthens the trustworthiness of my results. My findings have significant implications for dietary behavioural interventions in women with obesity during pregnancy, not just for GDM prevention. Diet is an important modifiable risk factor to improve outcomes in pregnancy, so by providing clear

pointers for further research opportunities and for practice, I hope this thesis helps to further the development of effective interventions supporting women during pregnancy to improve their diet.

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Appendix 1.1. Characteristics of some previous GDM prevention trials

	Participants		Interventions						
Study	**Eligibility**	**Baseline glucose test (e.g. OGTT, fasting glucose)**	**Content**	**Provider**	**Mode**	**Level of personal contact**	**Sessions**		
							N	**Frequency**	**Length per session**
Luoto 2011 (505) Finland	At least one of: -Pre-pregnancy BMI ≥25 kg/m^2 -Previous GDM or glucose intolerance in previous pregnancy or macrosomic baby - Family history of diabetes (first- or second-degree relative	Yes: 11.5% abnormal	**Control:** Usual care, which includes some dietary counselling and little PA advice	Nurses	Individual	Face-to-face	Unclear	Unclear	Not reported
			Intervention: Leisure PA advice as per national recommendations, with progressive increase to 800 MET minutes + Dietary advice based on national recommendation: consume 5 portions of fruit and vegetables/day, wholemeal products, fat-free or low-fat milk, milk alternatives and mean, eat fish twice a week, moderate amounts of soft table spreads, oil in cooking and baking, seldom consumption of high-fat and sugary foods (≤10% energy intake from saturated fat, 5-10% popyunsaturated fat, 25-30% total fat, <10% saccharose , 25-35 g/day fibre) + Weight gain recommendations (IOM)	Nurses	Individual with option for PA group meetings	Face-to-face	5	Unclear, but PA group meetings were monthly	120 min
Poston 2015 (143) UK	15-18 weeks' gestation Aged >16 years BMI ≥30 kg/m^2 Singleton pregnancy	No	**Control:** Standard antenatal care						
			Intervention: Healthy eating, not necessarily reducing energy intake, adjusted to individual diet and culture, swapping carbohydrate-rich foods with a medium-to-high GI, with lower-GI foods, and reducing saturated fat + PA advice on incremental increases in walking at a moderate intensity, with additional options for women already engaging in some PA	Health trainer	Individual	Primarily face-to-face, but also telephone or email if missed a session	8	Weekly	60 min
Koivusalo 2016 (225) Finland	Planning pregnancy or <20 weeks' gestation Pre-pregnancy BMI ≥30 kg/m^2 and/or history of GDM	Yes: 34.6% abnormal	**Control:** General information leaflets on diet and PA + Health education as part of usual care	Study nurses	Individual	Leaflets	3 during pregnancy, but for study assessments (on	Every 3 months during pregnancy (but for study assessments)	Not reported

	Participants		Interventions						
Study	**Eligibility**	**Baseline glucose test (e.g. OGTT, fasting glucose)**	**Content**	**Provider**	**Mode**	**Level of personal contact**	**Sessions**		
							N	**Frequency**	**Length per session**
	Aged ≥18						top of antenatal appointments)		
			Intervention during pregnancy: Advice to not gain weight during the first two trimesters if BMI ≥30 kg/m^2 + Dietary advice based on national recommendations: optimising fruit and vegetable consumption, whole-grain products, low-fat dairy, vegetable fats, fish, and low-fat meat, reducing sugary foods, following the plate model (half vegetables, quarter starchy foods, quarter protein foods). (1600-1800kcal/day, 40-50% of energy from carbohydrates, 30-40% fat, and 20-25% protein) + Group session with a dietitian + Minimum of 150 minutes of moderate-intensity PA/week, with planning and updating an individual PA programme.	Study nurses and dietitians	Individual and group	Face-to-face	At least 3 (on top of antenatal appointments): 1 group session + 3 study visits, with additional visits if needed (e.g. if goals were not met)	Every 3 months during pregnancy	Group session: 120 min Individual sessions: not reported
McCarthy 2016 (480) Australia	Booking or early pregnancy BMI ≥25 kg/m^2 <20 weeks' pregnancy Aged ≥18 years Singleton pregnancy English speaking	No	**Control:** Information card on targets for GWG + Self-referral or professionally initiated referral to the hospital dietitian was available, but research staff did not initiate this.	Research midwife, but discussion of weight gain with doctors and/or midwives at antenatal appointments	Individual	N/A	N/A	N/A, just follow-up was as part of usual care.	N/A
			Intervention: Serial self-weighing + Simple dietary and weight management advice based on national healthy eating recommendations + Self-referral or professionally initiated referral to the hospital dietitian was available, but research staff did not initiate this.	Research midwife, but discussion of weight gain with doctors and/or midwives at antenatal appointments	Individual	Face-to-face		Weekly self-monitoring + One-off dietary consultation Follow-up was as part of usual care.	Self-weighing: N/A Dietary consultation: 30 min

Study	Participants		Interventions						
	Eligibility	Baseline glucose test (e.g. OGTT, fasting glucose)	Content	Provider	Mode	Level of personal contact	Sessions		
							N	Frequency	Length per session
Bruno 2017 (239) Italy	Pre-pregnancy BMI ≥25 kg/m^2 Aged >18 years Singleton pregnancy 9-12 weeks' gestation	Yes: no % of abnormal OGTT given	**Control:** PA advice based on ACOG recommendations on 150 minutes of moderate-intensity activity/week + General recommendations on diet and PA based on national guidelines: avoid foods with high GI, reduce saturated fat, increase vegetable and fruit with low GI, but no specific indication on food quantities, caloric intake, meal composition, or meal distribution	Dietitian	Individual	Face-to-face	1 counselling session	One-off counselling session Study follow-up visits at 16, 20, 28, and 36 weeks' gestation	60 min
			Intervention: PA advice based on ACOG recommendations on 150 minutes of moderate-intensity activity/week + Personalised dietary intervention: low-GI diet, low saturated fat intake, 1500 kcal/day with extra 200 kcal/day and 300 kcal/day for women with obesity and overweight due to giving PA advice, based on consumption of plant foods, cereals, legumes and fish, with olive oil as the main source of fat, and moderate to no consumption of red wine. Goal was for 3 main meals and 3 snacks giving 55% of total energy from carbohydrates (80% complex, 20% simple, but minimum 225 g/day), 20% protein, and 25% fat.	Dietitian	Individual	Face-to-face	1 initial counselling session + 4 follow-up counselling sessions	Counselling at enrolment, and then at 16, 20, 28, and 36 weeks' gestation	Initial counselling: 60 min Follow-up counselling: not reported
Al Wattar 2019 (228) UK	Singleton pregnancy <18 weeks' gestation Aged ≥16 years High risk of pregnancy complications: any obesity, or raised serum TGL, or chronic hypertension	No	**Control:** Usual dietary advice as per national guidelines on antenatal care, weight management, and hypertension in pregnancy						
			Intervention: Dietary education for Mediterranean-style diet: high intake of fruit and vegetables, non-refined grains, legumes, moderate-to-high consumption of fish, small-to-moderate intake of poultry and dairy, low consumption of red and processed meat, avoidance of sugary drinks, fast food, and food rich in animal fat, high intake of nuts (30 g/day), and high intake of extra virgin olive oil as the main source of fat (0.5 L/week) + Grocery shopping advice +	Dietitian or trained allied health professional	Individual and group	Face-to-face group, and telephone individual sessions	3 face-to-face + 2 telephone	Face-to-face sessions at 18. 20, and 28 weeks' gestation, and telephone sessions at 24 and 32 weeks' gestation	Not reported

	Participants		Interventions						
Study	**Eligibility**	**Baseline glucose test (e.g. OGTT, fasting glucose)**	**Content**	**Provider**	**Mode**	**Level of personal contact**	**Sessions**		
							N	**Frequency**	**Length per session**
			Cooking recipes for a healthy diet + Advice for appropriate meal choices at restaurants + Group sessions, with encouragement to involve partners and family + Provision of nuts and olive oil throughout the study						
Assaf-Balut 2017 (232) Spain	8-12 weeks' gestation at first gestational visit, and 12-14 weeks' gestation at first study visit Aged ≥18 years Singleton pregnancy Acceptance and consent of participation in the study	Yes: no % of abnormal fasting blood glucose given	**Control:** Mediterranean-style diet recommendations: ≥2 servings/day of vegetables, ≥3 servings/day of fruit (avoiding juices), 3 servings/day of skimmed dairy, wholegrain cereals, 2-3 servings of legumes/week, moderate-to-high consumption of fish, low consumption of red and processed meat, avoidance of refined grains, processed baked foods, pre-sliced bread, soft drinks, fresh juices, fast food and precooked meals, with key recommendation to restrict consumption of dietary fat, including extra virgin olive oil and nuts + Individualised dietary advice at each visit according to GWG (e.g. reduction in calories if excessive GWG) + Walk at least 30 minutes/day	Midwives	Unclear, but suggestive of just individual	Face-to-face	4	Dietary advice 1 week after enrolment + Nutritional reinforcement at standard routine care appointments: at 12-14, 24-28, and 36-38 weeks' gestation, and at delivery	Not reported
			Intervention: Mediterranean-style diet recommendations: ≥2 servings/day of vegetables, ≥3 servings/day of fruit (avoiding juices), 3 servings/day of skimmed dairy, wholegrain cereals, 2-3 servings of legumes/week, moderate-to-high consumption of fish, low consumption of red and processed meat, avoidance of refined grains, processed baked foods, pre-sliced bread, soft drinks, fresh juices, fast food and precooked meals, with key recommendation to consume at least 40 ml of extra virgin olive oil, and a handful of pistachios (25-30g) per day, provided by the study +	Dietitian	Individual and group	Face-to-face	4	Initial group session 1 week after enrolment + Nutritional reinforcement during standard routine care appointments: at 12-14, 24-28, and 36-38 weeks' gestation	Group session: 60 min Nutritional reinforcement sessions: not reported

	Participants		Interventions						
Study	**Eligibility**	**Baseline glucose test (e.g. OGTT, fasting glucose)**	**Content**	**Provider**	**Mode**	**Level of personal contact**	**Sessions**		
							N	**Frequency**	**Length per session**
			Individualised dietary advice at each visit according to GWG (e.g. reduction in calories if excessive GWG) + Walk at least 30 minutes/day						
Zhang 2019 (504) China	≤16 weeks' gestation at first antenatal visit Aged 18 to 45 years BMI ≥24 kg/m^2 Would take routine prenatal examinations	No	**Control:** Standard nutrition and PA consultation according to national recommendations, with individualised diet assessment and diet planning + Advice to keep GWG according to IOM guidelines	Dietitians, but also study nurses answered any dietary queries	Individual	Face-to-face and telephone	3 consultations incorporated into routine antenatal care + At least 4 telephone follow-up interviews	Consultation interviews: at first antenatal visit, at 24-28 weeks' gestation, and at 34-36 weeks' gestation Telephone follow-up interviews: at least once a month between consultation visits	Not reported
			Intervention: Standard nutrition and PA consultation according to national recommendations, with individualised diet assessment and diet planning, involving GI and glycaemic load calculations and diet plan to achieve low-GI diet, as well as provision of knowledge on combining foods in meals, and cooking techniques to achieve lower GI + Mobile application to help select food types and amount of intake for every meal + Advice to keep GWG according to IOM guidelines	Dietitians, but also study nurses answered any dietary queries	Individual	Face-to-face, telephone, and mobile application	3 consultations incorporated into routine antenatal care + At least 4 telephone follow-up interviews	Consultation interviews: at first antenatal visit, at 24-28 weeks' gestation, and at 34-36 weeks' gestation Telephone follow-up interviews: at least once a month between consultation visits	Not reported
Ding 2019 (231) China	BMI ≥24 kg/m^2 at the start of pregnancy Aged <35 years <12 weeks' gestation Active on WeChat (a messaging smartphone application) Willing to be randomly assigned to one of the groups Able to follow the intervention plan	No	**Control:** Asked to follow the WeChat public account of the hospital: a free instant messaging smartphone application, through which participants were educated with general knowledge and skills about nutrition and weight management during pregnancy + Basic medical care and health education	N/A	Individual	Smartphone application	N/A	N/A	N/A

	Participants		Interventions						
Study	**Eligibility**	**Baseline glucose test (e.g. OGTT, fasting glucose)**	**Content**	**Provider**	**Mode**	**Level of personal contact**	**Sessions**		
							N	**Frequency**	**Length per session**
	No previous GDM		**Intervention:** Asked to follow the WeChat public account of the hospital: a free instant messaging smartphone application, through which participants were educated with general knowledge and skills about nutrition and weight management during pregnancy + Enrolment into WeChat group: offering the ability to ask questions about diet at any time, and get answers from a dietitian, and receive messages from a dietitian about dietary guidelines for pregnancy + Personalised nutrition counselling once a month based on the national guidelines for diagnosis and treatment of GDM. Diet advice included: no less than 1500 kcal/day at early pregnancy, and 1800 kcal/day at mid-pregnancy, general healthy eating principles with 50-60% of energy intake from carbohydrates, <30% from fat, and 1.0-1.3 g/kg/day protein + Asked to follow the WeChat official account of hospital to receive detailed pregnancy diet and exercise information, including a total of 90 messages about dietary guidelines in pregnancy + Asked to initiate a daily PA plan (e.g. walk for at least 6000 steps/day) + Basic medical care and health education	Dietitians and clinical nutritionists	Individual	Face-to-face and smartphone application			
Dodd 2014 (144) Australia	BMI ≥25 kg/m^2 at antenatal booking Singleton pregnancy 10-20 weeks' gestation	No	**Control:** Standard care						
			Intervention: Diet advice in planning session, with opportunity to problem solve for barriers: advice based on national recommendations to maintain balance of carbohydrates, fat and protein, and reduce foods high in refined carbohydrates and saturated fat, increase fibre intake, have 2 portions of fruit, 5 of vegetables, and 3 servings dairy per day +	Research dietitian and trained research assistants	Individual	Face-to-face and telephone	One-off consultation/ planning session + 2 phone sessions + 2 follow-up visits for reinforced lifestyle advice (unclear if done as	Consultation/ planning session within 2 weeks of randomisation + 1 phone session at 22, and 1 at 24 weeks' gestation +	Not reported

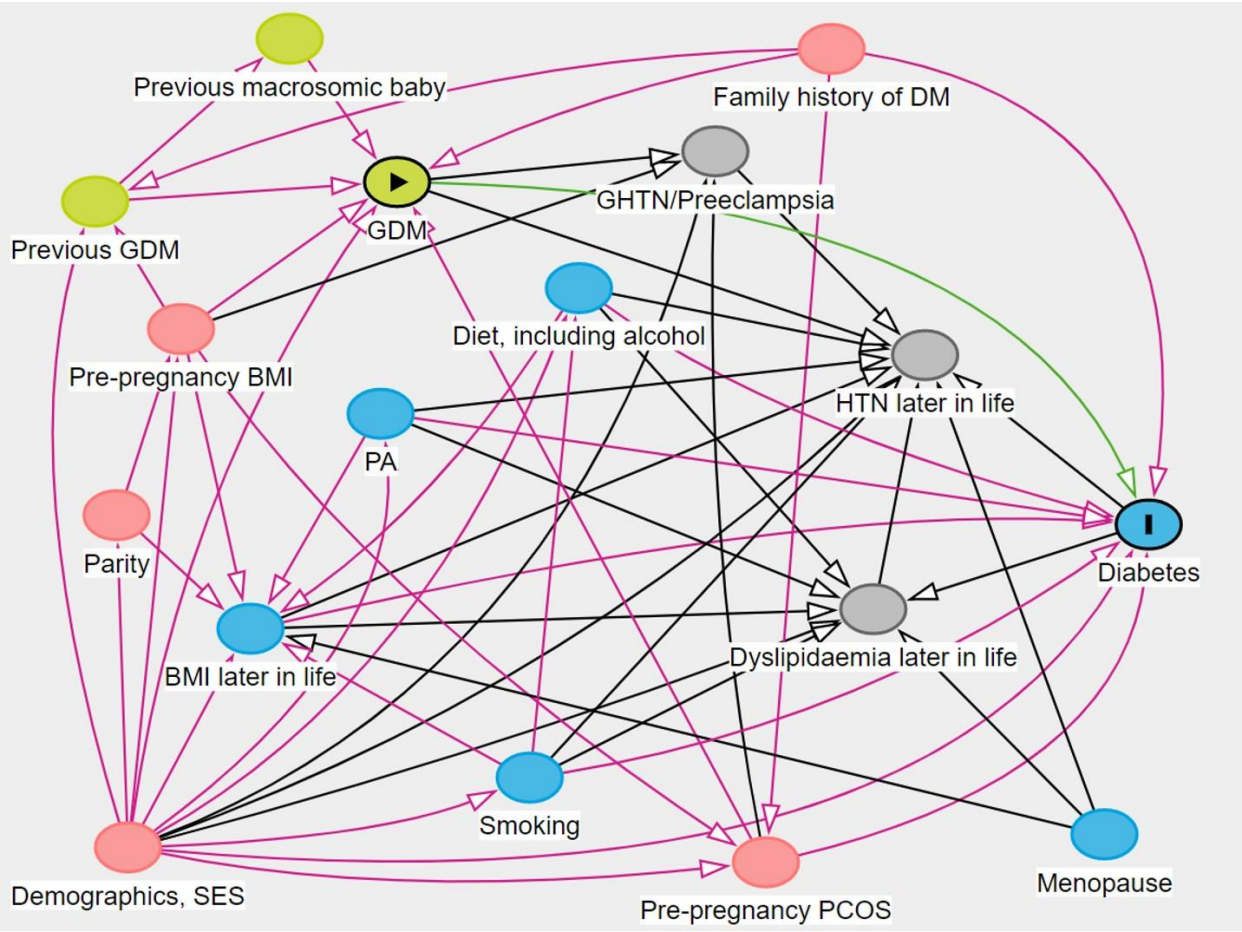
	Participants		Interventions						
Study	**Eligibility**	**Baseline glucose test (e.g. OGTT, fasting glucose)**	**Content**	**Provider**	**Mode**	**Level of personal contact**	**Sessions**		
							N	**Frequency**	**Length per session**
			PA advice in planning session, with opportunity to problem solve for barriers: increase amount of walking and incidental activity				part of routine appointments)	1 visit at 28, and 1 at 36 weeks' gestation	
Petrella 2014 (240) **I**taly	Pre-pregnancy BMI ≥25 kg/m^2 Aged ≥18 years Singleton pregnancy No previous GDM <20 weeks' gestation		**Control:** Simple nutritional booklet about lifestyle based on the national guidelines for healthy eating in pregnancy	N/A	Individual	N/A	N/A	N/A	N/A
			Intervention: Therapeutic Lifestyle Changes group diet: 1500 kcal/day, consisting of 3 main meals and 3 snacks, with addition of 200 kcal/day and 300 kcal/day for women with obesity and overweight respectively, with primary focus on decreasing high-GI foods, and substituting them with alternatives, redistributing the number of meals along the day, with a last snack 2 hours after dinner, and with macronutrient content consisting of 55% of energy intake from carbohydrate (at least 225 g/day), 20% protein, and 25% fat (mostly unsaturated). + Counselling session, including advice on appropriate GWG + PA advice on developing a more active lifestyle, generally consistent with the advice for the general population (30 minutes of moderate-intensity activity 3 times a week)	Dietitian in collaboration with gynaecologist	Individual	Face-to-face	5: Initial counselling session and follow-up appointments (unclear if part of routine care or extra)	Counselling session at baseline, and then follow-up visits for adherence at 16, 20, 28, and 36 weeks' gestation	Counselling session: 60 min Follow-up sessions: not reported
Simmons 2017 (254) European countries, including the UK	Aged ≥18 years <20 weeks' gestation At risk of GDM because of pre-pregnancy BMI ≥29 kg/m^2	Yes: no % of abnormal OGTT given	**Control:** Usual care						
			Healthy eating: Advice to reduce sugary drinks and replace them with alternatives, eat more non-starchy vegetables, choose higher-fibre foods over low-fibre ones, watch portion size, increase intake of proteins, reduce fat intake by reducing foods like fast food, fried foods, and eat less carbohydrates by reducing intake of starchy foods +	Lifestyle coach		Face-to-face and optional telephone	5 face-to-face sessions + ≤4 telephone sessions	At least 4 face-to-face sessions were expected to occur before 24 to 28 weeks' gestation, and the intervention was completed by 35 weeks' gestation	Face-to-face sessions: 30-45 min Telephone sessions: ≤20 minutes

	Participants		Interventions						
Study	**Eligibility**	**Baseline glucose test (e.g. OGTT, fasting glucose)**	**Content**	**Provider**	**Mode**	**Level of personal contact**	**Sessions**		
							N	**Frequency**	**Length per session**
			Advice to achieve a maximum of 5kg GWG for those with BMI 30 and above, or minimise further GWG if this was already exceeded						
			PA: Advice to incorporate light and moderate-intensity PA into daily life, reduce sedentary time, incorporate resistance activities, increase the number of steps taken per day, be more active during the weekends + Advice to achieve a maximum of 5kg GWG for those with BMI 30 and above, or minimise further GWG if this was already exceeded	Lifestyle coach		Face-to-face and optional telephone Face-to-face and optional telephone	5 face-to-face sessions + ≤4 telephone sessions	At least 4 face-to-face sessions were expected to occur before 24 to 28 weeks' gestation, and the intervention was completed by 35 weeks' gestation	Face-to-face sessions: 30-45 min Telephone sessions: ≤20 minutes
			Healthy eating +PA: Both healthy eating and PA advice as above + Advice to achieve a maximum of 5kg GWG for those with BMI 30 and above, or minimise further GWG if this was already exceeded	Lifestyle coach			5 face-to-face sessions + ≤4 telephone sessions	At least 4 face-to-face sessions were expected to occur before 24 to 28 weeks' gestation, and the intervention was completed by 35 weeks' gestation	Face-to-face sessions: 30-45 min Telephone sessions: ≤20 minutes
Herring 2016 (229) USA	Aged ≥18 years Self-identification as African American <20 weeks' gestation First trimester BMI 25-45 kg/m^2 Medicaid recipient Cell phone ownership with unlimited text messaging Facebook member	No	**Control:** Standard care + Information on optimal GWG	N/A	Individual	N/A	N/A	N/A	N/A
			Intervention: Technology-based behavioural lifestyle intervention: limiting sugary drinks to 1 cup/day, limiting junk and high-fat food to no more than 1/day, stick with 1 plate of food per meal, as well as Increasing walking gradually to 5000 steps/day, and self-weighing weekly with encouragement to meet IOM recommendations Delivered through daily text messages tailored to each behavioural goal, plus self-monitoring text messages 3-4 times/week to enhance behavioural adherence, accompanied by feedback from the health coach. Participants also received raffle entries as motivator to respond to self-monitoring prompts	Health coach	Individual	Face-to-face, telephone, and text	8 adjunct to routine appointments: 1 baseline face-to-face, and the rest on the telephone	One-off face-to-face baseline session Phone sessions: weekly for the first 2 study weeks, and then twice a month therafter	Baseline session: not reported Phone sessions: 15-20 min

	Participants		Interventions						
Study	**Eligibility**	**Baseline glucose test (e.g. OGTT, fasting glucose)**	**Content**	**Provider**	**Mode**	**Level of personal contact**	**Sessions**		
							N	**Frequency**	**Length per session**
			+ Social media group providing a forum for support and additional behavioural skills training via links and to websites and videos + Counselling phone calls to reinforce the skills and problem-solve						
Ferrara 2020 (230) USA	Pre-pregnancy BMI between 25 and 40 kg/m^2 Aged ≥18 years Singleton <13 weeks' gestation	No	**Control:** Usual antenatal care: periodic health education newsletters, including IOM GWG guidelines, and information on healthy eating and PA in pregnancy + 4 study newsletters that focused on women's health and safety during pregnancy without addressing GWG	N/A	Individual	N/A (just printed information)	N/A	N/A	N/A
			Intervention: Usual antenatal care: periodic health education newsletters, including IOM GWG guidelines, and information on healthy eating and PA in pregnancy + 4 study newsletters that focused on women's health and safety during pregnancy without addressing GWG + Lifestyle intervention adapted by the Diabetes Prevention Programme, and mainly delivered by telehealth: daily self-weighing, healthy eating, PA (150 minutes moderate-to-vigorous intensity per week), stress management, with the goal to limit GWG	Dietitian	Individual	Face-to-face, printed information, and telephone	2 face-to-face sessions + 11 telephone sessions + Optional maintenance telephone sessions ~6	13 weekly sessions and then once every two weeks optional telephone sessions for maintenance until 38 weeks' gestation	First face-to-face session: 52.9 min Last face-to-face session: 36.8 min Core telephone sessions: 25.6 min Maintenance telephone sessions: 20.5 min

OGTT: oral glucose tolerance test; **BMI:** body mass index; GDM: gestational diabetes mellitus; **T1DM:** type 1 diabetes mellitus; **T2DM:** type 2 diabetes mellitus; **GWG:** gestational weight gain; **IOM:** Institute of Medicine; **N/A:** not applicable; **MET:** metabolic equivalent of task; **PA:** physical activity; **GI:** glycaemic index; **ACOG:** American College of Obstetricians and Gynaecologists; **TGL:** triglycerides; NICE: National Institute for Health and Care Excellence

Appendix 2.1. Directed Acyclic Graph for the association between GDM, and the risk of incident diabetes



Exposure | Outcome | Ancestor of outcome | Ancestor of outcome

Ancestor of exposure and outcome (confounder)

Biasing pathway | Causal pathway | Neither biasing, nor causal pathway

Variables for which I decided to adjust (either true confounders, or in the confounding pathway):

Population demographics:

- **Age** (Touchscreen and HES maternity): age when had first child
- **Ethnicity** (Touchscreen): White vs Black vs Asian vs Other (mixed, other, not recorded)

Socioeconomic status:

- **Townsend score** calculated for individual participants: quintiles 1-5 plus unknown
- **Education** (Touchscreen): higher degree (college, university or professional degree/qualification) vs any school degree or vocational qualification (A-level, AS-level, O-level, GCSE, CSE, NVQ, HND or HNC) vs unknown

***Family history* of diabetes** (Touchscreen): no vs yes vs unknown

Health behaviours:

- **Smoking** (Touchscreen): never vs previous (ex-smoker) vs current vs unknown
- **Physical activity** (Touchscreen): meeting vs not meeting the recommendations for at least 150 minutes of moderate activity or at least 75 minutes of vigorous activity per week (284), based on MET score, vs unknown
- **Dietary intake** (Touchscreen):
    - **Fruit and vegetable intake:** meeting vs not meeting the recommendation of 5 portions of fruit and vegetable per day (285), vs unknown
    - **Saturated fat intake:** none vs low (less than once week) vs moderate (1-4 days/week) vs high (5 days per week or more), based on frequency of saturated fat intake from beef, pork, lamb, cheese, and spreads, vs unknown
    - **Alcohol consumption:** none vs occasional (<1 unit/week) vs moderate (1-14 units/week), heavy (>14 units/week) (286), vs unknown

  NB1. These dietary factors were selected because of evidence for their role in the development of CVD, and/or HTN, diabetes, and mortality (287-290).

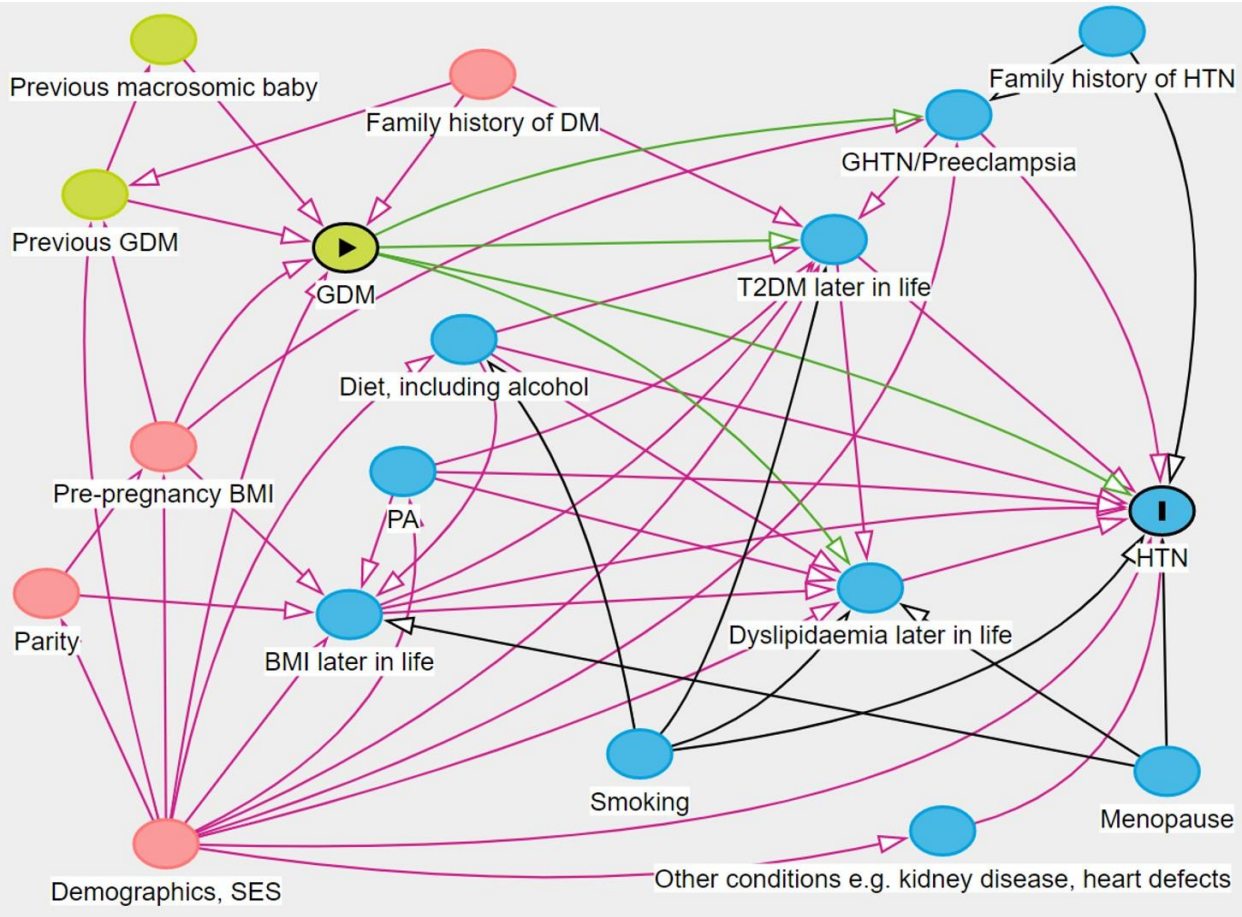
Physical factors and medical conditions:

- **BMI group** (average of height and weight measurements across assessment time points): underweight (<18.5 kg/m^2) vs healthy weight (18.5 to <25 kg/m^2) vs overweight (25 to <30 kg/m^2) vs obese I (30 to <35 kg/m^2) vs obese II & III (35+ kg/m^2) vs unknown
- **Number of live births** (Touchscreen) as proxy of parity

NB2. Pre-pregnancy BMI was not available.
NB3. PCOS data not available.

GDM: gestational diabetes mellitus; **CVD:** cardiovascular disease; **DM:** diabetes mellitus; **BMI:** body mass index; **SES:** socioeconomic status; **PA:** physical activity; **GHTN:** gestational hypertension; **HTN:** hypertension; **PCOS:** polycystic ovary syndrome; **HES:** hospital episode statistics; **A-level:** advanced level; **AS-level:** advanced subsidiary level; **O-level:** ordinary level; **GCSE:** general certificate of secondary education; **CSE:** certificate of secondary education; **NVQ:** national vocational qualification; **HND:** higher national diplomas; **HNC:** higher national certificates; **MET:** metabolic equivalent of task; **HES:** hospital episode statistics

Appendix 2.2. Directed Acyclic Graph for the association between GDM, and the risk of incident hypertension



Variables for which I decided to adjust (either true confounders, or in the confounding pathway):

Population demographics:

- **Age** (Touchscreen and HES maternity): age when had first child
- **Ethnicity** (Touchscreen): White vs Black vs Asian vs Other (mixed, other, not recorded)

Socioeconomic status:

- **Townsend score** calculated for individual participants: quintiles 1-5, plus unknown
- **Education** (Touchscreen): higher degree (college, university or professional degree/qualification) vs any school degree or vocational qualification (A-level, AS-level, O-level, GCSE, CSE, NVQ, HND or HNC) vs unknown

***Family history* of HTN and diabetes** (Touchscreen): no vs yes vs unknown

NB1. Black arrows for family history of HTN, but still adjusted for, because it affects the outcome (540).

Health behaviours:

- **Smoking** (Touchscreen): never vs previous (ex-smoker) vs current vs unknown
- **Physical activity** (Touchscreen): meeting vs not meeting the recommendations for at least 150 minutes of moderate activity or at least 75 minutes of vigorous activity per week (284), based on MET score, vs unknown
- **Dietary intake** (Touchscreen):
  - **Fruit and vegetable intake:** meeting vs not meeting the recommendation of 5 portions of fruit and vegetable per day (285), vs unknown
  - **Saturated fat intake:** none vs low (less than once week) vs moderate (1-4 days/week) vs high (5 days per week or more), based on frequency of saturated fat intake from beef, pork, lamb, cheese, and spreads, vs unknown
  - **Alcohol consumption:** none vs occasional (<1 unit/week) vs moderate (1-14 units/week), heavy (>14 units/week) (286), vs unknown

NB2. These dietary factors were selected because of evidence for their role in the development of CVD, and/or HTN, diabetes, and mortality (287-290).

Physical factors and medical conditions:

- **BMI group** (average of height and weight measurements across assessment time points): underweight (<18.5 kg/m^2) vs healthy weight (18.5 to <25 kg/m^2) vs overweight (25 to <30 kg/m^2) vs obese I (30 to <35 kg/m^2) vs obese II & III (35+ kg/m^2) vs unknown
- **GHTN or Preeclampsia:** no vs yes
  - Not available from Touchscreen questionnaire
  - Coded as combined GHTN-Preeclampsia in verbal interviews
  - HES: hospital admission/episode for pregnancy-induced hypertension without significant proteinuria (ICD-10: O13) or pregnancy-induced hypertension with significant proteinuria (ICD-10: O14.0-O14.9)
- **Number of live births** (Touchscreen): as proxy of parity
- **Menopausal status** (Touchscreen): no vs yes vs unknown

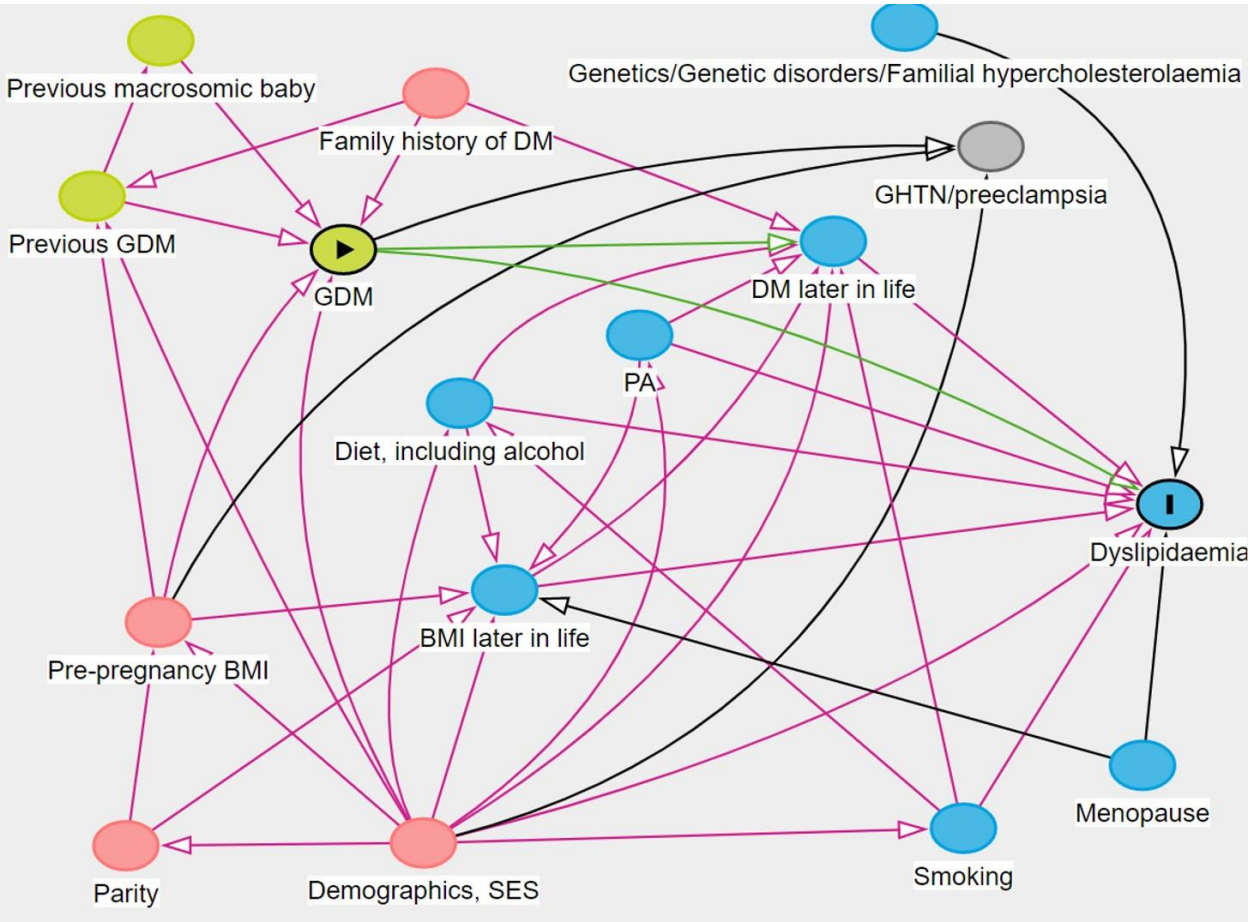
NB3. Pre-pregnancy BMI was not available

NB4. Although GHTN/Preeclampsia has a green arrow, it usually happens around the same time as the exposure (GDM), therefore, was adjusted for in the main model, rather than being explored as mediator.

NB5. Black arrows for menopause, but still adjusted for, because it is a risk factor for HTN (541).

GDM: gestational diabetes mellitus; **CVD:** cardiovascular disease; **DM:** diabetes mellitus; **BMI:** body mass index; **SES:** socioeconomic status; **PA:** physical activity; **GHTN:** gestational hypertension; **HTN:** hypertension; **HES:** hospital episode statistics; **A-level:** advanced level; **AS-level:** advanced subsidiary level; **O-level:** ordinary level; **GCSE:** general certificate of secondary education; **CSE:** certificate of secondary education; **NVQ:** national vocational qualification; **HND:** higher national diplomas; **HNC:** higher national certificates; **MET:** metabolic equivalent of task; **HES:** hospital episode statistics

Appendix 2.3. Directed Acyclic Graph for the association between GDM, and the risk of incident dyslipidaemia



Exposure | Outcome | Ancestor of outcome | Ancestor of outcome

Ancestor of exposure and outcome (confounder)

Biasing pathway | Causal pathway | Neither biasing, nor causal pathway

Variables for which I decided to adjust (either true confounders, or in the confounding pathway):

Population demographics:

- **Age** (Touchscreen and HES maternity): age when had first child
- **Ethnicity** (Touchscreen): White vs Black vs Asian vs Other (mixed, other, not recorded)

Socioeconomic status:

- **Townsend score** calculated for individual participants: quintiles 1-5, plus unknown
- **Education** (Touchscreen): higher degree (college, university or professional degree/qualification) vs any school degree or vocational qualification (A-level, AS-level, O-level, GCSE, CSE, NVQ, HND or HNC) vs unknown

***Family history* of diabetes** (Touchscreen): no vs yes vs unknown

NB1. Family history of dyslipidaemia not available.

Health behaviours:

- **Smoking** (Touchscreen): never vs previous (ex-smoker) vs current vs unknown
- **Physical activity** (Touchscreen): meeting vs not meeting the recommendations for at least 150 minutes of moderate activity or at least 75 minutes of vigorous activity per week (284), based on MET score, vs unknown
- **Dietary intake** (Touchscreen):
  - **Fruit and vegetable intake:** meeting vs not meeting the recommendation of 5 portions of fruit and vegetable per day (285), vs unknown
  - **Saturated fat intake:** none vs low (less than once week) vs moderate (1-4 days/week) vs high (5 days per week or more), based on frequency of saturated fat intake from beef, pork, lamb, cheese, and spreads, vs unknown
  - **Alcohol consumption:** none vs occasional (<1 unit/week) vs moderate (1-14 units/week), heavy (>14 units/week) (286), vs unknown

  NB2. These dietary factors were selected because of evidence for their role in the development of CVD, and/or HTN, diabetes, and mortality (287-290).

Physical factors and medical conditions:

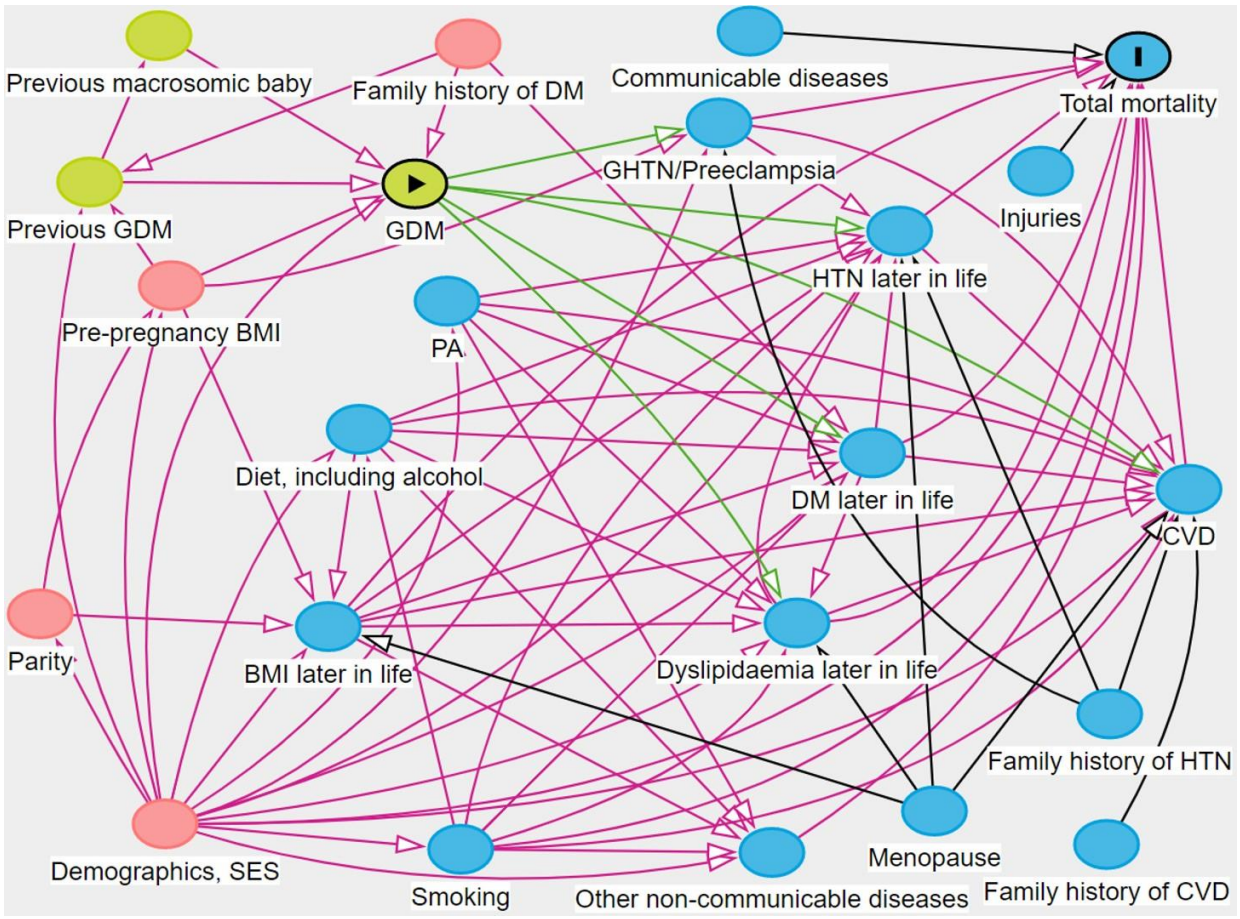
- **BMI group** (average of height and weight measurements across assessment time points): underweight (<18.5 kg/m^2) vs healthy weight (18.5 to <25 kg/m^2) vs overweight (25 to <30 kg/m^2) vs obese I (30 to <35 kg/m^2) vs obese II & III (35+ kg/m^2) vs unknown
- **Parity** (Touchscreen): self-reported number of live births
- **Menopausal status** (Touchscreen): no vs yes vs unknown

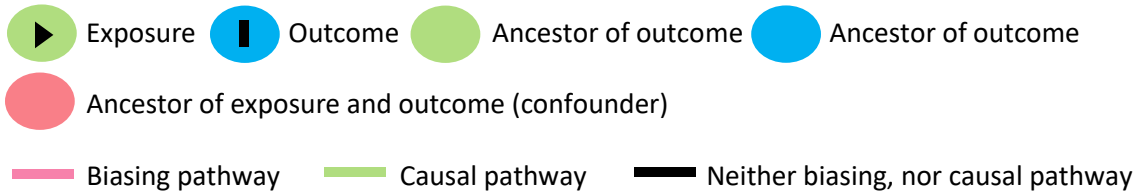
NB3. Pre-pregnancy BMI was not available.

NB4. Back arrows for menopause, but still adjusted for, because of consistent evidence that it affects the outcome (542).

