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

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Abstract

Aim: To test the feasibility and acceptability of a reduced-carbohydrate dietary program, intended to reduce the risk of gestational diabetes.

Materials and Methods: Fifty-one pregnant women at <20 weeks' gestation, with body mass index ≥30 kg/m^2, and a normal baseline oral glucose tolerance test (OGTT), were randomized 2:1 to an intervention or control group and followed-up until delivery. The dietary intervention aimed at providing 130–150 g carbohydrate/day. Feasibility outcomes assessed at 24–28 weeks' gestation, included adoption of the reduced-carbohydrate diet by the intervention group, and retention of all participants, assessed by completion of a second OGTT. Changes in glycemia, weight gain and dietary intake, and the maternal and neonatal outcomes were also assessed. Participants were interviewed about their experience of the intervention and the study.

Results: Forty-nine of 51 participants attended the follow-up OGTT, a retention rate of 96% (95% confidence interval [CI] 86.8%–98.9%). In the intervention group, carbohydrate intake at follow-up was 190.4 (95% CI 162.5–215.6) g/day, a reduction of −24.6 (95% CI −51.5–2.4) g/day from baseline. Potentially favourable effects of the intervention on glucose control, weight gain and blood pressure were observed, but the study was not powered to detect significant differences in these. Participants found the intervention acceptable, and were content with the study processes, but some reported barriers to sustained adherence, mainly pertaining to competing priorities.

Conclusions: Retention was high, suggesting the study processes are feasible, but the carbohydrate reduction in the intervention group was small, and did not meet progression criteria, limiting the likelihood of achieving the desired goal to prevent gestational diabetes. Trial registration number: ISRCTN16235884.

KEYWORDS
clinical trial, dietary intervention, obesity therapy, primary care, real-world evidence, weight control

1 | INTRODUCTION

Obesity affects up to approximately one quarter of women of reproductive age worldwide, and is one of the most commonly presenting risk factors in obstetric practice.[1–3] Obesity and excessive gestational weight gain (GWG) increase the risk of