GDM: gestational diabetes mellitus; **CVD:** cardiovascular disease; **DM:** diabetes mellitus; **BMI:** body mass index; **SES:** socioeconomic status; **PA:** physical activity; **GHTN:** gestational hypertension; **HTN:** hypertension; **HES:** hospital episode statistics; **A-level:** advanced level; **AS-level:** advanced subsidiary level; **O-level:** ordinary level; **GCSE:** general certificate of secondary education; **CSE:** certificate of secondary education; **NVQ:** national vocational qualification; **HND:** higher national diplomas; **HNC:** higher national certificates; **MET:** metabolic equivalent of task; **HES:** hospital episode statistics

Appendix 2.4. Directed Acyclic Graph for the association between GDM, and the risk of all-cause mortality





Variables for which I decided to adjust (either true confounders, or in the confounding pathway):

Population demographics:

- **Age** (Touchscreen and HES maternity): age when had first child
- **Ethnicity** (Touchscreen): White vs Black vs Asian vs Other (mixed, other, not recorded)

Socioeconomic status:

- **Townsend score** calculated for individual participants: quintiles 1-5, plus unknown
- **Education** (Touchscreen): higher degree (college, university or professional degree/qualification) vs any school degree or vocational qualification (A-level, AS-level, O-level, GCSE, CSE, NVQ, HND or HNC) vs unknown

***Family history* of CVD, diabetes, HTN** (Touchscreen): no vs yes vs unknown

NB1. Black arrows for family history of CVD and HTN, but still adjusted for, because family history of CVD or circulatory diseases affect CVD (283), a major cause of death in women.

Health behaviours:

- **Smoking** (Touchscreen): never vs previous (ex-smoker) vs current vs unknown
- **Physical activity** (Touchscreen): meeting vs not meeting the recommendations for at least 150 minutes of moderate activity or at least 75 minutes of vigorous activity per week (284), based on MET score, vs unknown
- **Dietary intake** (Touchscreen):
    - **Fruit and vegetable intake:** meeting vs not meeting the recommendation of 5 portions of fruit and vegetable per day (285), vs unknown
    - **Saturated fat intake:** none vs low (less than once week) vs moderate (1-4 days/week) vs high (5 days per week or more), based on frequency of saturated fat intake from beef, pork, lamb, cheese, and spreads, vs unknown
    - **Alcohol consumption:** none vs occasional (<1 unit/week) vs moderate (1-14 units/week), heavy (>14 units/week) (286), vs unknown

NB2. These dietary factors were selected because of evidence for their role in the development of CVD, and/or HTN, diabetes, and mortality (287-290).

Physical factors and medical conditions:

- **BMI group** (average of height and weight measurements across assessment time points): underweight (<18.5kg/m^2) vs healthy weight (18.5 to <25kg/m^2) vs overweight (25 to <30kg/m^2) vs obese I (30 to <35kg/m^2) vs obese II & III (35+ kg/m^2) vs unknown
- **GHTN or Preeclampsia:** no vs yes
    - Not available from Touchscreen questionnaire
    - Coded as combined GHTN-Preeclampsia in verbal interviews
    - HES: hospital admission/episode for pregnancy-induced hypertension without significant proteinuria (ICD-10: O13) or pregnancy-induced hypertension with significant proteinuria (ICD-10: O14.0-O14.9)
- **Parity** (Touchscreen): self-reported number of live births
- **Menopausal status** (Touchscreen): no vs yes vs unknown

NB2. Pre-pregnancy BMI was not available.

NB3. Although GHTN/Preeclampsia has a green arrow, it usually happens around the same time as the exposure (GDM), therefore, was treated as a confounder.

NB4. Black arrows for menopause, but still adjusted for, because of evidence that it affects mortality (543).

GDM: gestational diabetes mellitus; **CVD:** cardiovascular disease; **DM:** diabetes mellitus; **BMI:** body mass index; **SES:** socioeconomic status; **PA:** physical activity; **GHTN:** gestational hypertension; **HTN:** hypertension; **HES:** hospital episode statistics; **A-level:** advanced level; **AS-level:** advanced subsidiary level; **O-level:** ordinary level; **GCSE:** general certificate of secondary education; **CSE:** certificate of secondary education; **NVQ:** national vocational qualification; **HND:** higher national diplomas; **HNC:** higher national certificates; **MET:** metabolic equivalent of task; **HES:** hospital episode statistics

Appendix 2.5. Derivation of variables from the UK Biobank questionnaire and interviews

Variables	**Categories used in analysis**	**UK Biobank variable (ID), source, time point** (where relevant)
Sociodemographic characteristics		
Age	Age	Age at first birth – using the smallest age from: • HES maternal age at delivery if available • Age at first birth if only child (ID: 3872)† • Age at first birth if multiple children (ID: 2754)†
Ethnicity	White Black Asian Other (other ethnicities and unknowns – includes missing, did not know and preferred not to answer)	Ethnic background (ID: 21000)* – most recent time point available
Townsend index	Quintiles 1-5 (high index indicates most deprivation) Unknown (missing)	Townsend index (ID: 189)*
Education	Higher degree (college or university degree, or professional qualifications) Any school degree (A levels, AS levels, O levels, GCSEs or CSEs), or vocational qualifications (NVQ, HND or HNC),or none of the above or unknown Unknown (missing, none of the above, and preferred not to answer)	Qualifications (ID: 6138)† – highest qualification reported among the time points of assessment

Family history		
Family history of CVD	No Yes Unknown (missing)	Family history of CVD (ID: 20107, 20110, 20111, values 2, 1, 8)† - present if reported in at least one time point
Family history of diabetes	No Yes Unknown (missing)	Family history of diabetes (ID: 20107, 20110, 20111, value 9)† - present if reported in at least one time point
Family history of hypertension	No Yes Unknown (missing)	Family history of hypertension (ID: 20107, 20110, 20111, value 8)† - present if reported in at least one time point
Physical factors and medical conditions		
BMI	Underweight (<18.5) Healthy weight(18.5 to <25) Overweight (25 to <30) Obese I (30 to <35) Obese II & III (35+) Unknown (because of weight and/or height not taken)	BMI (ID: 21001)‡ – average from available time points
GHTN/PE	No (includes missing) Yes	GHTN/PE (ID: 20002, value 1073) – present if reported in at least one time point
Menopause	No Yes (if responded to questions saying they have experienced the menopause)	Had menopause (ID: 2724)† - present if reported in at least one time point

	Unknown (missing and preferred not to answer)	
Parity	Parity	Live births (ID: 2734)† – maximum number of live births reported among available time points
Incident CVD	No (includes missing and preferred not to answer) Yes	Present if reported in at least one time point from: Touchscreen questionnaire: CVD diagnosed by doctor (ID: 6150, options for heart attack, angina, stroke)† Verbal interviews: ID: 20002, with values 1074, 1075, 1076, 1079, 1081, 1086 for angina, heart attack/myocardial infarction, heart failure, cardiomyopathy, stroke, and subarachnoid haemorrhage, respectively
Incident diabetes	No (includes missing and preferred not to answer) Yes	Touchscreen questionnaire: diabetes diagnosed by doctor (ID: 2443)†, and/or insulin use (ID: 6153)† - present if reported in at least one time point Verbal interviews: ID: 20002, with values 1223, 1220, 1222, for type 2 diabetes, diabetes, and type 1 diabetes, respectively, and/or metformin use (ID: 20003) – present if reported in at least one time point Diabetes from HbA1c measurement (ID: 30750) – average from available time points

Incident hypertension	No (includes missing and preferred not to answer) Yes	Touchscreen questionnaire: hypertension diagnosed by doctor (ID: 6150, option for high blood pressure)†, and/or medication for blood pressure (ID: 6153, option for blood pressure lowering medication)† - present if reported in at least one time point Verbal interviews: ID: 20002, with values 1072 and 1065 for essential hypertension and hypertension respectively – present if reported in at least one time point Systolic blood pressure, automated reading / manual reading (ID: 4080 / 93)‡ – average from available time points Diastolic blood pressure, automated reading / manual reading (ID: 4079 / 94)‡ – average from available time points
Incident dyslipidaemia	No (includes missing and preferred not to answer) Yes	Touchscreen questionnaire: cholesterol lowering medication (ID: 6153, it is an option)† - present if reported in at least one time point Verbal interviews: ID: 20002, with value 1473 Total cholesterol (ID: 30690)§ – average from available time points HDL cholesterol (ID: 30760)§ – average from available time points LDL cholesterol (ID: 3080)§ – average from available time points non-HDL cholesterol – calculated as total cholesterol minus HDL cholesterol

		TGL (ID: 30870)§ – average from available time points Ratio of total cholesterol on HDL cholesterol
Health behaviours		
Smoking	Never Previous Current Unknown	Smoking status (ID: 20116)† – latest time point available
Physical activity	Not meeting recommendations Meeting recommendations Unknown (missing, did not know, preferred not to answer)	Number of days/week of vigorous physical activity 10+ minutes (ID: 904)† – average from available time points; Duration of vigorous activity (ID: 914)† – average from available time points Number of days/week of moderate physical activity 10+ minutes (ID: 884)† – average from available time points; Duration of moderate activity (ID: 894)† – average from available time points Number of days/week walked 10+ minutes (ID: 864)† –average from available time points; Duration of walks (ID: 874)† – average from available time points
Fruit and vegetable intake	Not meeting recommendations Meeting recommendation Unknown (missing, did not know, preferred not to answer)	Sum of: - Cooked vegetable portions per day (ID: 1289)† – average from available time points - Raw vegetable portions per day (ID: 1299)† – average from available time points

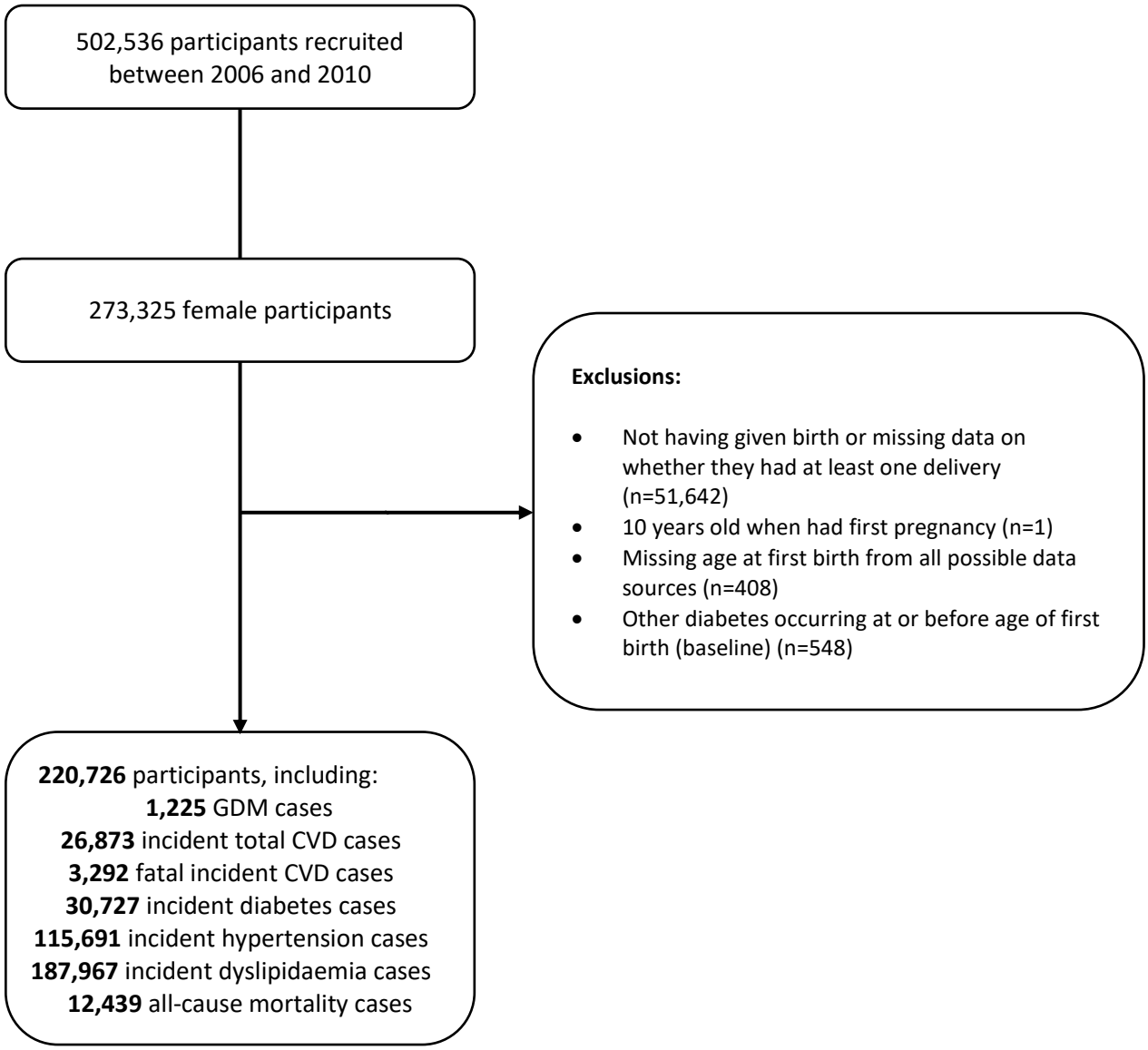
		- Fruit portions per day (ID: 1309)† – average from available time points
Saturated fat intake	None Low (<1 day/week) Moderate (1-4 days/week) High (5+ days/week) Unknown (missing, did not know, preferred not to answer)	Saturated fat intake score (days/week) – sum of: - Weekly beef intake (ID: 1369)† – average from available time points - Weekly lamb intake (ID: 1379)† – average from available time points - Weekly pork intake (ID: 1389)† – average from available time points - Weekly cheese intake (ID: 1408)† – average from available time points - Weekly spread intake (ID: 1428)† – latest time point available
Alcohol intake	Occasional (<1 unit/week) Moderate (1-14 units/week) Heavy (>14 units/week Unknown (missing, did not know, preferred not to answer)	Alcohol weekly intake (units/week) – sum of: - Weekly red wine intake (ID: 1568)† – amount of glasses per week multiplied by 2, and taking the average from available time points - Weekly beer and cider intake (ID: 1588)† – amount of pints per week multiplied by 2.5, and taking the average from available time points - Weekly champagne and white wine intake (ID: 1578)† – amount of glasses per week multiplied by 2, and taking the average from available time points

		- Weekly spirits intake (ID: 1598)† – amount of measures per week multiplied by 1, and taking the average from available time points - Weekly fortified wine intake (ID: 1608)† – amount of glasses per week multiplied by 2, and taking the average from available time points - Weekly other alcoholic drinks intake (ID: 5364)† – amount of glasses per week multiplied by 1, and taking the average from available time points - Monthly red wine intake (ID: 4407)† – amount of glasses per month multiplied by 2 and divided by 4.3, and taking the average from available time points - Monthly beer and cider intake (ID: 4429)† – amount of pints per month multiplied by 2.5 and divided by 4.3, and taking the average from available time points - Monthly champagne and white wine intake (ID: 4418)† – amount of glasses per month multiplied by 2 and divided by 4.3, and taking the average from available time points - Monthly spirits intake (ID: 4440)† – amount of measures per month multiplied by 1 and divided by 4.3, and taking the average from available time points

		- Monthly fortified wine intake (ID: 4451)† – amount of glasses per month multiplied by 2 and divided by 4.3, and taking the average from available time points - Monthly other alcoholic drinks intake (ID: 5364)† – amount of glasses per month multiplied by 1 and divided by 4.3, and taking the average from available time points

HES: hospital episode statistics; **AS-level:** advanced subsidiary level; **O-level:** ordinary level; **GCSE:** general certificate of secondary education; **CSE:** certificate of secondary education; **NVQ:** national vocational qualification; **HND:** higher national diploma; **HNC:** higher national certificate; **CVD:** cardiovascular disease; **GHTN/PE:** gestational hypertension/preeclampsia; **HDL:** high density lipoprotein; **LDL:** low density lipoprotein; **TGL:** triglycerides
*Recruitment questions, †Touchscreen questions, ‡Physical measurements, §Biological samples

Appendix 2.6. UK Biobank participant flowchart



GDM: gestational diabetes; **CVD:** cardiovascular disease

Appendix 3.1. Search strategies

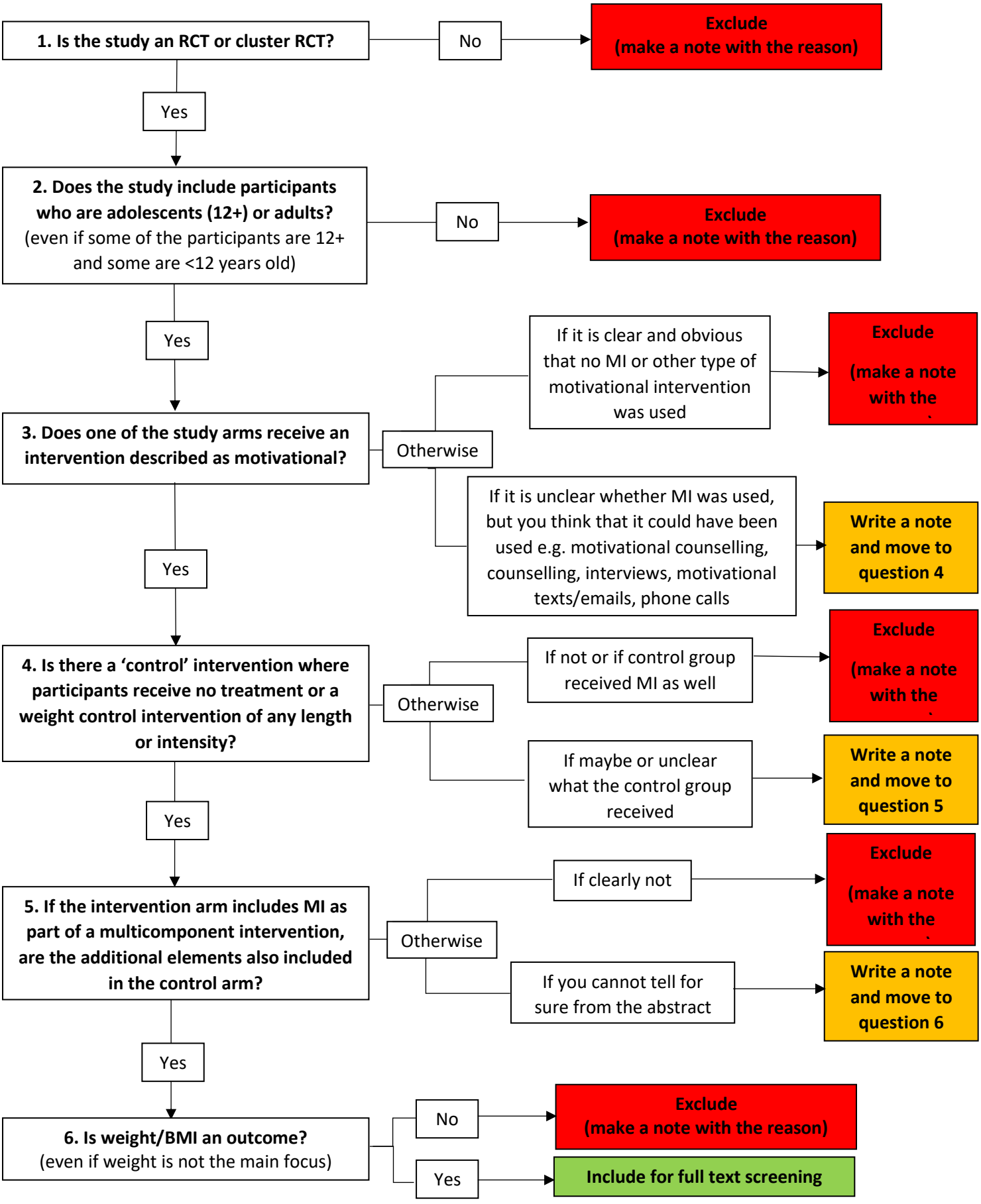
Medline (Ovid MEDLINE® Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE® Daily and Ovid MEDLINE®)		
	Searches	**Results**
1	overweight/ or exp obesity/	241860
2	(obes* or overweight).ti,ab,kw.	355160
3	Body Mass Index/	137004
4	Weight Loss/	39297
5	Weight Reduction Programs/	2555
6	Diet, Reducing/	11315
7	Body Weight Maintenance/	382
8	(weight adj5 (loss or losing or lose or reduc* or manage* or control* or maintain* or gain*)).ti,ab,kw.	230580
9	(body mass or bmi).ti,ab,kw.	305246
10	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9	769224
11	motivational interviewing/	2196
12	Motivation/ and Counseling/	1281
13	(motivat* adj2 (interview* or counsel* or advice or session?)).ti,ab,kw.	5325
14	(motivat* adj2 (practi* or behavi*)).ti,ab,kw.	7492
15	(motivat* adj2 (enhanc* or improv* or encourag* or facilitat*)).ti,ab,kw.	4070
16	motivation*.ti.	17096
17	11 or 12 or 13 or 14 or 15 or 16	30306
18	10 and 17	2073
19	randomized controlled trial.pt.	544277
20	controlled clinical trial.pt.	94418
21	randomized.ab.	534715
22	placebo.ab.	221625
23	drug therapy.fs.	2376743
24	randomly.ab.	366336
25	trial.ab.	568965
26	groups.ab.	2249459
27	19 or 20 or 21 or 22 or 23 or 24 or 25 or 26	5124381
28	exp animals/ not humans.sh.	4889065
29	27 not 28	4457427
30	18 and 29	930
Embase		
1	exp obesity/ or overnutrition/	569634
2	(obes* or overweight).ti,ab,kw.	525327
3	Body Mass/	503691
4	body weight change/ or exp body weight loss/	58874
5	exp body weight management/	54062
6	diet restriction/ or caloric restriction/	108778
7	(weight adj5 (loss or losing or lose or reduc* or manage* or control* or maintain* or gain*)).ti,ab,kw.	337659

Search strategies continued		
8	(body mass or bmi).ti,ab,kw.	534167
9	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8	1391318
10	motivational interviewing/	5679
11	(motivat* adj2 (interview* or counsel* or advice or session?)).ti,ab,kw.	7698
12	(motivat* adj2 (practi* or behavi*)).ti,ab,kw.	8295
13	(motivat* adj2 (enhanc* or improv* or encourag* or facilitat*)).ti,ab,kw.	5453
14	motivation*.ti.	18622
15	10 or 11 or 12 or 13 or 14	35437
16	9 and 15	3237
17	randomized controlled trial/	677309
18	single blind procedure/ or double blind procedure/	229735
19	crossover procedure/	68199
20	random*.tw.	1708275
21	(random or ((singl* or doubl*) adj (blind* or mask*)) or crossover or cross over or factorial* or latin square or assign* or allocat* or volunteer*).ti,ab.	1485953
22	17 or 18 or 19 or 20 or 21	2495608
23	(exp animals/ or nonhuman/) not human/	6800606
24	22 not 23	2184506
25	16 and 24	1068
PsycINFO		
1	exp overweight/	27609
2	(obes* or overweight).ti,ab,hw,id.	48209
3	weight loss/ or body weight/ or weight control/	19758
4	diets/ or dietary restraint/	15355
5	(weight adj3 (loss or losing or lose or reduc* or manage* or control* or maintain* or gain*)).ti,ab,hw,id.	31793
6	(body mass or bmi).ti,ab,hw,id.	32663
7	1 or 2 or 3 or 4 or 5	81642
8	motivational interviewing/	2707
9	(motivat* adj2 (interview* or counsel* or advice or session?)).ti,ab,hw,id.	5032
10	(motivat* adj2 (practi* or behavi*)).ti,ab,hw,id.	8762
11	(motivat* adj2 (enhanc* or improv* or encourag* or facilitat*)).ti,ab,hw,id.	4928
12	motivation*.ti.	34757
13	8 or 9 or 10 or 11 or 12	47076
14	7 and 13	1203
15	random*.ti,ab,hw,id.	218031
16	trial*.ti,ab,hw,id.	197502
17	controlled stud*.ti,ab,hw,id.	12977
18	placebo*.ti,ab,hw,id.	42291
19	((singl* or doubl* or trebl* or tripl*) and (blind* or mask*)).ti,ab,hw,id.	30710
20	(cross over or crossover or factorial* or latin square).ti,ab,hw,id.	32582
21	(assign* or allocat* or volunteer*).ti,ab,hw,id.	175865
22	treatment effectiveness evaluation/	26071
23	mental health program evaluation/	2216

Search strategies continued		
24	exp experimental design/	60203
25	(clinical trial or treatment outcome).md.	51397
26	15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25	566220
27	14 and 26	289
Cumulative Index to Nursing and Allied Health Literature		
	Query	Results
S11	S6 AND S9 Limiters - Clinical Queries: Therapy - Best Balance	416
S10	S6 AND S9	1,435
S9	S7 OR S8	17,215
S8	TI ((motivat* N2 (interview* or counsel* or advice or session*))) OR AB ((motivat* N2 (interview* or counsel* or advice or session*))) OR TI ((motivat* N2 (practi* or behavi*))) OR AB ((motivat* N2 (practi* or behavi*))) OR TI ((motivat* N2 (enhanc* or improv* or encourag* or facilitat*))) OR AB ((motivat* N2 (enhanc* or improv* or encourag* or facilitat*))) OR TI motivation*	15,746
S7	(MH "Motivational Interviewing")	3,718
S6	S1 OR S2 OR S3 OR S4 OR S5	280,381
S5	TI ((weight N3 (loss or losing or lose or reduc* or manage* or control* or maintain* or gain*))) OR AB ((weight N3 (loss or losing or lose or reduc* or manage* or control* or maintain* or gain))) OR TI("body mass" OR bmi) OR AB ("body mass" OR bmi)	149,217
S4	(MH "Weight Loss+") OR (MH "Weight Reduction Programs") OR (MH "Diet, Reducing") OR (MH "Weight Control")	36,190
S3	(MH "Body Mass Index")	88,124
S2	TI (obes* or overweight) OR AB (obes* or overweight)	118,389
S1	(MH "Obesity+")	105,993
Science Citation Index		
# 1	TS=(obes* or overweight) OR TS=(weight NEAR/3 (loss or losing or lose or reduc* or manage* or control* or maintain* or gain)) OR TS=("body mass" OR bmi)	853,759
# 2	TS=(motivat* NEAR/2 (interview* or counsel* or advice or session*)) OR TS=(motivat* NEAR/2 (practi* or behavi*)) OR TS=(motivat* NEAR/2 (enhanc* or improv* or encourag* or facilitat*)) OR TI=motivation*	59,179
# 3	#2 AND #1	2,403
# 4	TS=(random* or blind* or allocat* or assign* or trial* or placebo* or crossover* or cross-over*)	357,988
# 5	#4 AND #3	901
Cochrane		
#1	MeSH descriptor: [Overweight] explode all trees	
#2	(overweight OR obes*):ti,ab,kw	
#3	MeSH descriptor: [Body Mass Index] explode all trees	
#4	MeSH descriptor: [Weight Loss] this term only	
#5	MeSH descriptor: [Body Weight Changes] this term only	
#6	MeSH descriptor: [Weight Reduction Programs] explode all trees	
#7	MeSH descriptor: [Diet, Reducing] explode all trees	

Search strategies continued	
#8	((weight NEAR/3 (loss or losing or lose or reduc* or manage* or control* or maintain* or gain*))):ti,ab,kw
#9	(body mass or bmi):ti,ab,kw
#10	#1 or #2 or #3 or #4 OR #5 OR #6 OR #7 OR #8 or #9
#11	MeSH descriptor: [Motivational Interviewing] explode all trees
#12	((motivat* NEAR/2 (interview* or counsel* or advice or session*))):ti,ab,kw OR ((motivat* NEAR/2 (practi* or behavi*))):ti,ab,kw OR ((motivat* NEAR/2 (enhanc* or improv* or encourag* or facilitat*))):ti,ab,kw OR (motivation*):ti
#13	#11 OR #12
#14	#10 AND #13

Appendix 3.2. Abstract screening workflow



RCT: randomised controlled trial; **MI:** motivational interviewing; **BMI:** body mass index

Appendix 3.3. Full-text screening workflow

Find the full-text paper:

1. **Try to find the full text** and, either attach the pdf or copy and paste the URL.

2. **If this is a published study** (i.e. there are author and journal details) but you cannot find the full text, select it and tag it as "can't find full text" and don't do anything further.

3. **If in Covidence we have only the details from the trial registration site**, try to search if a paper has been published:
    - Sometimes the title of trial in the registration site, will match with or be very similar to the title of the published paper or you can search by the study's acronym, if one is used.
    - If you go into the trial registry site, there is sometimes a link to the published full text under the sub heading 'More Information'.
    - If you find a paper that you suspect talks about this study, you can compare the population, setting, authors, procedures to decide if this is it.
    - If you cannot find any paper about this study, tag as "can't find full text". Then from the information on the registry assess if it seems eligible or not. If clearly eligible → include even if we don't have the full text. If the information is unclear/inadequate to help decide or if it is obviously not eligible → write a note and exclude by choosing the reason.

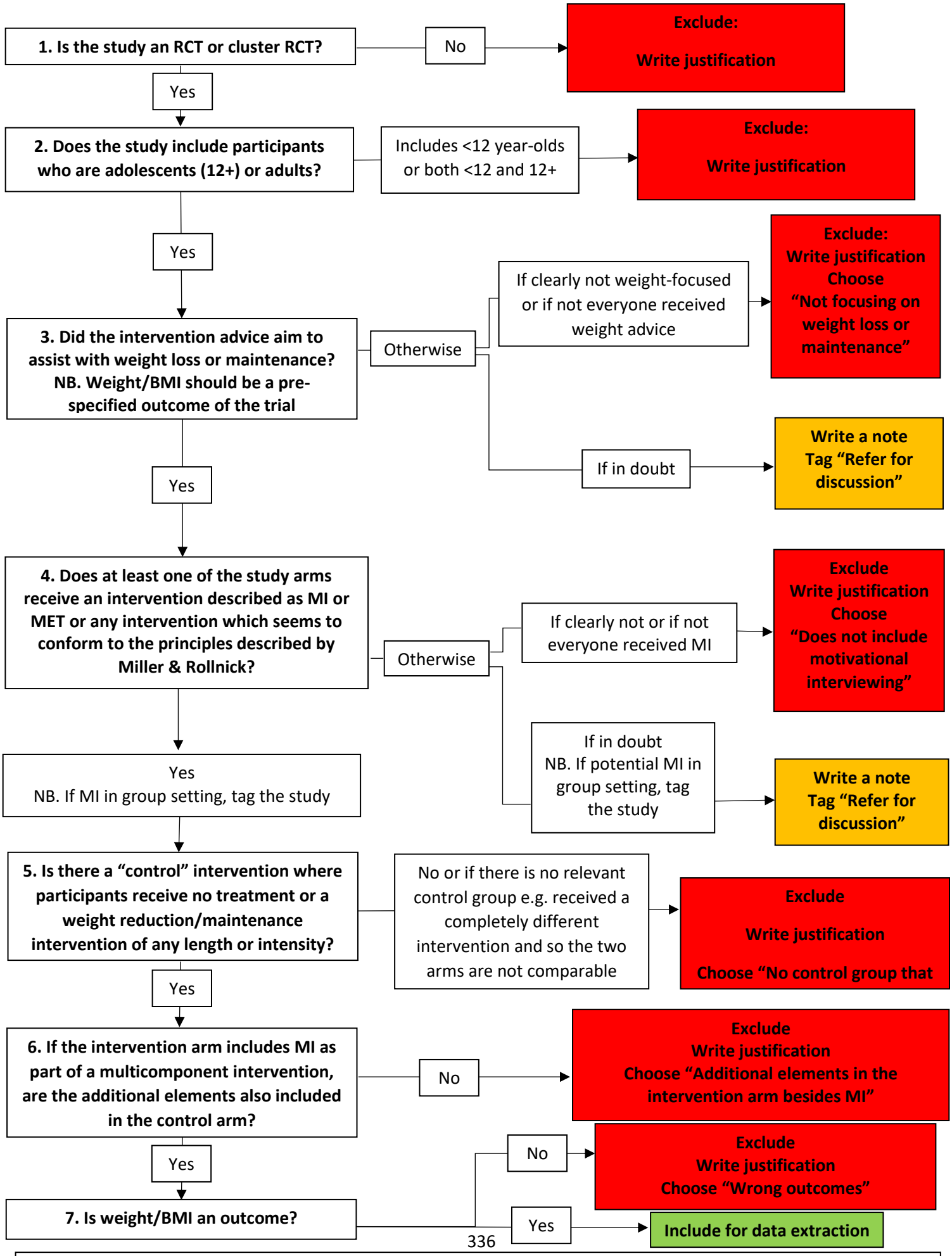
4. **If this is a paper talking about a study but it's not the main paper from which we can extract the results:**
    - Briefly check in the paper that you have found, if the study's design is mentioned, so as to quickly check if the study seems eligible.
    - If the study is clearly not eligible, then exclude by choosing the reason and writing a note.
    - If the study seems eligible, check if you can find the main results publication:
        - If you find the main publication, add the link to it in the notes. Read it to find out whether the study is actually eligible or not. If it is eligible, then tag the study as "Check for additional papers" and then click include. If it is not eligible, you do not need to tag because we won't be needing this study, so just exclude by choosing the reason and writing a note.
        - If you cannot find the main publication or do not have access to it, but from this secondary paper you found it seems that the study may be eligible, select the study and tag as "Check for additional papers" and then click include.

5. **If a study is ongoing and so no publications are available yet**, tag the study as "Ongoing study" and then exclude by choosing "Ongoing study".

6. **If the study comes from a dissertation, thesis or conference abstract without an actual publication**, exclude by choosing "Is a dissertation thesis/conference abstract".

7. **If the full text is not in English**, select the study and tag it as "Full text not in English", and don't do anything further.

Read the full-text paper



RCT: randomised controlled Trial; **MI:** motivational interviewing; MET: motivational enhancement therapy **BMI:** body mass index

Appendix 3.4. Data synthesis approaches

3.4.1 Combining two intervention arms receiving the same intervention

- Where means and SDs of outcomes were reported or obtainable for each arm, I used formulas recommended by the Cochrane Handbook (361).

Formulas for combining trial arms

	Arm 1	Arm 2	Combined arms
Sample size	N_1	N_2	N_1+N_2
Mean	M_1	M_2	$\frac{N_1*M_1 + N_2*M_2}{N_1+N_2}$
Standard deviation	SD_1	SD_2	$\sqrt{\frac{(N_1-1)*SD_1^2+ (N_2-1)*SD_2^2 + (N_1*N_2/N_1+N_2)*(M_1^2 +M_2^2 – 2M_1*M_2)}{N1 + N2 – 1}}$

- Where means and 95% CIs were reported for each arm, I combined the two arms with a meta-analysis, using the inverse variance method in a fixed-effects model.

3.4.2 Obtaining MD in weight change between trial arms

- Where studies already reported the difference in mean weight change between the trial arms, I used this directly in the analysis. In some studies, this difference was represented by a regression coefficient.
- Other studies reported mean weight change within each trial arm only, in which case I calculated the mean difference in weight changes between arms as follows:

mean weight change in intervention group – mean weight change in control group

- When studies reported only the mean weight at baseline and at follow-up for each arm, I first calculated the mean weight change within each arm from baseline to follow-up, and eventually, the difference in mean weight change between the arms as per formula above.

- Some studies reported only an F statistic for group-time interaction, which reflects how different the weight change is over time (from baseline to follow-up) depending on the trial arm allocation. Using the Campbell Collaboration online effect size calculators (F-test, 2-group) (362), I obtained the SMD in weight change between arms (parameter d).
- Where BMI data were only available, weight data were estimated either by given heights or using mean height by sex for a specific country (544). When studies in adolescents did not provide height, I assumed participants had reached maximum height which is similar to adult height. While his may be incorrect, the error should not differ by trial arm.

3.4.3 Obtaining SMD in psychological well-being change between trial arms

The formula I used to calculate SMD in psychological well-being score change between the arms, after having extracted the mean score change in each arm was:

Mean score change intervention – Mean score change control/ pooled SD,

where pooled SD = √{[(SD of mean score change in control)^2 + (SD of mean score change in intervention)^2]/2}

3.4.4 Obtaining the SE of MD in weight change between trial arms

- Where studies already reported the SE of the difference in mean weight change between the trial arms, I used this directly in my analysis.
- Where SEs were available for weight change in each trial arm only, I estimated the SE of the difference between arms using the following formula (361):

SE = √{[(SE of mean weight change intervention)^2 + (SE of mean weight change control^2)]}

- Where studies reported other measures of spread for either between or within arm differences, such as SD, 95% CI, I estimated the SE using standard conversion formulas (361):

SE = SD/√n, where n = number of participants for whom data are reported

SE = (Upper 95% CI limit – Lower 95% CI limit)/3.92

- Some studies reported P value for the difference in mean weight change between arms. Using an online calculator (545), I calculated a z score with a two-tailed test. The z score indicates the number of SDs a given data point lies above or below the mean. From this z score, I then calculated the SE of the difference in mean weight change between arms, using the following formula:

SE = mean difference in weight change between arms/z score

- Some studies reported an F statistic for group x time interaction, that is, how different the effect (i.e. the mean difference in weight change between arms) is at the beginning and the effect of time (i.e. the follow-up time point). Using the Campbell Collaboration online effect size calculators (F-test, 2-group), I obtained the variance and from there, the SE of the SMD as per formula below (361):

SE of standardised mean difference in weight change = √variance

3.4.5 Obtaining the SE of SMD in psychological well-being change between trial arms

- For psychological well-being outcomes, reporting of measures of spread from included studies followed a similar pattern as with weight outcomes. For this analysis, I used the Campbell Collaboration calculators which automatically calculate the variance (362). Then the SE of the SMD was calculated as per formula below (361):

SE of standardised mean difference in weight change = √variance

3.4.6 Steps for inflating SE in cluster RCTs

1. I extracted the mean size of each cluster, i.e. the number of clusters randomised to each trial arm.
2. I used an external estimate for the Intra-cluster Correlation Coefficient - an estimate of how similar the individuals are within the same cluster - from a weight loss cluster randomised trial (419).
3. I calculated a quantity called the "design effect" as follows:

*Design effect = 1 + (M-1) * ICC*

where M = the mean cluster size and ICC = Intra-cluster Correlation Coefficient

4. I inflated the SE of the effect estimate from the analysis that ignored the clustering as follows:

*SE * √(1 + (M-1) * ICC)*

where M = the mean cluster size and ICC = Intracluster Correlation Coefficien

Appendix 3.5. Detailed characteristics of included studies, participants and intervention programmes

Study	Participants					Groups	Interventions								
							Content	Provider	Provider training	Mode	Level of personal contact	Programme duration	Sessions		
													N	Frequency	Length per session
	Total	Female (%)	Age Mean (SD)	BMI Mean (SD)	Conditions for which seeking treatment/ prevention										
Studies with comparators of no or minimal intervention sorted by programme duration															
Joseph 2021 USA Adolescents	44	63	16.2 (1.4)	32.7 (NR)	Asthma and Overweight or Obesity	**Comparator:** Standard care	Standard care for asthma	Paediatricians		Individual	Face-to-face				
						Intervention: Tailored Discussion (MI)	Tailored discussion using MI incorporated into standard care for asthma management, drawing attention on achieving healthy weight	Paediatricians	1-hour training session on MI	Individual	Face-to-face	Single clinic visit	1	One-off	NR but it was noted that visits were longer than the control group as a result of the extra discussion
Buscemi 2011 USA Adults	70	85	19.7 (2.0)	32.8 (4.7)	Overweight or Obesity	**Comparator:** Assessment only	Handouts related to weight loss and fitness: campus recreation centre, diet/exercise websites, self-monitoring sheets, free dietitian contact, portion control, nutrition facts for fast food and sugar-sweetened beverages, personal trainer contact	Research assistant gave out handouts		Individual	N/A (handouts)			One-off provision of handouts	

Study	Participants					Groups	Interventions								
							Content	Provider	Provider training	Mode	Level of personal contact	Programme duration	Sessions		
													N	Frequency	Length per session
	Total	Female (%)	Age Mean (SD)	BMI Mean (SD)	Conditions for which seeking treatment/ prevention										
						Intervention: Brief Motivational Intervention	Handouts related to weight loss and fitness: campus recreation centre, diet/exercise websites, self-monitoring sheets, free dietitian contact, portion control, nutrition facts for fast food and sugar-sweetened beverages, personal trainer contact + Diet and physical activity advice for weight loss including MI principles	MI: 3 graduate students in clinical psychology	20 hours MI training and regular supervision from doctoral-level psychologist	Individual	Face-to-face and telephone	MI: suggestive of 2 weeks	2	MI: one-off face-to-face and one phone call 2 weeks after initial session	MI: face-to-face session: 50-60 minutes; Booster phone call: 7 minutes average length
Azami 2020 Iran Adults	70	100	28.5 (4.4)	30.3 (2.6)	Overweight or Obesity	**Comparator:** Routine preconception care	Routine preconception care								
						Intervention: MI	Counselling sessions including MI: education about food groups, weight loss, correcting	NR	NR	Groups of 8-12	Face-to-face	3 weeks	6	Twice a week	60-90 minutes, but final session took 100-120 minutes

Study	Participants					Groups	Interventions								
							Content	Provider	Provider training	Mode	Level of personal contact	Programme duration	Sessions		
													N	Frequency	Length per session
	Total	Female (%)	Age Mean (SD)	BMI Mean (SD)	Conditions for which seeking treatment/ prevention										
							food habits and behaviours								
Pakpour 2015 Iran Adolescents	238	45.4	15.7 (1.3)	33.0 (8.3)	Obesity	**Comparator:** Passive control	No details given								
						Intervention: MI with parental involvement	Diet and PA advice including MI	Registered dietitian + Sport and exercise specialist	Dietitian: 51 hours of MI training; Exercise specialist: 48 hours of MI training	Individual	Face-to-face	6 weeks	6	Weekly	40 minutes
Burrows 2021 Australia Adults	52	94	43.6 (12.2)	36.7 (6.8)	Addictive Overeating and Overweight or Obesity	**Comparator:** Waitlist control	Waitlist control								
						Intervention: Foodfix (MI)	Counselling sessions including MI and using Social Cognitive Theory, with aim to improve addictive eating: setting nutrition and health goals based on aspects of personality	Accredited Practising Dietitians	Experience in counselling	Individual	Telehealth platform or telephone	3 months	3	Week 1, 3 and 7	Baseline (week 1): 45min Second (week 3): 25-35min Final (week 7): 15-20min
Quintiliani 2021 USA Adults	102	88.2	46.5 (11.9)	31.2 (6.5)	Overweight or Obesity	**Comparator:** Brief tailored feedback	Printed feedback report on: current minutes of moderate physical activity, servings of fruits and vegetables, whole grains, high fat dairy foods,			Individual	Printed report			One-off	

Study	Participants					Groups	Interventions								
							Content	Provider	Provider training	Mode	Level of personal contact	Programme duration	Sessions		
													N	Frequency	Length per session
	Total	Female (%)	Age Mean (SD)	BMI Mean (SD)	Conditions for which seeking treatment/ prevention										
							high fat protein foods, and sugary drinks as self-reported in the baseline survey, national guidelines for each behaviour, tips to achieve these behaviours, and websites of diet and physical activity-related resources for more information								
						Intervention: Brief tailored feedback +MI	Printed feedback report on: current minutes of moderate physical activity, servings of fruits and vegetables, whole grains, high fat dairy foods, high fat protein foods, and sugary drinks as self-reported in the baseline survey, national guidelines for each behaviour, tips to achieve	MI: community health workers	Previous experience delivering MI + Four training sessions, 1–2 h in length, were held to review information on energy balance, nutrition/ physical activity	Individual	Face-to-face and telephone	12 weeks	12	Once a week	NR

Study	Participants					Groups	Interventions								
							Content	Provider	Provider training	Mode	Level of personal contact	Programme duration	Sessions		
													N	Frequency	Length per session
	Total	Female (%)	Age Mean (SD)	BMI Mean (SD)	Conditions for which seeking treatment/ prevention										
							these behaviours, and websites of diet and physical activity-related resources for more information + Diet and physical activity behavioural counselling sessions including MI, goal-setting, feedback		recommendations; MI strategies; and study-specific protocols						
Ferrara 2016 USA Adults	2280	100	32.04‡ (6.42§)	28.7** (6.7**) 31.2†† (6.4††)	Gestational Diabetes and Reduction of postpartum weight retention	**Comparator:** Usual care	Usual care during pregnancy and post-partum + Mailed recommendations on eating, PA and BMI with aim to prevent post-partum diabetes in women who have had gestational diabetes	NR		Individual	Usual care during pregnancy: telephone; Post-partum usual care: printed materials	Usual care during pregnancy: telephone gestational diabetes management: from diagnosis until delivery; Post-partum usual care (printed materials): from 6 weeks post-partum onward			

Study	Participants					Groups	Interventions								
							Content	Provider	Provider training	Mode	Level of personal contact	Programme duration	Sessions		
													N	Frequency	Length per session
	Total	Female (%)	Age Mean (SD)	BMI Mean (SD)	Conditions for which seeking treatment/ prevention										
						Intervention: Usual care + DPP-derived lifestyle intervention (including MI)	Usual care during pregnancy and post-partum + Mailed recommendations on eating, PA and BMI with aim to prevent post-partum diabetes in women who have had gestational diabetes + Counselling on healthy eating, PA and weight post-partum (MI)	Usual care NR; MI: coaches (dietitians)	MI: NR	Individual	Usual care during pregnancy: telephone; Post-partum usual care: printed materials; MI: telephone	Usual care during pregnancy: telephone gestational diabetes management: from diagnosis until delivery; Post-partum usual care (printed materials): from 6 weeks post-partum onward; MI post-partum: suggestive from 6 weeks until 6 months postpartum (approx. 18 weeks); From 7 months till 12 months post-partum:	MI post-partum: approximately 18	MI: Weekly sessions from 6 weeks up to 6 months postpartum	MI: the first session lasted a mean of 28.2 minutes (SD 8.6); subsequent sessions lasted a mean of 18.8 minutes (SD 7.4)

Study	Participants					Groups	Interventions								
							Content	Provider	Provider training	Mode	Level of personal contact	Programme duration	Sessions		
													N	Frequency	Length per session
	Total	Female (%)	Age Mean (SD)	BMI Mean (SD)	Conditions for which seeking treatment/ prevention										
												maintenance phase, with no sessions			
Woollard 1995 Australia Adults	166	46.6	58.3 (NR)	27.2 (5.5)	Hypertension	**Comparator:** Usual GP care	Usual GP care- routine treatment	GP							
						Intervention 1: Low intervention (including MI)	Routine GP care + Lifestyle intervention to improve blood pressure control including weight reduction, alcohol reduction and salt restriction, focusing on self-efficacy, PA and smoking cessation, using MI	Routine care: GP; MI: Nurse counsellors	MI: NR	MI: Individual	MI: Face-to-face and telephone	MI: 18 weeks	MI: 6	MI: every 4 weeks	MI: unclear for first face-to-face session; Telephone sessions were 15 minutes
						Intervention 2: High intervention (including MI)	Routine GP care + Lifestyle intervention to improve blood pressure control including weight reduction, alcohol reduction and salt restriction, focusing on self-efficacy, PA and smoking	Routine care: GP; MI: Nurse counsellors	MI: NR	MI: Individual	MI: face-to-face	MI: 18 weeks	MI: 6	MI: every 4 weeks	MI: 45 minutes

Study	Participants					Groups	Interventions								
							Content	Provider	Provider training	Mode	Level of personal contact	Programme duration	Sessions		
													N	Frequency	Length per session
	Total	Female (%)	Age Mean (SD)	BMI Mean (SD)	Conditions for which seeking treatment/ prevention										
							cessation, using MI								
Christie 2017 UK Adolescents	174	63	15[‡] (14-17[§])	32.0[‡] (29.0-35.1[§])	Obesity	**Comparator:** Enhanced care	Pre-written standardised educational session delivered to young people incorporating guidance on eating behaviours, healthy eating and activity	Primary care nurse or trained nurse practitioner	No training	Individual	Face-to-face	One-off session	1	One-off session within 3 months from recruitment	40-60 minutes
						Intervention: Healthy Eating Lifestyle Program (HELP)	Solution-focused and motivational weight management programme (includes MI)	Psychology graduates	5-day training on obesity and good clinical practice with 2 of the 5 days focusing on behaviour change techniques + Training in specific MI techniques and the use of solution-focused questioning	Individual	Face-to-face	6 months	12	NR	40-45 minutes

Study	Participants					Groups	Interventions								
							Content	Provider	Provider training	Mode	Level of personal contact	Programme duration	Sessions		
													N	Frequency	Length per session
	Total	Female (%)	Age Mean (SD)	BMI Mean (SD)	Conditions for which seeking treatment/ prevention										
Davis Martin 2006 USA Adults	144	100	41.8 (12)	38.9 (7.6)	Overweight or Obesity	**Comparator:** Standard care	Regular medical care	Physicians		Individual	Face-to-face	Seen as needed, for regular medical care	Seen, as needed, for regular medical care	Seen, as needed, for regular medical care	Seen, as needed, for regular medical care
						Intervention: Tailored intervention (including MI)	Diet and physical activity advice, culturally tailored incorporating MI	Physicians	2 hours of instruction on general obesity treatment + 7 hours of training on stage of change, MI, and techniques for behavioural treatment of obesity, and dietary recom-mendations, food labels and recipe modifi-cation	Individual	Face-to-face	6 months	6	Monthly	15 minutes
Hardcastle 2008	334	Unclear	50.2 (0.6¶)	33.65 (0.30¶)	Overweight or Obesity, and/or	**Comparator:** Control	Standard written information on diet and PA			Individual	Printed materials				

Study	Participants					Groups	Interventions								
							Content	Provider	Provider training	Mode	Level of personal contact	Programme duration	Sessions		
													N	Frequency	Length per session
	Total	Female (%)	Age Mean (SD)	BMI Mean (SD)	Conditions for which seeking treatment/ prevention										
UK Adults					Hypertension, and/or Dyslipidaemia	**Intervention:** Counselling including MI	MI-based counselling on diet and PA, with different strategies used depending on an individual's needs and readiness to change	PA specialist + Registered dietitian	Two 4-hour training sessions on MI and the nature of motivation	Individual	Face-to-face	6 months	At least 1 and up to 5	NR	20-30 minutes
Moeller 2019 Denmark Adults	37	100	30.5‡ (22.5; 34§)	32.7 (NR)	Obesity	**Comparator:** Standard advice	Standard diet and PA advice for weight loss via booklet	NR	NR	Individual	Booklet only	6 months			
						Intervention: Standard advice + MI	Standard diet and PA advice for weight loss via booklet + MI counselling	Nurse	Certified member of Motivational Interview Network of Trainers	Individual	Standard advice: booklet; MI: mix of face-to-face or video interviews with text messaging	6 months	MI: 10 face-to-face on average (6-12); Unclear how much text message contact	MI: once every two weeks	MI: NR
Sawyer 2020 USA Adults	140	60.3	59.4 (11.2)	34.4 (7.1)	Type 2 Diabetes and/or Hypertension	**Comparator:** Usual care	Attending regular physician visits and taking any prescribed medications	Primary care physician		Individual	Face-to-face				
						Intervention: MI	Tailored whole-person lifestyle intervention	Registered nurse	Trained in MI (no further	Individual	Face-to-face	6 months	4	NR	60 minutes

Study	Participants					Groups	Interventions								
							Content	Provider	Provider training	Mode	Level of personal contact	Programme duration	Sessions		
													N	Frequency	Length per session
	Total	Female (%)	Age Mean (SD)	BMI Mean (SD)	Conditions for which seeking treatment/ prevention										
							incorporating MI, focused on attainment of personal health goals, and including knowledge on self-monitoring and self-regulation, and identification of barriers to change		details given)						
Elliot 2007 USA Adults	365	3	41.5 (9)	27.5 (0.3¶)	Good health	**Comparator:** Testing-and results-only comparison condition	Information about test results; No goals for healthy lifestyle.			Individual	Mail and website	Active intervention was for 1 year			

Study	Participants					Groups	Interventions								
							Content	Provider	Provider training	Mode	Level of personal contact	Programme duration	Sessions		
													N	Frequency	Length per session
	Total	Female (%)	Age Mean (SD)	BMI Mean (SD)	Conditions for which seeking treatment/ prevention										
						Intervention: MI health coaching	Diet and physical activity advice, and advice for maintaining a healthy weight through counselling involving MI	Six counsellors skilled in MI	Although experien-ced counsellors, only two had significant experience with MI, and each completed approxima-tely 90 hours of MI training, including seminars, educational videotapes, personal coaching from an expert trainer, and practice with standardi-sed patients.	Individual	Mail and website; MI: face-to-face and telephone	Active intervention was for 1 year	MI: At least 4 with the possibilit y of up to 5 hours of additiona l face-to-face or phone contact	MI: NR	MI: 1 hour
Studies with comparators of lower intensity compared to MI sorted by programme duration															

Study	Participants					Groups	Interventions								
							Content	Provider	Provider training	Mode	Level of personal contact	Programme duration	Sessions		
													N	Frequency	Length per session
	Total	Female (%)	Age Mean (SD)	BMI Mean (SD)	Conditions for which seeking treatment/ prevention										
Everett 2021 Australia Adults	110	28	60.1 (10.6)	29.1 (4.9)	Coronary Heart Disease	**Comparator:** Usual care	Cardiac rehabilitation program: exercise, education and risk factor modification	Nurses		Individual (assumed)	Face-to-face	6 weeks	Assumed 6	Assumed weekly	NR
						Intervention: Usual care + MI	Cardiac rehabilitation program supplemented with MI to promote maintenance of coronary risk factor modification	Usual care: Nurses MI: researcher who was a nurse	MI: experien-ced registered nurse trained in MI	Individual (assumed)	Face-to-face	Usual care: 6 weeks MI: first 2 weeks of usual care program	Usual care: 6 MI: 2	Usual care: weekly MI: 1 week apart	Usual care: NR MI: 60 minutes
Currie 2017 USA Adolescents	64	56	14.4 (1.92)	38.3 (24.6)	Obesity	**Comparator:** Standard Care	Consultation with physician including PA, as well as with nutritionist, and access to medical family therapist as needed	Physician, nutritionist and medical family therapist if needed	N/A	Individual	NR	NR	1 with physician, 1 with nutrition-ist and medical family thera-pist as needed	One-off consultations with physician and dietitian, and access to medical family therapist as needed	1 hour with physician 1 hour with dietician; As needed for medical family therapist
						Intervention: Standard Care + PA intervention (including MI)	Consultation with physician including PA, as well as with nutritionist, and access to medical	Standard care: Physician, nutritionist and medical family therapist if needed;	Standard care: N/A; MI: 7 hours of MI training	Individual	Standard care: NR; MI: telephone	7 weeks	Standard care: 1 with physician, 1 with nutritioni	Standard care: one-off consultations with physician and dietitian, and	Standard care: 1 hour with physician 1 hour with dietician;

Study	Participants					Groups	Interventions								
							Content	Provider	Provider training	Mode	Level of personal contact	Programme duration	Sessions		
													N	Frequency	Length per session
	Total	Female (%)	Age Mean (SD)	BMI Mean (SD)	Conditions for which seeking treatment/ prevention										
							family therapist as needed + Newsletters and telephone calls to promote PA and weight loss, incorporating MI	MI: Research staff					st and medical family therapist as needed; MI: 7	access to medical family therapist as needed; MI: weekly	As needed for medical family therapist MI: average of 9.05 +/- 3.14 minutes; 50 minutes dose over the study period
Andre 2015 France Adolescents	16		14.4* (1.5*)	37.7 (NR)	Obesity	**Comparator:** PA	Physical training programme	NR	NR	Individual	Suggestive of face-to-face	2 months	8	Weekly	4 hours
						Intervention: PA + MI	Physical training programme + Psychological counselling (MI)	PA: NR; MI: therapist (clinician)	PA: NR; MI: NR	Individual	PA: suggestive of face-to-face; MI: suggestive of face-to-face		PA: 8; MI: 16	PA: weekly; MI: twice a week	PA: 4 hours; MI: 20 minutes
Davis 2011 USA Adolescents	32	100	15.8 (1.1)	33.4 (4.5)	Obesity	**Comparator:** Circuit Training	PA training	Trainer (no details given)		Individual	Face-to-face	16 weeks	32	Twice a week (non-consecutive days)	20-45 minutes cardio-vascular activity coupled

Study	Participants					Groups	Interventions								
							Content	Provider	Provider training	Mode	Level of personal contact	Programme duration	Sessions		
													N	Frequency	Length per session
	Total	Female (%)	Age Mean (SD)	BMI Mean (SD)	Conditions for which seeking treatment/ prevention										
															with 30-45 minutes strength training
						Intervention: Circuit Training + MI	PA training + MI counselling for PA	PA: trainer (no details given); MI: two trained research staff (both members of the Motivational Interviewing Network of Trainers)	MI: NR	Mixed individual and group	Face-to-face	16 weeks	PA: 32; MI: 8	PA: Twice a week (non-consecutive days); MI: Unclear	PA: 20-45 minutes cardio-vascular activity coupled with 30-45 minutes strength training; MI: NR
Lewis 2019 Australia Adults	61	77	49 (12.6)	47.8 (8.4)	Obesity	**Comparator:** Standard Obesity Management Service (OMS)	Assessment of medical complications of obesity + Education by a multidisciplinary team, on diet and PA and prescription of diet and PA + Case management support +	Multidisciplinary team of health professionals: doctors, nurses, psychologists, exercise physiologists, and dietitians	NR	Group	Face-to-face	Initial appointment, followed by a 4-week education group, followed by individual case management support	Varied	Varied	NR

Study	Participants					Groups	Interventions								
							Content	Provider	Provider training	Mode	Level of personal contact	Programme duration	Sessions		
													N	Frequency	Length per session
	Total	Female (%)	Age Mean (SD)	BMI Mean (SD)	Conditions for which seeking treatment/ prevention										
							Psychological support								
						Intervention: Standard Obesity Management Service (OMS) + Telephone and text support (including MI)	Assessment of medical complications of obesity + Education by a multidisciplinary team, on diet and PA and prescription of diet and PA + Case management support + Psychological support + Extra support remotely via telephone based on MI including: goal setting for PA, diet, stress/mood, sleep and lifestyle habits, self-monitoring +	Standard OMS: Multidisciplinary team of health professionals: doctors, nurses, psychologists, exercise physiologists, and dietitians; Tech support (MI): the primary investigator	NR	Standard OMS: Group; MI: individual	Standard OMS: Face-to-face; MI: telephone and text, but mainly telephone	Standard OMS: Initial appointment, followed by a 4-week education group, followed by individual case management support; MI: 4 months	Standard OMS: varied; MI: 4 telephone calls + 12 texts	Standard OMS: varied; MI: monthly telephone calls and weekly texts	Standard OMS: NR; MI: 10-30 minutes (telephone call)

Study	Participants					Groups	Interventions								
							Content	Provider	Provider training	Mode	Level of personal contact	Programme duration	Sessions		
													N	Frequency	Length per session
	Total	Female (%)	Age Mean (SD)	BMI Mean (SD)	Conditions for which seeking treatment/ prevention										
							texts to endorse autonomous motivation								
Mash 2014 South Africa Adults	1570	73.8	56.1 (11.6)	33.7 (7.5)	Type 2 Diabetes	**Comparator:** Control	Usual diabetes group education, including ad hoc educational talks, as well as occasional individual counselling during consultations	Health promoters	NR	Mixed individual and group	Face-to-face	NR	NR	NR	NR
						Intervention: Group intervention (including MI)	Group diabetes education based on MI, including diet, PA, medication advice and advice on preventing complications	Health promoters	6 days training	Group	Face-to-face	NR	4	NR	20-60 minutes
Smith 1997 USA Adults	22	100	62.4 (7)	34.7 (4.9)	Obesity and Type 2 Diabetes	**Comparator:** Standard Behavioural Weight Control	Nutritional information and training in behaviour modification of eating and exercise, incorporating self-monitoring of diet and PA and of blood glucose	Team of: nutritionist, psychologists, and exercise physiologists	NR	Group	Face-to-face	4 months	16	Weekly	NR

Study	Participants					Groups	Interventions								
							Content	Provider	Provider training	Mode	Level of personal contact	Programme duration	Sessions		
													N	Frequency	Length per session
	Total	Female (%)	Age Mean (SD)	BMI Mean (SD)	Conditions for which seeking treatment/ prevention										
						Intervention: Behavioural Weight Control with MI	Nutritional information and training in behaviour modification of eating and exercise, incorporating self-monitoring of diet and PA and of blood glucose + MI sessions on change	Standard program: team of nutritionist, psychologists, and exercise physiologist; MI: psychologists	Standard programme: NR; MI: half with a senior and half with a junior psycholo-gist, both experien-ced in MI (no further details)	Standard programme: group; MI: individual	Standard programme: face-to-face; MI: face-to-face	4 months	Standard programme:16; MI: 3	Standard programme: weekly; MI: one at the beginning and two at mid-treatment	NR
Allen 2013 USA Adults	33	77.9	44.9 (11.1)	34.3 (3.9)	Overweight or Obesity	**Comparator:** Weight loss smartphone application	One-off basic nutrition counselling + Self-management; mindful empowerment; real time feedback; motivators; opportunities for social networking	Basic nutrition session: NR	Basic nutrition session: NR	Individual	Basic nutrition session: face-to-face; Remotely: smart-phone application	6 months	Basic nutrition session: 1	Basic nutrition session: one-off	1 hour
						Intervention 1: Weight loss smartphone application +	Self-management; mindful empowerment; real time feedback; motivators and	MI: nutritionist coach	MI: NR	Individual	Remotely: smart-phone application;		MI:12	MI: weekly for the first month and biweekly for the second	1 hour

Study	Participants					Groups	Interventions								
							Content	Provider	Provider training	Mode	Level of personal contact	Programme duration	Sessions		
	Total	Female (%)	Age Mean (SD)	BMI Mean (SD)	Conditions for which seeking treatment/ prevention								N	Frequency	Length per session
						Intensive diet and exercise counselling (including MI)	opportunities for social networking + Intensive healthy eating and exercise counselling (MI)				MI: suggestive of face-to-face			through sixth month	
						Intervention 2: Weight loss smartphone application + Less intensive diet and exercise counselling (including MI)	Self-management; mindful empowerment; real time feedback; motivators and opportunities for social networking + Less intensive healthy eating and exercise counselling (MI)	MI: nutritionist coach	MI: NR	Individual	Remotely: smartphone application; MI: suggestive of face-to-face		MI: 6	MI: twice during the first month and then monthly from 2 to 6 months	1 hour
Carels 2007 USA Adults	55	86.8	48.2 (10)	35.8 (8.1)	Obesity	**Comparator:** BWLP	Weight loss program based on LEARN including advice on PA, reducing energy intake and fat intake	NR	NR	Group	Face-to-face	24 weeks	20	Unclear	75 minutes
						Intervention: BWLP + Stepped Care (including MI)	Weight loss program based on LEARN including advice on PA, reducing energy	BWLP: NR; MI: Clinical psychology doctoral student	BWLP: NR; MI: 20 hours of readings on MI, videos,	BWLP: group; MI: individual	Face-to-face		BWLP: 20; MI: 24	BWLP: unclear; MI: weekly	BWLP: 75 minutes; MI: 45-60 minutes

Study	Participants					Groups	Interventions								
							Content	Provider	Provider training	Mode	Level of personal contact	Programme duration	Sessions		
													N	Frequency	Length per session
	Total	Female (%)	Age Mean (SD)	BMI Mean (SD)	Conditions for which seeking treatment/ prevention										
							intake and fat intake + MI when failing to meet weight loss goals		role play and discussions of MI principles and strategies						
Sun 2020 China Adults	100	14.8%	41.8 (12.0)	33.7 (2.3)	Obesity	**Comparator:** Routine postoperative care	General postoperative health education, including knowledge about weight control, and advice on diet and exercise	Systematically trained interviewers and duty nurses	NR	Individual	Face-to-face and follow-up via telephone	6 months	NR	Education before discharge and follow-up at 1, 3, 6 months after discharge	NR
						Intervention: MI on the basis of routine postoperative care	General postoperative health education, including knowledge about weight control, and advice on diet and exercise + MI focusing on disease-related knowledge, diet and exercise, emotional intervention and review guidance	Systematically trained interviewers and duty nurses	Routine care: NR; MI: NR	Routine care: individual; MI: individual	Face-to-face and telephone	6 months	Routine care: NR; MI: 6	Routine care: education before discharge and follow-up at 1, 3, 6 months after discharge; MI: once a month	Routine care: NR; MI: Pre-intentional and intentional stages: 30 to 45 minutes each; Preparation, action, and maintenance stages each lasting 15 to 20 minutes;

Study	Participants					Groups	Interventions								
							Content	Provider	Provider training	Mode	Level of personal contact	Programme duration	Sessions		
													N	Frequency	Length per session
	Total	Female (%)	Age Mean (SD)	BMI Mean (SD)	Conditions for which seeking treatment/ prevention										
															Summary stage: 30 to 45 minutes
Saffari 2014 Iran Adults	327	100	34.3 (6)	35.1 (5.7)	Overweight or Obesity	**Comparator:** Control	One-off education session on diet and PA with a focus on weight loss	Health psychologist	NR	Group	Face-to-face	One-off session	1	One-off session	NR
						Intervention: MI	One-off education session on diet and PA with a focus on weight loss + Sessions about weight loss incorporating MI and focusing on diet, emotions, behavioural change, values of health behaviours for health outcomes, metabolic markers	Health psychologist	One-off education session: NR; MI: NR	One-off education session: group; MI: individual	One-off education session: face-to-face; MI: face-to-face	One-off education session; MI: 12 months	One-off educa-tion session: 1; MI: 5	One-off education session; MI: 1st (baseline), 3rd, 6th, 9th, and 12 months	One-off education session: NR; MI: 60 minutes
Simpson 2015 UK Adults	170	84.3	48.5‡ (23.16§)	34.1 (5.8)	Overweight or Obesity	**Comparator:** Control	Information pack with resources on weight loss and healthy lifestyle, and advice on weight loss maintenance			Individual and/or group	Face-to-face				

Study	Participants					Groups	Interventions								
							Content	Provider	Provider training	Mode	Level of personal contact	Programme duration	Sessions		
													N	Frequency	Length per session
	Total	Female (%)	Age Mean (SD)	BMI Mean (SD)	Conditions for which seeking treatment/ prevention										
							+ Option to access usual care e.g. attending a slimming club								
						Intervention 1: Intensive intervention (including MI)	Information pack with resources on weight loss and healthy lifestyle, and advice on weight loss maintenance + Option to access usual care e.g. attending a slimming club + Intervention based on self-monitoring, social support and on MI in the context of weight loss maintenance	MI: MI practitioners	MI: NR	Usual care option: Individual and/or group; MI: individual	Usual care option: face-to-face; MI: face-to-face and telephone	MI: 12 months	MI: 6 face-to-face + 9 tele-phone	MI: face-to-face: fortnightly for 3 months + telephone: monthly from 4-12 months	MI: face-to-face: 1 hour + telephone: 20 minutes
						Intervention 2: Less intensive intervention (including MI)	Information pack with resources on weight loss and healthy lifestyle, and advice on weight loss maintenance +	MI: MI practitioners	MI: NR	Usual care option: individual and/or group; MI: individual	Usual care option: face-to-face; MI: face-to-face and telephone	MI: 12 months	MI: 2 face-to-face + 2 tele-phone	MI: face-to-face: 2 weeks apart + telephone: at 6 and 12 months	MI: face-to-face: 1 hour + telephone: 20 minutes

Study	Participants					Groups	Interventions								
							Content	Provider	Provider training	Mode	Level of personal contact	Programme duration	Sessions		
													N	Frequency	Length per session
	Total	Female (%)	Age Mean (SD)	BMI Mean (SD)	Conditions for which seeking treatment/ prevention										
							Intervention based on self-monitoring, social support and on MI in the context of weight loss maintenance + Option to access usual care e.g. attending a slimming club								
Staite 2020 UK Adults	200	53	52.28 (7.94)	32.3 (5.8)	Prediabetes	**Comparator:** Web-based DPP via smartphone app	Diabetes prevention intervention providing education on diet, PA and mental resilience			Individual	Web-based via smart-phone app	12 months	22	Weekly for modules 1 to 6; Biweekly for modules 7 to 16; Monthly (4 weeks) for modules 17 to 22	
						Intervention: Web-based DPP via smartphone app + Motivational SMS (including MI)	Diabetes prevention intervention providing education on diet, PA and mental resilience + SMS using MI principles to support formation of healthy	MI: NR	MI: NR	DPP: individual; MI: individual	DPP: web-based via smart-phone app; MI: SMS	12 months	DPP: 22; MI: about 1440 messages in total	DPP: Weekly for modules 1 to 6; Biweekly for modules 7 to 16; Monthly (4 weeks) for modules 17 to 22; MI: 3-4 messages/	

Study	Participants					Groups	Interventions								
							Content	Provider	Provider training	Mode	Level of personal contact	Programme duration	Sessions		
	Total	Female (%)	Age Mean (SD)	BMI Mean (SD)	Conditions for which seeking treatment/ prevention								N	Frequency	Length per session
							intentions, encourage self-monitoring and promote social support							day	
Williams 2014 Australia Adults	54	100	47.3 (1.8)	25.1 (2.4)	Prevention of weight gain	**Comparator:** Self-directed intervention	Weight gain prevention intervention for healthy-weight, and weight loss intervention overweight participants: self-guided, focusing on diet and PA, achieved through individually tailored behaviour change strategies + strategies set by practitioners and mailed to participants	Practitioners	NR	Individual	Mailed, print	12 months		First mail out, one month after baseline, and second within a month of the three-month measures	
						Intervention: Health professional-led intervention (including MI)	Weight gain prevention intervention for healthy-weight, and weight loss intervention	One dietitian and two exercise physiologists	MI training including online courses, self-directed	Individual	Mailed, print + MI: face-to-face	12 months	4	Within 1 month of baseline measures, participants received an individual	60 minutes

Study	Participants					Groups	Interventions								
							Content	Provider	Provider training	Mode	Level of personal contact	Programme duration	Sessions		
	Total	Female (%)	Age Mean (SD)	BMI Mean (SD)	Conditions for which seeking treatment/ prevention								N	Frequency	Length per session
							overweight participants: self-guided, focusing on diet and PA, achieved through individually tailored behaviour change strategies + strategies set by practitioners and mailed to participants + MI counselling sessions		reading and workshops					counselling session with a Dietitian (1 x 60 min) and an Exercise Physiologist (1 x 60 min). The remaining 3 x 60 min individual counselling sessions were conducted by the same Dietitian 3, 6 and 9 months after the first appointment.	
Chapman 2018 China Adults	730	52.7	63.8 (8.3)	26.1 (11)	Type 2 Diabetes	**Comparator:** Usual care	Diabetes prevention and management	Physicians and other health professionals		Suggestive of individual	NR				
						Intervention: MI Health Coaching	Diabetes prevention and management + Health coaching to achieve targets in the guidelines (MI)	Usual care: physicians and other health professionals; MI: community doctors, nurses and psychologists	MI: Certification in coach-assisted chronic disease management (learning phase, 2-day intensive	Suggestive of individual	Face-to-face and telephone	18 months	25	0-3 months: 2 face-to-face and 2 telephone sessions per month; 3-6 months: 1 telephone and 2 face-to-face sessions;	Reported only for 0-3 months: 30 minutes each of face-to-dace sessions and 20

Study	Participants					Groups	Interventions								
							Content	Provider	Provider training	Mode	Level of personal contact	Programme duration	Sessions		
	Total	Female (%)	Age Mean (SD)	BMI Mean (SD)	Conditions for which seeking treatment/ prevention								N	Frequency	Length per session
									MI workshop, refresher workshops, monthly half-day advanced workshop, debriefing and feedback every 3 months)					6-12 months: 1 telephone and 1 face-to-face session; 12-18 months: 1 telephone session per 3 months and 1 face-to-face per month	minutes each of the telephone sessions
West 2016 USA Adults	398	89.7	48.4 (10.1)	36.0 (6.0)	Overweight or Obesity	**Comparator:** Group Internet Behavioural Weight Control Intervention	Group online chat weight control intervention focusing on education about diet and PA change, using self-management skills and other behavioural strategies, weekly homework and individualised therapist feedback	Experienced behavioural weight control counsellors	NR	Group	Online chat sessions (typed)	18 months	36	Weekly for the first 6 months and monthly for another 12 months	1 hour
						Intervention: Group Internet Behavioural Weight Control + MI Intervention	Group online chat weight control intervention focusing on education about	Weight program: Experienced behavioural	Weight program: NR;	Weight program: group;	Weight program: online chat sessions (typed);	18 months	Weight program me:36 group sessions;	Weight program: weekly for 6 months and then monthly	Weight program: 1 hour;

Study	Participants					Groups	Interventions								
							Content	Provider	Provider training	Mode	Level of personal contact	Programme duration	Sessions		
													N	Frequency	Length per session
	Total	Female (%)	Age Mean (SD)	BMI Mean (SD)	Conditions for which seeking treatment/ prevention										
							diet and PA change, using self-management skills and other behavioural strategies, weekly homework and individualised therapist feedback + MI chat sessions to clarify and amplify personal reasons for behaviour changes that promote weight loss and sustained weight maintenance	weight control counsellors; MI: MI counsellor (psychologist)	MI: Training and ongoing supervision in MI by a motivational interviewing network trainer and a clinical psychologist, plus group telephoning coaching weekly on MI spirit	MI: individual	MI: online chat sessions (typed)		MI: 6	for another 12 months; MI: 1st session after randomization and before group, 2nd after session 5, and the next 5 sessions were at 3-month intervals (week 18, 31 , 44 and 57)	MI: 30 minutes
Rodri-guez-Cristobal 2017 Spain	864	77.2	53.7 (15.7)	34.1 (4.8)	Overweight or Obesity	**Comparator:** Usual care	Standard weight loss intervention including advice on diet and PA for weight loss	Doctors	NR	Individual	Face-to-face	24 months	NR	Every 3 months	NR

Study	Participants					Groups	Interventions								
							Content	Provider	Provider training	Mode	Level of personal contact	Programme duration	Sessions		
													N	Frequency	Length per session
	Total	Female (%)	Age Mean (SD)	BMI Mean (SD)	Conditions for which seeking treatment/ prevention										
Adults						**Intervention:** Usual care + MI	Standard weight loss intervention including advice on diet and PA for weight loss + Group MI counselling	Nurse	Usual care: NR; MI: Trained by an expert psychologist focusing on group motivation for lifestyle changes, workshops, role play, including written guidance on disease, healthy habits and diet to standardise delivery	Usual care: individual; MI: group	Face-to-face	24 months	Usual care: NR; MI: 32	Usual care: every 3 months; MI: once fortnightly during weeks 1 to 12, and then monthly from week 13 to 32	Usual care: NR; MI: 1 hour
Studies with comparators of similar intensity to MI sorted by program duration															
Mirkarimi 2017 Iran Adults	100	100	37.9 (9.0)	28.5 (1.9)	Overweight or Obesity	**Comparator:** Nutrition education	Nutrition education including importance of overweight and obesity, healthy	Nutritionist and health education specialist	NR	Group	Face-to-face	2 weeks	4	NR	2 hours

Study	Participants					Groups	Interventions								
							Content	Provider	Provider training	Mode	Level of personal contact	Programme duration	Sessions		
													N	Frequency	Length per session
	Total	Female (%)	Age Mean (SD)	BMI Mean (SD)	Conditions for which seeking treatment/ prevention										
							dietary patterns, behavioural change, PA								
						Intervention: MI	Weight loss intervention based on MI including nutrition education, importance of overweight and obesity, healthy dietary patterns, behavioural change, PA	Psychologist	NR	Group	Face-to-face	2 weeks	5	NR	2 hours
Macdonell 2012 USA Adolescents	49	79.5	15.11 (1.35)	35.36 (7.8)	Overweight or Obesity	**Comparator:** Nutrition counselling	Manualized nutrition counselling, including caregiver participation	Registered dietitian		Individual	Face-to-face	10 weeks	4	Weeks 1, 2, 6 and 10	60 minutes
						Intervention: MI	MI intervention on healthy eating and PA, with caregiver participation, including change plan for weight loss	Registered dietitian	16 hours of initial training and weekly supervision from a member of the MI network of Trainers	Individual	Face-to-face	10 weeks	4	Weeks 1, 2, 6 and 10	60 minutes
DiMarco 2009	39	82	39.9 (8.84)	32.36 (3.05)	Overweight or Obesity	**Comparator:** Standard guided self-help	Self-help weight loss program focusing on	Graduate students in	Each therapist treated a	Assumed individual	Face-to-face	Suggestive of 11 weeks	8	First 5 were weekly and the	1st and 5th sessions: 1 hour; The

Study	Participants					Groups	Interventions								
							Content	Provider	Provider training	Mode	Level of personal contact	Programme duration	Sessions		
													N	Frequency	Length per session
	Total	Female (%)	Age Mean (SD)	BMI Mean (SD)	Conditions for which seeking treatment/ prevention										
USA Adults						behavioural weight loss treatment	motivational issues but not incorporating MI	clinical psychology	pilot participant prior to the study and trainer listened to pilot session tapes; Therapists met for weekly group supervision and all session 1 and 5 tapes were reviewed by the first author; MI: Training by a senior clinical psycholo-gist					subsequent 3 were bi-weekly	other 6 sessions: 30 minutes
						Intervention: Guided self-help behavioural weight loss treatment + MI	Self-help weight loss program incorporating MI	Graduate students in clinical psychology		Assumed individual	Face-to-face	Suggestive of 11 weeks	8	First 5 were weekly and the subsequent 3 were bi-weekly	1st and 5th sessions: 1 hour; The other 6 sessions: 30 minutes
Barnes 2014 USA Adults	59	76.4	47.9 (10.5)	35.3 (7.0)	Overweight or Obesity	**Comparator:** Nutrition Psychoeducation (attention control)	Nutritional psychoeducation sessions providing basic nutritional information (e.g.	Medical assistants	One 8-hour training session +	Individual	Face-to-face and by phone	12 weeks	5	NR but same as MI group	NR but same as MI group

Study	Participants					Groups	Interventions								
							Content	Provider	Provider training	Mode	Level of personal contact	Programme duration	Sessions		
													N	Frequency	Length per session
	Total	Female (%)	Age Mean (SD)	BMI Mean (SD)	Conditions for which seeking treatment/ prevention										
							fruit/vegetable intake) + Website for setting weight/intake and PA goals + Weight loss manual No further discussion about motivation, goal setting or personalised feedback		Separate 60-90-minute group supervi-sions once every three weeks						
						Intervention: MI and Internet Condition	Nutritional sessions incorporating MI counselling to enhance motivation for weight loss, weight-related goals, and treatment adherence + Website for setting weight/intake and PA goals	Medical assistants	MI: two 8-hour training sessions by a member of the MI Network of Trainers	Individual	Face-to-face and by phone	12 weeks	5	NR	Initial session: 60-minutes Thereafter 20 minutes

Study	Participants					Groups	Interventions								
							Content	Provider	Provider training	Mode	Level of personal contact	Programme duration	Sessions		
													N	Frequency	Length per session
	Total	Female (%)	Age Mean (SD)	BMI Mean (SD)	Conditions for which seeking treatment/ prevention										
							+ Weight loss manual Personalised feedback based on food tracking at patients' discretion								
LaRose 2020 USA Adults	47	81	21.9 (1.9)	33.2 (4.6)	Overweight or Obesity	**Comparator:** Standard BWLP	Standard BWLP based on self-regulation, addressing diet and PA for weight loss and including, self-monitoring and goal setting	Doctoral students in psychology	Trained by a clinical psycholo-gist	Individual	Face-to-face and email/ online contact	3 months	At least 2	Weekly	75-90 minutes
						Intervention: MI-enhanced BWLP	Adapted standard BWLP based on self-regulation, reflecting MI principles while retaining core BWLP content	Doctoral students in psychology	BWLP: trained by a clinical psycholo-gist; MI: two-day workshop by a practitioner of MI	Individual	Face-to-face and email/ online contact	3 months	At least 2	Weekly	75-90 minutes
Moss 2017 Canada	135	77.7	45.16 (11.30)	33.58 (6.26)	Overweight or Obesity	**Comparator:** BWLP	BWLP emphasizing gradual sustainable	Therapist	NR	Suggestive of individual	Face-to-face	12 weeks	2	Twice within 12 weeks	45 minutes

Study	Participants					Groups	Interventions								
							Content	Provider	Provider training	Mode	Level of personal contact	Programme duration	Sessions		
													N	Frequency	Length per session
	Total	Female (%)	Age Mean (SD)	BMI Mean (SD)	Conditions for which seeking treatment/ prevention										
Adults							weight loss and lifestyle changes, including diet and PA advice and behavioural change techniques + Semi-structured interview addressing health history, weight history, diet history, and dietary and PA habits								
						Intervention: BWLP + MI	BWLP emphasizing gradual sustainable weight loss and lifestyle changes, including diet and PA advice and behavioural change techniques + Semi-structured MI counselling on weight	Therapist	BWLP: NR; MI: over 20 hours and a total of 8 days of workshop training; Ongoing supervision was provided by a doctoral-level clinical psycholo-gist	Suggestive of individual	Face-to-face	12 weeks	2	Twice within 12 weeks	45 minutes

Study	Participants					Groups	Interventions								
							Content	Provider	Provider training	Mode	Level of personal contact	Programme duration	Sessions		
	Total	Female (%)	Age Mean (SD)	BMI Mean (SD)	Conditions for which seeking treatment/ prevention								N	Frequency	Length per session
									throughout.						
Befort 2008 USA Adults	44	100	44.3 (11.6)	39.8 (6.4)	Obesity	**Comparator:** BWLP + Health Education	Diet and exercise advice for weight loss and behavioural modification skill building based on Diabetes Prevention Programme 2002 + Didactic information and advice about health, but not on weight loss, in addition to the BWLP	BWLP: doctorate-level psychologist and masters-level counsellor or dietitian; Health education: advanced doctoral clinical psychology students	Doctorate-level psychologist and masters-level counsellor or dietitian	BWLP: groups of 12-14; Health education: individual	BWLP: face-to-face; Health education: face-to-face and by telephone	16 weeks	BWLP: 16; Health education: 4	BWLP: weekly; Health education: at weeks 0, 3, 8 and 13	BWLP: 90 minutes; Health education: 30 minutes
						Intervention: BWLP + MI	Diet and exercise advice for weight loss and behavioural modification skill building based on Diabetes Prevention Programme 2002 + MI counselling for motivation, adherence, changing	BWLP: doctorate-level psychologist and a masters-level counsellor or dietitian; MI: advanced doctoral clinical psychology students	BWLP: doctorate-level psychologist and masters-level counsellor or dietitian; MI: reading on MI, watching	BWLP: groups of 12-14; MI: individual	BWLP: face-to-face; MI: face-to-face and by phone	16 weeks	BWLP: 16; MI: 4	BWLP: Weekly; MI: weeks 0, 3, 8 and 13	BWLP: 90 minutes; MI: 30 minutes

Study	Participants					Groups	Interventions								
							Content	Provider	Provider training	Mode	Level of personal contact	Programme duration	Sessions		
													N	Frequency	Length per session
	Total	Female (%)	Age Mean (SD)	BMI Mean (SD)	Conditions for which seeking treatment/ prevention										
							behaviours, including a behavioural action plan based on self-identified goals		MI training videotapes, a 2-day training session, simulated counselling sessions						
Webber 2010 USA Adults	80	100	48.7 (10.6)	32.0 (3.7)	Overweight or Obesity	**Comparator:** Standard BWLP	Weight loss sessions including instructions on diet and PA	Dietitian	N/A	Group	Face-to-face	16 weeks	1 session at the begin-ning; 1 session at 4 weeks; 16 lessons on website	1 session at the beginning; 1 session at 4 weeks; 16 weekly lessons on website	NR
						Intervention: MI-enhanced BWLP	MI sessions including weight loss basics, diet and exercise advice, instructions on self-monitoring and study website, pros and cons of weight loss, importance and reasons for weight loss and	Dietitian	Trained in MI by the MI Network of Trainers	Group	Face-to-face	16 weeks	1 session at the begin-ning; 1 session at 4 weeks; 16 lessons on website	1 session at the beginning; 1 session at 4 weeks ; 16 weekly lessons on website	NR

Study	Participants					Groups	Interventions								
							Content	Provider	Provider training	Mode	Level of personal contact	Programme duration	Sessions		
													N	Frequency	Length per session
	Total	Female (%)	Age Mean (SD)	BMI Mean (SD)	Conditions for which seeking treatment/ prevention										
							goal setting and journaling								
Ball 2011 Canada Adolescents	32	60.8	15.4 (1.3)	35.7 (32.0 to 39.3[†])	Obesity	**Comparator:** Youth Lifestyle Programme	Programme: diet (fat intake); PA; self-esteem; relapse prevention; self-monitoring; goal setting + Parent participation	Registered dietitians and registered nurses	2 days	Individual	Face-to-face	16-20 weeks	16	Weekly	45-60 minutes
						Intervention: Healthy Initiatives Programme (including MI)	Programme: diet (fat intake); PA; self-esteem; relapse prevention; self-monitoring; goal setting + Parent participation + MI with behavioural and cognitive change strategies	Registered dietitians and registered nurses	2 days (including MI training)	Individual	Face-to-face	16-20 weeks	16	Weekly	45-60 minutes
Chee 2017 Malaysia Adults	115	77.4	55[‡] (8[§])	31.2[‡] (0.8[§])	Type 2 Diabetes	**Comparator:** Trans-cultural diabetes-specific nutrition algorithm with conventional	Personalised nutrition counselling for diabetes (medical nutrition therapy) including	Dietitian and physician	NR	Individual	Suggestive of face-to-face	6 months	2 sessions during interven-tion period	Followed up monthly by the dietitian and physician during the intervention	NR

Study	Participants					Groups	Interventions								
							Content	Provider	Provider training	Mode	Level of personal contact	Programme duration	Sessions		
													N	Frequency	Length per session
	Total	Female (%)	Age Mean (SD)	BMI Mean (SD)	Conditions for which seeking treatment/ prevention										
						counselling (tDNA-CC)	conventional counselling techniques						+ 2 sessions during follow-up	phase and subsequently every 3 months during the follow-up phase	
						Intervention: Trans-cultural diabetes-specific nutrition algorithm with motivational interviewing (tDNA-MI)	Personalised nutrition counselling for diabetes (medical nutrition therapy) incorporating MI	Dietitian and physician	NR	Individual	Suggestive of face-to-face	6 months	6 sessions during interven-tion period + 2 sessions during follow-up	Followed up monthly by the dietitian and physician during the intervention phase and subsequently every 3 months during the follow-up phase	NR
Freira 2018 Portugal Adolescents	97	72.2	15.96 (1.30)	29.4 (23.4)	Overweight or Obesity	**Comparator:** Conventional intervention	Diet, weight loss and PA advice based on conventional counselling style	Counselling: school nurse and resident in pediatrics; Diet prescription: dietitians; PA plan: PA teacher	NR	Individual	Face-to-face	6 months	3	Three months apart	30 minutes

Study	Participants					Groups	Interventions								
							Content	Provider	Provider training	Mode	Level of personal contact	Programme duration	Sessions		
													N	Frequency	Length per session
	Total	Female (%)	Age Mean (SD)	BMI Mean (SD)	Conditions for which seeking treatment/ prevention										
						Intervention: MI group	Diet, weight loss and PA advice based on MI	Conventional counselling: school nurse and resident in paediatrics; Diet prescription: dietitians; PA plan: PA teacher; MI: paediatrician	Paediatrician had formation in MI with two MI Network of Trainers members	Individual	Face-to-face	6 months	3	Three months apart	30 minutes
Bóveda-Fontán 2015 Spain Adults	227	62.1	53.9 (8.6)	28.4 (4.2)	Dyslipidaemia	**Comparator:** Standard practice (usual brief advice)	Brief routine care intervention on cardio- protective behaviours and improvement of blood lipid control	GP	Workshop on approach-ing patients with dyslipi-demia + Training via consulta-tion videotapes No training in patient interview-ing	Suggestive of individual	Face-to-face	Unclear, but suggestive of 12 months	NR	Unclear	NR

Study	Participants					Groups	Interventions								
							Content	Provider	Provider training	Mode	Level of personal contact	Programme duration	Sessions		
													N	Frequency	Length per session
	Total	Female (%)	Age Mean (SD)	BMI Mean (SD)	Conditions for which seeking treatment/ prevention										
						Intervention: MI	An MI-based approach in combination with brief routine care intervention on cardio- protective behaviours and improvement of blood lipid control	GP	16-hour training course on MI + Two recorded simulated visits + A feedback session + Training enhance-ment (internet, SMS, feedback, group sessions)	Suggestive of individual	Face-to-face	Unclear, but suggestive of 12 months	NR	Unclear	NR
West 2007 USA Adults	217	100	53 (10)	36.5 (5.5)	Overweight or Obesity and Type 2 diabetes	**Comparator:** Group-based behavioural weight control programme	Weight loss programme followed by weight maintenance; Focuses on attainable and sustainable changes in diet and PA, strong emphasis on goal setting and	Weight program: multi-disciplinary team: behaviourist, nutritionist, exercise physiologist, and diabetes educator;	NR	Weight programme: group; Health education: individual	Weight programme: face-to-face; Health education: face-to-face	18 months	Weight programme: 42; Health education: 5	Weight programme: weekly for 6 months and then monthly for another 6 months; Health education: first session before group	Weight programme: NR; Health education: 45 minutes

Study	Participants					Groups	Interventions								
							Content	Provider	Provider training	Mode	Level of personal contact	Programme duration	Sessions		
													N	Frequency	Length per session
	Total	Female (%)	Age Mean (SD)	BMI Mean (SD)	Conditions for which seeking treatment/ prevention										
							problem solving, self-monitoring, stimulus control, social support, cognitive restructuring and relapse prevention + Information about diabetes, obesity, weight loss and specific recommendations to individuals with diabetes + Individual health education sessions matched to number and length to MI group, client cantered approach	Health education: health educator						program and then at 3, 6, 9 and 12 months	
						Intervention: Group-based behavioural weight control programme + MI	Weight loss programme followed by weight maintenance; Focuses on attainable and sustainable	Weight programme: multi-disciplinary team: behaviourist, nutritionist, exercise	Weight programme : NR; MI: trained but no details provided	Weight programme : group; MI: individual	Weight programme : face-to-face; MI: face-to-face	18 months	Weight programme: 42; MI: 5	Weight programme: weekly for 6 months and then monthly for another 6 months;	Weight programme : NR; MI: 45 minutes

Study	Participants					Groups	Interventions								
							Content	Provider	Provider training	Mode	Level of personal contact	Programme duration	Sessions		
													N	Frequency	Length per session
	Total	Female (%)	Age Mean (SD)	BMI Mean (SD)	Conditions for which seeking treatment/ prevention										
							changes in diet and PA, strong emphasis on goal setting and problem solving, self-monitoring, stimulus control, social support, cognitive restructuring and relapse prevention + Information about diabetes, obesity, weight loss and specific recommendations to individuals with diabetes + Individual MI sessions exploring personally relevant factors of motivation to lose with and how weight loss fits into future goals	physiologist, and diabetes educator; MI: Licensed clinical psychologists						MI: first session before group and then at 3, 6, 9 and 12 months	
Drevenhorn 2012 Sweden	213	NR	NR	31.3 (4.2)	Hypertension and/or Dyslipidaemia	**Comparator:** Usual care	Usual care from nurses for hypertension management	Nurses		Individual	Face-to-face				

Study	Participants					Groups	Interventions								
							Content	Provider	Provider training	Mode	Level of personal contact	Programme duration	Sessions		
													N	Frequency	Length per session
	Total	Female (%)	Age Mean (SD)	BMI Mean (SD)	Conditions for which seeking treatment/ prevention										
Adults						**Intervention:** Nurse education-patient counselling (includes MI)	Consultations based on MI incorporated in usual care delivered by special educated nurses for increasing adherence to hypertension management	Nurses	3-day residential training course on the Stages of Change model, MI, guidelines for cardio-vascular prevention	Individual	Face-to-face	Not explicitly reported but 2-year weight data are available and the intervention was incorporated into usual care	NR	NR	NR
Heinrich 2010 The Netherlands Adults	584	44.9	59 (5.27)	28.2 (5.5)	Type 2 Diabetes	**Comparator:** Usual care	Consultations for diabetes management and support for self-management through a web platform including: information and tools to support self-reflection, goal setting, problem solving and active patient participation	Nurses	No MI training	Individual	Face-to-face and web	2 years	Quarterly for 2 years, so assumed 8	Quarterly	NR
						Intervention: MI-based counselling	Consultations for diabetes management and support for self-management through a web platform	Nurses	21.5 counselling training hours and 5 hours optional	Individual	Usual care: web; MI: face-to-face	MI: 2 years	Quarterly for 2 years, so assumed 8	MI: Quarterly	NR

Study	Participants					Groups	Interventions								
							Content	Provider	Provider training	Mode	Level of personal contact	Programme duration	Sessions		
													N	Frequency	Length per session
	Total	Female (%)	Age Mean (SD)	BMI Mean (SD)	Conditions for which seeking treatment/ prevention										
							including: information and tools to support self-reflection, goal setting, problem solving and active patient participation + Health behaviour change counselling based on MI, fitted into diabetes care consultations		group meetings						

MI: motivational interviewing; **SD:** Standard Deviation; **BMI:** body mass index; **NR:** not reported; **PA:** physical activity; **BWLP:** behavioural weight loss programme; **GP:** general practitioner; **DPP:** Diabetes Prevention Programme; **tDNA-CC:** Trans-cultural diabetes-specific nutrition algorithm with conventional counselling; **tDNA-MI:** Trans-cultural diabetes-specific nutrition algorithm with motivational interviewing

* Mean and SD of age is for the whole sample which included a third arm which was not relevant to our analysis. It was assumed that the Mean and SD of age are similar for the two relevant groups, due to randomisation;
† 95% Confidence Interval (95%CI);
‡ Median;
§ Interquartile range (IQR) or 25; 75 quartiles;
¶ Standard Error;
** Pre-gravid. Weight changes are reported compared to pre-gravid weight;
†† At gestational diabetes diagnosis;
‡‡ Range.

Blank cells indicate judgement as not applicable.

Appendix 3.6. Risk of bias assessment of included studies

Study ID	Random sequence generation (Selection bias)	Allocation concealment (Selection bias)	Blinding of outcome assessment (Detection bias)	Incomplete outcome data (Attrition bias)	Selective reporting (Reporting bias)	Other risk of bias
Allen 2013	UNCLEAR	UNCLEAR	LOW	HIGH	LOW	LOW
Support for judgement:	"The SLIM (Smart coach for Lifestyle Management) study randomized 68 eligible participants to receive one of four interventions for six months: (1) an established intensive diet and exercise counseling intervention, or (2) an established intensive diet and exercise counseling plus self-monitoring smartphone intervention, or (3) a less intensive diet and exercise counseling plus self-monitoring smartphone	"The SLIM (Smart coach for Lifestyle Management) study randomized 68 eligible participants to receive one of four interventions for six months: (1) an established intensive diet and exercise counseling intervention, or (2) an established intensive diet and exercise counseling plus self-monitoring smartphone intervention, or (3) a less intensive diet and exercise counseling plus self-monitoring smartphone intervention, or (4) self-monitoring smartphone intervention only." No further detail provided	Weight was objectively measured: "Weight and height were measured with research participants in light clothing using a stadiometer and balance scale."	"Forty-three (63%) returned at six months for follow-up measurements. Retention rates in the four groups ranged from 59% to 69%." Since the total follow-up rate was <70%, the risk has been set as high.	"The protocol was approved by the Johns Hopkins University Institutional Review Board." No protocol or clinical trial registry available to confirm all outcome measures have been reported. However, all relevant, outlined outcomes listed in the Methods section were reported in the results.	N/A

Study ID	Random sequence generation (Selection bias)	Allocation concealment (Selection bias)	Blinding of outcome assessment (Detection bias)	Incomplete outcome data (Attrition bias)	Selective reporting (Reporting bias)	Other risk of bias
	intervention, or (4) self-monitoring smartphone intervention only." No further detail provided					
Andre 2015	UNCLEAR	UNCLEAR	UNCLEAR	LOW	LOW	LOW
Support for judgement:	"randomly assigned to three groups" No further detail provided.	"randomly assigned to three groups" No further detail provided.	No detail provided on how weight was assessed.	Twenty-four participants were recruited, and data for all participants are reported. Analysis was complete cases.	No clinical trial record or protocol available to assess for selective reporting, but all relevant to our review outcomes outlined in the methods section, are reported in the results.	N/A
Azami 2020	LOW	LOW	LOW	LOW	LOW	LOW
Support for judgement:	"The women who filled the pre-test questionnaire were randomly divided into MI and control groups by blocked randomization using random allocation software with	"The allocation type was written in a paper and put inside non-transparent envelopes which were numbered respectively (allocation concealment). Next, the envelopes were opened from number 1 and continued to the last one with respect to the entrance of each individual into the	Weight objectively measured: "Weight, without shoes and the least costumes, was measured by Seca digital scale (Germany) with 100 g of approximation (scale performance was daily checked by a 500 g calibration scale)"	Figure 1 (flow chart) suggests no loss to follow-up and analysis was complete cases.	Trial registration record suggests that the Short Form of IPAQ physical activity scale was a primary outcome but not reported. Also, dietary and exercise stage of changes, and eating behavior outcomes listed in the register but not reported. However, these are not relevant	There was statistically significant difference in BMI between groups at baseline, however, some imbalances may be expected and be due to chance. So since otherwise the randomization worked well, we decided this is low risk of bias.

Study ID	Random sequence generation (Selection bias)	Allocation concealment (Selection bias)	Blinding of outcome assessment (Detection bias)	Incomplete outcome data (Attrition bias)	Selective reporting (Reporting bias)	Other risk of bias
	block sizes of 4 and 6 stratified according to their BMI (BMI=25-29.9 and BMI=30-35) with the allocation ratio of 1:1.”	study. For allocation concealment, allocation randomized sequence generation and envelope preparation were carried out by a person outside the study. For each health center, half of the envelopes were allocated to obese women and the other half were delivered to women with overweight."			outcomes to the current review.	
Ball 2011	UNCLEAR	LOW	LOW	HIGH	LOW	LOW
Support for judgement:	Only information given is: "The study biostatistician, who had no contact with either participants or intervention providers, performed all randomization and intervention allocation tasks."	"The study biostatistician, who had no contact with either participants or intervention providers, performed all randomization and intervention allocation tasks."	"Height and weight were measured; BMI, BMI percentile and BMI z-score were subsequently calculated." "The research team and participants (but not intervention providers) were blinded to group allocation."	Baseline (n); HIP = 17; YLP = 15; WLC = 14 Post treatment n (%); HIP = 10 (58.8%); YLP = 9 (60%); WLC = 11 (78.6%) "Attrition timing varied within each group, but did not differ between groups (Table 3). While approximately 40% of participants dropped out of YLP and HIP..." Since total follow-up rate was 59% < 70%, the risk was set as high.	No published protocol or trial registration so we cannot be sure. But the outcomes of interest for us are reported, so we put low risk. But they also measured: dietary intake, physical activity, aerobic fitness, total cholesterol, high-density lipoprotein cholesterol, low-density lipoprotein cholesterol, triglycerides, insulin, glucose, systolic and	N/A

Study ID	Random sequence generation (Selection bias)	Allocation concealment (Selection bias)	Blinding of outcome assessment (Detection bias)	Incomplete outcome data (Attrition bias)	Selective reporting (Reporting bias)	Other risk of bias
					diastolic blood pressure, which they don't report.	
Barnes 2014	UNCLEAR	UNCLEAR	LOW	LOW	LOW	LOW
Support for judgement:	"Participants were randomly assigned, stratified by BED diagnosis, to one of three conditions", but there is no information on how randomization was done.	No information on this.	"Weight was measured at all assessment points using a large capacity digital scale (Brand: Med-Weigh; Model: MS4600)."	"Patient retention for the 12-month follow-up assessment was 23/30 (76.7%) in MIC, 26/29 (89.7%) in NPC, and 49/59 (83.1%) overall. Retention rates did not differ significantly between the conditions (p=0.12)."	On the clinical trials registration, it states weight outcomes to be reported at 3-months from baseline, and 6-months follow-up, but they actually reported 3-months from baseline and 12-months follow up. However, for our analyses, we only needed weight at 3-month and 12-month follow-up therefore, for the analyses' purposes we judged this as low risk.	N/A
Befort 2008	LOW	LOW	LOW	LOW	LOW	LOW
Support for judgement:	"Participants were randomized sequentially using a closed envelope procedure that was created by the study	"Participants were randomized sequentially using a closed envelope procedure that was created by the study statistician, concealed from the investigators and data collection	"Participants were weighed without shoes to the nearest 0.1 pound using a digital scale (Tanita TBF-310)."	76.7% of participants were followed-up for the outcome of interest (weight). Six women in MI and 4 women in HE were lost to follow-up. There was <20% difference in the proportion followed-up	All outcomes measured were reported.	N/A

Study ID	Random sequence generation (Selection bias)	Allocation concealment (Selection bias)	Blinding of outcome assessment (Detection bias)	Incomplete outcome data (Attrition bias)	Selective reporting (Reporting bias)	Other risk of bias
	statistician, concealed from the investigators and data collection staff, and allocated by the individual counsellors."	staff, and allocated by the individual counsellors."		between the groups. The analysis was complete cases.		
Bóveda-Fontán 2015	LOW	LOW	LOW	LOW	LOW	LOW
Support for judgement:	"The participating practitioners will be allocated to each arm of the study by using the simple randomization method in a 1:1 ratio for IG and CG, using the software EPIDAT 3.0."	For randomization of GPs is mentioned that: "centered, blind, simple randomization was performed at a 1:1 ratio"	"Variables collected during the visits were: age, sex, marital status, education level, social class, family status, family history of premature cardiovascular disease, comorbidity, current drugs consumption, snuff consumption (smoker, ex-smoker, non-smoker, number of cigarettes/day in case of smokers), and alcohol intake (basic units of alcohol/week), anthropometric data (weight, height, body mass index, waist circumference, blood pressure, heart rate)..."	Attrition in both groups is reported. Overall follow-up rate was 86.3% (>70%) and the difference in the percentage of followed-up participants between the two groups was <20%. Analysis was complete cases.	All outlined outcomes were reported in the results. Weight outcomes are not reported for all participants, but only reported for overweight and obese participants. However, these comprised the majority of the sample.	"On the other hand, this study might be subject to attentional bias -Hawthorne effect [55]- by which just the fact of being included in a study -and even before receiving the intervention- the subject may present behavioral changes. This might explain the improvements also observed in the CG, which in this case might affect both, professionals and patients. It is difficult to avoid this bias, since it is inherent to most trials, especially to experimental trials."
Burrows 2021	LOW	LOW	HIGH	HIGH	LOW	LOW

Study ID	Random sequence generation (Selection bias)	Allocation concealment (Selection bias)	Blinding of outcome assessment (Detection bias)	Incomplete outcome data (Attrition bias)	Selective reporting (Reporting bias)	Other risk of bias
Support for judgement:	"Upon completion, participants were randomly allocated, by a blinded researcher, to either the intervention group or a 3-month wait-list control group using block randomisation with sequences generated by a random-number generator."	"Upon completion, participants were randomly allocated, by a blinded researcher, to either the intervention group or a 3-month wait-list control group using block randomisation with sequences generated by a random-number generator."	"self-reported anthropometrics (height and weight) which were converted by researchers to BMI."	Overall follow-up rate <70%.	All outcomes in trial register reported in publication.	N/A
Buscemi 2011	UNCLEAR	UNCLEAR	LOW	LOW	LOW	LOW
Support for judgement:	“Randomization was stratified by gender and weight status (obese vs. overweight).”	There is no information about concealment of the allocation sequence.	No information about whether the research assistant who performed measurements was blind to group allocation. However, weight and BMI measured objectively, so rated as low risk.	Loss to follow up clearly documented for each group. Total follow-up rate was 85.7%. 82% were followed-up in the intervention group and 88% in the control group. Therefore difference between groups <20%.	No protocol or trial registry available, but all outcomes relevant to this review were reported.	N/A
Carels 2007	LOW	UNCLEAR	LOW	LOW	LOW	LOW

Study ID	Random sequence generation (Selection bias)	Allocation concealment (Selection bias)	Blinding of outcome assessment (Detection bias)	Incomplete outcome data (Attrition bias)	Selective reporting (Reporting bias)	Other risk of bias
Support for judgement:	"A project coordinator randomly assigned (using computerized random number generator) participants to the BWLP (n = 27) or BWLP + SC (n = 28) group following enrolment but prior to the beginning of treatment."	It is unclear whether allocation was concealed from the project coordinator randomly assigning participants.	“Body weight was measured using a digital scale (BF-350e; Tanita, Arlington Heights, IL) to the closest 0.1 lb.”	"There were no significant differences between the groups on attrition" and >70% of overall study participants were followed-up. Analysis was complete cases.	All outcomes measured were reported.	N/A
Chapman 2018	LOW	LOW	LOW	LOW	LOW	UNCLEAR
Support for judgement:	"Following stratification, CHCs will be randomly allocated into the control or intervention groups using block randomisation by computerised random allocation software."	"The sampling procedure produced an ordered list of eligible participants; CHS recruiting officers systematically invited eligible participants into the study." "Randomisation will be performed prior to baseline assessment of participants and CHCs will be the unit of randomisation. A member of the research team, blinded	"Weight will be measured by a beam balance scale and height by a stadiometer attached to a wall."	711 participants completed baseline data collection. At all follow-up time points, >70% of overall participants were followed-up and the difference of follow-up rate between the groups was <20%. Analyses were also complete cases.	Outcome measures listed in the protocol and clinical trial record are reported in the publications for all time points measured.	"A further explanation for the significant improvement in HbA1c and numerous secondary outcomes among both treatment groups is the possible contamination between CHSs. While every attempt was made to avoid contamination between CHSs, the study received a considerable amount of media attention

Study ID	Random sequence generation (Selection bias)	Allocation concealment (Selection bias)	Blinding of outcome assessment (Detection bias)	Incomplete outcome data (Attrition bias)	Selective reporting (Reporting bias)	Other risk of bias
		to CHC identity, will be responsible for central randomisation."				throughout the intervention phase, which may have resulted in participants and CHS staff altering their usual behaviour." Therefore, unclear risk of contamination.
Chee 2017	LOW	UNCLEAR	LOW	LOW	LOW	LOW
Support for judgement:	"Patients were randomized to receive UC or a structured lifestyle intervention based on the Malaysian tDNA using a random allocation software."	Further detail needed.	"Weight was measured using a digital weighing scale (Tanita HD-319, Tanita, Japan)", so this was rated as low risk despite authors not stating who did this and if they were blind to treatment allocation.	Overall follow-up rate >70% at all time points and difference in percentage followed-up between groups <20%. Analyses were complete cases.	On the trial registry they list "change in Weight Efficacy Lifestyle scores", however this is not reported. Although we extracted data on weight-related self-efficacy where available, this was not a primary or secondary outcome, so we selected low risk of bias here.	N/A
Christie 2017	LOW	LOW	LOW	HIGH	HIGH	LOW
Support for judgement:	From protocol: "Randomisation to the HELP Trial is performed using a secure website. A minimisation protocol will be	From protocol: "Randomisation to the HELP Trial is performed using a secure website. A minimisation protocol will be used for randomisation [20]. Allocation to treatment	"The primary outcome (BMI, calculated from measured height and weight) was assessed by trained CRF nurses blind to treatment status."	Authors conducted both multiple imputation and completers analyses which did not differ at all time points. However, overall, less than 70% of	DAWBA is of interest to our study and is mentioned that "Data were missing at follow-up in >50% of cases, therefore we were unable to assess the effect of the	N/A

Study ID	Random sequence generation (Selection bias)	Allocation concealment (Selection bias)	Blinding of outcome assessment (Detection bias)	Incomplete outcome data (Attrition bias)	Selective reporting (Reporting bias)	Other risk of bias
	used for randomisation [20]. Allocation to treatment will ensure balance in respect of one key prognostic variable (sex). The program design has been successfully used by HSRU in several trials and incorporates the use of a library of stored procedures to calculate the appropriate treatment based on subgroup totals stored in SQL Server 2005 data tables. Allocation will be 1:1 to Intervention: Control. The program will generate a 5-digit Study ID. The first 2 digits identify the	will ensure balance in respect of one key prognostic variable (sex). The program design has been successfully used by HSRU in several trials and incorporates the use of a library of stored procedures to calculate the appropriate treatment based on subgroup totals stored in SQL Server 2005 data tables. Allocation will be 1:1 to Intervention: Control. The program will generate a 5-digit Study ID. The first 2 digits identify the recruiting centre (Centre IDs will be allocated when they join the study) and the last3 identify the individual patient recruited. This Study ID number can then be used subsequently to maintain patient anonymity. At the time of randomisation the HSRU user will select values for the		participants are reported for weight outcomes.	intervention on DAWBA outcomes."Also, no available data at 52 weeks for weight and other well-being and psychological scales.	

Study ID	Random sequence generation (Selection bias)	Allocation concealment (Selection bias)	Blinding of outcome assessment (Detection bias)	Incomplete outcome data (Attrition bias)	Selective reporting (Reporting bias)	Other risk of bias
	recruiting centre (Centre IDs will be allocated when they join the study) and the last3 identify the individual patient recruited. This Study ID number can then be used subsequently to maintain patient anonymity. At the time of randomisation the HSRU user will select values for the minimising variable Gender, then click on the 'Randomise' button. The study number and the allocated treatment will be displayed and this data then conveyed	minimising variable Gender, then click on the 'Randomise' button. The study number and the allocated treatment will be displayed and this data then conveyed to the Trial Manager."				

Study ID	Random sequence generation (Selection bias)	Allocation concealment (Selection bias)	Blinding of outcome assessment (Detection bias)	Incomplete outcome data (Attrition bias)	Selective reporting (Reporting bias)	Other risk of bias
	to the Trial Manager."					
Currie 2017	LOW	UNCLEAR	LOW	HIGH	LOW	LOW
Support for judgement:	"Because PA levels differ by sex, randomization was completed with a block on sex. A computer generated randomization list was created by an individual not associated with the study."	"Because PA levels differ by sex, randomization was completed with a block on sex. A computer generated randomization list was created by an individual not associated with the study."No further details provided.	Clinic staff measured the adolescents' height to the nearest 0.1cm and weight using a digital scale to the nearest 0.1kg.	"...the attrition rates were high (overall: 38%) and more control (57%) than intervention (21%) participants returned for the follow-up visit."	All outcome measures stated on trials register were reported.	N/A
Davis 2011	UNCLEAR	LOW	LOW	UNCLEAR	UNCLEAR	LOW
Support for judgement:	"Randomization was blocked by intervention group to achieve balance in randomization." No further detail.	"Allocations were concealed from participants until after pretesting."	"A certified healthcare provider preformed a detailed physical exam" However, unclear if they were blind to treatment allocation. But: "Weight... measured first thing in the morning, after the overnight fast, to the nearest 0.1 kg using a beam medical scale", so we can say low risk.	Unclear what was the % followed-up from each group, thus cannot judge for the between group differences in attrition: "Of the 130 potential subjects who were available for consenting, 44 subjects qualified for the program. Of these, 38 completed the program (evaluable participants), 12 in the	It doesn't actually list weight and BMI as outcomes but it isn't exactly clear in the paper what the specific primary and secondary outcomes are.	N/A

Study ID	Random sequence generation (Selection bias)	Allocation concealment (Selection bias)	Blinding of outcome assessment (Detection bias)	Incomplete outcome data (Attrition bias)	Selective reporting (Reporting bias)	Other risk of bias
				C group, 14 in the CT group, and 12 in the CT + MI group. Reasons for dropouts included lost interest (n= 1), too many absences to exercise class (n = 4), and taking college preparation classes (n =1)."		
Davis Martin 2006	LOW	LOW	LOW	LOW	LOW	LOW
Support for judgement:	"Eight physicians practicing at two clinics were randomly assigned to provide one of the two treatment conditions. Specifically, the randomization utilized clinic as a stratification variable, and the associated physicians' practices within each stratum were assigned to level of treatment under	"Eight physicians practicing at two clinics were randomly assigned to provide one of the two treatment conditions. Specifically, the randomization utilized clinic as a stratification variable, and the associated physicians' practices within each stratum were assigned to level of treatment under a balanced randomization. The basis of the randomization was the within-stratum ranks of a uniform (0, 1) (pseudo-) random deviate generated for	"Participants' weight and BMI were also obtained at baseline and 6 months. Weight was measured in pounds, with the patient standing with her arms at her side, facing the scale, with shoes and other heavy items removed. Height was measured by stadiometer with shoes removed during the baseline assessment visit."	Judging from the complete cases analyses numbers, overall follow-up rate was 73.6% difference in between-group % followed-up was <20%.	Outcomes in paper all reported.	N/A

Study ID	Random sequence generation (Selection bias)	Allocation concealment (Selection bias)	Blinding of outcome assessment (Detection bias)	Incomplete outcome data (Attrition bias)	Selective reporting (Reporting bias)	Other risk of bias
	a balanced randomization. The basis of the randomization was the within-stratum ranks of a uniform (0, 1) (pseudo-) random deviate generated for each participating physician. This resulted in a nested design, with participants recruited for the study being identified with the randomization assignment of their primary care physician. The purpose of using a nested design was to reduce the likelihood of treatment contamination in the control subjects, and for this reason, only	each participating physician. This resulted in a nested design, with participants recruited for the study being identified with the randomization assignment of their primary care physician. The purpose of using a nested design was to reduce the likelihood of treatment contamination in the control subjects, and for this reason, only the intervention physicians were trained in the use of the active treatment components."				

Study ID	Random sequence generation (Selection bias)	Allocation concealment (Selection bias)	Blinding of outcome assessment (Detection bias)	Incomplete outcome data (Attrition bias)	Selective reporting (Reporting bias)	Other risk of bias
	the intervention physicians were trained in the use of the active treatment components."					
DiMarco 2009	UNCLEAR	UNCLEAR	LOW	HIGH	LOW	LOW
Support for judgement:	"Eligible participants were randomly assigned to GSH(n=19)or GSH/MI (n=20)." No further detail provided.	"Eligible participants were randomly assigned to GSH(n=19)or GSH/MI (n=20)." No further detail provided.	Weight measured objectively: "Following a standardized telephone screen, eligible individuals attended an in-person evaluation where they completed an informed consent form and study measures, and had their height and weight measured." Also: "Participants completed post-treatment study measures at the last session."	Authors must have applied an imputation method to account for attrition but this is not clearly documented. Only that intention to treat analysis was conducted. 13/39 randomized participants dropped out, therefore, overall follow-up rate was 66.7% (<70%).	No protocol or clinical trial page to confirm whether all pre-specified outcome measured were reported but all relevant to our review outcomes in methods are reported in the results section	
Drevenhorn 2012	UNCLEAR	UNCLEAR	LOW	LOW	HIGH	HIGH
Support for judgement:	"randomly allocated to an intervention (IG) or control group (CG) "	No information on who randomized participants or how they were randomized.	"The nurses in both groups were to include patients, record laboratory and lifestyle variables and continue the follow-up for two years to evaluate the	89% followed up in intervention group and 85% in control group (<20% difference). Overall follow-up rate was 88.3%.	Outcomes not reported for one-year follow-up. Basic demographic data of participants not reported (age, gender). Stages of change seem	It was not clear what the researchers actually did in this study. In some cases we needed to assume, e.g. what was provided to the control group.

Study ID	Random sequence generation (Selection bias)	Allocation concealment (Selection bias)	Blinding of outcome assessment (Detection bias)	Incomplete outcome data (Attrition bias)	Selective reporting (Reporting bias)	Other risk of bias
			training..." Also: "Nurses in the control group continued with their usual care, did not record any consultations" These suggest that the nurses themselves collected the outcome data, including weight, and they were not blinded, however, since they would have measured the weight, and it was not self-reported, then we judged as low risk.		to have been measured but not reported.	
Elliot 2007	LOW	UNCLEAR	LOW	LOW	LOW	LOW
Support for judgement:	"All members of a specific station or workgroup were allocated to the same study condition, and an independent individual unfamiliar with the department's used a program for generating random numbers to	"All members of a specific station or workgroup were allocated to the same study condition, and an independent individual unfamiliar with the department's used a program for generating random numbers to assign units from station or workgroup triads to one of the three conditions."	"Research staff, different from those performing the MI counseling and implementing the team program, obtained fitness indices and anthropometric measures (height, weight, body composition, and body mass index)."	Control: 79% follow-up; MI: 82% follow-up. Overall follow-up was 80.5% and difference in % followed-up between Control and MI was<20%. Analysis was complete cases.	They report weight-related outcomes. They also report well-being outcome but according to trial registration page they should report enhanced quality of life which is not clear if is the same as the well-being scale reported. We assumed is the same and so risk of bias was judged as low.	N/A

Study ID	Random sequence generation (Selection bias)	Allocation concealment (Selection bias)	Blinding of outcome assessment (Detection bias)	Incomplete outcome data (Attrition bias)		Selective reporting (Reporting bias)	Other risk of bias
	assign units from station or workgroup triads to one of the three conditions."						
Everett 2021	LOW	LOW	UNCLEAR	LOW		LOW	LOW
Support for judgement:	"the study statistician generated the allocation sequence of 1:1 control and intervention groups using simple randomization with Microsoft® Excel syntax = IF(RAND()<0.5,' A','B')."	"An administrative assistant not involved in study recruitment prepared consecutively numbered sealed opaque envelopes containing the allocation sequence. These were stored in a locked cabinet in the nursing research unit, distant to the study setting. Central randomization by email was used to ensure allocation concealment."	It seems the 12 month measures were performed by blinded personnel but not the other measures.	78.8% followed-up in intervention group and 82.8% in control (<20% difference). Overall follow-up rate >70%. Analysis was complete cases.		BMI is described as a secondary outcome and is reported.	N/A
Ferrara 2016	LOW	LOW	LOW	LOW at 6 months	HIGH at 12 months	LOW	LOW
Support for judgement:	"All 44 KPNC facilities were randomized to either usual care or intervention	"All 44 KPNC facilities were randomized to either usual care or intervention conditions.	"All investigators, data collectors, and health care providers were blinded to condition assignment." Also:	It is unclear if imputation was used for missing data. Judging from the numbers of people		Pre-specified outcomes were reported at baseline and follow-up in the paper and supplementary files.	N/A

Study ID	Random sequence generation (Selection bias)	Allocation concealment (Selection bias)	Blinding of outcome assessment (Detection bias)	Incomplete outcome data (Attrition bias)	Selective reporting (Reporting bias)	Other risk of bias
	conditions. Randomization was blocked on facility size (i.e., the expected annual number of women with GDM, in three strata: <25, 25–74, and ≥75). A restricted randomization scheme was used to ensure acceptable between-condition balance (i.e., maximum between-condition relative difference) in expected racial/ethnic distributions and the number of women contacted by an ongoing unrelated observational study, both overall and within facility	Randomization was blocked on facility size (i.e., the expected annual number of women with GDM, in three strata: <25, 25–74, and ≥75). A restricted randomization scheme was used to ensure acceptable between-condition balance (i.e., maximum between-condition relative difference) in expected racial/ethnic distributions and the number of women contacted by an ongoing unrelated observational study, both overall and within facility size stratum (11,13). All investigators, data collectors, and health care providers were blinded to condition assignment." Also: "With treatment conditions for enumerated allocations labeled as groups A and B, one allocation was randomly chosen via a	"Primary outcome analysis for the effect of the intervention included only clinic-measured postpartum weights."	reported at each follow-up time point, we have assumed complete cases data is reported. Overall follow-up rate was >70% at 6 months but <70% at 12 months.	Self-efficacy questionnaire was listed as an outcome to be collected at baseline and 6month post-partum in protocol publication but not in the main publication. However, since self-efficacy is more of an exploratory outcome, rather than a primary or secondary outcome in our review, we judged that risk as low. Also, author informed us that self-efficacy data has not yet been analyzed.	

Study ID	Random sequence generation (Selection bias)	Allocation concealment (Selection bias)	Blinding of outcome assessment (Detection bias)	Incomplete outcome data (Attrition bias)	Selective reporting (Reporting bias)	Other risk of bias
	size stratum (11,13). All investigators, data collectors, and health care providers were blinded to condition assignment." Also: "With treatment conditions for enumerated allocations labeled as groups A and B, one allocation was randomly chosen via a random number generator, with the seed supplied by a non-study staff person (SAS® software function RANUNI) [16]. At a separate time and location, via a flip of a coin, another non-study staff person assigned	random number generator, with the seed supplied by a non-study staff person (SAS® software function RANUNI) [16]. At a separate time and location, via a flip of a coin, another non-study staff person assigned group A and B to intervention/usual care groups, witnessed by the GEM study biostatistician (C.P.Q.)."				

Study ID	Random sequence generation (Selection bias)	Allocation concealment (Selection bias)	Blinding of outcome assessment (Detection bias)	Incomplete outcome data (Attrition bias)	Selective reporting (Reporting bias)	Other risk of bias
	group A and B to intervention/usual care groups, witnessed by the GEM study biostatistician (C.P.Q.)."					
Freira 2018	LOW	LOW	LOW	LOW	LOW	LOW
Support for judgement:	"The allocation sequences were generated by a computerized number generator. The sample was chosen using a cluster blocked randomization in which the cluster unit was the school. The block size was fixed, with 100 participants randomly selected and invited to participate at each school, allowing stratification of the sample by the schools. "	"the research team met with the PE teachers to uniformize the measurement methods, and a random sample of 80 out of the 800 students was evaluated for reliability. Measures of weight and height were highly reliable with 1-week test-retest (Cronbach's alpha > 0.98 for all measures). The research coordinator wrote one invitation letter to the participant and another one to his/her caregiver, explaining the intervention and the study's scope. Invitation letters were delivered to the	Data measured objectively, and "Allocation was blinded both from the participant's and data collectors side."	91% and 80% of participants followed-up in intervention and control group respectively. Analysis was complete cases.	Their outcome measures in the trial registry are different. There are linked papers that do address these however. Weight data requested and provided by author, and socio-economic data reported in another linked publication, therefore, low risk.	N/A

Study ID	Random sequence generation (Selection bias)	Allocation concealment (Selection bias)	Blinding of outcome assessment (Detection bias)	Incomplete outcome data (Attrition bias)	Selective reporting (Reporting bias)	Other risk of bias
		students by their teachers. Allocation was blinded both from the participant's and data collectors side, but not from the interviewer, due to the nature of the study"				
Hardcastle 2013	LOW	LOW	LOW	HIGH	LOW	HIGH
Support for judgement:	"Randomisation was achieved by sorting the data (patient records) into strata defined by gender and age. The patients within each stratum were divided into blocks of 12 and then randomly allocated to the intervention and control groups in the ratio of 7:5, using computer generated random numbers. Unequal groups (in the ratio of	"A statistician, who had no contact with the participants, was asked to randomly allocate the participants in the ratio of 7:5 to the intervention and control groups."	"The practice nurse was blind to the treatment allocated to each patient at baseline and all subsequent assessments…" Also: "Weight was measured using the Seca model 701 scale."	There was less than a 20% difference in the dropouts in the two groups at all time points. However, overall follow-up rate at all time points was <70%. Also, weight data were imputed by last observation carried forward which is highly biased method.	All outcome measures were reported.	There may be differences between groups in the participant characteristics of those who dropped out. Also those accepting the invitation to enter the trial were more likely to be females, have a higher BMI, and a lower SBP and cholesterol (recruitment bias).

Study ID	Random sequence generation (Selection bias)	Allocation concealment (Selection bias)	Blinding of outcome assessment (Detection bias)	Incomplete outcome data (Attrition bias)	Selective reporting (Reporting bias)	Other risk of bias
	7:5) were unlikely to have an effect on the power of the test and were done because we expected a higher number of dropouts in the intervention group. This is a form of stratification and is considered acceptable to avoid ending up (by chance) with groups that are unbalanced by age and/or sex."					
Heinrich 2010	LOW	UNCLEAR	LOW	UNCLEAR	LOW	LOW
Support for judgement:	"With a computerized randomizer, two districts (18 nurses) were assigned to the experimental condition and two districts (15 nurses) were assigned to the	"With a computerized randomizer, two districts (18 nurses) were assigned to the experimental condition and two districts (15 nurses) were assigned to the usual care condition."	"Nurses could not be blinded but assessment of outcomes was done by an independent observer."	“From a total of 36 general practices, 584 patients started in our study of which 537 (92%) filled out the baseline questionnaire, 447 (77%) filled out the questionnaire at twelve months follow up and finally 423 (72%) filled out the questionnaire	All outlined outcomes relevant to us are reported.	N/A

Study ID	Random sequence generation (Selection bias)	Allocation concealment (Selection bias)	Blinding of outcome assessment (Detection bias)	Incomplete outcome data (Attrition bias)	Selective reporting (Reporting bias)	Other risk of bias
	usual care condition."			at 24 months. Of all patients, 389 (67%) filled out all three questionnaires and 32 (5%) filled out none." This suggests >70% overall follow-up rate, but not clear what the attrition rate was between groups. And this was about just the self-administered questionnaire. No information on outcomes of interest such as weight or psychological outcomes.		
Joseph 2021	UNCLEAR	UNCLEAR	UNCLEAR	HIGH	HIGH	LOW
Support for judgement:	No method described for randomisation.	"Pediatricians seeing adolescents in 8 clinics and consenting to the randomization were randomized to an intervention or standard care"	Weight/BMI taken from the EMR - presumably measured objectively but does not state.	In the control group 68% were followed-up at 12 months and in the intervention group 96%. Therefore difference in loss to follow-up between groups is <20%. However, overall follow-up rate was <70%. Analysis was complete cases.	BMI outcome of interest not reported for 6-month follow-up, only for 12-month follow-up.	N/A
LaRose 2020	UNCLEAR	UNCLEAR	LOW	HIGH	LOW	LOW

Study ID	Random sequence generation (Selection bias)	Allocation concealment (Selection bias)	Blinding of outcome assessment (Detection bias)	Incomplete outcome data (Attrition bias)	Selective reporting (Reporting bias)	Other risk of bias
Support for judgement:	"Participants were assigned to one of two conditions: motivational interviewing-enhanced BWL (MIBWL) or standard BWL. Randomization was stratified based on sex and race/-ethnicity (non-Hispanic White vs. racial/ethnic minority)." No further information provided. Also, no baseline table available to check if the randomization was done correctly.	"Participants were assigned to one of two conditions: motivational interviewing-enhanced BWL (MIBWL) or standard BWL. Randomization was stratified based on sex and race/-ethnicity (non-Hispanic White vs. racial/ethnic minority)." No further information provided. Also, no baseline table available to check if the randomization was done correctly.	"Assessments were completed by trained and certified assessors who were masked to treatment allocation" Also, "Weight was measured to the nearest .01 kg in light clothes without shoes using a calibrated digital scale at 0 and 3 months."	Difference in % follow-up between the groups is >20% (48% vs 71%) and overall follow-up rate 59.6% (<70%).	All relevant to our review outcome measures are specified and reported in the paper and in registration page.	N/A
Lewis 2019	LOW	LOW	LOW	LOW	LOW	LOW
Support for judgement:	"Participants were stratified based on age and gender and entered sequentially into	"Participants were stratified based on age and gender and entered sequentially into four computer-generated	“Outcome measures were obtained at baseline, 4, and 8 months by the primary investigator.” Also, “Anthropometrical	"Of the 61 adults who began the trial, 93% (n =57) completed the 4-month outcome measures…There was an equal dropout rate	All outcome measures on trial registration page are reported.	N/A

Study ID	Random sequence generation (Selection bias)	Allocation concealment (Selection bias)	Blinding of outcome assessment (Detection bias)	Incomplete outcome data (Attrition bias)	Selective reporting (Reporting bias)	Other risk of bias
	four computer-generated randomization lists (female >50 years; male >50 years; female <50 years; male <50 years) by a trained researcher with no involvement in the study. Block randomization with randomly selected block sizes of either four, six, or eight were used to achieve balance within the intervention groups."	randomization lists (female >50 years; male >50 years; female <50 years; male <50 years) by a trained researcher with no involvement in the study."	changes were measured using weight, body mass index (BMI), and waist circumference. Waist circumference was measured in the horizontal plane mid-way between the lowest rib and the iliac crest." These indicate that a scale would have been used for weight measurements, therefore, even assessor was not blinded, we assumed they would record the number they saw on the scale and wouldn't write a completely different number.	between the two groups."		
Macdonell 2012	UNCLEAR	UNCLEAR	LOW	LOW	LOW	UNCLEAR
Support for judgement:	There is no information on how the project manager randomly assigned the participants: "After baseline, the project	There is no information on how the project manager randomly assigned the participants: "After baseline, the project manager randomly assigned (stratified by gender) half the	"Data collectors were blind to study condition.	"Thirty-one dyads (70.5%) completed the post-treatment data collection (68% of MI and 77% of control)." Difference in % followed-up between groups <20%. Overall follow-up rate 70.5%.	Have reported data for all the primary outcomes measured.	It is not clear whether the results reported are for the adolescents only, or for adolescents and caregivers.

Study ID	Random sequence generation (Selection bias)	Allocation concealment (Selection bias)	Blinding of outcome assessment (Detection bias)	Incomplete outcome data (Attrition bias)	Selective reporting (Reporting bias)	Other risk of bias
	manager randomly assigned (stratified by gender) half the participants to receive the MI intervention and the other half a nutrition counseling control."	participants to receive the MI intervention and the other half a nutrition counseling control."				
Mash 2014	LOW	UNCLEAR	LOW	HIGH	LOW	LOW
Support for judgement:	"Community health centres that agreed to participate were randomly allocated by computer generated random numbers to either control or intervention groups. All type 2 diabetic patients attending the selected health centre on the recruitment days were	No information provided.	"It was not possible to blind the health promoters, patients or data collection teams as to whether the health centre was a control or intervention site." However, weight was measured using electronic scales and we deem this enough to rate as low risk.	Overall follow-up rate 55.2% (<70%). Analysis was complete cases.	Protocol published beforehand and outcomes reported.	N/A

Study ID	Random sequence generation (Selection bias)	Allocation concealment (Selection bias)	Blinding of outcome assessment (Detection bias)	Incomplete outcome data (Attrition bias)	Selective reporting (Reporting bias)	Other risk of bias
	invited to participate in the study. Recruitment days were when the health centre had a diabetic club. Centres were visited weekly until the sample of 40 patients per health centre was obtained."					
Mirkarimi 2017	UNCLEAR	UNCLEAR	UNCLEAR	LOW	LOW	HIGH
Support for judgement:	No information on how the participants were randomized: "To avoid selection bias, simple randomized allocation method was used."	No information on how the participants were randomized: "To avoid selection bias, simple randomized allocation method was used."	No information on how weight was assessed (e.g. measured by a researcher or self-reported).	One of the linked references informs about 2 dropouts from control group and 6 from intervention group. The whole sample was 100 participants. Therefore, this risk was deemed low.	All outcome measures were reported.	There are many inconsistencies in results between the different publications.
Moeller 2019	LOW	LOW	LOW	LOW	LOW	LOW
Support for judgement:	"Following first visit, a computer-	"Following first visit, a computer-randomization was	Weight objectively measured: "Assessments of	"Five and four drop outs were observed in	Clinical trial registered on clinicaltrials.gov. All	N/A

Study ID	Random sequence generation (Selection bias)	Allocation concealment (Selection bias)	Blinding of outcome assessment (Detection bias)	Incomplete outcome data (Attrition bias)	Selective reporting (Reporting bias)	Other risk of bias
	randomization was performed in blocks of two and four, blinded to authors."	performed in blocks of two and four, blinded to authors."	weight, hip, waist circumference, and biochemistry were performed at first visit and after 6 months."	MI+SA and SA groups, respectively" This is translated to 64% follow-up rate in intervention group and 71% in the control group. Difference in the % followed-up between the groups <20%. Overall, 28/37 participants were followed-up i.e. 75.6%.	expected outcomes reported.	
Moss 2017	LOW	LOW	LOW	LOW	LOW	LOW
Support for judgement:	"Immediately prior to the first interview, the first author randomly allocated participants to either the MI or control group with Minim, a computerized randomization program (http://www-users.york.ac.uk/~mb55/guide/minim.htm). Minimization was used to allow for the	"Immediately prior to the first interview, the first author randomly allocated participants to either the MI or control group with Minim, a computerized randomization program (http://www-users.york.ac.uk/~mb55/guide/minim.htm)." "Participants were blind to treatment group assignment."	"Weight measurements were collected by TrymGym staff members (at baseline and the end of BWLP) or a research assistant (6-month follow-up), who were blind to participants' treatment condition. Change ratings were collected online prior to the first interview, and in-person immediately after the first and second interviews."	From participant flow diagram, loss to follow-up was small. More than 90% of participants were followed-up at all time points and difference in % follow-up was <20% between the groups.	Some measures in the trial registry e.g. self-efficacy, are not reported in the paper, but since this isn't an outcome that we are willing to analyse, for the purposes of this review we judged the risk as low.	N/A

Study ID	Random sequence generation (Selection bias)	Allocation concealment (Selection bias)	Blinding of outcome assessment (Detection bias)	Incomplete outcome data (Attrition bias)	Selective reporting (Reporting bias)	Other risk of bias
	balancing of groups on participant gender, the only covariate upon which we elected to ensure group equivalence."					
Pakpour 2015	LOW	UNCLEAR	LOW	LOW	LOW	LOW
Support for judgement:	'To ensure adequate concealment of allocation, a research coordinator performed the randomization procedure by using a computer-generated randomization schedule/sequence (SPSS version 17.0, IBM SPSS Statistics, IBM Corporation, Armonk, NY)'	"After recruitment and consenting procedures were completed, baseline data were collected, and a research coordinator assigned adolescents randomly to the 3 groups." No further details provided.	'Anthropometric measures at baseline and 12 months after randomization were taken by 2 assessors blinded to group allocation'.	Numbers lost to follow up are clearly reported for each group, the overall follow-up rate was 95.8% and the difference between percentage followed-up in the two groups is not more than 20%. Analysis was complete cases.	All outcomes listed on trial registry are reported.	N/A
Quintiliani 2021	LOW	LOW	LOW	LOW	LOW	LOW

Study ID	Random sequence generation (Selection bias)	Allocation concealment (Selection bias)	Blinding of outcome assessment (Detection bias)	Incomplete outcome data (Attrition bias)	Selective reporting (Reporting bias)	Other risk of bias
Support for judgement:	“Our randomization scheme was constructed by a biostatistician using SAS software (Cary, NC)”	“Randomization was embedded within CuesWeight, such that after a participant was consented and completed the baseline assessment, the Research Assistant clicked a button on the website which determined intervention or control group allocation”	Weight (primary outcome) was measured in each participant’s home using a portable digital scale (Omron model SC100) with shoes and heavy clothing such as coats removed.	More than 90% of participants in each group were followed-up and difference in % followed-up between the groups was <20%.	Relevant outcomes to this review are outlined in the methods and given in the results.	N/A
Rodriguez-Cristobal 2017	LOW	UNCLEAR	LOW	HIGH	HIGH	LOW
Support for judgement:	"Basic areas were randomly assigned to either control or intervention group as per a computer generated randomization schedule."	"The participating healthcare professional (nurse) will select the first two patients with visits during the pre-established recruitment period, who met the study criteria."	"The weight measurement will be done always in the same conditions (the patient wearing underwear only, barefoot, and at the same time of day)."	"Approximately 60 and 47% of the participants in intervention and control group respectively had their weight measured at 24 months" Less than 20% in follow-up rate at final follow-up. However, overall, follow-up rate was <70%. Analysis was complete cases.	The following outcome measures are listed in the published protocol but are not reported: "Quality of life and food assessment through SF questionnaire 36 validated in Spain by Alonso [24], and dietary survey, 3 day record, (quantitative and qualitative) at the beginning and end of the study [25]." Of those, quality of life is a secondary outcome in	N/A

Study ID	Random sequence generation (Selection bias)	Allocation concealment (Selection bias)	Blinding of outcome assessment (Detection bias)	Incomplete outcome data (Attrition bias)	Selective reporting (Reporting bias)	Other risk of bias
					our review therefore, risk was deemed high.	
Saffari 2014	UNCLEAR	UNCLEAR	LOW	UNCLEAR	LOW	LOW
Support for judgement:	"There are eight urban health centers in Qazvin City and four of them were randomly selected using multi-stage random sampling. The centers were then randomly assigned into two groups, control and MI." But no information on how the health centers were selected or randomized.	Unclear how centers were assigned in randomization.	Body weight was measured in light clothes using a calibrated digital scale (down to 10 g).	92% overall follow-up rate, but unclear what was the follow-up rate in each group, and therefore unclear what is the difference in % follow-up between the two groups. Authors seem to have conducted imputation for weight data but unclear which method they have used.	Reported results for all measures taken.	N/A
Sawyer 2020	LOW	LOW	LOW	UNCLEAR	LOW	LOW
Support for judgement:	"Randomization into the intervention group or control group was conducted by computerized	“The random allocation sequence was concealed from the program specialist using slips of paper sealed in envelopes until it was time to	Weight was measured at the primary care physician practice or a laboratory, so assumed it was measured objectively.	The overall attrition rate was 26%, but we don't know the attrition rate within each group so as to get the difference in % followed-up.	No protocol available but they report in the results all the outcomes they outline in the data collection section of the methods.	"There were only significant differences between the groups in the baseline biometric measures of BMI and waist circumference." Also: "As the

Study ID	Random sequence generation (Selection bias)	Allocation concealment (Selection bias)	Blinding of outcome assessment (Detection bias)	Incomplete outcome data (Attrition bias)	Selective reporting (Reporting bias)	Other risk of bias
	protocol using SAS software, facilitated by a trained team member as the participants were enrolled into the study. A statistician generated the random allocation sequence. The program specialist enrolled participants and assigned them to a group. "	assign a participant to a group. Blinding did not occur."				intervention group had higher BMI and waist circumference compared with the control group at baseline, this greater change was expected." However, randomization was generally successful and some differences may be expected due to chance. So deemed there is no other risk of bias.
Simpson 2015	LOW	LOW	LOW	LOW	LOW	UNCLEAR
Support for judgement:	"Allocation to groups was by remote telephone randomisation, stratified by region and minimised by age, gender, ethnicity, source of recruitment (GP, exercise referral,	Randomization was provided by "the Bristol Randomised Trials Collaboration randomisation service", who were not involved in the trial.	"Outcome assessors were also involved in recruitment and randomisation and were therefore not blind to allocation" However, outcomes were objectively measured and therefore we deem this low risk.	No difference of more than 20% in follow-up between the groups, and overall follow-up rate >70%. Analysis was complete cases.	Have reported on absolutely everything in a very long report.	Had to change the trial to a feasibility study due to low recruitment.

Study ID	Random sequence generation (Selection bias)	Allocation concealment (Selection bias)	Blinding of outcome assessment (Detection bias)	Incomplete outcome data (Attrition bias)	Selective reporting (Reporting bias)	Other risk of bias
	slimming club, community), percentage weight loss and current BMI. The service was provided by the Bristol Randomised Trials Collaboration randomisation service. This used a bespoke system written in the programming language C++."					
Smith 1997	UNCLEAR	UNCLEAR	LOW	LOW	LOW	LOW
Support for judgement:	No information on randomization or even number per group.	No information given.	"Baseline and post-treatment (4-month) assessments were conducted by trained technicians blind to group assignment."	>70% overall follow-up. We don't know how many people were randomized in each group at the start, however, the risk was deemed low because 10 and 6 participants were followed-up from the control and intervention group respectively. It is implausible that difference in %	Very little data reported e.g. no baseline weight, baseline, BMI for each group, no number of people in each group. However, weight change is reported and it's the main outcome in this review, therefore, risk was judged as low.	N/A

Study ID	Random sequence generation (Selection bias)	Allocation concealment (Selection bias)	Blinding of outcome assessment (Detection bias)	Incomplete outcome data (Attrition bias)	Selective reporting (Reporting bias)	Other risk of bias
				followed-up between the groups would be more than 20%.		
Staite 2020	LOW	LOW	LOW	LOW	LOW	LOW
Support for judgement:	"Randomization of participants was conducted by the data manager from an independent clinical trials unit using computer-generated randomization blocks of random sizes and stratified by surgery in a 1:1 ratio."	"Allocation concealment of the randomization list was held in a password-locked computer. This was an open-label study, but outcome assessors, laboratory technicians, and researchers entering and scoring the data were blinded to patients' allocations."	"Weight was measured in light clothing, without shoes, to 0.01 kg" Also: "This was an open-label study, but outcome assessors, laboratory technicians, and researchers entering and scoring the data were blinded to patients' allocations."	% difference in follow-up between groups is <20% and 78% overall were followed-up. Analysis was complete cases.	They don't report results for self-efficacy, but 1) this is self-efficacy for exercise so not relevant to our review and 2) self-efficacy is not a primary or secondary outcome in our review, but rather an exploratory outcome, something we will look at out of interest.	N/A
Sun 2020	LOW	UNCLEAR	UNCLEAR	LOW	LOW	LOW
Support for judgement:	"According to a random number table, 100 patients who met the inclusion and exclusion criteria were randomly divided into an intervention	Other than mention of the random number table, no other information on how participants were randomized.	No information on how weight was assessed.	88/100 participants completed the study and between group difference in % follow-up was <20%.	All outlined outcomes reported and especially all outcomes relevant to our review.	N/A

Study ID	Random sequence generation (Selection bias)	Allocation concealment (Selection bias)	Blinding of outcome assessment (Detection bias)	Incomplete outcome data (Attrition bias)	Selective reporting (Reporting bias)	Other risk of bias
	group and a control group, with 50 cases in each group."					
Webber 2010	UNCLEAR	UNCLEAR	LOW	LOW	LOW	LOW
Support for judgement:	"Participants were randomized to one of two study groups" - this is the only information given on randomization.	"Participants were randomized to one of two study groups" - this is the only information given on randomization.	"Body weight was measured at baseline, four and 16 weeks by trained research assistants, blinded to group assignment."	>70% overall follow-up and <20% difference in follow-up between groups based on complete cases analysis data.	Cannot access protocol or trial registry but all measures mentioned in methods are reported.	N/A
West 2007	LOW	LOW	LOW	LOW	LOW	LOW
Support for judgement:	"Randomized using a sequentially numbered, closed-envelope procedure."	"217 (38% African-American) women were randomized using a sequentially numbered, closed-envelope procedure."	"Body weight was measured without shoes using a calibrated balance beam scale."	"Attrition in the sample was modest (93% retention at 18 months), and study dropouts did not differ on baseline demographic factors, initial weight, or diabetes control compared with study completers. The majority of individual sessions were attended by most participants in both conditions, with no differences between conditions in number	"Analyses of weight and BMI yielded comparable results; therefore, only weight results are presented." Have stated why they haven't reported BMI data, and all other outcome measures were reported.	N/A

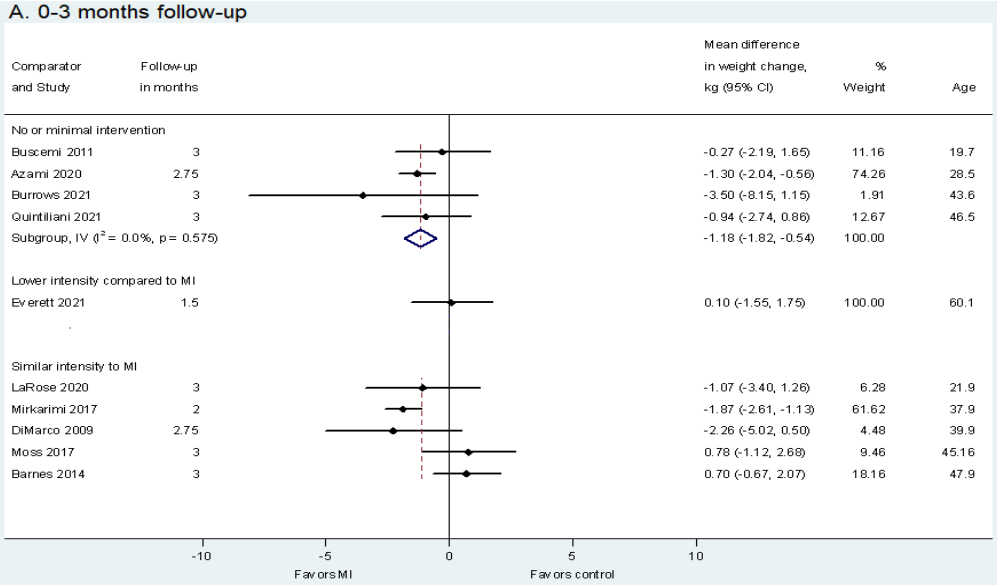
Study ID	Random sequence generation (Selection bias)	Allocation concealment (Selection bias)	Blinding of outcome assessment (Detection bias)	Incomplete outcome data (Attrition bias)	Selective reporting (Reporting bias)	Other risk of bias
				of individual sessions received." 12-month data show similar retention rates, therefore risk was deemed low. Analyses were complete cases.		
West 2016	LOW	UNCLEAR	LOW	LOW	LOW	LOW
Support for judgement:	"Participants indicated availability for pre-determined group times; these intact groups were stratified by baseline BMI percentile and then randomized using a biased coin approach."	No information given.	"The primary outcomes are change in body weight at 6 and 18 months post randomization, measured in-person by a digital scale."	"Follow-up data were provided by 90% of randomized participants at 6-months and 81% at 18-months, with no difference between conditions in retention rates." Also, "Group-specific multiple imputations (k=6) were implemented for missing weight data using baseline covariates, including sex, race, education, age, and obesity status (BMI ≥ 30). Comparison of imputed and complete case data averages at each time point and longitudinally appeared consistent.	Clinical trials registration includes motivation measures but these were not reported. Also measured treatment fidelity but did not report outcomes. However, these are not in our primary or secondary outcomes for this review although we are interested in looking at them. So we have deemed this risk low for this particular review.	N/A

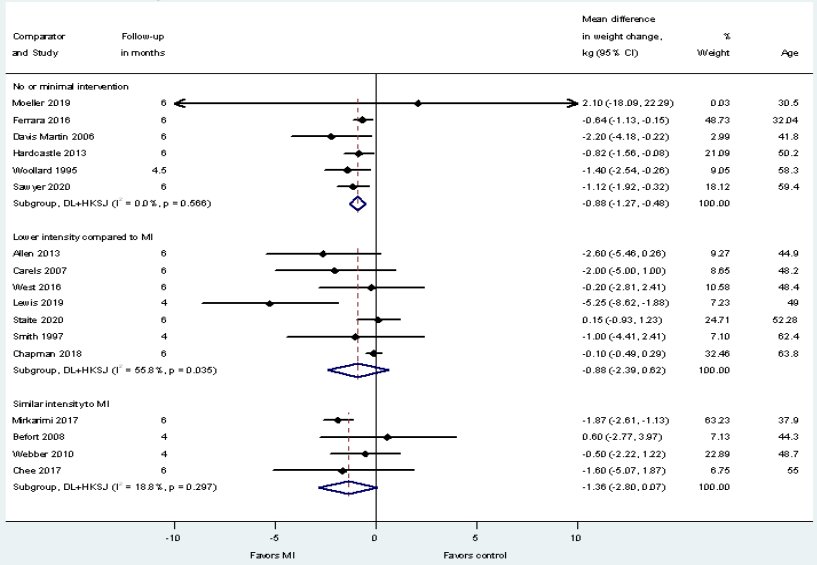
Study ID	Random sequence generation (Selection bias)	Allocation concealment (Selection bias)	Blinding of outcome assessment (Detection bias)	Incomplete outcome data (Attrition bias)	Selective reporting (Reporting bias)	Other risk of bias
				All analyses of weight changes at each time point were conducted with imputed data using a mixed linear model with repeated measures nested within participants and participants nested within randomized clusters (online chat groups)."		
Williams 2014	LOW	UNCLEAR	LOW	LOW	LOW	LOW
Support for judgement:	"Women were categorised by BMI as healthy weight (HW) (18.5 o25 kg m 2) or overweight (OW) (25 - <30 kg/m ^{2}), according to their baseline measures, and then randomly assigned to the MI or SDI group using computer-generated number sequences (one list for each BMI group) compiled	"Women were categorised by BMI as healthy weight (HW) (18.5 o25 kg m 2) or overweight (OW) (25 - <30 kg/m ^{2}), according to their baseline measures, and then randomly assigned to the MI or SDI group using computer-generated number sequences (one list for each BMI group) compiled by a statistician using the ProcPlan procedure in SAS Version 9.2 (SAS Institute Inc, Cary,NC, USA)"	"The primary outcome measure, weight, was collected by a trained assistant at baseline and 3 and 12 months after the intervention commenced."	The difference between the % of the intervention group followed- up, and the % of the control group followed up is less than 20% at all time points. Overall follow-up rate was >70% at 12 months. Those completed the 12-month follow-up were invited to the monitoring phase until 24 months, during which no loss to follow-up was observed.	Data for all relevant outcome measures reported in the published protocol are available.	N/A

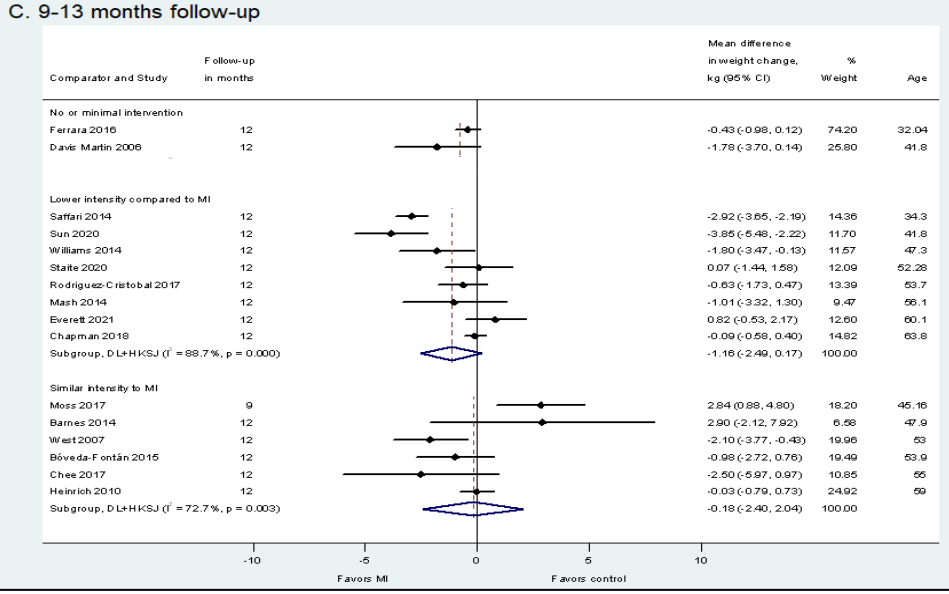
Study ID	Random sequence generation (Selection bias)	Allocation concealment (Selection bias)	Blinding of outcome assessment (Detection bias)	Incomplete outcome data (Attrition bias)	Selective reporting (Reporting bias)	Other risk of bias
	by a statistician using the ProcPlan procedure in SAS Version 9.2 (SAS Institute Inc, Cary,NC, USA)"					
Woollard 1995	UNCLEAR	UNCLEAR	LOW	UNCLEAR	LOW	LOW
Support for judgement:	No other information given apart from: "One hundred and sixty-six agreed to enter into an 18 week controlled trial and were randomized to 1 of three groups"	No other information given apart from: "One hundred and sixty-six agreed to enter into an 18 week controlled trial and were randomized to 1 of three groups"	Weight objectively measured: "All patients were assessed before and after the 18 week programme." "Height, weight and 24 h urinary sodium were measured."	Enrolled 166 participants. Baseline and follow-up data for 146 participants (88%) and we have assumed this analysis was with complete cases. No mention of attrition rate within each group though.	Lifestyle questionnaire including self-efficacy measures described in methods but not reported. We cannot know if it was meant to be an outcome as no protocol available. However, self-efficacy is not a primary or secondary outcome, but rather something we will look at out of interest, not something we will analyze, and therefore the risk was deemed low for this particular review.	N/A

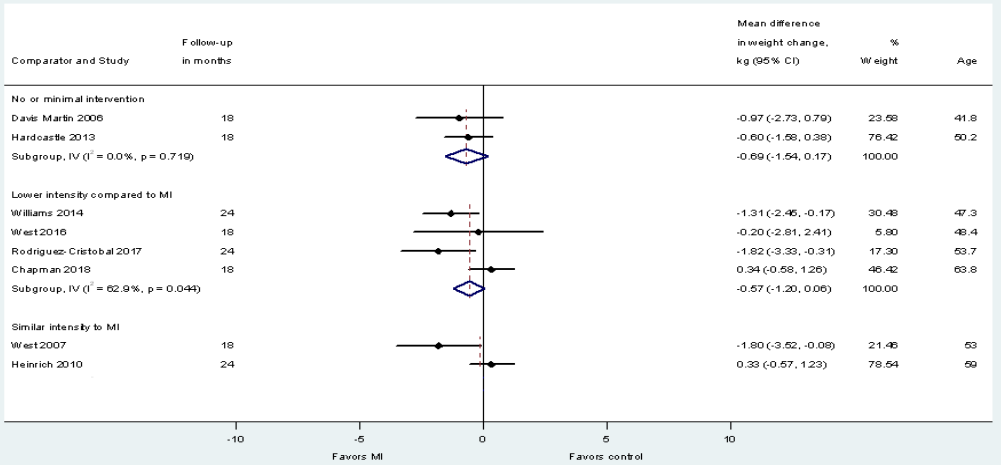
N/A: Not Applicable; **IPAQ:** International Physical Activity Questionnaire; **BMI:** Body Mass Index; **HIP:** Healthy Initiatives Programme; **YLP:** Youth Lifestyle Programme; **WLC:** Wait List Control; **BED:** Beck Depression Inventory; **MIC:** Motivational Interviewing and Internet Condition; **NPC:** Nutrition Psychoeducation; **MI:** Motivational Interviewing; **HE:** Health Education; **CHCs:** Community Health Centers; **BWLP:** Behavioral Weight Loss Programme; **SC:** Stepped Care; **UC:** Usual Care; **tDNA:** Trans-cultural diabetes-specific nutrition algorithm; **HELP:** Healthy Eating and Lifestyle Programme; **HSRU:** Health Services Research Unit; **CRF:** Clinical Research Facility; **DAWBA:** Development and Well-being Assessment; **PA:** Physical Activity Intervention; **CT:** Circuit Training; **GSH:** Guided Self-help; **PE:** Physical Education; **KPNC:** Kaiser Permanente Northern California; **SBP:** Systolic Blood Pressure; **SA:** Standard Advice; **SDI:** Self-directed Intervention.

Appendix 3.7. Mean difference (in kg) in weight change in adults between MI and comparator (control) groups, using fixed-effects (A and D) or random-effects (B and C) meta-analysis, by age





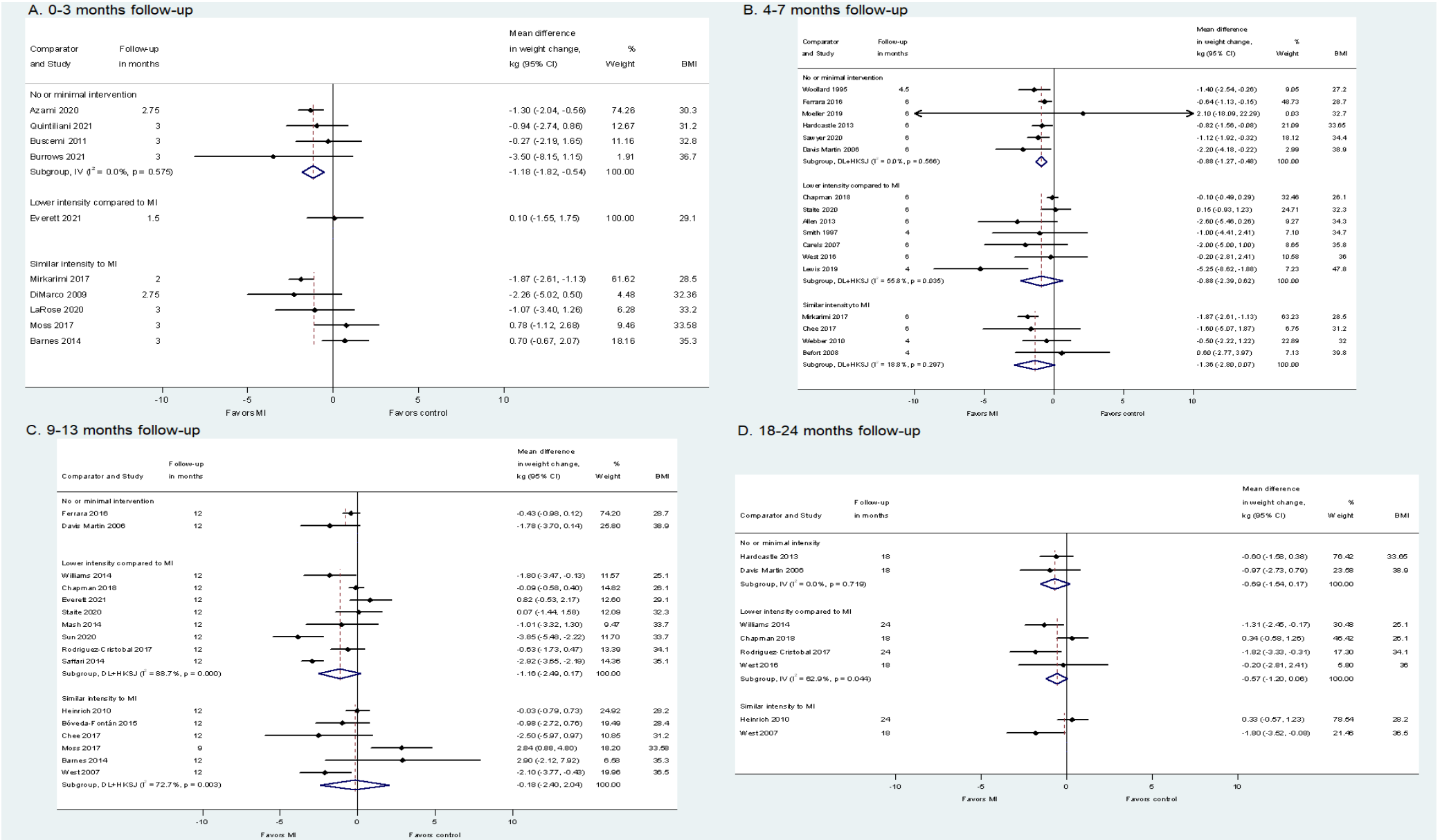




DL: DerSimonian–Laird; **HKSJ:** Hartung–Knapp–Sidik–Jonkman; **IV:** inverse variance; **MI:** motivational interviewing

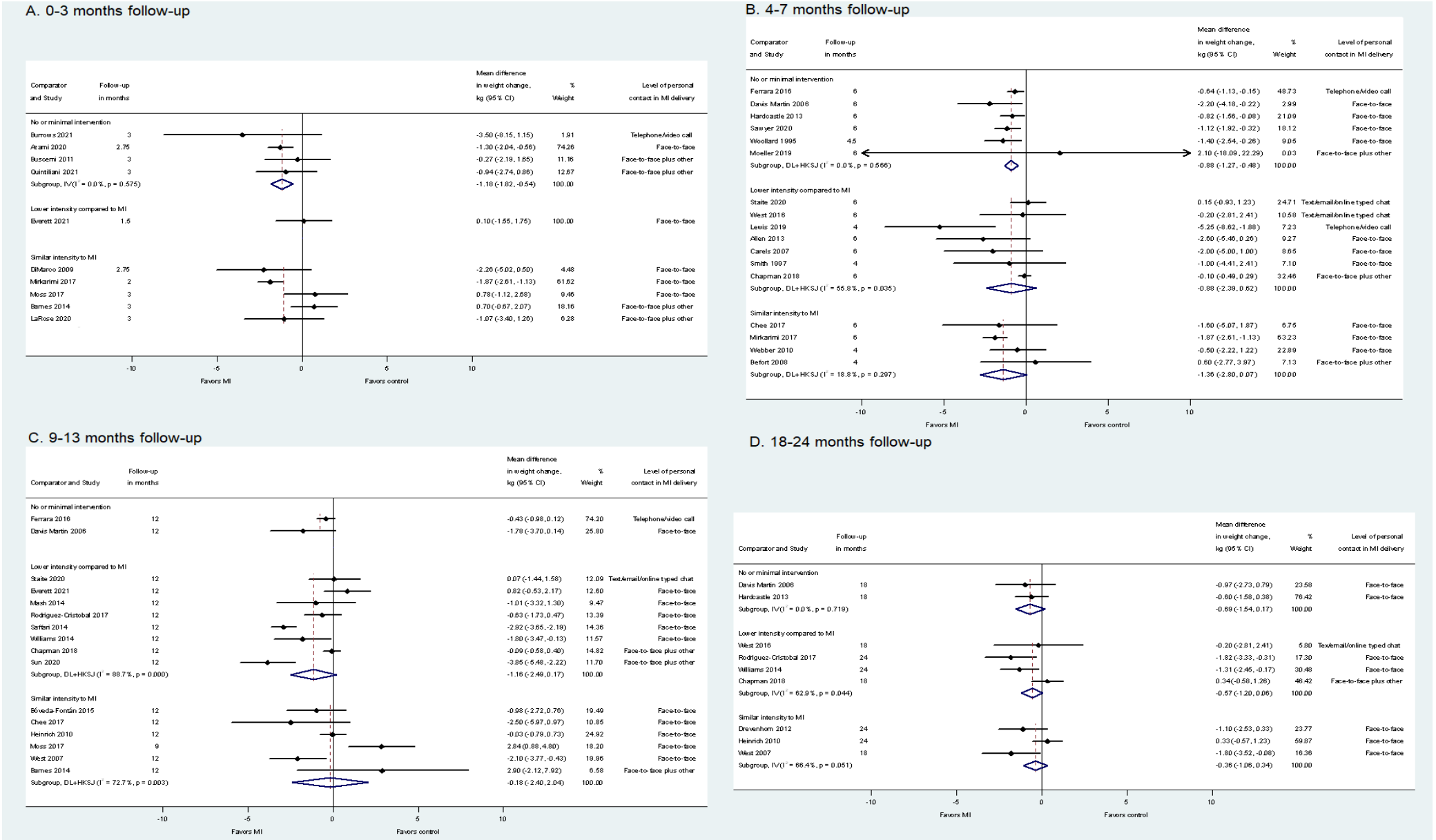
A&D: fixed-effects meta-analysis; **B&C:** random-effects meta-analysis

Appendix 3.8. Mean difference (in kg) in weight change in adults between MI and comparator (control) groups, using fixed-effects (A and D) or random-effects (B and C) meta-analysis, by Body Mass Index



DL: DerSimonian–Laird; **HKSJ:** Hartung–Knapp–Sidik–Jonkman; **IV:** inverse variance; **MI:** motivational interviewing; **BMI:** body mass index. **A&D:** fixed-effects meta-analysis; **B&C:** random-effects meta-analysis. Drevenhorn et al. (18-24 months follow-up, similar-intensity subgroup) excluded from this analysis as did not report BMI data.

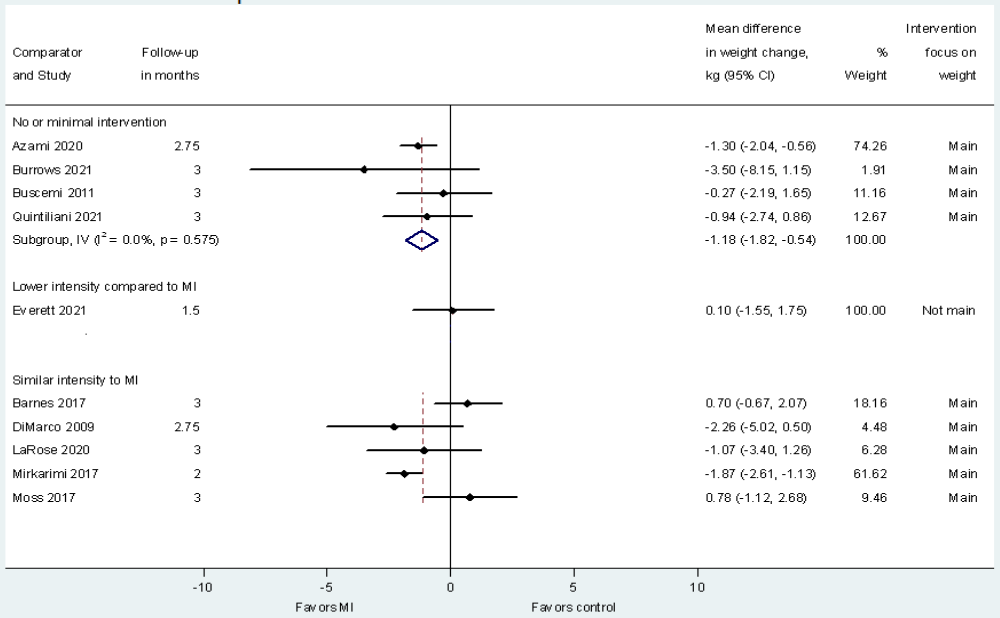
Appendix 3.9. Mean difference (in kg) in weight change in adults between MI and comparator (control) groups, using fixed-effects (A and D) or random-effects (B and C) meta-analysis, by level of personal contact in MI delivery



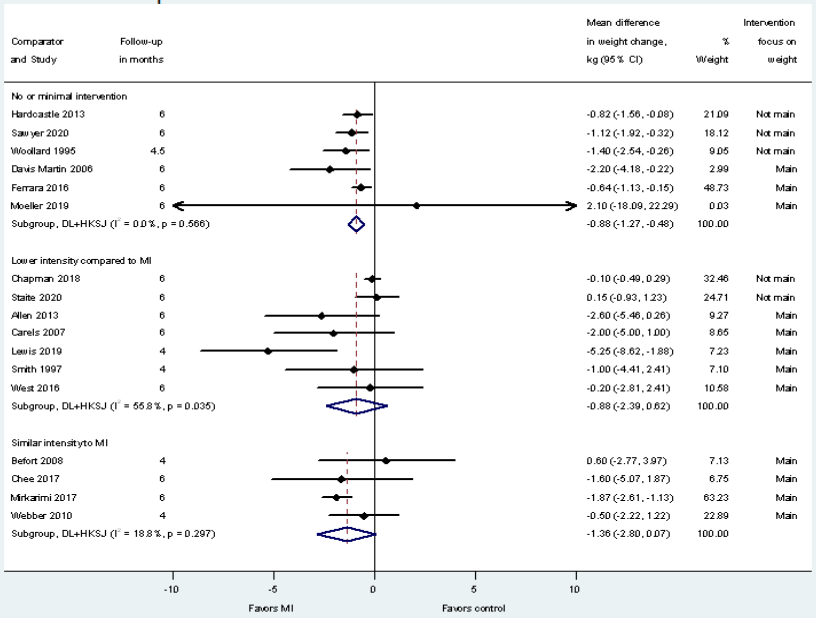
DL: DerSimonian–Laird; **HKSJ:** Hartung–Knapp–Sidik–Jonkman; **IV:** inverse variance; **MI:** motivational interviewing. **A&D:** fixed-effects meta-analysis; **B&C:** random-effects meta-analysis.

Appendix 3.10. Mean difference (in kg) in weight change in adults between MI and comparator (control) groups, using fixed-effects (A and D) or random-effects (B and C) meta-analysis, by intervention focus on weight

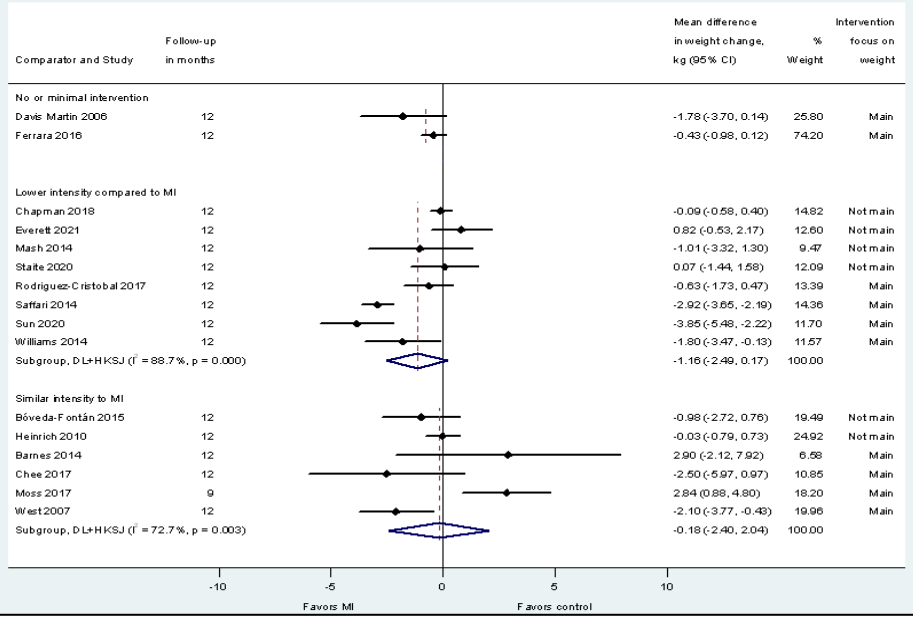
A. 0-3 months follow-up



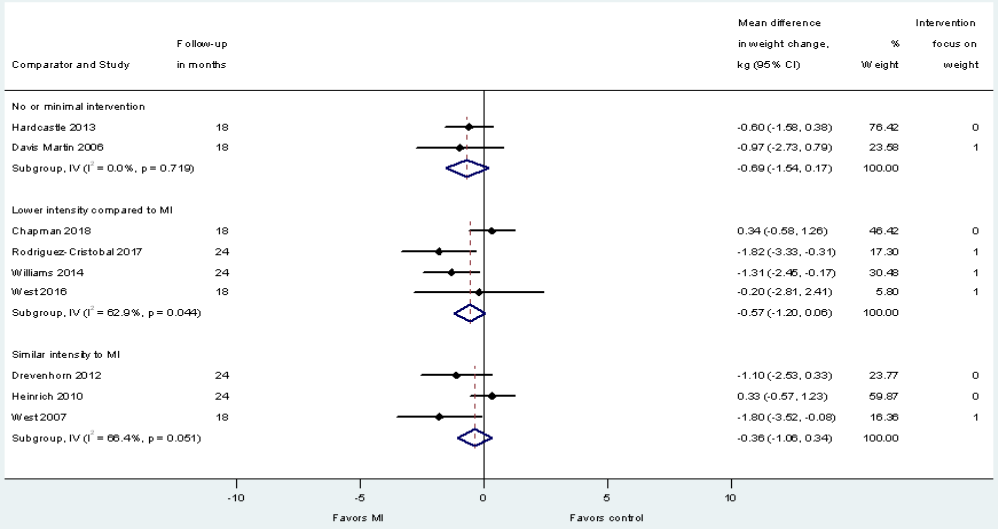
B. 4-7 months follow-up



C. 9-13 months follow-up



D. 18-24 months follow-up



DL: DerSimonian–Laird; **HKSJ:** Hartung–Knapp–Sidik–Jonkman; **IV:** inverse variance; **MI:** motivational interviewing. **A&D:** fixed-effects meta-analysis; **B&C:** random-effects meta-analysis.

Appendix 4.1. Quotes from the PPI scoping exercise

It would have been easier to implement changes earlier in pregnancy.

It's all a bit overwhelming to be honest. At first I cried when I found out I'd developed it (gestational diabetes), there was so much information to take in I did not know which way to turn.

When I think of traditional low carb diets I'm thinking Atkins diet, but what you're suggesting just sounds like healthy eating and good common sense to me […]

There's so many foods that I'm not allowed to eat during pregnancy anyway, cutting out a few more carbs doesn't seem like so much of a chore.

I mean I don't mind coming here, it's just that the parking is so horrendously bad!

I must admit I didn't know too much about gestational diabetes before my doctor suggested that I have an OGTT. I looked for information online and asked my sister-in-law who is a midwife what she recommended, there's so much conflicting information out there.

I got the usual advice on what foods to avoid, like soft cheese and raw eggs, but I didn't have a clue what foods to eat for a healthy diet. I didn't even know that it was carbohydrate that affected blood glucose

I was really upset when I was diagnosed this time. I literally tried everything not to have it (GDM) with this baby.

Being part of a research study that could help mums in future would be worthwhile, as long as there were not too many extra visits.

I had (gestational) diabetes in my last pregnancy, it was a nightmare! I had to regularly take my blood glucose- and I hate the sight of blood! I ended-up taking medication (metformin) which caused me anxiety as I didn't know if this would harm my baby. If this (trial) had been offered to me as a potential way to reduce my risk of getting it (GDM) this time around I would have jumped at the opportunity.

I had IVF to get pregnant, so it wasn't easy for me. My diet and lifestyle probably didn't help, I know I'm overweight – but I promised myself that if it did ever happen, I would become a healthier person.

All the leaflets get a bit much- I didn't read half of them. What I really needed was some simple clear advice.

I didn't even know that gestational diabetes was a thing, but because my dad has type 2 diabetes, I was told that I should have a test. I was upset when I found out I had developed the condition and angry I hadn't known more before.

My husband and I decided to use this baby as an opportunity to become healthier, so we're doing it together! I would have been happy to reducing carbohydrate, we could have done this as a team.

Appendix 4.2. Main intervention booklet



Contents

Page 3	The RECORD programme
Page 5	Guide to the RECORD programme
Page 6	REFRAIN guide
Page 8	REDUCE guide
Page 9	REPLACE guide
Page 10	Food choices
Page 16	Food safety
Page 17	Portion sizes
Page 18	Balanced plate
Page 19	Meal and snack suggestions
Page 23	Food labels
Page 26	Frequently asked questions
Page 27	What if I develop GDM?
Page 28	Additional information

The RECORD programme

What is Gestational Diabetes?

Gestational diabetes mellitus (GDM) is a condition that develops during pregnancy, in which women's blood glucose (or "blood sugar") levels are too high.

Who is at risk?

Women who carry too much weight at the start of pregnancy, or who gain too much weight whilst pregnant, are at greater risk of developing GDM.

How does it happen?

Eating foods containing carbohydrates (carbs) causes a rise in blood glucose. The body responds by producing a hormone called insulin, which pushes glucose into the cells of the body to be used as fuel, which helps to lower blood glucose levels.

During pregnancy, you need more insulin to control your blood glucose. GDM develops when either your body does not produce enough insulin, or when it cannot respond properly to the insulin that is produced.

Why is it a problem?

GDM increases the risk of complications during pregnancy:

- Your baby growing bigger than normal, which increases the risk of injury to your baby during birth, and the chances of needing caesarean section.
- Premature birth: giving birth before 37 weeks of pregnancy.
- Preeclampsia: having high blood pressure during pregnancy.
- Your baby having low blood glucose levels or yellowing of the skin and eyes (jaundice) after birth, which may require hospital treatment.

GDM can also lead to increased risks after pregnancy such as:

For you: GDM in future pregnancies; Type 2 diabetes; High blood pressure; Heart disease

For the child: Obesity; Type 2 diabetes; Heart disease

Treatments for GDM are available, but the aim of the RECORD programme is to reduce the chances of developing GDM in the first place, to minimise the risks to you and your baby.
The programme is designed to help you reduce the amount of carbs that you eat. This may lead to smaller rises in blood glucose, so you will naturally need less insulin. Eating less from carbs may also help you control the amount of weight you gain during your pregnancy. Overall, the programme may help to reduce your chances of developing GDM.

What happens if I develop GDM?

If you develop GDM, controlling your blood glucose levels can help to lower the risk of complications for you and your baby. You will receive advice on making healthier food choices and being physically active. If these changes are not sufficient to keep your blood glucose on target, medication will also be required (tablets or insulin injections). See more details on page 27.

"When I was diagnosed, I felt scared and confused. I had no idea what gestational diabetes was. My pregnancy was at higher risk and now things would have to change – I had to watch my eating and my weight, and check my blood sugars 6 times a day. It was overwhelming. But I was determined to make healthy eating work. If not, I'd be put on tablets or insulin injections.

At first I struggled; cutting down on my favourite sweet snacks, watching my portions. There was always thinking before eating anything, and then the worry of the blood sugar reading on the monitor. But after a few weeks, I became used to it. I decided to make this journey less frustrating by changing one thing every week, instead of trying everything at once. This was a huge relief. Using my hands as a guide to estimate my portion sizes was practical. With time, I also discovered new favourite recipes and healthier snacks. That's not to say that I didn't indulge here and there, but all in moderation.

Not every week was a success; too many potatoes one week, birthday parties on another, but on the whole, my sugars were well managed. I had a healthy baby and avoided the medications. Looking back, I realise that GDM made me learn to look after myself. But I wish there had been something I could do to avoid developing it [GDM] in the first place."

-Julie, 36, diagnosed with GDM during her first pregnancy

Guide to the RECORD programme

The RECORD programme is based on **three main principles (the three R's)**:

REFRAIN

REFRAIN from having sugary foods and drinks



REDUCE

REDUCE the amount of starchy carb that you eat to a moderate level



REPLACE

REPLACE
refined starchy carbs with wholegrain, unrefined versions, and sugary foods and drinks, with lower-carb and lower/no-sugar alternatives



In the next pages, you will find a practical guide for following the three R's, as well as swap options, healthy eating advice for pregnancy, meal suggestions and recipes to discover new favourites.

REFRAIN guide

DRINKS



✗

You should avoid all drinks with added sugar, including fizzy drinks, squashes, cordials and energy drinks.



✗

You should also avoid fruit juices and smoothies as they are high in natural sugars.



✓

Have tea and coffee without sugar. You can add artificial sweeteners if you wish for more sweetness. See page 15 for more information on caffeine intake during pregnancy.

Milk contains natural sugar, but less than sugary drinks. You can have milk every day, alone, as part of a meal/snack, or in tea/coffee, but keep in mind that large amounts will affect your blood glucose levels.

REFRAIN guide

FOODS



You should avoid sugary foods such as sweets, cakes, pastries, puddings, biscuits, chocolate, ice-cream, for now.

Avoid spreading jam or marmalade on your bread. You can use nut butters or Marmite instead.

Avoid adding sugar, honey or syrup to foods. You can add artificial sweeteners instead.

Find out swap options in the REPLACE section.



Breakfast cereals can be high in sugar e.g. cornflakes, crispies, granola, clusters. Check the food labels to choose breakfast cereal with less than 5g of sugar per 100g or with a green label for sugar. Healthier options are in the REPLACE section.

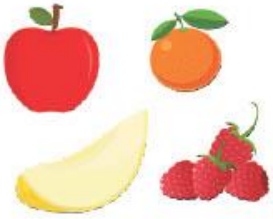
Cereal bars are often considered a "healthy" snack, but many are surprisingly high in sugar. Check out some healthier swaps in the REPLACE section, and find a full list of preferable snacks on page 22.



Yoghurt contains natural sugar, but less than sugary foods.

You can have yoghurt in your everyday diet, but keep in mind that large amounts will affect your blood glucose levels.

Many flavoured yoghurts have added sugar. Therefore, choose plain yoghurt. For extra flavour, you can add some spices, nuts and/or lower-sugar fruit, such as berries. Alternatively, you can go for a flavoured diet yoghurt with no added sugar such as Muller Light, Light & Free.



Fruit contains natural sugars but also has fibre and vitamins. Therefore, it is preferable compared to chocolate, cakes, pastries and other sugary foods.

Try not to have large amounts or too often during the day, as this will affect your blood glucose levels. For example, try to include 1-2 portions of whole fruit every day, as part of a meal or as an occasional snack. See page 12 and portion guide on page 17 for more information.

REDUCE guide

REDUCE the amount of starchy foods (e.g. bread, potatoes, rice, pasta, grains, yams, cassava, plantain) on your plate at main meals:

- **These foods should take up no more than 1/4 of your plate or be about the size of your fist or a small tennis ball.** Fill your plate with extra vegetables (at least 1/2 of your plate) so that you feel full at the end of meals.
- **Have one portion of these foods in each main meal. For meals based on beans and pulses**, which have quite a bit of carb in them, limit the amount of other carb-containing foods (i.e. bread, potatoes, rice, pasta, grains, yams, cassava, plantain), **to half a portion (i.e. less than 1/4 of your plate).**

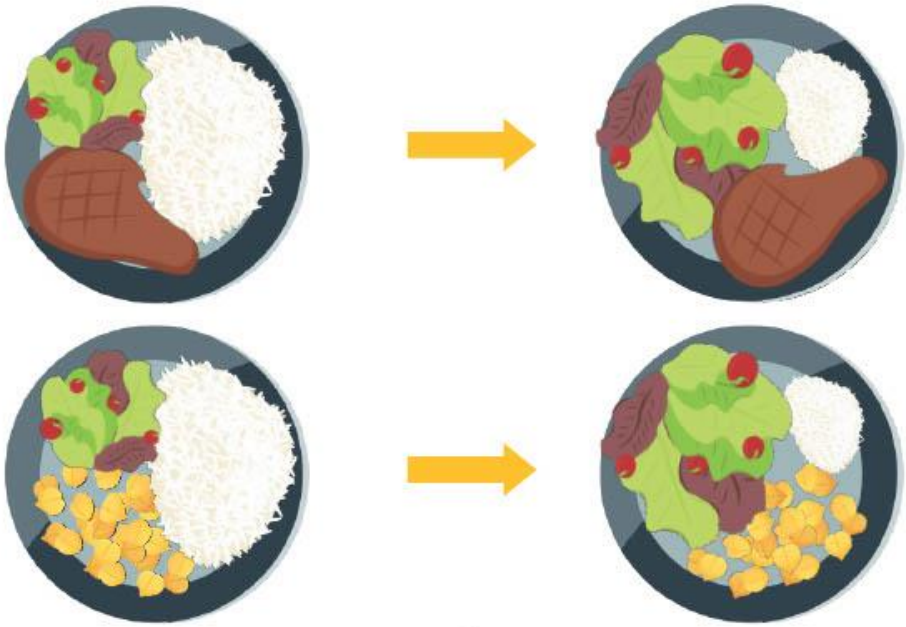
Here are some ideas:

Pasta lover? Have small amount of pasta and add bulk to it by adding courgette/carrot/butternut squash spaghetti.

Cauliflower rice is a great low-carb alternative to rice or potato. Serve it alongside a small portion of rice or potato and a protein source, as part of a main meal. You can find it frozen and ready-riced or make it on your own if you're feeling creative (see recipe booklet page 33).

Pizza lover? Make your own using wholemeal tortilla wraps or pitta bread as a base instead of dough, top with salsa, vegetables and cheese.

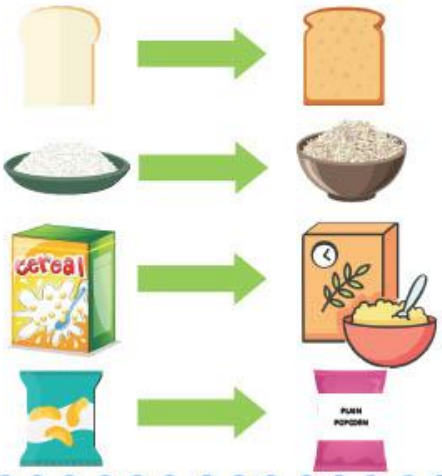
Missing savoury pasties or sausage rolls? Try a sandwich with thin/medium slices of wholegrain bread, a wrap, or a small bread roll with savoury fillings such as egg, salad, cheese.



REPLACE guide

Starchy food swaps:

REPLACE refined starchy carbs with high fibre wholegrain versions. The fibre will slow down the rate that glucose is released into your blood. It can also help reduce the risk of constipation.



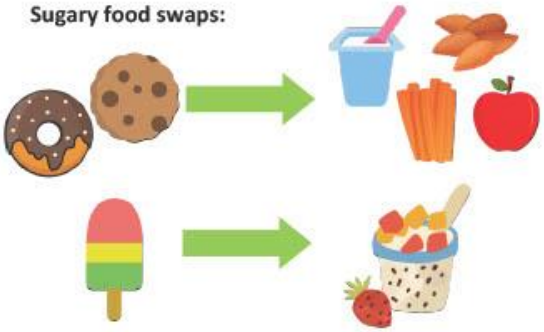
Swap white bread with wholegrain, seeded, granary or rye. Swap white pitta bread, wraps, chapatti, or naan bread with wholemeal.

Swap white rice for brown rice and white pasta for wholegrain versions or try other grains such as bulgur wheat, spelt, quinoa, buckwheat, millet, freekeh.

Swap cornflakes, crispies, granola, clusters and other sugary cereal, with plain porridge, plain wheat biscuits, unsweetened muesli, plain All-Bran or bran cereals.

Swap crisps for a small pack (10-20g) of plain popcorn as an occasional snack.

Sugary food swaps:



Swap sweets, cakes, pastries, puddings, biscuits, chocolate, cereal bars, for lower-sugar snacks such as plain yoghurt, small handful of nuts, sugar-free jelly, veggie sticks with a dip, a portion of fruit. See page 22 for a full list of tasty snack options.

Swap ice-cream for homemade frozen yoghurt made with lower-sugar fruit (mix blended fruit with plain yoghurt and freeze – see recipe booklet page 43).

Sugary drink swaps:



Swap drinks with added sugar such as regular cola and other fizzy drinks, squashes, cordials and energy drinks, with their sugar-free/diet alternatives e.g. diet cola, no added sugar/diet lemonade, no added sugar squash.

Try chilled spring/sparkling water and add a slice of lemon to make it refreshing.

Mix unsweetened cocoa powder with hot milk. Add artificial sweetener if needed.

Have tea or coffee without added sugar. You can add artificial sweetener if you wish for more sweetness.

Food choices

During your pregnancy, it is important that you follow some general healthy eating and food safety rules. Healthy eating in pregnancy can help you maintain good health and supports the development of your baby. The suggestions below will help you get the right balance of foods and nutrients. But when you are pregnant, your needs for some vitamins and minerals increase. Speak to your midwife or doctor about supplements that you may need to take.

No need to "eat for two"

Pregnancy is not a time to diet, but it is important that you control the amount of weight that you gain. There is no need to "eat for two", even if you are expecting more than one babies.

Every day you should be having the following:

- at least 8-10 glasses of **water or other sugar-free drinks**
- plenty of **lower-carb vegetables or salad**
- a portion of **starchy food** at each main meal, or half a portion in bean/pulse-based meals
- a portion of **protein-rich food** 2-3 times a day
- a portion of **dairy or calcium-fortified dairy alternatives** 2-3 times a day
- 1-2 portions of **whole fruit**
- small amount of **healthy oils and spreads**

You can also chew on sugar-free chewing gum or sugar-free mints if you wish.

Following these principles, your diet should follow this pattern:



"Pregnancy is an opportunity to reassess your diet and lifestyle."

-Mary, 31, pregnant with first baby

Food choices

Starchy foods

Go for wholegrain varieties where possible (see REPLACE pg 9)

Starchy foods include:


any foods made with flour


bread


rice

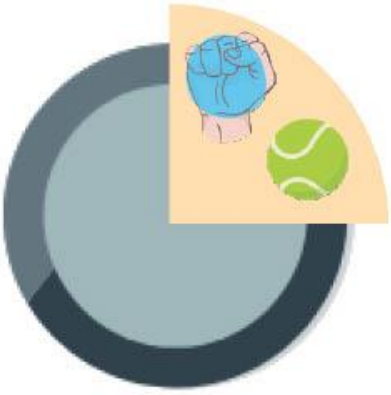

pasta, noodles


beans and pulses


breakfast cereal


couscous and grains e.g. quinoa, bulgur wheat, barley, spelt, millet


some vegetables, e.g. potatoes, sweet potatoes, yams, plantain, cassava



Try to have a small portion of starchy food with each main meal.

Aim for this to cover about 1/4 of your plate or to be the size of your fist or a small tennis ball.

Note for vegetarian/vegan meals:

Many vegetarian or vegan meals are based on beans and pulses. These are rich in protein but also contain quite a bit of carb.

If you wish to add a starchy food to a bean/pulse-based meal, then limit it to half a portion (e.g. one thin/medium slice of bread instead of two, 2 baby potatoes instead of 4, half a fist-sized portion of pasta, rice, grains, which is about 2 heaped tablespoons).

Food choices

Fruit

Fruit contains natural sugars but less than foods with added sugar. However, be mindful to not have large amounts. For example, try to include 1-2 portions of whole fruit every day, as part of a meal or as an occasional snack. Find out what a portion of fruit is on page 17.

All fruit is ok to have, but it's best to choose more often fruit with a lower sugar content such as:



a handful of berries



a small apple, pear, peach, nectarine, orange, grapefruit



2 small plums, satsumas, clementines, tangerines



a medium slice of melon

Always wash fresh fruit carefully

Things to keep in mind:

- **Have fruit with the skin wherever possible.**
- **It's best to eat your fruit whole, rather than drink it.** Sugars in fruit are released when they are juiced or blended ("free sugars") and they are quickly absorbed, leading to rapid increase in blood glucose levels.

  On the other hand, sugars contained in the structure of the whole fruit are released slower and so the increase in blood glucose is steadier.

Food choices

Vegetables and salad

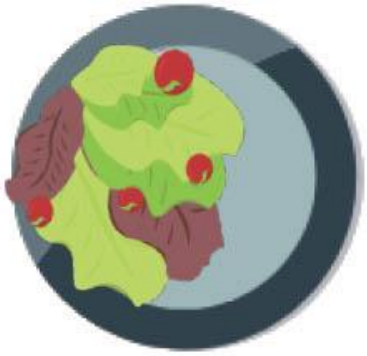
Eat plenty of vegetables, whether fresh, frozen or canned.

The only vegetables to limit are potatoes, sweet potatoes, yams, plantain or similar foods. These contain much more carbohydrate than other vegetables and so they count as one of your starchy foods portions.

Try to have at least 3-4 portions of vegetables every day:

- Fill half of the plate with vegetables or have a bowl of salad with your meals.
- Add plenty of the lower-carb veg to stews, soups, casseroles and stir-fries.
- Have veggie sticks as a snack.
- If you feel like having second helpings, fill up on more veggies or salad.
- Use courgette, carrot or butternut squash spaghetti when wanting to add extra pasta, or cauliflower rice instead of adding extra rice.





Protein foods

Protein is important to help your developing baby to grow. Include a portion of a protein-rich food in your meals 2 or 3 times a day. See page 16 for food safety rules.


fish and seafood
(fresh, frozen, smoked, canned)


chicken and turkey
(remove the skin)


nuts and seeds (watch portion)



Quorn™


all beans, chickpeas and lentils


beef, lamb, pork
(lean cuts or trim off visible fat)


eggs


tofu

Food choices

Dairy and dairy alternatives

Dairy foods contain protein and calcium which is important to encourage strong bone growth in your baby and protect your bones too. If you only have dairy-free alternatives, try to choose mostly soya-based drinks and yoghurts, because they have more protein than others, and go for calcium-fortified unsweetened versions. See page 16 for food safety rules.

Aim to have a portion of dairy 2-3 times a day.

- Choose lower-fat varieties where possible, such as skimmed/semi-skimmed milk, and cheeses such as feta, mozzarella, ricotta, cream cheese, cottage cheese, quark, fromage frais, and reduced-fat hard cheese.
- Choose plain yoghurt to which you can add flavour by adding spices, nuts or lower-sugar fruit or go for a diet no added sugar yoghurt, such as Muller Light, Light & Free.
- Swap cream for cream cheese in creamy dishes, and use quark or plain yoghurt in desserts.



Oils and spreads

Choose healthy sources of oils and spreads in place of butter or coconut oil. "Healthier" fats are found in rapeseed oil, olive oil, sunflower oil, and spreads made from these oils. Nuts, seeds and avocados also contain healthy fats. These healthier fats are rich in unsaturated fats and can help to lower the blood cholesterol and protect against heart disease and stroke. Fats and spreads which are high in saturated fatty acids increase blood cholesterol and can damage the blood vessels.



Remember that all fats are high in calories.
You may find helpful to:

- Use spray oil or add a teaspoon of oil per person while cooking.
- Avoid fried foods and choose grilled, boiled, steamed, poached, baked, stir-fried foods.
- Spread fats thinly on bread.

Food choices

Drinks

It's important to drink enough every day to avoid becoming dehydrated. Dehydration can lead to feeling unwell and getting headaches and constipation.

Everyone should aim to have at least 6-8 glasses of fluids every day. When you are pregnant you need a bit more fluid, so try to have about 8-10 glasses (1.8-2.3 litres or 3-4 pints) a day.

Avoid drinking alcohol during your pregnancy, as it is harmful for your baby.

Limit caffeine to no more than 200mg per day. That's about 2 cups of coffee or 3 cups of tea. You can drink decaffeinated versions instead, or try herbal or fruit teas, or squeeze a lemon into hot water.

For a full list of healthy drinks, have a look at the REPLACE section on page 9.





Flavourings and condiments

Make your meals more interesting by adding a variety of flavourings and condiments. Here are some ideas which you can use freely in your everyday cooking:

Lemon or lime juice	Worcestershire sauce
Vinegars e.g. white wine, sherry or balsamic vinegar	Mustard
	Fresh or dried herbs
Soy sauce	Spices
Miso paste	Chilli
Fish sauce	Ginger



Food safety

Most foods are safe to eat during pregnancy. But there are some things you should be careful about or avoid, to reduce risk to your baby.

Fruit and veg:

Always wash fresh fruit and vegetables carefully.

Protein foods:

Fish:

- Have no more than 2 portions of oily fish per week, e.g. salmon, sardines, herring or mackerel, as they may contain pollutants.
- Try to have no more than 2 tuna steaks or 4 cans of tuna a week.
- Avoid swordfish, shark and marlin, as they contain more mercury than other fish.
- Raw or lightly cooked fish and shellfish should be avoided, as it may be contaminated with bacteria, viruses or toxins.

Meat/poultry:

- Meat and poultry should be thoroughly cooked all the way through. There should be no pink parts or traces of blood, and the juices should have no pink or red in them.
- Cold, pre-packed meats such as ham and corned beef are safe to eat. But, cold cured meats, like salami, pepperoni, chorizo, prosciutto, should be cooked thoroughly.
- Avoid liver and liver products e.g. pâté. These foods contain lots of vitamin A, which can be harmful to the baby. Avoid vegetarian pâté too as it can contain listeria – a bacteria which causes an infection.
- Avoid game meats, including goose, partridge, pheasant, as they may contain lead shot.

Eggs:

Only eggs that are produced under the British Lion Code of Practice are safe to be consumed raw or partially cooked during pregnancy, as they come from birds that have been vaccinated against salmonella. They have a red lion logo on their shell. Any other eggs should not be consumed raw or partially cooked including in mousse, mayonnaise or soufflé.

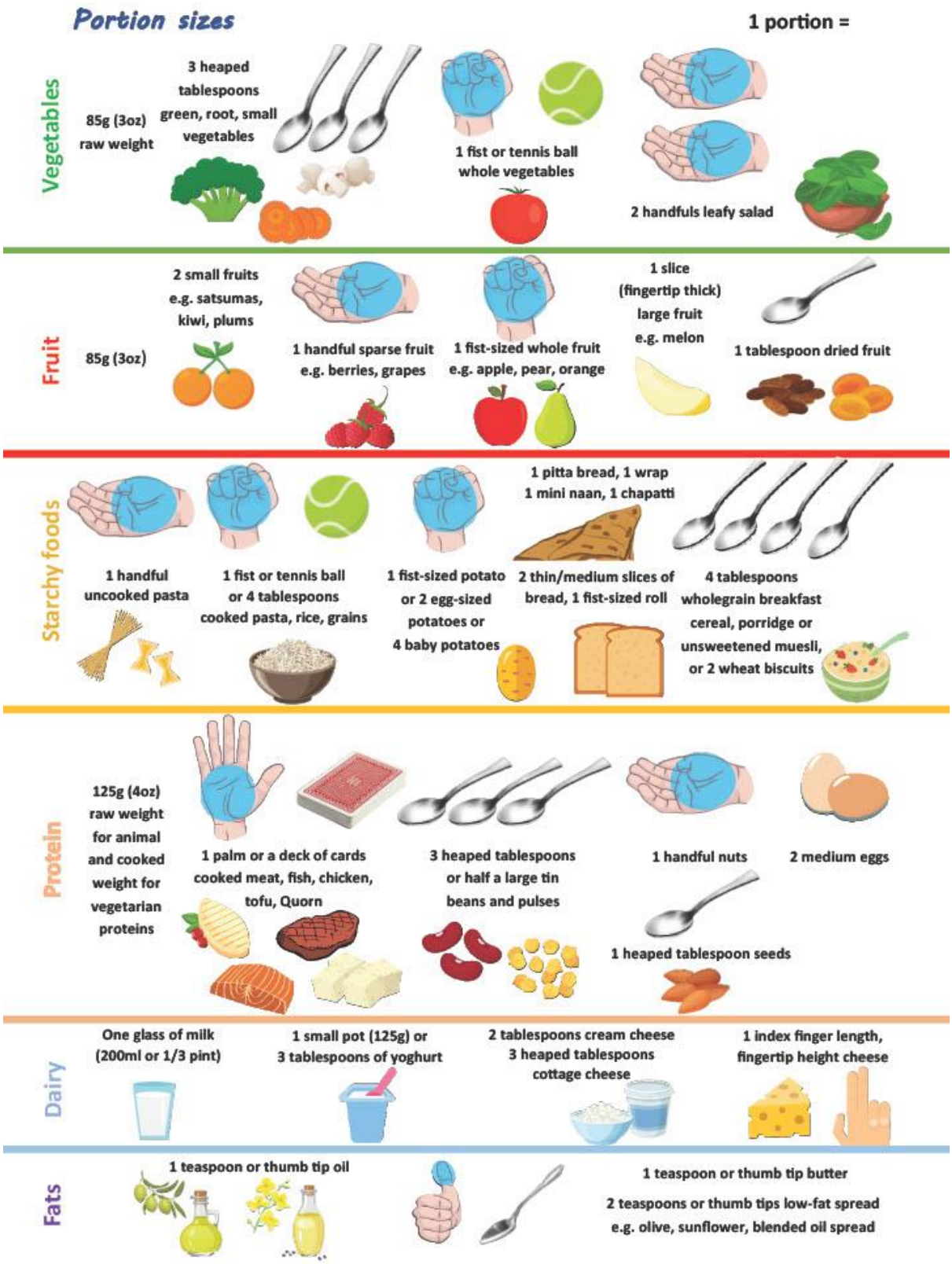
Dairy:

You should avoid dairy foods that have not been pasteurised because they may contain listeria, a bacteria which can lead to an infection (listeriosis). These foods include:

- Unpasteurised cow's milk, goats' milk or sheep's milk
- Any foods made from unpasteurised milk, such as soft goats' cheese

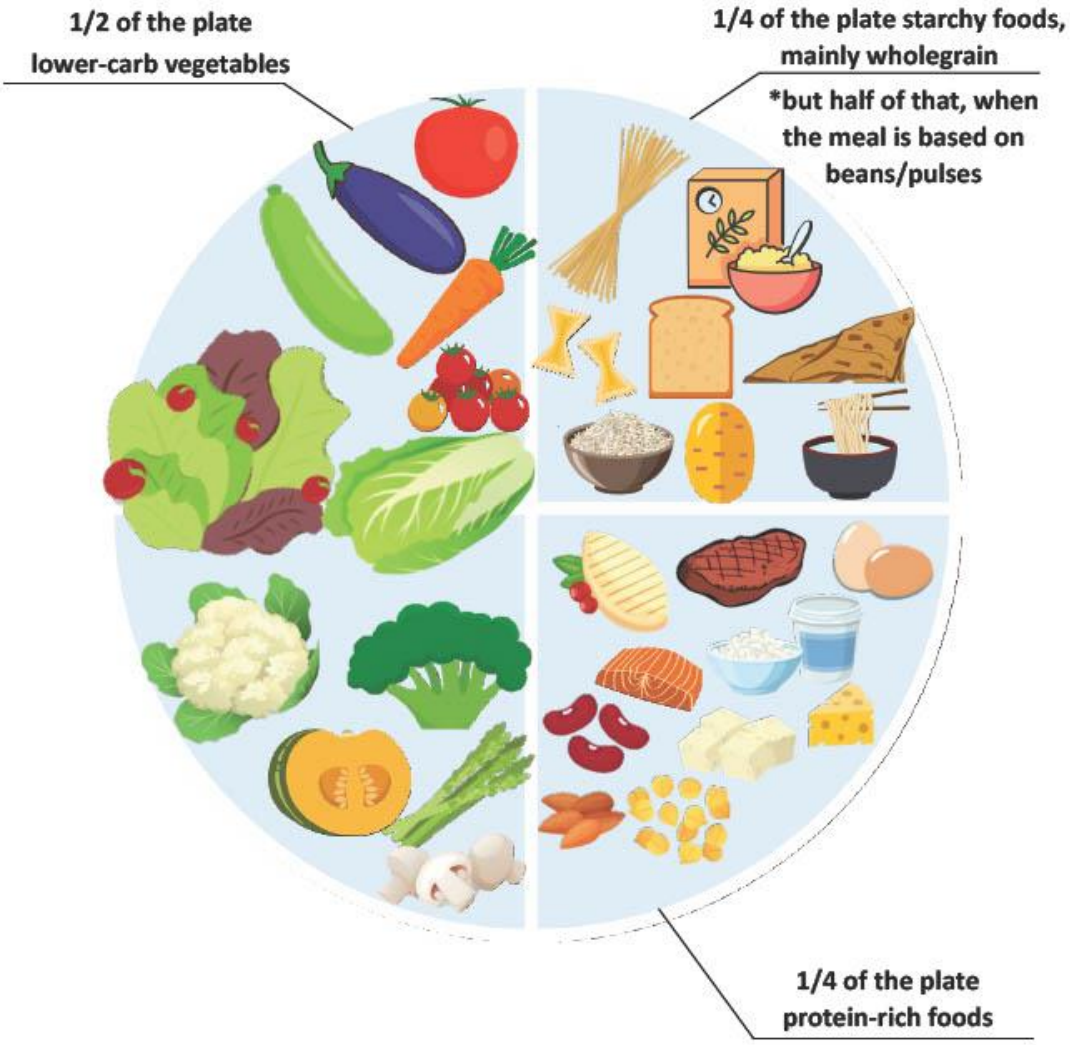
Soft cheeses with a white coating on the outside should also be avoided during pregnancy as they have more moisture which can help bacteria to grow. These include:

- Mould-ripened soft cheeses with a white coating on the outside, e.g. brie, Camembert, chevre.
- Soft blue cheeses, such as Danish blue, Gorgonzola and Roquefort


Portion sizes
1 portion =
Vegetables
85g (3oz) raw weight
3 heaped tablespoons green, root, small vegetables
1 fist or tennis ball whole vegetables
2 handfuls leafy salad
Fruit
85g (3oz)
2 small fruits e.g. satsumas, kiwi, plums
1 handful sparse fruit e.g. berries, grapes
1 fist-sized whole fruit e.g. apple, pear, orange
1 slice (fingertip thick) large fruit e.g. melon
1 tablespoon dried fruit
Starchy foods
1 handful uncooked pasta
1 fist or tennis ball or 4 tablespoons cooked pasta, rice, grains
1 fist-sized potato or 2 egg-sized potatoes or 4 baby potatoes
1 pitta bread, 1 wrap 1 mini naan, 1 chapatti
2 thin/medium slices of bread, 1 fist-sized roll
4 tablespoons wholegrain breakfast cereal, porridge or unsweetened muesli, or 2 wheat biscuits
Protein
125g (4oz) raw weight for animal and cooked weight for vegetarian proteins
1 palm or a deck of cards cooked meat, fish, chicken, tofu, Quorn
3 heaped tablespoons or half a large tin beans and pulses
1 handful nuts
2 medium eggs
1 heaped tablespoon seeds
Dairy
One glass of milk (200ml or 1/3 pint)
1 small pot (125g) or 3 tablespoons of yoghurt
2 tablespoons cream cheese
3 heaped tablespoons cottage cheese
1 index finger length, fingertip height cheese
Fats
1 teaspoon or thumb tip oil
1 teaspoon or thumb tip butter
2 teaspoons or thumb tips low-fat spread
e.g. olive, sunflower, blended oil spread

Balanced plate

You can control your portions and get the balance right in three simple steps when your plate follows the method below:



Meal and snack suggestions

You can use any of the suggestions below or mix and match the RECORD recipes to suit yourself.

Breakfast

- 1 portion of plain wholegrain cereal/unsweetened muesli **WITH** skimmed/semi-skimmed unsweetened milk **OR** plain yoghurt
- 1 small portion of porridge oats (27g), made up **WITH** skimmed/semi-skimmed unsweetened milk as per packet instructions. If you wish for a fruity porridge, top with lower-sugar fruit such as berries, or see recipe booklet page 4.
- 1 portion of fruit served **WITH** plain yoghurt
- 1 crumpet or 3 plain crackers or 3 rice cakes or 2 crispbreads **WITH** nut butter/Marmite **AND** 1 portion of lower-sugar fruit
- 2 thin/medium slices of wholegrain bread/toast **WITH** cooked mushrooms, spinach, tomato **AND**
  - **EITHER** 1-2 eggs (boiled/poached/scrambled/omelette)
  - **OR** tofu scramble
- Cooked mushrooms, tomatoes **WITH** grilled turkey ham or vegetarian ham/protein pieces or tofu scramble **AND**
  - **EITHER** 2 thin/medium slices of wholegrain bread/toast
  - **OR** half a can of no added sugar baked beans and 1 thin/medium slice of wholegrain bread/toast
- Vegetarian sausage grill: 2 grilled vegetarian sausages **WITH** tomatoes, mushrooms **AND** 2 thin/medium slices of wholegrain bread/toast
- Poached smoked haddock **WITH** spinach, tomatoes **AND** 2 thin/medium slices of wholegrain bread/toast
- Avocado **AND** 1-2 eggs (boiled/poached/scrambled) or tofu scramble **AND** 2 thin/medium slices of wholegrain bread/toast. You can also add vegetables if you wish e.g. tomato, spinach, mushrooms.

Meal and snack suggestions

Light meal

- Sandwich with 2 thin/medium slices of wholegrain bread **OR** 1 fist-sized wholegrain roll **OR** 1 wholemeal wrap or 1 pitta bread **WITH**
  Fillings:
  - lean meat/poultry (e.g. chicken/turkey) or vegetarian protein slices/pieces or tinned fish and salad
  - egg and salad
  - tuna and cucumber
  - cream cheese and salad
  - cream cheese and salmon
  - hummus and salad

- Soup containing lower-carb vegetables and optional lean meat/poultry/fish/vegetarian protein pieces, **WITH** 2 thin/medium slices of wholegrain bread/toast **OR** 1 fist-sized wholegrain roll

- Soup made of half a can of beans/pulses and lower-carb vegetables, **AND** half portion of other starchy food (e.g. 1 thin/medium slice of wholegrain bread/toast or half a wholegrain roll).

- Half a can of no added sugar baked beans **WITH** 1 thin/medium slice of wholegrain bread/toast **AND** a salad

- Salad vegetables **WITH** lean meat/poultry/fish/cheese/egg/tofu/vegetarian protein slices or pieces, **AND**
  - **EITHER** 2 thin/medium slices of wholegrain bread
  - **OR** small amount (size of fist or 4 tablespoons) of rice/pasta/grains/potato (2 egg-sized or 4 baby)

- Salad vegetables, herbs and spices mixed **WITH** half a can of chickpeas or other beans/pulses **AND half portion** of other starchy food (e.g. 2 tablespoons brown rice/grains or 1 thin/medium slice of wholegrain bread or 2 baby potatoes)

- Fist-sized jacket potato in its skin with filling **AND** salad. Fillings: tinned fish, lean meat/poultry/ vegetarian protein pieces, cheese, coleslaw

Meal and snack suggestions

Main meal

- Roast/grilled lean chicken/beef/lamb/pork/vegetarian protein pieces **WITH** plenty of vegetables (at least 1/2 of the plate) **AND** small portion (1/4 of the plate) of wholegrain pasta/rice/grains/ potatoes/sweet potato/yam/cassava/plantain **OR** 2 thin/medium slices of bread
- Grilled vegetarian sausages **WITH** plenty of vegetables (at least 1/2 of the plate) **AND** small portion (1/4 of the plate) of wholegrain pasta/rice/grains/potatoes/sweet potato/yam/cassava/plantain **OR** 2 thin/medium slices of bread
- Grilled/steamed/oven-baked fish **WITH** plenty of vegetables (at least 1/2 of the plate) **AND** small amount (1/4 of the plate) of wholegrain pasta/rice/grains/potatoes/sweet potato/yam/cassava/ plantain **OR** 2 thin/medium slices of bread
- Small amount of wholemeal pasta (fist-sized portion) **WITH** extra bulk from courgette/carrot/ butternut squash spaghetti, **AND** meat/vegetarian bolognaise, **AND** salad
- Open homemade burger: one slice of a burger bun at the bottom **AND** one leaf of lettuce on the top instead of a second slice. Fillings: grilled chicken/beef/ meat-free burger/vegetarian protein pieces, with tomato, onion, lettuce, cheese, sauce. Serve with salad.
- Lean meat/fish/vegetable curry **WITH** small amount (1/4 of the plate or size of fist) of brown rice/potato **OR** 1 **mini** naan bread/1 chapatti **AND** plenty of salad (at least 1/2 of the plate)
- Chickpea curry/dahl (half a can pulses) **WITH half portion** of other starchy food (e.g. 2 tablespoons brown rice or 2 baby potatoes or half chapatti or 1 thin/medium slice of wholegrain bread) **AND** plenty of salad (at least 1/2 of the plate)
- Stew or casserole made with lower-carb vegetables **AND** optional lean meat/poultry/fish/ vegetarian pieces **AND** small portion of potatoes (2 egg-sized or 4 baby).
- Stew or casserole made with lower-carb vegetables and half a can of beans/pulses **WITH half portion** of other starchy food (e.g. 2 baby potatoes or 1 thin/medium slice of wholegrain bread)

Meal and snack suggestions

Snacks

It's not necessary to have between meal snacks. Just listen to your body and eat only when you are truly hungry. If you do go for a snack, here are some preferable options.

Lower-carb:

- Small handful of nuts
- Small pot (120-125g) or 3 tablespoons of plain yoghurt
- Sugar-free jelly
- Carrot/celery/cucumber sticks **WITH** cottage cheese **OR** plain yoghurt mixed with herbs and spices (e.g. mint, garlic), **OR** hummus
- Couple of slices of turkey/vegetarian ham **WITH** cucumber, tomato

Moderate-carb:

- 1 portion of fruit
- Small pot (120-125g) or 3 tablespoons of plain yoghurt **WITH** a sprinkle of lower-sugar fruit, such as berries
- Small pot of diet (no added sugar) yoghurt e.g. Muller Light, Light & Free
- Couple of breadsticks/plain crackers/rice cakes/crispbreads **WITH** cheese **OR** 2 tablespoons hummus/cream cheese
- 1 crumpet or 3 plain cream crackers or 3 rice cakes or 2 crispbreads **WITH** nut butter/Marmite
- Small packet (10-20g) or a handful of plain unsweetened popcorn

"Looking back, I wish that from the moment I had become pregnant, that I had stopped snacking throughout the day on sweet things, particularly in the evenings, immediately before going to bed. I also wish I had substituted some of the high sugar foods, including fruit, for other foods such as nuts or protein-rich foods. I often think that if I had done this, as well as maintaining some exercise, then I would not have been diagnosed with GDM."

-Afsha, 31, diagnosed with GDM in second pregnancy

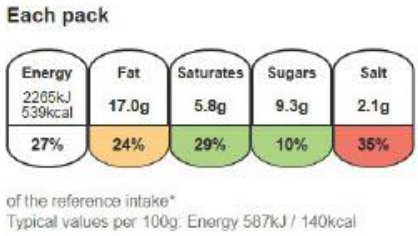
Food labels

Food labels can be confusing, but the information they provide is useful if you want to make healthier choices and to make it easier to follow the RECORD programme. It's going to take a bit of work from you to find the foods that fit with the programme, but once you have found them, it will be much quicker the next time.

How can I tell if a food fits with the RECORD programme?

1. Some products may have "front of pack" labels, that give you at-a-glance information about what's inside the food or drink. Sometimes they use colour-coding based on the traffic light system, to give you an idea about whether the product is low (green), medium (amber) or high (green) in a nutrient.

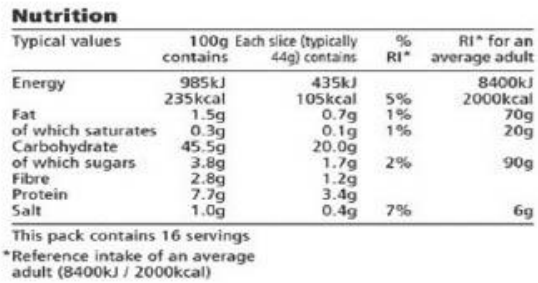
Check that the sugar light is green. Try to choose products that have as many green lights as possible or fewer red lights.



Some foods might have "front of pack" labels, but without the traffic light colour-coding e.g. some breakfast cereal or yoghurts. In this case, turn over the pack and look at the nutrition information table. **The product is low in sugar if it has less than 5g of sugar per 100g.** You can also use the table below to help you make healthier choices.

All measures per 100g	Low	Medium	High
Fat	3g or less	3.1g to 17.5g	More than 17.5g
Saturated fat	1.5g or less	1.6g to 5g	More than 5g
Sugars	5g or less	5.1g to 22.5g	More than 22.5g
Salt	0.3g or less	0.3g to 1.5g	More than 1.5g

2. Look at the nutrition information at the back or side of the pack. **The amount of carbohydrate per serving should not exceed approximately 40g for a meal and 10-15g for a snack.**



Nutrition

Typical values	100g contains	Each slice (typically 44g) contains	% RI*	RI* for an average adult
Energy	985kJ 235kcal	435kJ 105kcal	5%	8400kJ 2000kcal
Fat	1.5g	0.7g	1%	70g
of which saturates	0.3g	0.1g	1%	20g
Carbohydrate	45.5g	20.0g		
of which sugars	3.8g	1.7g	2%	90g
Fibre	2.8g	1.2g		
Protein	7.7g	3.4g		
Salt	1.0g	0.4g	7%	6g

This pack contains 16 servings

*Reference intake of an average adult (8400kJ / 2000kcal)

Food labels

Is there an easier way to tell?

You need to check the food label on the pack to be sure. It will take some work the first time you try to look at food labels while shopping, but next time you will know what to choose and you'll be much quicker. There are some rules of thumb to make it easier:

- Ready meals with chicken or fish are generally ok, but be careful about the sauce. Sometimes the sauce is made with a lot of fat. Try most of the times to go for meals with sauces based on tomato, lemon, vinegar, herbs.
- Many ready meals include a starchy food. Choose meals where the carbohydrates per serving are approximately no more than 40g.
- Sandwiches and ready meals with less than, or about 300 calories per serving, are most of the times fine. Just check that the carbohydrates per serving are approximately no more than 40g.
- Some supermarkets offer a range of healthier meals, but you still need to check for the amount of carbohydrate per serving (approximately no more than 40g). Examples include:

  Tesco: "Healthy Living", "Beautifully Balanced"

  Sainsbury's: "Be Good to Yourself", "My Goodness!"

  M&S: "Balanced for you"

  ASDA: "Fresh Tastes", "High Protein"

  Iceland: "Slimming World"

  Waitrose: "LoveLife", "Thrive"

  Lidl: "Chef select" and "Ready to Cook" vegetables and salads

  Aldi: "Specially selected" salads



"I used to pick up Chinese takeaway on my way home after a long day when I wanted something quick. But since starting in the programme, I was surprised by how easy and quick is to make a tasty stir-fry by myself. I am keeping portions of chopped veggies and all I have to do is add them into the pan with a block of noodles, some soy sauce and I have myself a healthy comfort alternative."

–Lucy, 29, pregnant with first baby

Food labels

TESCO





ALDI



M&S

EST. 1884



Sainsbury's





Waitrose





25

Frequently asked questions

What if I eat out?

If you eat out occasionally (e.g. once/twice a month or on special occasions), you shouldn't worry too much about what you eat. However, if you are eating out more often, you can plan about making choices that fit with the RECORD programme. Here are some ideas:

- Choose foods that have been grilled, stir-fried, steamed, baked, rather than fried.
- Instead of foods with a rich or cream sauce, go for foods with tomato-based sauce.
- Follow the plate method: some starchy foods (1/4 of the plate), some protein (1/4 of the plate) and plenty of vegetables or salad.
- Ask for dressings/sauces to be served on side so you can choose how much to use.
- Split pasta between two people.
- Share a thin crust pizza and choose tomato sauce and vegetables as toppings, and a salad side dish.
- Choose fresh fruit/fruit salad for dessert.
- If you are reaching for take-away, have ready-to-cook packs in your freezer for a quick stir-fry.

What if I can't resist tempting treats?

If having biscuits and chocolates in your cupboard makes it impossible to resist, avoid buying them. Instead, have healthy snacks (e.g. nuts, yoghurt, fruit) within reach. If passing by a chip shop and the smell makes you want to go in, try another route.

What if other people tempt me with unhealthy foods?

It is important that your family and friends know what you are doing and understand why it is so important. By telling them, they can support you and encourage you.

If you live with others, ask them to help you by getting rid of tempting foods or put them somewhere you won't ordinarily notice them. Ask them to be supportive and not eat tempting snacks in front of you. Besides, trying healthy snacks will be good for everyone.

"My partner and I are trying to create healthy eating habits for our daughter too. She now enjoys cooking with us and happily eats a lot of vegetables."

-Trisha, 38, pregnant with second baby

If colleagues regularly bring in tempting treats, practice a "thank you but no" response. Explain you are taking extra care to protect your baby. Bring in your own healthy treat so you can continue to socialise with your team.

What if I crave unhealthy foods for comfort?

There are non-food related ways to occupy, comfort or reward yourself. Think, what takes your mind off things? What else feels like a treat? Examples include: music, knitting, colouring, crafts, crosswords, a book, talking to someone, a long walk, pregnancy yoga, swimming. Make a plan in advance so that when the moment strikes, you have an alternative already in mind.

What if I slip up?

Don't beat yourself up. We all have days where things don't go to plan. Learn from the lapse and plan what to do next time to avoid it. Try to get back to your plan as soon as possible. Look at your motivation chart and remember how you will feel if you achieve your goals.

What if I develop GDM?



The RECORD programme has been designed to help prevent GDM, but it is possible that some women will still develop high blood glucose. If you have GDM, this will be diagnosed by an Oral Glucose Tolerance Test between 24 and 28 weeks of your pregnancy.

You will receive all appropriate medical treatment to manage your diabetes. You will have a diabetes care team to look after you and suggest the best treatment option for you. You will be offered dietary advice which recommends limiting carbohydrates, and therefore, you can continue following the RECORD programme, but your care team will also give you additional information and support.

You may be able to control your diabetes with diet only, but if diet is not sufficient to achieve your target blood glucose levels, you may need tablets or insulin injections. You may also be offered extra appointments with your midwife or doctor and tests to ensure that you are closely monitored.

We know that pregnancy is in itself a lot to think about and having GDM may make you feel worried. You may even feel frustrated that you have come so far trying to stick to a dietary programme and still developed GDM. But it was not all for nothing. Women with GDM are encouraged to adopt a lower-carb diet, so all your efforts so far will be useful in helping to control your blood glucose levels. You will also receive extra support to help manage your diabetes and have a healthy pregnancy and birth.

Additional information

Pregnancy

NHS – Your pregnancy and baby guide
https://www.nhs.uk/conditions/pregnancy-and-baby/

Gestational diabetes

NHS – Gestational diabetes
https://www.nhs.uk/conditions/gestational-diabetes/

Diabetes UK – Gestational diabetes
https://www.diabetes.org.uk/diabetes-the-basics/gestational-diabetes

Diabetes UK – Everyday life with gestational diabetes
https://www.diabetes.org.uk/resources-s3/2019-10/Gestational-Guide-June-2019.pdf

Emotional support

NHS – Your pregnancy and baby guide
https://www.nhs.uk/conditions/pregnancy-and-baby/mental-health-problems-pregnant/

Healthy eating

NHS – Lifestyle Management of Gestational Diabetes website
http://gdmhealthylifestyle.co.uk/

NHS – Healthy diet in pregnancy
https://www.nhs.uk/conditions/pregnancy-and-baby/healthy-pregnancy-diet/

Start4Life
https://www.nhs.uk/start4life/pregnancy/healthy-eating-pregnancy/

Recipes

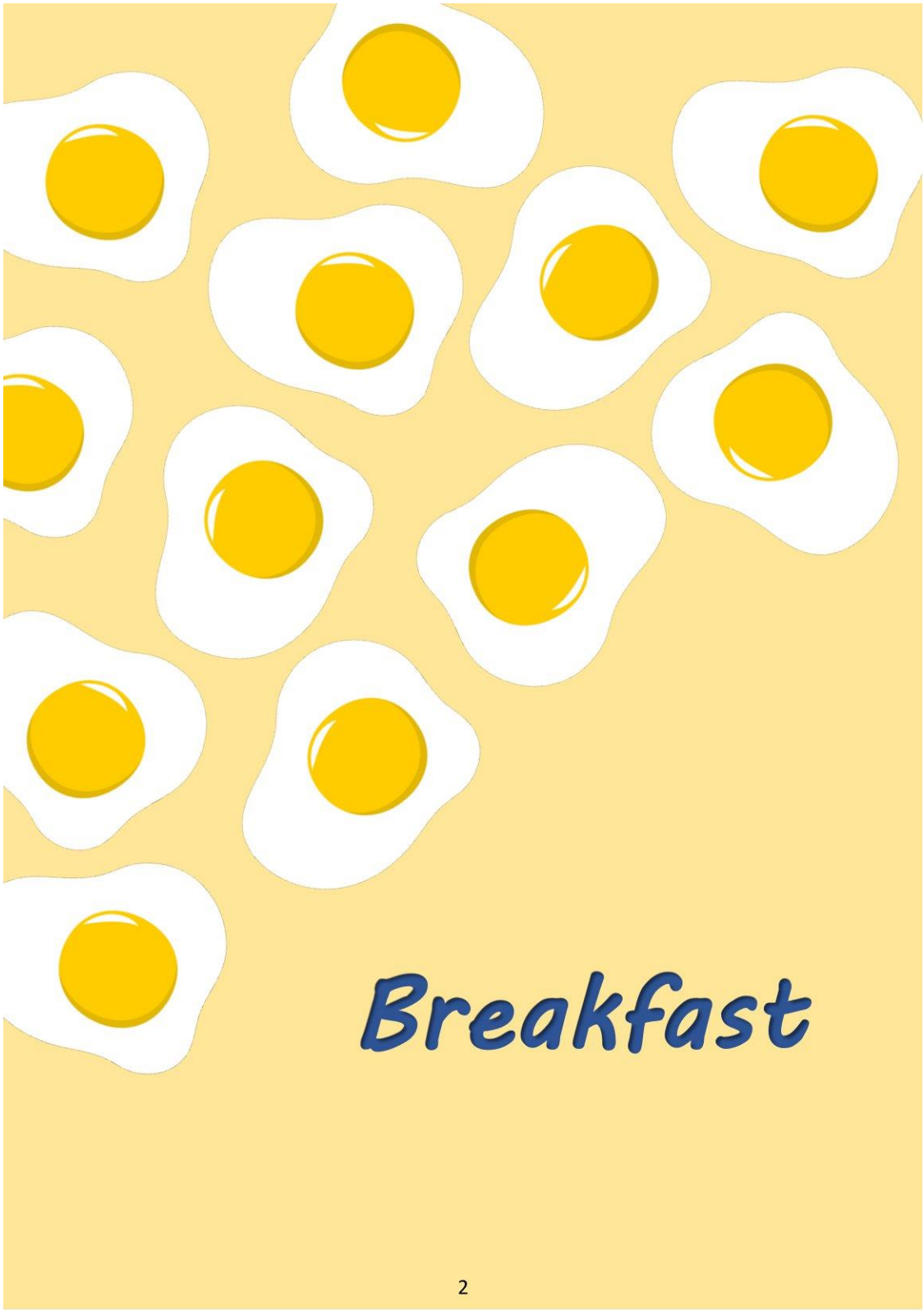
Here are some places you can find more recipe ideas. These haven't been created for the RECORD programme, so keep checking the amount of carbs and portion sizes of carb-containing foods, just like for ready meals.

Book: Carbs & Cals Gestational Diabetes: 100 Recipes Designed by Diabetes Specialist Dietitians, by Chris Cheyette and Yello Balolia

Diabetes UK – Enjoy Food
https://www.diabetes.org.uk/guide-to-diabetes/recipes

Appendix 4.3. Recipe booklet




Breakfast



Fruit and nut yoghurt (serves 1)

Ingredients

- 85g (3oz) or 1 handful fresh strawberries or 1 small apple/pear, sliced
- 125g or 3 tablespoons plain yoghurt
- 1/4 teaspoon ground cinnamon
- 1 tablespoon plain nuts e.g. almonds, walnuts

Method

- Mix the cinnamon into the yoghurt and fold in the sliced fruit.
- Place in a serving bowl and sprinkle with the nuts.



Fruity porridge (serves 1)

Ingredients

- 1 sachet porridge oats (or 27g)
- 1 cup milk
- 1 portion of lower-sugar fruit e.g. berries or small apple/pear
- 1 teaspoon cinnamon
- Optional: 1 teaspoon artificial sweetener

Method

- Boil the milk and water in a saucepan.
- Stir in the contents of 1 sachet or 27g of oats, the fruit and the sweetener (optional).
- Simmer for 2 minutes, stirring occasionally until the milk and water are absorbed.
- Serve with a sprinkle of cinnamon.



Scrambled eggs (serves 1)

Ingredients

- 1 teaspoon olive oil or rapeseed oil
- 1 spring onion, sliced
- 4 cherry tomatoes, chopped
- 1/4 red pepper, chopped
- Optional: 1 pickled jalapeno pepper, sliced

Serve with

2 thin/medium slices of wholegrain bread

Method

- Heat the oil in a small non-stick frying pan and add the vegetables.
- Sauté for 2-3 minutes, and then add the eggs.
- Stir the mixture over the heat until the eggs have scrambled and have been cooked through.



Omelette (serves 1)

Ingredients

- 2 medium eggs
- 2 squirts of spray oil
- 1 medium (125g/5oz) tomato, chopped or 50g (2oz) fresh mushrooms, sliced
- salt and pepper to taste

Serve with

2 thin/medium slices of wholegrain bread

Method

- Pre-heat the grill.
- Break the eggs into a bowl, add a tablespoon of cold water, salt and pepper to taste, and beat lightly.
- Heat a non-stick pan, spray with oil and add the eggs.
- Pull the cooked eggs away from the side of the pan and tip allowing liquid raw egg to come into contact with the heated pan. Sprinkle tomato or mushrooms on top and place under the grill until cooked through.



Tofu scramble (serves 1)

Ingredients

- Spice mix: 1/4 teaspoon yeast extract, 1/4 teaspoon chilli flakes, 1/4 teaspoon ground cumin, 1/4 teaspoon turmeric
- 2 teaspoons olive oil or rapeseed oil
- 100g (4oz) mushrooms, sliced
- 2 spring onions, chopped
- 100g (4oz) firm tofu

Serve with

2 thin/medium slices of wholegrain bread

Method

- Mix the spices together in a small bowl.
- Heat the oil in a frying pan and add the vegetables.
- Sauté the vegetables for 4-5 minutes until they start to brown.
- Add the spice mix and stir thoroughly to combine.
- Add the tofu and break the block up with a spoon until scrambled and cooked through.



Quorn™/turkey ham grill (serves 1)

Ingredients

- 2 slices turkey/Quorn™ ham
- 1 teaspoon olive oil or rapeseed oil
- 1 medium tomato
- 2 large flat mushrooms

Serve with

2 thin/medium slices of wholegrain bread

Method

- Halve the tomato and peel the mushrooms.
- Brush the tomato, the mushrooms and ham with the oil.
- Grill for 5 minutes each side or until brown.



Vegetarian sausage grill (serves 1)

Ingredients

- 2 Quorn™ or other vegetarian sausages
- 1 teaspoon olive oil or rapeseed oil
- 1 medium tomato

Serve with

2 thin/medium slices of wholegrain bread

Method

- Halve the tomato and peel the mushrooms.
- Brush the tomato, mushrooms and sausages with the oil.
- Grill the tomato and mushrooms for 5 minutes on each side or until brown.
- Grill the sausages on each side as per packet instructions.



Pancakes (serves 8)

Ingredients

- 100g wholegrain flour
- 1 medium egg beaten
- 300ml skimmed or semi-skimmed milk
- 1 teaspoon olive oil or rapeseed oil

Serve with

- Cottage cheese or plain yoghurt and one portion of lower-sugar fruit e.g. berries or small apple/pear
- Cinnamon and cardamom sprinkle

Method

- Put the flour in a bowl and add the beaten egg. Add the milk gradually while beating the mix.
- In a hot non-stick frying pan add the oil. Add 2-3 table-spoons batter and swirl the pan gently to help the mix spread a little around the pan.
- Leave until the batter forms a crust on the edges and bubbles in the middle. Let it cook for 1-2 minutes. Flip and cook the other side for 1 minute or until golden.



Light meal



Spicy chickpeas (serves 2)

Ingredients

- 400g (14oz) can chickpeas
- 400g (14oz) can tomatoes
- 1 medium onion, peeled and sliced
- 1 clove garlic, peeled and finely chopped
- 2 squirts of spray oil
- 1 teaspoon ground cumin
- 1 teaspoon ground coriander
- 1/2 teaspoon dried chilli flakes
- Salt and pepper to taste

Method

- Heat a medium pan and spray with the oil.
- Add the onion and garlic and cook gently until soft.
- Add the spices and stir for a couple of minutes over the heat.
- Add the tomatoes, drained chickpeas and salt and pepper to taste, and bring to a boil. Cover and simmer for 20-30 minutes. Sprinkle with chopped coriander.

Serve with

Salad **AND** 2 tablespoons brown rice **OR**
1 thin/medium slice of wholegrain bread



Cottage cheese salad (serves 1)

Ingredients

- 100g (4oz) cottage cheese
- 1 tablespoon fresh chives, chopped
- 2 spring onions, finely chopped
- 1 red chilli, de-seeded and finely chopped (optional)
- Mixed salad: lettuce, tomatoes, cucumber
- 2 egg-sized **OR** 4 baby potatoes in their skins, boiled, chopped

Method

Combine the cottage cheese, chives, chilli (optional), spring onions and potatoes, and serve piled on a bed of mixed salad.



Turkey/chicken/Quorn™ with potatoes and coleslaw

(serves 1)

Ingredients

- 75g (3oz) (size of palm) roast/ grilled skinless turkey/chicken breast **OR** half a packet Quorn™ chicken style pieces
- 100g (4oz) white cabbage, finely sliced or grated
- 50g (2oz) carrots, peeled and grated
- 1 spring onion, finely chopped
- Half a small pot or 1-1.5 tablespoons plain yoghurt
- 1/2 teaspoon mustard

Method

- Mix the grated cabbage, car rot and chopped onion in a bowl with the yoghurt and mustard. Add salt and pepper to taste.
- Arrange the salad leaves on a plate and pile the coleslaw and potatoes in the centre.
- Serve the turkey/chicken/ Quorn™ pieces.



Tortilla-base pizza (serves 1)

Ingredients

- 1 regular size wholemeal tortilla wrap
- 50g (2oz) mozzarella cheese
- 1 tablespoon tomato puree
- 1/2 a medium tomato, thinly sliced
- 4 olives
- Fresh basil leaves

Serve with

Mixed salad leaves

Method

- Preheat the oven to 180 degrees.
- Spread the tomato puree, mozzarella, tomato slices, olives and basil over the tortilla wrap.
- Bake until the cheese has melted.
- Serve with plenty of mixed salad leaves.

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Tuna salad Niçoise (serves 2)

Ingredients

- 100g (4oz) green beans, trimmed and halved
- 100g (4oz) mixed salad leaves
- 1/4 of medium cucumber, sliced
- 2 small (100g/4oz) tomatoes, quartered
- 2 medium eggs, hard-boiled, shelled and quartered
- 25g (1oz) olives, canned in brine
- 1 can (100g) tuna canned in water or brine
- 2 teaspoons olive oil
- 2 teaspoons balsamic vinegar
- 4 egg-sized or 8 baby potatoes in their skins, boiled, chopped

Method

- To make the dressing, whisk the olive oil and balsamic vinegar and add salt and pepper to taste.
- Boil the beans for 2 minutes, until just tender and drain.
- In a large bowl, mix the salad leaves, cucumber, tomatoes and beans.
- Drain the tuna and mix with the salad.
- Add the eggs, olives and potatoes.
- Pour over the dressing and combine with the rest of the salad.



Smokey baked beans (serves 2)

Ingredients

- 400g (14oz) cannellini or haricot beans, drained.
- 1 clove garlic, peeled and crushed
- 1 medium onion, peeled and chopped
- 1 teaspoon oregano,
  1/2 teaspoon dried thyme,
  1 teaspoon ground cumin,
  1/2 teaspoon smoked paprika,
  1 bay leaf
- 1 tablespoon red wine vinegar
- 2 tablespoons tomato puree
- 1 vegetable stock dissolved in 1/2 pint of water
- Stevia sweetener (optional)
- Salt and pepper to taste

Method

- Heat a non-stick pan and spray oil in it.
- Add the garlic and onions, and cook until soft but not browned.
- Add the rest of the ingredients. Add Stevia only if you want a sweeter taste. Bring to the boil.
- Cover and simmer gently for 10-15 minutes, adding more water if necessary.

Serve with

Salad and 1 thin/medium slice of wholegrain bread per person



Lentil salad (serves 2)

Ingredients

- 400g (14oz) can of green or Puy lentils, drained
- 1/4 medium cucumber, finely chopped
- 2 small tomatoes, finely chopped
- 1 small red onion, finely chopped
- 2 tablespoons fresh mint, finely chopped
- 2 tablespoons fresh coriander, finely chopped
- 2 teaspoons olive oil
- 1/2 teaspoon mustard
- 2 teaspoons white wine vinegar

Method

- To make the dressing, whisk the mustard, olive oil, and vinegar, and season to taste.
- Combine the rest of the ingredients in a large bowl, add the dressing and mix well.

Serve with

1 thin/medium slice of wholegrain bread per person



Main meal



Beef/Quorn™ spaghetti Bolognese (serves 4)

Ingredients

- 400g (1lb) lean minced beef (5% fat) **OR** 1 packet (500g) Quorn™ mince
- 1 clove garlic, peeled and crushed
- 1 medium onion , finely chopped
- 1 medium carrot, peeled and finely chopped
- 400g (14oz) canned tomatoes
- 1 vegetable or beef stock dissolved in 1/3 pint of water
- 2 teaspoons dried oregano

Serve with

Salad and small portion (1/4 plate or size of fist) of whole wheat spaghetti.

You can increase the volume of spaghetti with courgette, butternut squash or carrot spaghetti

Beef/Quorn™ spaghetti Bolognese (continued)



- Dry fry the beef mince in a non-stick pan until brown, or, if using Quorn™, spray a bit of oil, add the mince and stir until it gets colour.
- Add the garlic, onion, carrot, and cook for another 4-5 minutes until the vegetables are cooked but not coloured.
- Add the canned tomatoes, stock, oregano and salt and pepper to taste, and bring to the boil.
- Cover and simmer for 1 hour.



Curry, chicken/Quorn™ (serves 2)

Ingredients

- 2 small skinless chicken breasts (250g/8oz), cut into small chunks **OR** 1 packet (300g) Quorn™ chicken pieces
- 1 clove garlic, crushed
- 1 medium onion, finely chopped
- 1 red chilli, sliced (optional)
- 2 teaspoons ground cumin, 1 teaspoon ground coriander, 1 teaspoon turmeric
- 400g (14oz) canned tomatoes
- 1 chicken or vegetable stock cube dissolved in 1/3 pint of water

Method

- Add 2 squirts of spray oil in a non-stick pan and add the chicken breast or Quorn™ pieces. Cook them until coloured.
- Add the onion, coriander, turmeric, and cook for 2 minutes.
- Add the tomatoes, stock, salt and pepper to taste, and bring to the boil.
- Cover and simmer for 30 minutes.

Serve with

1 small chapatti or 1 mini naan bread **OR** small portion of brown rice (1/4 of plate or size of fist), per person



Stir-fry (serves 2)

Ingredients

- 200g (8oz) lean pork/beef/ chicken, sliced OR 1 packet (300g) Quorn™ chicken style pieces
- 1 clove garlic, crushed
- 1 tablespoon tomato puree
- 1 tablespoon lemon juice
- Chilli flakes (optional)
- 2 teaspoons sesame or rapeseed oil
- 3 spring onions, chopped
- 1 medium pepper (150g/6oz), sliced
- 50g (2oz) baby corn
- 300g packet bean sprouts
- 1/4 teaspoon Chinese five spice
- 1-2 tablespoons soy sauce
- 1 nest of whole wheat noodles per person

Method

- Marinate the pork/beef/ chicken/Quorn™ in a mix of garlic, chilli flakes, tomato puree, lemon juice.
- Heat the oil in a wok or non-stick pan, and stir-fry the mixture for 5 minutes.
- Add the spring onions, pepper, baby corn and bean sprouts, and cook for another 3-4 minutes.
- Lower the heat, add a little water, and the five spice, and stir-fry for another 5-10 minutes.
- Cook the noodles as per instructions on the packet and then mix into the pan.
- Add soy sauce to taste.



Stir-fry, prawn/tofu (serves 2)

Ingredients

- Spray oil
- 1 teaspoon ground or grated fresh ginger
- 1 garlic glove, crushed
- 1 red chilli, finely chopped (optional)
- 4 spring onions, chopped
- 1 large carrot, sliced
- 2 medium peppers, sliced
- 200g Savoy cabbage, shredded
- 2 tablespoons soy sauce
- 2 tablespoons rice wine or dry sherry
- 1/2 teaspoon Chinese five spice powder
- 250g (10oz) cooked prawns **OR** 200g firm tofu.
- 1 nest of whole wheat noodles per person

Method

- Add 2 squirts of spray oil in a hot non-stick pan.
- Add the ginger, garlic and chilli, and stir-fry for 1-2 minutes.
- Add the onions, carrot, peppers, cabbage, and stir-fry for further 5 minutes, until softened but not brown.
- Add the soy sauce, rice wine or sherry, and Chinese five spice, and cook for a further 2

- 3 minutes.
- Add the prawns or tofu and cook until thoroughly cooked through.
- Cook the noodles as per instructions on the pack, and then mix into the pan.



Baked fish and chips (serves 4)

Ingredients

For the fish:

- 4 frozen hake/cod fish fillets (100g each)
- 50g breadcrumbs
- 1 lemon, zested
- 25g grated reduced-fat cheese
- 2 tablespoons parsley, chopped
- 1 tablespoon olive oil or rapeseed oil

For the chips:

- 2 egg-sized potatoes in their skins per person
- Olive oil or rapeseed oil for drizzle
- 1 teaspoon sweet paprika

Baked fish and chips (continued)



- Preheat the oven to gas 7/220°C, fan/200°C.
- Cut each potato into 1cm-wide slices, then into 1cm-thick sticks.
- Cook the potato sticks in boiling water or in the microwave for 3 minutes, and drain well.
- Add the potato sticks into a roasting pan and drizzle with the oil so they are all evenly coated. Sprinkle with the paprika and bake for 10 minutes in the preheated oven.
- Place the frozen fish fillets on a lightly oiled baking sheet.
- Put the breadcrumbs in a bowl, then add the lemon zest, cheese, parsley and 1 tablespoon of oil. Season with black pepper and mix.
- After 10 minutes in the oven, turn the chips, and brush with a little oil if they are sticking. Return them to the middle shelf of the oven and put the fish fillets on the top shelf.
- Bake for another 5 minutes.
- Drain off any liquid from the fish baking pan.
- Add breadcrumb mixture on top of each fish fillet, pressing firmly with the back of a spoon.
- Return to the oven and leave everything to cook for another 15 minutes, or until the crumbs are golden and the potatoes are golden and crisp.
- Serve with boiled peas on the side.



Chilli, beef/Quorn™ (serves 4)

Ingredients

- 400g (1lb) lean minced beef (5% fat) **OR** 1 packet (500g) Quorn™ mince.
- Spray oil
- 1 medium onion, finely chopped
- 1 clove garlic, peeled and crushed
- 1 red chilli, finely chopped
- 1/2 teaspoon ground ginger
- 1 medium bell pepper sliced
- 1 teaspoon ground cumin
- 1 tablespoon balsamic vinegar
- 400g (14oz) canned chopped tomatoes
- 400g (14oz) canned red kidney beans
- 2 teaspoons tomato puree
- 1 vegetable or beef stock cube dissolved in 1/3 pint water

Chilli, beef/Quorn™ (continued)

Method

- Dry fry the beef mince in a non-stick pan until brown or if using Quorn™ mince, spray the pan with oil and stir until it gets colour.
- Add to the pan: garlic, onion, chilli, pepper, and cook for 4-5 minutes until the vegetables are soft but not coloured.
- Add the ground cumin, ginger and balsamic vinegar.
- Add the tomatoes, canned kidney beans, stock, salt and pepper to taste, and bring to the boil.
- Cover and simmer for 1 hour.

Serve with

Salad and small portion of boiled brown rice (size of fist or 4 tablespoons) per person

Want more rice?

See page 33



Jerk chicken/Quorn™ (serves 4)

Ingredients

- 8 chicken thighs, bone in **OR** 1 packet (300g) Quorn™ chicken style pieces
- 1 lime, halved

For the marinade:

- 1 bunch spring onions, chopped
- Thumb-sized piece ginger, chopped
- 2 garlic cloves
- 1/2 a small onion
- 2 scotch bonnet chillies, chopped
- 1/2 a teaspoon dried thyme
- Juice of 1 lime
- 2 tablespoons soy sauce
- 2 tablespoons olive or rapeseed oil
- Granulated sweetener to taste
- 1 tablespoon ground allspice

Method

- Combine the ingredients for the marinade with 1 teaspoon of salt, and blend to a purée.
- Make a few slashes in the chicken thighs, if using. Pour the marinade over the chicken/Quorn™ and rub it everywhere. Cover and leave to marinate overnight in the fridge.
- Heat to 180°C /160 °C fan/gas 4. Put the chicken/Quorn™ in a roasting tin with the halved lime. Cook for 45 minutes until tender and cooked through, and squeeze the roasted lime over it.

Serve with

Salad and small portion of boiled brown rice (size of fist or 4 table-spoons) per person



Stuffed peppers (serves 4)

Ingredients

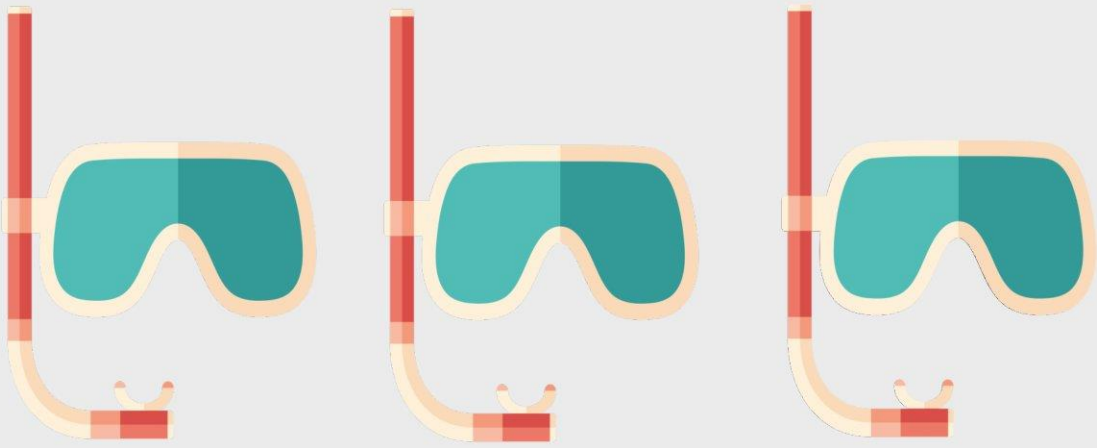
- 4 medium bell peppers, with tops cut off and deseeded.
- 200g (8oz) lean beef mince (5% fat) **OR** 1 packet (500g) Quorn™ mince
- 4 spring onions, chopped
- 1 medium courgette, chopped
- 100g (4oz) mushrooms, sliced
- 1 vegetable or beef stock cube dissolved in 1/3 pint water
- 1 teaspoon tomato puree
- 1 teaspoon mixed herbs
- Grated cheese

Serve with

Small portion of potatoes e.g.2 egg-sized or 4 baby potatoes, per person.

Method

- Preheat the oven to 190°C, fan oven 170°C.
- Place the peppers in a baking dish.
- In a hot non-stick pan, dry fry the beef mince until browned (if using), or spray some oil and cook the Quorn™ mince until coloured.
- Add the spring onions, courgette and mushrooms. Cook gently for 2 minutes.
- Stir in the stock and add the herbs and tomato puree. Cook gently for about 15 minutes, until the stock has been absorbed. Add extra stock or water if needed. Remove from the heat and season.
- With a spoon place the mixture into the peppers and sprinkle the grated cheese over them. Bake for 15-20 minutes.



Sides and dips



Stuffed mushrooms (serves 2)

Ingredients

- 2 large flat mushrooms, such as Portobello
- Spray oil
- 1 spring onion, chopped
- Spinach
- Cheese of preference, such as feta cheese, ricotta
- Salt and pepper to taste

Method

- Preheat the oven to 200°C (fan 180°C/gas mark 6).
- Remove the stalks from the mushrooms and dice them finely.
- Spray a frying pan with some spray oil, then sauté the spring onion until softened, but not coloured.
- Toss the spinach in and continue to cook until it has wilted. Then remove from the heat and drain off any excess moisture. Mix in cheese and season with a little salt and pepper.
- Spoon the mixture into the mushrooms and place them on a baking tray. Cook in the oven for 10-12 minutes, or until the mushrooms are cooked.



Cauliflower rice

Use cauliflower rice to add bulk and flavour to your regular rice portion. You can buy it ready riced or make it from scratch as follows:

Ingredients

1 small cauliflower

Method

- Remove the leaves and base, and cut it into chunks.
- Put the chunks in a food processor for about 30 seconds until it looks like rice. If you don't have a food processor, grate it instead.
- Steam the cauliflower rice for at least 5 minutes or cover and cook it on high heat in the microwave for 3 minutes.
- Either mix with the regular rice or serve on the side.



Creamy spinach (serves 4-6)

Ingredients

- 1kg bag frozen spinach, defrosted and drained well.
- 200g tub soft cheese with garlic and herbs.
- Pinch of nutmeg.

Method

- Melt the soft cheese in a saucepan.
- Add the spinach and stir well to combine.
- Heat gently until warmed through.
- Add the nutmeg, season with salt and pepper, and serve.



Tzatziki

Ingredients

- 1/4 cucumber, peeled, deseeded and sliced
- 400g plain natural or Greek yoghurt
- 1/2 lemon, juiced
- 2 garlic cloves, finely diced or minced
- 1/2 teaspoon dried mint or 8-10 fresh mint leaves, finely chopped

Method

- Slice the cucumber lengthways and remove the seeds. Grate and sprinkle with 1/2 teaspoon of salt. Mix and put aside.
- Let the cucumber sit for 10 minutes. Then squeeze any further liquid out of the cucumber by pressing with the back of a wooden spoon.
- In a bowl, combine the yoghurt, lemon juice, garlic and mint. Add the drained cucumber and a little black pepper, and mix well.



Raita

Ingredients

- 1/4 medium cucumber, peeled and grated
- 125g or 3 tablespoons plain yoghurt
- 2 tablespoons fresh coriander, chopped

Method

Mix the grated cucumber with the yoghurt, the fresh coriander and salt and pepper to taste.



Cauliflower mash (serves 4)

Ingredients

- 1 whole cauliflower
- 1/4 of a cup whole milk
- 2 tablespoons butter/spread
- 60g grated cheese
- Salt and pepper to taste

Method

- Chop the head of the cauliflower into florets. Bring a pot of water to boil. Add the cauliflower and boil for 15 minutes, or until the cauliflower is soft.
- Drain the cauliflower, then return to the pot.
- Add the butter/spread, salt, and milk/cream to the cauliflower.
- Mash the ingredients together until most of the milk is absorbed and the texture is creamy.
- Add pepper and the grated cheese and stir to combine.



Lemony green beans (serves 2)

Ingredients

- 200g green beans, trimmed
- 1 lemon, zested and juiced
- 1-2 tablespoon olive or rapeseed oil

Method

- Bring a pan of salted water to the boil.
- Boil or steam the green beans for 4-5 minutes, until tender.
- In a bowl, zest and juice the lemon. Add the oil, salt and pepper, and whisk to combine.
- Drain the cooked beans, and combine with the dressing. Add extra lemon if necessary.



Pudding



Fruity yoghurt jelly (serves 4)

Ingredients

- 1 sachet (23g) sugar-free fruit jelly crystals
- 200g (8oz) fresh or frozen fruit e.g. sliced strawberries, mixed berries
- 200g (8oz) plain yoghurt

Method

- Put the fruit in a large heat-proof dish.
- Pour the jelly crystals into a jug or bowl, and add 1/2 pint (284ml) boiling water. Stir until they melt.
- Once the crystals melt, remove from the heat and leave the jelly to cool for 10-15 minutes.
- Then gradually stir in the yoghurt until they combine.
- Pour the mixture over the fruit and refrigerate until set (5-6 hours).



Spiced fruit yoghurt (serves 1)

Ingredients

- 2 small plums or 1 small apple or pear, sliced
- 1 clove
- 1/4 teaspoon ground cinnamon
- 1/4 teaspoon grated orange zest (optional)
- Sweetener to taste (optional)
- 125g pot or 3 tablespoons of plain yoghurt

Method

- Halve or cut the fruit in quarters.
- Place the fruit in a small pan with 4-5 tablespoons of water, the spices and the orange zest, and sweetener to taste if you prefer something sweeter.
- Bring to the boil and simmer for about 10-15 minutes until the fruit is tender.
- Remove from the heat, allow to cool, remove the clove and serve with yoghurt.



Gooseberry fool (serves 2)

Ingredients

- 200g (8oz) gooseberries, topped and tailed
- Sweetener
- 125g pot or 3 tablespoons of plain yoghurt or fromage frais

Method

- Put the gooseberries in a pan with a little water and cook gently until soft.
- Puree the gooseberries in a blender and then press through a sieve to remove the seeds.
- Fold the yoghurt or fromage frais into the fruit puree.
- Add sweetener to taste and mix it well.
- Divide the fools into 2 individual glasses or dessert bowls and chill.



Berry frozen yoghurt (serves 2)

Ingredients

- 200g (8oz) frozen strawberries or other berries
- 125g pot or 3 tablespoons of plain yoghurt
- Sweetener to taste

Method

- Place all ingredients into a food processor or blender and blend until smooth.
- Put the mix into a loaf or small pan.
- Freeze until solid.

Appendix 4.4. Example meal planner

Example meal planner

You should aim to spread the foods that contain carbs across your meals so as to keep your blood glucose levels steady throughout the day. **Remember that carbs should come only from whole fruit, foods with starchy carbs (including beans and pulses), milk and yoghurt. You should avoid sugary foods and drinks.**

The RECORD programme provides you with a wide range of meal suggestions and recipes. Here are some ideas on how to put your main meals together into daily meal plans. If you feel hungry between meals, you can find snack ideas in the main booklet (page 22).

Day	Breakfast	Light meal	Main meal
1	1 portion unsweetened muesli with semi-skimmed milk	Sandwich with 2 thin/medium slices wholegrain bread, egg, cheese and vegetables	Beef stir-fry with vegetables and 1 nest of whole wheat noodles
2	1 small pot of plain yoghurt with a portion of fresh fruit and a small handful of nuts	Turkey salad with homemade coleslaw Small portion of potatoes (e.g. 4 baby potatoes)	Dahl (half a can of pulses) with half chapatti and plenty of salad (at least 1/2 of the plate)
3	Omelette with 2 thin/medium slices wholegrain bread	Tortilla-base pizza and salad	Oven-baked fish with plenty of vegetables (at least 1/2 of the plate) and small amount (1/4 of the plate) of potatoes
4	Small portion of plain porridge oats (1 sachet or 27g) made with semi-skimmed milk and topped with raspberries	Smokey baked beans 1 thin/medium slice wholegrain bread Salad	Vegetarian bolognaise with small portion (fist-sized) of wholemeal spaghetti and extra courgette/butternut squash spaghetti
5	1 crumpet with Marmite/nut butter and 1 small apple	Cottage cheese salad with 4 baby potatoes	Grilled fish with plenty of vegetables (at least 1/2 of the plate) and small portion (1/4 of the plate) of grains e.g. quinoa, bulgur wheat
6	Avocado and 2 eggs scrambled on 2 thin/medium slices wholegrain bread	Small jacket potato in its skin with cheese and salad	Quorn™ chicken style curry Cauliflower rice 1 small chapatti Salad
7	Two Quorn™ grilled sausages with cooked mushrooms, tomatoes, half a can of no added sugar baked beans, and 1 thin/medium slice wholegrain bread	Vegetable soup (from lower-carb vegetables) and 2 thin/medium slices wholegrain bread with spread	Roast chicken/turkey/pork/beef/Quorn™ chicken style, with 4 roast baby potatoes and roast vegetables

Appendix 4.5. Personal action plan booklet



Think about why you are changing your diet. It's going to be a journey with ups and downs. The benefits of changing your diet are often high – for example, feeling better, reducing the risk of GDM or the risk of heart disease and diabetes in the future. But there may be some "costs" too – for example, having to watch your portions or having to eat less of some of your favourite foods. From this perspective, the changes may start to look a bit more difficult. But we know that it really helps people stick to a programme if they identify their motives and then looking back at them as they progress through the programme, and especially if they hit tough times. Below are examples of what other women think are the advantages and disadvantages of changing their diet to control their weight gain and blood glucose.

CHANGING MY EATING	
Advantages	**Disadvantages**
• *Reduced risk of GDM, medication, insulin* • *Lower chances of health risks for my baby*	• *Not having favourite snacks feels restrictive* • *Need to find ways to reduce temptation*
NOT CHANGING MY EATING	
Disadvantages	**Advantages**
• *I may gain too much weight* • *More difficulty doing usual activities*	• *I can eat whatever I want*

Now fill in your own chart:

CHANGING MY EATING	
Advantages	**Disadvantages**
NOT CHANGING MY EATING	
Disadvantages	**Advantages**

When the things you write in the left columns are more important than those in the right columns, your motivation will be high.

Set a goal

Think about what changes you want to make, and list them here. Use the "three R's" and the healthy eating information in the main booklet to guide you on what to put down. There are a few examples of how the RECORD programme may help you, to get started. There is space to add your own.

I want to…	
Cut down on sugary foods and drinks	
Moderately reduce the amount of starchy foods I am eating	
Eat more wholegrain foods	
Switch to healthier snacks	
Reduce take-away	

Set a goal

✓Think it through

Think about what you are going to do to achieve the changes, how and when you will do it (you can use pages 5-8). It may be easier to link an action to a situation – for example, eating a salad with lunch and dinner, nibbling on vegetable sticks if feeling peckish while waiting for the food to be ready or watching TV.

✓Be realistic

It is likely that you will feel overwhelmed if you try to change too many things at once. Start with a few changes, and allow yourself time to get used to them. Once you feel that they have become part of your routine, think about what you can do next.

✓Plan in advance

Think about what you need to do in advance to help you make a change. Also think about what could get in your way and how you will overcome it and people that might be able to help.

✓Track your progress

For the first two weeks of the programme, take 5 minutes each day to keep track of your progress by using the "Daily 5-minute challenge" cards in the back pocket. Thereafter, you can do this once a week ("Weekly 5-minute challenge"). Each time you are due for a support session, you should also write down the progress against your goals using pages 9-14. When things get challenging, looking at your progress might increase your motivation to keep going. Keeping a check on your progress can help you spot any problems early on and to get back on track.

✓Reward yourself

Regularly (e.g. every week), treat yourself with rewards if you have achieved a goal. Rewards should be non-food related. Find something that makes you feel good—for example, having a massage, going to the theatre, reading a book.

Goal sheets

MY GOAL IS:

.....

.....


Write down what steps you will take:

1 .....

2 .....

3 .....

MY GOAL IS:

.....

.....


Write down what steps you will take:

1 .....

2 .....

3 .....

Goal sheets

MY GOAL IS:

.....

.....


Write down what steps you will take:

1 .....

2 .....

3 .....

MY GOAL IS:

.....

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Write down what steps you will take:

1 .....

2 .....

3 .....

Goal sheets

MY GOAL IS:

.....

.....


Write down what steps you will take:

1 .....

2 .....

3 .....

MY GOAL IS:

.....

.....


Write down what steps you will take:

1 .....

2 .....

3 .....

Goal sheets

MY GOAL IS:

.....

.....


Write down what steps you will take:

1 .....

2 .....

3 .....

MY GOAL IS:

.....

.....


Write down what steps you will take:

1 .....

2 .....

3 .....

Your progress

Goal	Date I set the goal	Progress at around 16 weeks of pregnancy	How do I feel about my progress?	What will I keep the same and what will I change to meet my goal?

Your progress

Goal	Date I set the goal	Progress at around 18 weeks of pregnancy	How do I feel about my progress?	What will I keep the same and what will I change to meet my goal?

Your progress

Goal	Date I set the goal	Progress at around 20 weeks of pregnancy	How do I feel about my progress?	What will I keep the same and what will I change to meet my goal?

Your progress

Goal	Date I set the goal	Progress at around 24-28 weeks of pregnancy	How do I feel about my progress?	What will I keep the same and what will I change to meet my goal?

Your progress

Goal	Date I set the goal	Progress at around 32 weeks of pregnancy	How do I feel about my progress?	What will I keep the same and what will I change to meet my goal?

Your progress

Goal	Date I set the goal	Progress at around 36 weeks of pregnancy	How do I feel about my progress?	What will I keep the same and what will I change to meet my goal?

Appendix 4.6. Behavioural goal monitoring cards

RECORD

Reduced-carbohydrate intervention to prevent gestational diabetes

Daily 5-minute challenge

Taking 5 minutes to keep track of your progress can help to reinforce the changes you are making. For the first 2 weeks of the programme, take 5 minutes each day to fill this in. Write the goals you set for each week and tick the box if you feel that you met a goal on a particular day. Keeping track of goals has been shown to increase people's success in changing their diet. At the end of each week, look back over what you have achieved. In the notes you can write what helped you achieve a goal or if there is any area that you kept finding difficult. There is also space to reflect on how you feel about your progress, and to set a reward to look forward to for when you achieve one or more goals. For next week, try setting one or up to 2-3 goals maximum. If you managed to achieve one or more goals on 4 out of 7 days of a week, try increasing it to 5 days as next week's goal. You can discuss your progress and any challenges with us at your next support session.

Week 1

Goal(s)	m	t	w	t	f	s	s	notes
Did I eat anything that doesn't fit with the RECORD programme? Make a note of it here. It will help you spot patterns and plan how to stop that slip the next time.								

How do I feel?	Reward(s)	Goal(s) for next week

Don't worry if you slip up

There will be ups and downs, so don't worry if you miss a day or two. Learn from it and keep going.

Week 2

Goal(s)	m	t	w	t	f	s	s	notes
Did I eat anything that doesn't fit with the RECORD programme? Make a note of it here. It will help you spot patterns and plan how to stop that slip the next time.								

How do I feel?	Reward(s)	Goal(s) for next week

Don't worry if you slip up

There will be ups and downs, so don't worry if you miss a day or two. Learn from it and keep going.

RECORD

Reduced-carbohydrate intervention to prevent gestational diabetes

Weekly 5-minute challenge

After the first two weeks, try completing this 5-minute challenge once a week for the rest of the duration of the programme. Checking up on your progress once a week can help you to keep on track, but also to recognise when you might need to ask for help or advice. Write the goals you set for each week and tick the box if you feel that you met a goal on most days of the week. In the notes you can write what helped you achieve a goal, if there is any area that you kept finding difficult or how you feel about your progress. Try setting one or up to 2-3 goals for next week. A goal can also be to maintain something that you have already achieved. You can discuss your progress and any challenges with us at your next support session

Don't worry if you slip up

There will be ups and downs, so don't worry if you miss a day or two. Learn from it and keep going.

Week 3 Goal(s)	Did I achieve this goal on most days?	Notes
Did I eat anything that doesn't fit with the RECORD programme? Make a note of it here. It will help you spot patterns and plan how to stop that slip the next time.		Goal(s) for next week

Week 3 reward(s):

Week 4 Goal(s)	Did I achieve this goal on most days?	Notes
Did I eat anything that doesn't fit with the RECORD programme? Make a note of it here. It will help you spot patterns and plan how to stop that slip the next time.		Goal(s) for next week

Week 4 reward(s):

Week 5 Goal(s)	Did I achieve this goal on most days?	Notes
Did I eat anything that doesn't fit with the RECORD programme? Make a note of it here. It will help you spot patterns and plan how to stop that slip the next time.		Goal(s) for next week

Week 5 reward(s):

Week 6 Goal(s)	Did I achieve this goal on most days?	Notes
Did I eat anything that doesn't fit with the RECORD programme? Make a note of it here. It will help you spot patterns and plan how to stop that slip the next time.		Goal(s) for next week

Week 6 reward(s):

Week 7 Goal(s)	Did I achieve this goal on most days?	Notes
Did I eat anything that doesn't fit with the RECORD programme? Make a note of it here. It will help you spot patterns and plan how to stop that slip the next time.		Goal(s) for next week

Week 7 reward(s):

Week 8 Goal(s)	Did I achieve this goal on most days?	Notes
Did I eat anything that doesn't fit with the RECORD programme? Make a note of it here. It will help you spot patterns and plan how to stop that slip the next time.		Goal(s) for next week

Week 8 reward(s):

Week 9 Goal(s)	Did I achieve this goal on most days?	Notes
Did I eat anything that doesn't fit with the RECORD programme? Make a note of it here. It will help you spot patterns and plan how to stop that slip the next time.		Goal(s) for next week

Week 9 reward(s):

Week 10 Goal(s)	Did I achieve this goal on most days?	Notes
Did I eat anything that doesn't fit with the RECORD programme? Make a note of it here. It will help you spot patterns and plan how to stop that slip the next time.		Goal(s) for next week

Week 10 reward(s):

Week 11 Goal(s)	Did I achieve this goal on most days?	Notes
Did I eat anything that doesn't fit with the RECORD programme? Make a note of it here. It will help you spot patterns and plan how to stop that slip the next time.		Goal(s) for next week

Week 11 reward(s):

Week 12 Goal(s)	Did I achieve this goal on most days?	Notes
Did I eat anything that doesn't fit with the RECORD programme? Make a note of it here. It will help you spot patterns and plan how to stop that slip the next time.		Goal(s) for next week

Week 12 reward(s):

Week 13 Goal(s)	Did I achieve this goal on most days?	Notes
Did I eat anything that doesn't fit with the RECORD programme? Make a note of it here. It will help you spot patterns and plan how to stop that slip the next time.		Goal(s) for next week

Week 13 reward(s):

Week 14 Goal(s)	Did I achieve this goal on most days?	Notes
Did I eat anything that doesn't fit with the RECORD programme? Make a note of it here. It will help you spot patterns and plan how to stop that slip the next time.		Goal(s) for next week

Week 14 reward(s):

Week 15 Goal(s)	Did I achieve this goal on most days?	Notes
Did I eat anything that doesn't fit with the RECORD programme? Make a note of it here. It will help you spot patterns and plan how to stop that slip the next time.		Goal(s) for next week

Week 15 reward(s):

Week 16 Goal(s)	Did I achieve this goal on most days?	Notes
Did I eat anything that doesn't fit with the RECORD programme? Make a note of it here. It will help you spot patterns and plan how to stop that slip the next time.		Goal(s) for next week

Week 16 reward(s):

Week 17 Goal(s)	Did I achieve this goal on most days?	Notes
Did I eat anything that doesn't fit with the RECORD programme? Make a note of it here. It will help you spot patterns and plan how to stop that slip the next time.		Goal(s) for next week

Week 17 reward(s):

Week 18 Goal(s)	Did I achieve this goal on most days?	Notes
Did I eat anything that doesn't fit with the RECORD programme? Make a note of it here. It will help you spot patterns and plan how to stop that slip the next time.		Goal(s) for next week

Week 18 reward(s):

Week 19 Goal(s)	Did I achieve this goal on most days?	Notes
Did I eat anything that doesn't fit with the RECORD programme? Make a note of it here. It will help you spot patterns and plan how to stop that slip the next time.		Goal(s) for next week

Week 19 reward(s):

Week 20 Goal(s)	Did I achieve this goal on most days?	Notes
Did I eat anything that doesn't fit with the RECORD programme? Make a note of it here. It will help you spot patterns and plan how to stop that slip the next time.		Goal(s) for next week

Week 20 reward(s):

Week 21 Goal(s)	Did I achieve this goal on most days?	Notes
Did I eat anything that doesn't fit with the RECORD programme? Make a note of it here. It will help you spot patterns and plan how to stop that slip the next time.		Goal(s) for next week

Week 21 reward(s):

Week 22 Goal(s)	Did I achieve this goal on most days?	Notes
Did I eat anything that doesn't fit with the RECORD programme? Make a note of it here. It will help you spot patterns and plan how to stop that slip the next time.		Goal(s) for next week

Week 22 reward(s):

Week 23 Goal(s)	Did I achieve this goal on most days?	Notes
Did I eat anything that doesn't fit with the RECORD programme? Make a note of it here. It will help you spot patterns and plan how to stop that slip the next time.		Goal(s) for next week

Week 23 reward(s):

Week 24 Goal(s)	Did I achieve this goal on most days?	Notes
Did I eat anything that doesn't fit with the RECORD programme? Make a note of it here. It will help you spot patterns and plan how to stop that slip the next time.		Goal(s) for next week

Week 24 reward(s):

Appendix 4.7. Home monitoring booklet



During the RECORD programme you need to monitor your blood glucose and blood ketone levels, as well as your weight.

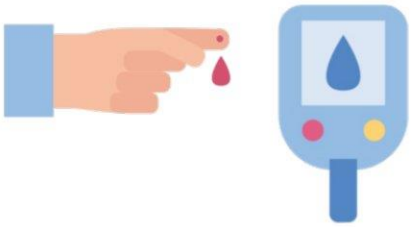
See the printed instructions in the back pocket on how to take a finger prick. You should log all the blood measurements that you take into the application connected to the meter. This can be done automatically via Bluetooth, or you can enter the readings manually. Alternatively, you can send the readings to us via text message on +44 (0)7860026178.

Blood glucose

Monitoring your blood glucose levels can help to understand how blood glucose varies and progresses throughout pregnancy, as well as understand better how what you eat affects it. It will also provide an extra check for you and your clinical care team.

See page 4 on when you need to measure your blood glucose.

If you develop gestational diabetes during the course of the study, your clinical care team will give you more specific advice on when and how often to measure your blood glucose, and which should be your blood glucose targets. They will be monitoring your blood glucose readings closely, so that they can best advise you on the management of your diabetes.



Blood ketones

Monitoring your blood ketone levels can help to understand how blood ketones vary and progress throughout pregnancy. You would not normally be asked to monitor your blood ketones if you were not taking part in this study, so the regular ketone monitoring also provides the advantage of an extra check for you and your clinical care team.

Ketones are compounds that the body produces when it's breaking down fat to produce energy. This happens if glucose – the usual source of energy – is not readily available to the body, for example, when the body has used up all its stores (e.g. during fasting, long periods of exercise), or if you are not eating enough carbohydrates. Ketones may also be produced when the body does not produce enough of the hormone insulin, or when it loses the ability to use the insulin that is produced, as happens when someone has diabetes. Without insulin available or working properly, the glucose can't get into the cells to provide energy and so the body switches to breaking down fat stores. As a result ketones are produced.

Some women who are pregnant may have mildly elevated ketone levels. This is because of changes in the way the body responds to insulin which usually suppresses ketone production. Ketones may also be increased temporarily in the morning after not eating for many hours, if you skip a meal, if you experience vomiting, or if you have an infection.

As with many things in the body, having raised ketones is not a problem as long as the level is not too high or for too long or too often. The RECORD programme has been designed to ensure that you get adequate amount of carbohydrate to prevent elevated ketone levels. The dietary advice we provide is the same as provided in routine care if women develop gestational diabetes. The only difference is that we ask you to follow this advice earlier in pregnancy to check whether it helps to prevent gestational diabetes in the first place.

See page 4 on when you need to measure your blood ketones.

When to measure your blood glucose and ketone levels

You should take **a blood glucose and ketone measurement on two days of the week**, **first thing in the morning, before you eat or drink anything apart from water** (these are your fasting levels).

If you are feeling unwell or:

- you are sick
- your breath smells fruity (like pear drop sweets, or nail varnish)
- you are passing a lot of urine (more than usual)
- you are really thirsty (more than usual)
- you feel confused
- you faint

⇒ **Make sure you rest, eat something if you can, and drink enough water.**

⇒ **If you are still unwell, contact your clinical care team directly for advice: midwife, GP or the Maternity Assessment Unit at the John Radcliffe (JR) Hospital (tel. 01865 220221). Before contacting your clinical care team, take a blood glucose and ketone measurement. This will help them to advise you appropriately.**

⇒ **It would also be helpful to log these non-scheduled readings on to the app connected to your meter or send them to us via text message.**

Feeling unwell or having symptoms is common during pregnancy and is not necessarily a bad sign. However, if at any point you are concerned about any symptoms it is important to contact your clinical care team.

If you develop gestational diabetes, your clinical care team may ask you to monitor your blood glucose more often during the day and on more days of the week. You will receive specific advice if this is necessary.

Weight

Putting on weight during pregnancy is normal and expected as your baby grows. However, gaining too much weight can increase your risk for gestational diabetes and high blood pressure.



If you are carrying one baby:

- **In the first trimester of pregnancy** it is recommended to gain no more than 0.5-2kg (1-4lbs or 0.08-0.3 stones).

- **In the second and third trimester**, the recommended amount of weight gain depends on your Body Mass Index before you became pregnant. This should be about 0.17-0.27kg (0.4-0.6lbs or 0.03-0.04 stones) per week, therefore approximately another 4-7kg (9-15lbs or 0.6-1stones).

If you are carrying twins, there are no available recommendations with regards to how much weight you should aim to gain each week or during each trimester. However, it is recommended that you gain throughout pregnancy, about 11-19kg (25-42lbs or 1.8-3 stones) in total.

No recommendations exist for pregnancies with more than two babies, but the RECORD programme has been designed to help you avoid gaining too much weight.

When to measure your weight

You should measure your weight once a week. Monitoring your weight at home will help us check you are on track throughout your pregnancy and offer you extra advice and support if needed.

Please remember to send us your weekly measurements via text. In pages 7-10 there are optional weight charts where you can record your weekly weight measurements for your reference.

How to measure your weight

1) Right place

Put the scales on an even hard surface. For example, try to find a space with tiles or wooden floor. If your home has carpet, try to find a piece of wood or other hard surface to put under the scales.

2) Calibrate

Each time you move the scales, let them recalibrate. To do this, press the scale with your foot to wake them up and wait for the display to read 0.0kg before stepping on.

3) Right time

It's best to weigh yourself first thing in the morning, after having gone to the toilet and before eating or drinking anything. Ideally you should be wearing very light clothes (e.g. night clothes) or nothing at all. This will give the most reliable results and make it easier to assess changes in your weight.

Understanding your weight measurements

Over the course of your pregnancy you should expect to gain 5-9kg (11-20lbs or 0.8-1.4 stones) in total. But as at any other time of life, your weight may fluctuate from week to week. This is not a cause for concern. If you lose weight for two or more consecutive weeks, you should aim to eat a little more until your weight stabilises. For example, try having an extra snack during your day.

However, most women gain more weight during their pregnancy than is necessary and this can lead to health problems for you and your baby. The RECORD programme has been designed to help you avoid gaining too much weight by cutting out sugary foods and drinks, and reducing the amount of starchy carbohydrates. But this is not a diet plan and you should not restrict your intake in other ways. Monitoring your weight every week, will help you stay on track. We can give you advice and support, if necessary, to manage your weight.

Weight monitoring charts

Week 1							
Day	1	2	3	4	5	6	7
Weight							

Week 2							
Day	1	2	3	4	5	6	7
Weight							

Week 3							
Day	1	2	3	4	5	6	7
Weight							

Week 4							
Day	1	2	3	4	5	6	7
Weight							

Week 5							
Day	1	2	3	4	5	6	7
Weight							

Week 6							
Day	1	2	3	4	5	6	7
Weight							

Weight monitoring charts

Week 7							
Day	1	2	3	4	5	6	7
Weight							

Week 8							
Day	1	2	3	4	5	6	7
Weight							

Week 9							
Day	1	2	3	4	5	6	7
Weight							

Week 10							
Day	1	2	3	4	5	6	7
Weight							

Week 11							
Day	1	2	3	4	5	6	7
Weight							

Week 12							
Day	1	2	3	4	5	6	7
Weight							

Weight monitoring charts

Week 13							
Day	1	2	3	4	5	6	7
Weight							

Week 14							
Day	1	2	3	4	5	6	7
Weight							

Week 15							
Day	1	2	3	4	5	6	7
Weight							

Week 16							
Day	1	2	3	4	5	6	7
Weight							

Week 17							
Day	1	2	3	4	5	6	7
Weight							

Week 18							
Day	1	2	3	4	5	6	7
Weight							

Weight monitoring charts

Week 19							
Day	1	2	3	4	5	6	7
Weight							

Week 20							
Day	1	2	3	4	5	6	7
Weight							

Week 21							
Day	1	2	3	4	5	6	7
Weight							

Week 22							
Day	1	2	3	4	5	6	7
Weight							

Week 23							
Day	1	2	3	4	5	6	7
Weight							

Week 24							
Day	1	2	3	4	5	6	7
Weight							

When to measure your blood glucose and ketone levels

You should take **a blood glucose and ketone measurement on two days of the week, first thing in the morning, before you eat or drink anything apart from water** (these are your fasting levels).

If you are feeling unwell or:

- you are sick
- your breath smells fruity (like pear drop sweets, or nail varnish)
- you are passing a lot of urine (more than usual)
- you are really thirsty (more than usual)
- you feel confused
- you faint

⇒ **Make sure you rest, eat something if you can, and drink enough water.**

⇒ **If you are still unwell, contact your clinical care team directly for advice: midwife, GP or the Maternity Assessment Unit at the John Radcliffe (JR) Hospital (tel. 01865 220221). Before contacting your clinical care team, take a blood glucose and ketone measurement. This will help them to advise you appropriately.**

⇒ **It would also be helpful to log these non-scheduled readings on to the app connected to your meter or send them to us via text message.**

Feeling unwell or having symptoms is common during pregnancy and is not necessarily a bad sign. However, if at any point you are concerned about any symptoms it is important to contact your clinical care team.

If you develop gestational diabetes, your clinical care team may ask you to monitor your blood glucose more often during the day and on more days of the week. You will receive specific advice if this is necessary.

During the study, you need to monitor your blood glucose and blood ketone levels.

See the printed instructions on how to take a finger prick. You should log all the blood measurements that you take into the application connected to the meter. This can be done automatically via Bluetooth, or you can enter the readings manually. Alternatively, you can send the readings to us via text message on +44 (0)7860026178.

Blood glucose

Monitoring your blood glucose levels can help to understand how blood glucose varies and progresses throughout pregnancy, as well as understand better how what you eat affects it. It will also provide an extra check for you and your clinical care team.

See page 4 on when you need to measure your blood glucose.

If you develop gestational diabetes during the course of the study, your clinical care team will give you more specific advice on when and how often to measure your blood glucose, and which should be your blood glucose targets. They will be monitoring your blood glucose readings closely, so that they can best advise you on the management of your diabetes.



RECORD

HOME MONITORING BOOKLET

Blood ketones

Monitoring your blood ketone levels can help to understand how blood ketones vary and progress throughout pregnancy.

Ketones are compounds that the body produces when it's breaking down fat to produce energy. This happens if glucose – the usual source of energy – is not readily available to the body, for example, when the body has used up all its stores (e.g. during fasting, long periods of exercise), or if you are not eating enough carbohydrates. Ketones may also be produced when the body does not produce enough of the hormone insulin or when it loses the ability to use the insulin that is produced, as happens when someone has diabetes. Without insulin available or working properly, the glucose can't get into the cells to provide energy and so the body switches to breaking down fat stores. As a result ketones are produced.

Some women who are pregnant may have mildly elevated ketone levels. This is because of changes in the way the body responds to insulin which usually suppresses ketone production. Ketones may also be increased temporarily in the morning after not eating for many hours, if you skip a meal, if you experience vomiting, or if you have an infection.

As with many things in the body, having raised ketones is not a problem as long as the level is not too high or for too long or too often. You would not normally be asked to monitor your blood ketones if you were not taking part in this study, so the regular ketone monitoring also provides the advantage of an extra check for you and your clinical care team.

See page 4 on when to measure your blood ketones.

Appendix 5.1. Recruitment flyer

Is there any compensation for taking part?

We realise that taking part in a study can be inconvenient, and to make up for that we offer £30 at each study visit (£60 in total) in the form of a gift card or bank transfer, for taking part.

What should I do if I am interested in the study?

If you are interested in taking part, or you would like more information about the study, please speak to a research midwife or the main researcher present in the waiting area, or contact the study team using the contact details below.

Tel: 01865 617 857

Email: record@phc.ox.ac.uk

Chief Investigator: Dr Nerys Astbury

DPhil student: Moscho Michalopoulou

The RECORD study and this leaflet have been reviewed and approved by the South-Central Oxford B Research Ethics Committee.
(Ref: 20/SC/0442)
Version: 1.2 16th February 2021

This study is being run by the University of Oxford's Nuffield Department of Primary Care Health Sciences and is supported by the Oxford-Medical Research Council (MRC) Doctoral Training Partnership and the National Institute for Health Research (NIHR) Biomedical Research Centre (BRC).

RECORD

Dietary intervention to prevent gestational diabetes

We'd like to invite you to take part in the "RECORD" study.

This study aims to test if it is possible to deliver a dietary programme designed to reduce the risk that women who are pregnant will develop gestational diabetes.

Why?

Gestational diabetes (GDM) is a condition that develops during pregnancy, in which women's blood glucose (or "blood sugar") levels are too high. GDM can lead to health complications for both the mother and the baby during pregnancy and later in life.

Carrying or gaining too much weight whilst pregnant, increases the chances of developing GDM.

What we eat affects our weight and blood glucose levels. Pregnancy is not a time to diet, but it's important that you control the amount of weight that you gain and that you keep your blood glucose levels within a healthy range, to minimise the risk of developing GDM.

Treatments for GDM are available, but the aim of the RECORD programme is to help reduce the chances of developing GDM in the first place.

Who are we looking for?

We are looking for 60 women with a raised Body Mass Index (BMI of 30 or above), which is a risk factor for developing GDM. If you are interested in the study, or would like more information, you can speak to a research midwife or the main researcher who are available in the ultrasound waiting area, and can check your eligibility.

What will I have to do?

You will be asked to attend two visits at the hospital with the study team, over the next six months, one at the start, and one for follow-up.

Each of the two visits will include:



An Oral Glucose Tolerance Test, which involves giving small blood samples before and after having a special sugar drink. This test can detect if you have developed GDM.



Measurement of weight, height and blood pressure.



Questionnaires about yourself, including your diet and quality of life.

We will also ask you to take a finger prick at home twice a week throughout the study, for measuring some markers in your blood, in order to closely monitor you and your baby.



What is the dietary programme being tested?

Two thirds of women will be assigned by chance to the RECORD programme group, while one third will receive any dietary advice that may be given as part of routine pregnancy care.

If you are in the RECORD programme group:



Eating carbohydrates (e.g. bread, rice, pasta, potato, sugar) can affect our weight and blood glucose. Healthier levels of carb intake may help to control the amount of weight that you gain during your pregnancy, and may lead to smaller increases in blood glucose, which may reduce GDM risk.



You will receive one face-to-face session, combining dietary advice with written materials, to help you moderately reduce, but not cut out, your carb intake, until you give birth, while maintaining a healthy balanced diet.



We will ask you to weigh yourself once a week until the delivery of your baby.



You will have six 15-minute phone sessions (one of which can be in-person if preferred), to support you in following the programme.

Appendix 5.2. Participant information sheet for main RECORD trial

Chief Investigator:
Dr Nerys Astbury
DPhil Student:
Moscho Michalopoulou
Tel: 01865 617 857
Email: record@phc.ox.ac.uk

RECORD

Reduced-carbohydrate intervention to prevent gestational diabetes

PARTICIPANT INFORMATION SHEET

We would like to invite you to take part in this research study. Before you decide, it is important that you understand why the research is being done and what it would involve for you. Please take time to read this information, and discuss it with others if you wish. If anything is not clear, or if you would like more information, please ask us.

What is the purpose of the study?

This study is a PhD educational project, aiming to test if it is possible to deliver a dietary programme designed to reduce the risk that women who are pregnant will develop gestational diabetes (GDM). GDM is a condition that develops usually during the second or third trimester of pregnancy, in which women's blood glucose levels are high. It can lead to health complications for the mother and the baby during pregnancy and later in life. Carrying or gaining too much weight during pregnancy, increases the chances of developing GDM. Effective ways to help women who are at increased risk of GDM to control their weight and blood glucose levels early in pregnancy are needed.

What we eat affects our weight and blood glucose levels. Carbohydrates are the main source of energy (calories) and eating carbohydrates leads to rise in blood glucose. We therefore developed a new dietary programme to help you moderately reduce, but not cut out, the amount of carbohydrate that you eat, while maintaining a balanced diet.

This small study will test if it is possible to deliver the new programme alongside routine appointments and how well women can follow this advice for approximately 6 months. We will monitor the impact of the programme on some markers in the blood, and explore its effect on weight gain and other health outcomes throughout pregnancy. If the programme is feasible and well-liked, we will run a bigger study aiming to help prevent GDM.

Why have I been invited?

We are looking for 60 women who are at increased risk of developing GDM. Your most recent weight and height measurements suggest that you may have a raised Body Mass Index, which is a risk factor for GDM.

Do I have to take part?

No, you don't have to take part. Taking part is voluntary. If you decide not to take part, this will not affect the care you receive during pregnancy and delivery. If you decide to take part but then change your mind, you can withdraw at any time without giving us a reason. This will not affect the care that you receive.

What will happen to me if I decide to take part?

If you decide to take part, you will be asked to attend two research study visits at the hospital with the study team. One visit will happen before you are 20 weeks pregnant, and the other visit will happen around 24-28 weeks of pregnancy. This second visit replaces a visit that you would be required to attend even if you were not taking part in the study. Each visit will be scheduled in the morning and will last for approximately 2 hours.

Preparation for study visits: You will be asked to arrive to these appointments after an overnight fast. This means you should not eat or drink anything (apart from water) from the night before the visit. You should also avoid smoking, vaping, using nicotine replacement therapy and chewing sugar gum since the previous night.

First study visit: At the first study visit (before 20 weeks of pregnancy), the researcher will go through this information sheet with you and you will have the opportunity to ask any questions about the study. If you are happy to take part, you will be asked to sign a consent form and you will be given a copy to keep. With your consent, we will complete the following procedures:

- **Oral Glucose Tolerance Test (OGTT):** We will collect a small blood sample and then ask you to drink a special sugar drink. We will collect further small blood samples after 1 and 2 hours. The OGTT tests how well your body handles the ingestion of sugar.
- **Study assessments:** Whilst you are waiting, we will measure your height, weight and blood pressure, and ask you to fill in questionnaires about yourself, including your usual diet and quality of life.

You will also be allocated to one of the study groups. Two-thirds of participants will be assigned to the RECORD diet group, who will be guided to moderately reduce their carbohydrate intake, whilst the other participants will be assigned to the control group, who will continue to receive the usual care and support given to women who are pregnant. Having a control group helps us test if our intervention is more beneficial compared to the usual dietary advice. Group allocation is entirely down to chance and will be decided by a computer programme. You cannot choose which group you are in and you won't be able to change group allocation once you have been allocated.

Two groups:

- **Intervention group:** If you are assigned to the RECORD diet group, we ask that you follow the dietary advice and recommendations to the best of your ability until the delivery of your baby. During the first study visit, you will be advised to moderately reduce, but not cut out, the amount of carbohydrate in your diet. You will receive a booklet, meal and recipe ideas and other materials to help you follow the dietary advice. We will arrange another six brief sessions to support you through the diet plan, at a convenient time, when you are around 16, 18, 20, 24-28, 30 and 34 weeks pregnant. These sessions will be by telephone, except the one at 24-28 weeks, which is on the same day as your second study visit and can be either on the telephone or face-to-face. All support sessions will take a maximum of 15 minutes. We will ask your permission to audio-record the face-to-face and telephone sessions. You will also be asked to monitor your weight once a week and send the measurements to the study team. We can lend you weighing scales if you don't own a set.
- **Control group:** If you're assigned to the control group, you will continue to receive any dietary advice that is given as part of the routine pregnancy care.

Blood glucose and ketone monitoring: Everyone taking part will be asked to measure their blood glucose and ketone levels at home twice a week for the duration of the study, using a monitor we will provide. You can log your measurements into a mobile phone/tablet/iPad application or text them to the study team. The study team and members of the clinical care team will have access to these readings. Taking part in this study will not affect any other treatment you may be receiving.

Follow-up study visit: During the follow-up appointment at 24-28 weeks of pregnancy, we will repeat the procedures conducted at the first study visit. The OGTT conducted at this visit will determine whether you have developed GDM. You would usually have this same test at this time at the hospital or your GP practice, even if you were not taking part in the study. To avoid having the same test twice, our test will replace the test you would usually have and we will share the results with your clinical care team.

Diagnosis of GDM: If the results of this second OGTT indicate that you have developed GDM, you will have the same access to medical care and any necessary medications, regardless of your study group allocation. Everyone will be offered routine care dietary advice for GDM, which is similar to that we are testing in this study. Therefore, if you are in the intervention group, you can continue following the RECORD moderately reduced-carbohydrate programme, and weigh yourself weekly until delivery.

Optional discussion: After the follow-up visit, if you are in the RECORD diet group, we may ask if you would be willing to have an in-depth discussion on the phone with a member of the study team about your experiences of the intervention. This is entirely optional. We will provide you with more details during your follow-up visit.

End of study-health outcomes: With your consent, we will access your medical records after the delivery of your baby. This will enable us to compare health outcomes of the mothers and new-borns between the two study groups.

What should I consider?

You may not be able to take part if you have certain medical conditions or taking medication that might make the dietary advice we are giving unsuitable for you. These include: taking metformin, being diagnosed with GDM at the first study visit, having diabetes before pregnancy, a serious medical condition (e.g. heart failure, serious liver or kidney disease, or disease of the nervous system), serious mental health problems requiring hospital stays, current or previous eating disorders affecting your physical and mental health, or very bad nausea or vomiting. To be able to take part, we also need to confirm that you are not carrying a baby with a serious medical condition identified during scans, that you have not had an organ transplant or weight loss surgery, that you are able to understand spoken and written English, and that you are not taking part in other intervention research studies that may affect your weight, health behaviours or blood glucose control. If you are eligible and decide to take part, you can continue to take your regular prescribed or over-the-counter medication during the study.

Are there any possible disadvantages or risks from taking part?

Severely restricting carbohydrate intake may lead to increased ketone levels, compounds that are produced when glucose – which mainly comes from carbohydrate foods – is not available to the body. It is not expected that the RECORD programme will lead to increased ketones because it has been designed to ensure you get adequate amount of carbohydrate which is the same as advised in routine care if women are diagnosed with GDM. The only difference is that we ask you to follow this advice earlier in pregnancy and in a more structured way. In addition, no evidence is available to determine any effect of the diet on the unborn child. We will provide you with a device to monitor both your blood glucose and ketone levels as an extra check. We will also ask you to measure your blood glucose and ketones if you are unwell and contact your clinical care team for advice if required.

You will be asked to fast overnight before each study visit. Some people can feel lightheaded or unwell if they don't eat for long periods of time. Once we have finished the tests, we will provide you with a light breakfast before you leave the hospital. You will be asked to provide small blood samples and as with any blood sample, there is possibility of stinging and a risk that you develop some bruising around the area, which should go away in a few days. Some people may feel faint while the sample is taken, but all blood samples will be taken by health care professionals who are trained and experienced in these procedures. Finally, all measures against coronavirus will be taken during the study visits as per Government guidance.

What are the possible benefits of taking part?

If you are randomised to the RECORD diet group you will receive detailed advice, support and guidance on your diet early in pregnancy. In addition, the knowledge gained in this study may help to plan a bigger study which may help in the future other women who are pregnant, to control their weight gain and blood glucose levels with diet alone, and to possibly reduce their risk of developing GDM.

Will my General Practitioner/family doctor (GP) be informed of my participation?

With your consent, we will notify your GP of your participation in this study and we will share with them the results of any relevant blood tests.

Will my taking part in the study be kept confidential?

Any data that we collect about you during this study will be kept strictly confidential. You will be assigned a unique study code to avoid identification with your name. Responsible members of the University of Oxford and the Oxford University Hospitals NHS Foundation Trust, may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

Will I be reimbursed for taking part?

You will be offered £30 at each study visit (£60 in total) in the form of gift cards or bank transfer according to your preference, to compensate you for the time, inconvenience and expenses such as parking costs, associated with attending the study visits. If you prefer a bank transfer, we will ask your permission to collect your bank details.

What will happen to the samples I give?

Your blood samples will be analysed to measure blood glucose, HbA1c (average blood glucose levels of the past 2-3 months), insulin, and to estimate a measure of insulin resistance. The samples will then be destroyed and will not be used for other purposes.

What will happen to my data?

Data protection regulation requires that we state the legal basis for processing information about you. In the case of research, this is 'a task in the public interest.' The University of Oxford is the data controller and is responsible for looking after your information and using it properly.

We will be using information from you and your medical records, in order to undertake this study and will use the minimum personally-identifiable information possible. We will keep identifiable information about you for a year after the study has finished (e.g. contact details), in order to prepare and send you a summary of the study results. This excludes any research documents with personal information, such as consent forms, which will be held securely at the University of Oxford for 5 years after the end of the study. Audio-recordings from the intervention sessions will be encrypted and kept securely in a password protected computer at the University of Oxford. Members of the study team will listen to these audio-recordings to assess how well the intervention is delivered. The audio files will then be deleted. The Oxford University Hospitals NHS Foundation Trust will use your name, home address and

contact details, to contact you about the research study, and to oversee the quality of the study. They will keep identifiable information about you from this study in keeping with local policies for retention of medical records. Data protection regulation provides you with control over your personal data and how it is used. When you agree to your information being used in research, however, some of those rights may be limited in order for the research to be reliable and accurate. Further information about your rights with respect to your personal data is available at https://compliance.web.ox.ac.uk/individual-rights .To find out more about how we use your information contact us on 01865 617 857 or record@phc.ox.ac.uk .

What will happen if I don't want to carry on with the study?

If you decide now that you want to take part, but change your mind later, you can withdraw from the study at any point and without giving us a reason. If you decide to withdraw we will use any data, including blood samples, which we have collected from you up to the point at which you decide to withdraw, unless you explicitly request us to delete/destroy them.

What will happen to the results of this study?

The results of this study will help us design future studies with the aim of helping women who are pregnant to reduce their risk of developing GDM. These studies may help to change guidelines about ways to prevent GDM. The overall study results may be presented at scientific conferences or published in scientific journals. This research will also contribute to the fulfilment of a doctoral thesis and educational qualification (Doctor of Philosophy) at the University of Oxford. On successful submission of the thesis, it will be deposited in the University archives, and will be available to the public. All results will be presented or published in a form that does not identify you. We will send you a summary of the study results once the study has finished and data has been analysed (from late 2022 onward).

What if we find something unexpected?

We will share any relevant blood test results with your direct clinical care team and GP. They will be in touch if anything unexpected is found.

What if there is a problem?

The University of Oxford, as Sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this study. NHS indemnity operates in respect of the clinical treatment which is provided. If you wish to complain about any aspect of the way in which you have been approached or treated, or how your information is handled during the course of this study, you should contact Dr Nerys Astbury or Moscho Michalopoulou on 01865 617 857 or record@phc.ox.ac.uk ; or you may contact the University of Oxford Clinical Trials and Research Governance (CTRG) office on 01865 616480, or the head of CTRG, email: ctrg@admin.ox.ac.uk .The Patient Advisory Liaison Service (PALS) is a confidential NHS service that can provide you with support for any complaints or queries you may have regarding the care you receive as an NHS patient. PALS is unable to provide information about this research study. If you wish to contact the PALS team please contact 01865 221473 or PALS@ouh.nhs.uk .

How have patients and the public been involved in this study?

We have discussed this research with women affected by GDM. They helped to shape the ideas for this research and to determine the questions we are trying to answer. In designing this study, we have taken into account their opinions on what information women who are pregnant would like to have available to help them change their diet in order to control their weight and blood glucose levels. A patient representative has provided feedback on the intervention materials and will continue to be involved throughout the study.

Who is organising and funding the study?

The study is sponsored by the University of Oxford. The research is funded by the Oxford-Medical Research Council Doctoral Training Partnership and the National Institute for Health Research Oxford Biomedical Research Centre.

Who has reviewed the study?

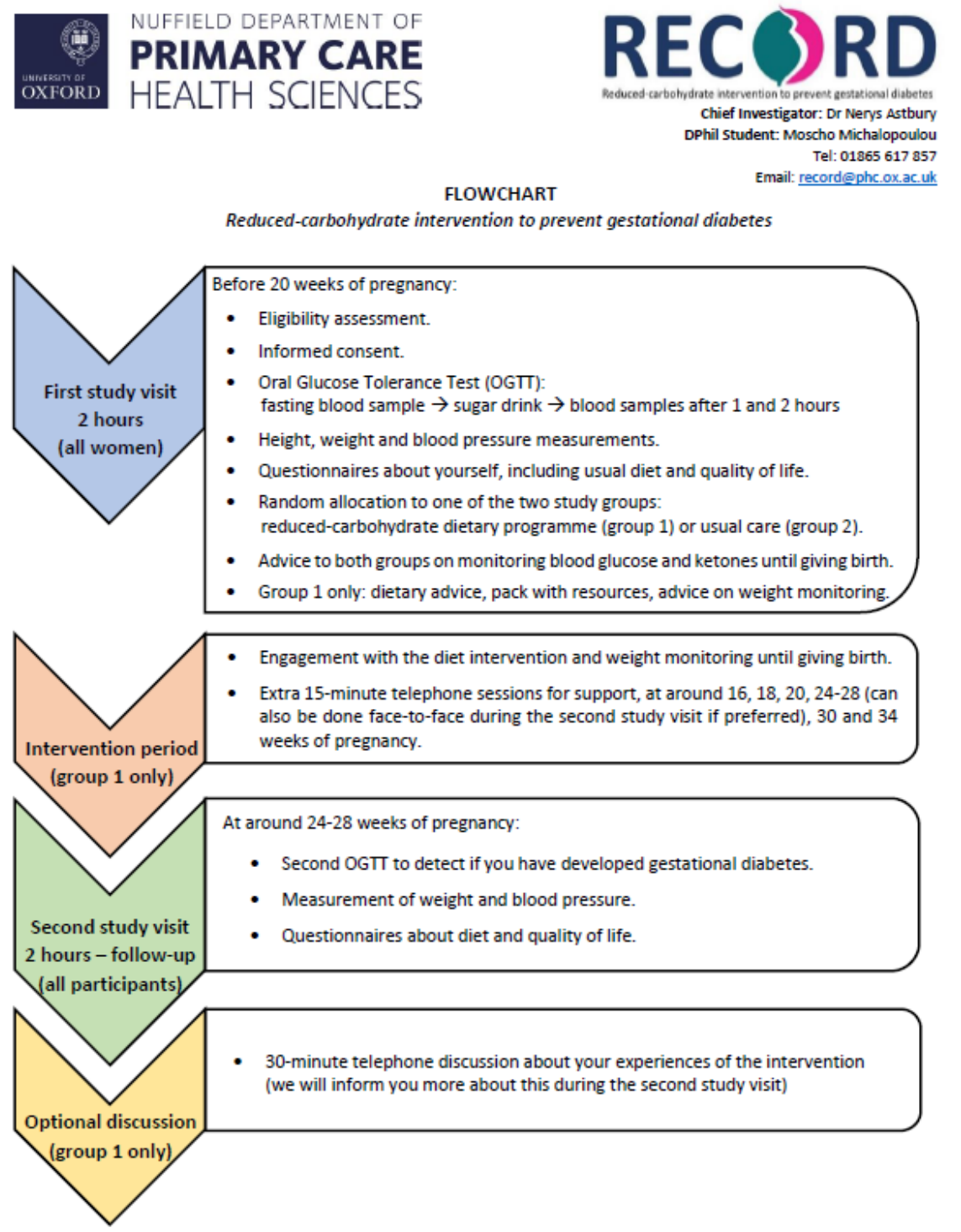
Research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect participants' interests. The South-Central Oxford B Research Ethics Committee has approved the ethics of this study.

Further information and contact details

Please contact Dr Nerys Astbury or Moscho Michalopoulou on 01865 617 857 or record@phc.ox.ac.uk .

Thank you for considering taking part in this study.

Appendix 5.3. RECORD study flowchart



Appendix 5.4. Directions to the assessment centre

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RECORD
Reduced-carbohydrate intervention to prevent gestational diabetes

Directions to the assessment centre for the baseline and follow-up visits

Oxford Centre for Diabetes, Endocrinology and Metabolism (OCDEM)

Churchill Hospital
University of Oxford
Headington
Oxford OX3 7LE

By walking: 15 min walk from the centre of Headington and 10 min walk from the Churchill Hospital site – entrances from Churchill Drive and Roosevelt Drive, both of Old Road

By cycling: Cycle parking available throughout the Churchill Hospital site (see Oxfordshire County Council cycle network map).

By park & ride: **Good option as car parking on the Churchill Hospital site is limited and surrounding residential roads are permit holders parking only.**

Stop: OCDEM (Stop C6) – services 700 and 900 operated by Stagecoach, Monday to Friday – 1 min walk from OCDEM main entrance

Stop: East Entrance (Stop C7), on Churchill Drive – services 700 and 900 operated by Stagecoach, Monday to Friday – 4 min walk from OCDEM main entrance

By car: **Parking is "pay on foot" and there is limited number of available parking spaces.**

Car park 3 is the nearest to OCDEM.

From the east: M40 junction 8 or 8a, A40 then A420 to Headington and follow the signs.

From the north: M40 junction 9, A34 then A40 northern ring road, turning off for Marston (B4150), then towards Headington and follow the signs.

From the south and west: Approach from the A4142 eastern ring road and B4495 towards Headington and follow the signs.

By rail (from Oxford railway station): 3 miles from the Churchill Hospital site

Taxi – 15 min

45 min bus ride: walk to stop: Frideswide Square (Stop R7) on Park End Street (3 min walk from railway station) – service 400 Park & Ride until stop: Headington School (Stop B8) on Headington Road. Cross over for stop: Headington School (Stop B9) on the same road – service 700 or 900 until stop: OCDEM (Stop C6).

Bus service 280 between Oxford and Aylesbury, operated by Arriva Sapphire – stop: Oxford Rail Station, R5 to stop: Headington Shops. Walk all the way down to the end of Lime Walk and cross over Old Road at the traffic lights to reach the Churchill Hospital site.

Appendix 5.5. Consent for main RECORD trial

NUFFIELD DEPARTMENT OF PRIMARY CARE HEALTH SCIENCES

RECORD
Reduced-carbohydrate intervention to prevent gestational diabetes

CONSENT FORM

Reduced-carbohydrate intervention to prevent gestational diabetes

Chief investigator: Dr Nerys Astbury, **DPhil Student:** Moscho Michalopoulou
☎ 01865 617 857
record@phc.ox.ac.uk

	Please initial each box
1. I confirm that I have read the participant information sheet and flowchart of participation dated 12th July 2021 (version 1.2) for this study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.	
3. I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from University of Oxford, from regulatory authorities and from the Oxford University Hospitals NHS Foundation Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.	
4. I understand that members of the research team will collect data from my medical notes. I give permission for these individuals to have access to my records.	
5. I consent to provide blood samples which will be used for this research study only. I consider these samples a gift to the University of Oxford and understand I will not gain any direct personal or financial benefit from them.	
6. I understand that the intervention sessions I may attend or complete over the phone may be audio-recorded for quality purposes. I agree to audio-recording of these sessions.	
7. I understand that I will be offered £30 at each study visit (£60 in total) in the form of gift cards or bank transfer according to my preference, for the time, inconvenience and expenses associated with attending the study visits. I understand that only if I prefer a bank transfer, the research team will need to collect my bank details and I give permission for the research team to collect these.	
8. I agree to my General Practitioner being informed of my participation in the study.	
9. I agree to take part in the above study.	

PRINT Participant name	Participant signature	Date
PRINT Researcher name	Researcher signature	Date

**1 copy for participant; 1 copy for researcher site file; 1 copy to be kept in medical notes, original to be returned to central research team*

Appendix 5.6. Sample size calculations based on progression criteria

Progression criterion 1: Adoption of the reduced-carbohydrate diet by the intervention group

I would like ideally the intervention group to consume no more than 130-150 g of total carbohydrate/day, i.e. approximately 140 g/day.

The 95% CI around this estimate was calculated using the following formula:

95% CI = estimate ± 1.96 * standard error (SE), where SE = SD/√n, n = sample size

In my case,

- estimate = 140 g/day
- SD of carbohydrate intake in the female UK population is 66 g/day (427)
- SE = 66/√n

If n=40 people in the intervention group, SE = 66/√40 = 10.44.

Therefore 95% CI = 140 g ± 1.96 * 10.44 = 140 g ± 20.5 → 119.5 to 160.5 g

The desirable CI threshold needs to be set above the higher end of the CI, because higher consumption means less success of the diet. I set the threshold at 170 g total carbohydrate/day. The mean carbohydrate intake at follow-up in the intervention group would need to be <170g and the 95% CI around should not include 170g, to give the green light for a full RCT.

Progression criterion 2: Retention rate, i.e. proportion of all participants completing an OGTT at 24-28 weeks' gestation

I would like ideally at least 80% of all participants to complete an OGTT at 24-28 weeks' gestation.

For this progression criteria, I used the following formula to estimate the 95% CIs (546):

95% CI = estimate ± 1.96 * SE, where SE= √((p*q)/n), p = estimate, q = 1-p

In my case,

- p = percentage expected to be seen = 0.80
- q = 1-p = 0.20
- SE = √((0.80*0.20)/n)

If n = 60, SE = 0.05 or 5%.

Therefore, 95% CI = 80% ± 1.96 * 5 → 70.2 to 89.8%

Threshold was set at 70%. The retention rate would need to be at least 80%, with estimated 95% CI around it that does not include 70%, to give the green light for a full RCT.

Exploratory power calculation:

This is a feasibility trial, therefore, a power calculation is not needed. But to confirm my sample size, I explored a power calculation for a full RCT that would aim to prevent GDM. According to the NDNS,

total carbohydrate intake accounts for 46% of total daily energy intake for women 19-64 years old (427). This is equivalent to 230 g of total carbohydrate/day, for a recommended diet of 2000 kcal/day for women. I set my adoption criterion threshold at 170 g/day. Using the software G Power 3.1.9.7, assuming that the control group's dietary intake will remain materially unchanged at approximately 230 g/day, and that the variance of daily carbohydrate intake for both groups is 66 g/day (from NDNS), using an Independent Samples t-test at 90% power, alpha of 0.05, and randomisation ratio 2:1, the total sample size needed would be 60 people.

Revision of progression criteria with a smaller sample of 51 participants:

Progression criterion 1:

If sample size is N=51 participants, which means n=34 participants in the intervention group, SE = 66/√34 = 11.4.

Therefore, 95% CI = 140 g ± 1.96 * 11.4 = 140 g ± 22.3 → 117.7 to 162.3 g

The desirable CI threshold needs to be set above the higher end of the CI, because higher consumption means less success of the diet. The threshold I set originally at 170 g total carbohydrate/day, still stands.

Eventually, dietary data at follow-up were available for n=28 intervention participants.

Therefore, assuming SE = 66/√28 = 12.5

95% CI = 140 g ± 1.96 * 12.5 = 140 g ± 24.5 → 115.5 to 164.5 g

So, the threshold at 170 g/day still stands.

Progression criterion 2:

If sample size is N=51, then SE = √((0.80*0.20)/51) = 0.05 or 5%, i.e. same as with a sample of 60 people, therefore, 95% CI and threshold stay the same as originally planned.

Appendix 5.7. Participant information sheet for qualitative sub-study

NUFFIELD DEPARTMENT OF PRIMARY CARE HEALTH SCIENCES

RECORD
Reduced-carbohydrate intervention to prevent gestational diabetes

Chief Investigator: Dr Nerys Astbury
DPhil Student: Moscho Michalopoulou
Tel: 01865 617 857
Email: record@phc.ox.ac.uk

RECORD

Reduced-carbohydrate intervention to prevent gestational diabetes-Qualitative Interviews

PARTICIPANT INFORMATION SHEET

We would like to invite you to take part in an informal interview about your experiences of the RECORD study. Before you decide, it is important that you understand why this interview is being done and what it would involve for you. Please take time to read this information, and discuss it with others if you wish. If there is anything that is not clear, or if you would like more information, please ask us.

What is the purpose of the informal interview?

We would like to know how participants feel about the RECORD intervention. We will discuss with you to understand your experiences of the dietary programme and use the feedback to refine the intervention.

Why have I been invited?

We are looking for up to 30 women from the main RECORD study so that we can explore their views about the RECORD diet advice. You have been invited to take part because you have been allocated to the RECORD diet intervention group.

Do I have to take part?

No, taking part in the interview is entirely voluntary. You may decide not to take part in the interview and this will not affect your participation in the main RECORD study or the clinical care you receive. If you decide now to take part, but at a later time decide that you no longer wish to participate, you can withdraw from the study. If you decide to withdraw for any reason, we will keep any information already collected about you.

What will happen to me if I decide to take part?

We will invite you to talk about your experience of the RECORD intervention and provide feedback, on a day and time that is convenient for you. This will involve discussing with the researcher over the phone for approximately 30 minutes. We will audio-record this discussion.

What should I consider?

We would expect you to talk about your experiences of attempting to follow the RECORD intervention, of taking part in the study, and of monitoring your weight, blood glucose and ketone levels. The discussion will be audio-recorded.

Are there any possible disadvantages or risks from taking part?

The risks of taking part in this interview are extremely minimal. However, it is possible that some of the questions asked during the interview may cause you embarrassment or distress. The questions will focus on exploring your experiences of the dietary advice you were given and of taking part in the main RECORD study. If you feel uncomfortable about answering any of the questions, you can decline to answer any question and the interviewer will move on to the next question.

What are the possible benefits of taking part?

Although there are no direct benefits to you from taking part, your participation may help researchers understand which components of the dietary intervention work well and which don't work so well. This may help future decisions with respect to making consistent dietary advice routinely available during antenatal care in the NHS.

Will my taking part in the informal interview be kept confidential?

Any information that we collect about you during this discussion will be kept strictly confidential. We will not disclose your participation in these interviews to your GP. We will use a unique study code to avoid identification with your name. Responsible members of the University of Oxford and the Oxford University Hospitals NHS Foundation Trust, may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

Will I be reimbursed for taking part?

You will be compensated for your time with £20 for taking part in the interview in the form of a gift card or bank transfer, according to your preference. This is in addition to any compensation you may receive from taking part in the main RECORD study. If you prefer a bank transfer, we will ask your permission to collect your bank details (if not already done so).

What will happen to my data?

Data protection regulation requires that we state the legal basis for processing information about you. In the case of research, this is 'a task in the public interest.' The University of Oxford is the data controller and is responsible for looking after your information and using it properly.

We will use your contact details to arrange the interview and will use the minimum personally-identifiable information possible. We will keep identifiable information for a year after the main study has finished (e.g. contact details), in order to prepare and send you a summary of the study results. We will ask you to verbally consent on the telephone to take part in the interviews and will record your consent on a consent form. We will send a signed copy of the consent form to you in the post. The interviews will be audio-recorded. The audio-recording will be encrypted and stored securely on a password protected server separately from any personal information held about you. The audio-recording will then be typed-out by an approved transcriber service. The recording passed to the transcriber will be identified by a study code number, rather than any of your personal details. The transcriber will not retain the recording after they have been typed out and returned to the research team. This processing of data will be formalised in a written agreement to ensure it is undertaken confidentially and securely. The original audio-recording will then be deleted. The original consent form with your recorded verbal consent will be held securely at the University of Oxford for 5 years after the end of the main RECORD study and will then be destroyed. The pseudonymised transcription from your audio-recorded interview will be stored securely on an encrypted and password-protected server for 3 years after the end of the main study and will then be deleted.

Data protection regulation provides you with control over your personal data and how it is used. When you agree to your information being used in research, however, some of those rights may be limited in order for the research to be reliable and accurate. Further information about your rights with respect to your personal data is available at https://compliance.web.ox.ac.uk/individual-rights .You can find out more about how we use your information by contacting us on 01865 617 857 or record@phc.ox.ac.uk .

What will happen if I don't want to carry on with the interview?

Participation is voluntary and participants may change their minds at a later stage. If you decide to withdraw from this interview, it will not affect the care you receive from any relevant service. If you decide to withdraw from this interview, you will remain in the main RECORD study, unless you notify us otherwise. If you withdraw from this interview after we have already started the discussion, unless you state otherwise, any data already collected will be used as detailed in this participant information sheet.

What will happen to the results of this study?

The transcriptions of the interviews will be coded and all these coded interviews will be analysed to determine whether there are similar themes identified. We plan to publish the findings in scientific journals and present the results at conferences. Please be reassured that you will not be identified in these outputs. If your quotes are used

they will be identified by an anonymous pseudonym. When these publications or reports become available (from late 2022 onward), we will send you a copy of the results. Some of the research being undertaken will also contribute to the fulfilment of a doctoral thesis and educational qualification (Doctor of Philosophy) at the University of Oxford.

What if there is a problem?

The University of Oxford, as Sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this interview. If you wish to complain about any aspect of the way in which you have been approached or treated during the course of this study, you should contact the Chief Investigator Dr Nerys Astbury, or the DPhil Student and main researcher, Moscho Michalopoulou, on 01865 617 857 or record@phc.ox.ac.uk . Alternatively, you may contact the University of Oxford Clinical Trials and Research Governance (CTRG) office on 01865 616480, or ctrg@admin.ox.ac.uk .

How have patients and the public been involved in this study?

Potential participants have been actively involved in developing the questions asked during the interviews.

Who is organising and funding the study?

The RECORD study, including the informal interviews, is sponsored by the University of Oxford. The research is funded by the Oxford-Medical Research Council (MRC) Doctoral Training Partnership and the National Institute for Health Research (NIHR) Oxford Biomedical Research Centre.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect participants' interests. The South-Central Oxford B Research Ethics Committee has approved the ethics of this study.

Further information and contact details:

Please contact Dr Nerys Astbury or Moscho Michalopoulou on 01865 617 857 or record@phc.ox.ac.uk .

Thank you for reading this information.

Appendix 5.8. Consent form for qualitative sub-study

NUFFIELD DEPARTMENT OF PRIMARY CARE HEALTH SCIENCES

RECORD
Reduced-carbohydrate intervention to prevent gestational diabetes

VERBAL CONSENT FORM

Reduced-carbohydrate intervention to prevent gestational diabetes – Qualitative Interviews

Chief investigator: Dr Nerys Astbury
DPhil Student: Moscho Michalopoulou
☎ 01865 617 857
record@phc.ox.ac.uk

Thank you for expressing interest in taking part in an in-depth interview about your experiences of the RECORD diet intervention and of the study. Before we begin the interview, I need to ask you some questions to confirm that you agree to participate in this part of the RECORD study, that you understand how your data will be used, and that you give permission for your data to be used in these ways.
Please confirm your full name. (Researcher taking consent to record this under "Name of Participant" below)

	Researcher to tick each box
1. Do you confirm that you have read and understood the information sheet dated 5th January 2021 (Version 1.1) for this study? Have you had the opportunity to consider the information, ask questions and have these answered satisfactorily?	☐
2. Do you understand that your participation is voluntary and that you are free to withdraw at any time without giving any reason, without your medical care or legal rights being affected?	☐
3. Do you understand that Responsible members of the University of Oxford and the Oxford University Hospitals NHS Foundation Trust, may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations? Do you give your permission for these individuals to have access to this data?	☐
4. Do you agree to the audio-recording of the interview and the use of anonymised quotes in research reports and publications?	☐
5. Do you understand that you will be offered £20 for taking part in the interview, in the form of a gift card or bank transfer according to your preference? Do you understand that only if you prefer a bank transfer, the research team will need to collect your bank details (if not already done so)? In this latter case, do you give permission for the research team to collect these details (if not already done so)?	☐
6. Do you agree to take part in this study/interview?	☐

Name of Participant

_____

Name of Researcher taking consent Date Signature

_____ _____ _____

*1 copy for participant (e.g. posted or emailed securely to participant); 1 copy for researcher site file; 1 copy to be kept in medical notes, original to be kept by the central research team

Appendix 5.9. Qualitative interviews semi-structured topic guide

RECORD Semi-structured Interview Guide

Purpose: To explore participants' experience of the RECORD dietary intervention, and of participating in the study.

1. **Introduction**
   - **Interviewer's name, occupation, role in the study**
   - **Interviewer's role in the interview:** to hear what the participant has to say about their experience of the RECORD dietary intervention, and of participating in the study.
   - **More specifically, objectives are:**
     - To understand the participant's ideas, perspectives and experience of the RECORD study.
     - To obtain feedback from participant on the dietary consultation they received, the content of the RECORD dietary programme, their overall experience from the programme, the intervention materials, and the impact (if any) of the programme on their diet moving forward.

2. **Narrative**
   - **Why did you decide to take part in the RECORD study?**
     - Possible prompts:
       How much had you thought about gestational diabetes before the study? What did you know about it before the study?
   - **How did you feel when you were asked to take part in the RECORD study?**

3. **The RECORD dietary programme**
   - **What were you told to do as part of the RECORD diet?**
     - Alternative way of asking this: What were the most important features/parts of the RECORD diet for you?
     - Possible prompt: How useful was the dietary consultation when the programme was explained?
   - **Ok so you were told (answer to above), how did you feel about making those changes?**
     - Possible prompts:
       Was it easy/hard?
       Which bits (if any) did you find easy to follow, and which bits were difficult?-*Alternatives to this question: what did you find easy/difficult to follow?*
       Which of the changes (if any) were you able to stick to?
       Did you set any goals? If so, were they realistic and achievable or challenging? How important was to you to be working towards your goals?
       You've spoken about the fact you found XXX difficult- how did you cope with those difficulties?
       How did the changes you mentioned impact your daily life? How did they fit with your usual lifestyle, family habits etc.?
       How did you feel about the brief support sessions? Would you have preferred to be contacted more or less often?
       What did you like or dislike?
   - **Which (if any) were the positives/negatives from taking part in the study?**
   - **What are your thoughts about the written materials?**
     - Possible prompts:

Were there any of the materials or any sections that you found particularly interesting or useful?
Which components of the materials did you use? How did you find the components you talked about? E.g. main booklet, meal and snack suggestions, menu planner, recipes, personal action plan, goal setting charts, goal monitoring charts.
Is there anything that would have made the materials better?

- **Did you receive any dietary advice during your appointments with your midwife or doctor? What were you advised to do?**

4. **Study procedures**
   - **What did you think of the study's procedures?**
     - Possible prompts:
       How did you find coming to the hospital for an extra visit (first study visit) outside of your routine hospital appointments?
       Overall, how did you find the procedures taking place during your study visits?
       How did you feel about completing the OGTTs?

   - **How did you feel about monitoring your weight, blood glucose and blood ketones?**

5. **Future**
   - **How do you feel that this dietary programme may impact your diet moving forward?**

6. **Messages to others**
   - **Do you have a message for other women who are at risk of developing gestational diabetes?**

Appendix 5.10. Detailed results of some process outcomes

Number of eligible women approached and enrolled per month

Over 10 months of recruitment, of the approached women, 361 were initially eligible (all criteria apart from baseline OGTT), and invited to take part (36 eligible women approached per month). Fifty-five of the 361 (15%) initially eligible women consented to take part and were randomised, and 51 of these were fully eligible and enrolled in the study. This is equivalent to a recruitment of 5-6 participants per month, and enrolment of 5 participants per month, over 10 months.

Percentage of intervention participants completing the initial and support sessions

All 34 participants in the intervention group (100%) completed the initial dietary consultation, 26 (76.5%) in-person and 8 (23.5%) on the telephone. I planned to offer up to 6 support sessions as needed. On average, I offered 4 support sessions, of which, participants completed an average of 3. Twelve intervention participants (35.3%) completed all support sessions that they were offered.

More specifically, n (%):

- No support sessions: 3 (8.8%)
- 1 support session: 4 (11.8%)
- 2 support sessions: 5 (14.7%)
- 3 support sessions: 10 (29.4%)
- 4 support sessions: 5 (14.7)
- 5 support sessions: 6 (17.6%)
- 6 support sessions: 1 (2.9%)

The reasons for not completing all support sessions included (n, %):

- Requested, but not response: 12 (36.4%)
- Other commitments or health problems: 4 (12.1%)
- Not particularly interested in the diet: 2 (6.1%)

- Participant explicitly expressed they were unable to follow the advice no matter how much support we offer, e.g. due to emotional relationship with food: 2 (6.1%)
- Delivery before being offered all sessions: 1 (3%)
- No more sessions needed because participant was doing very well with the diet: 6 (18.2%)
- Withdrew from the study: 3 (9.1%)
- Loss to follow-up: 2 (6.1%)
- Participant mistakenly recorded as control by myself: 1 (3%)

Percentage of participants in each group who attend the follow-up visit

Because some participants completed their OGTTs with their clinical team, and therefore, did not need to attend a visit with the study team, I have determined this outcome based on the number of participants in each group who completed a dietary recall at follow-up (24-28 weeks' gestation), as this was the assessment that required the most effort after the OGTT. It should be noted that I could not attend the follow-up visit for 2 people in the control group, and these visits were conducted by the research nurses administering all the questionnaires. Due to technical issues with the laptops available by the research nurses on these days, it was not possible for these participants to complete their follow-up dietary recall online during their visit, and I instead emailed the questionnaire to them to complete at home after the visit. However, these participants did not complete them, even after reminding them. Overall, 24 of 34 (82.4%) participants in the intervention group, and 15 of 17 (88.2%) participants in the control group completed a dietary recall at follow-up.

Proportion of participants who record their blood glucose and blood ketones every week

Engagement with glucose and ketone monitoring varied. I asked participants who developed GDM during the study to continue monitoring their ketones until delivery, but all apart from one of these participants stopped monitoring ketones at this point. Almost a third of participants completed at least one fasting capillary glucose and one fasting capillary ketone measurement on all weeks they were required to do so, from their enrolment until delivery or the point of exit from the study. Forty-

three percent of participants completed all fasting glucose measurements they were required to. The average participation lasted for 23 weeks, which means that I was expecting to receive on average 46 measurements of glucose and 46 measurements of ketone levels per participant. I received an average of 40 glucose measurements per participant (87% completion rate), and an average of 36 ketone measurements per participant (78.3% completion rate).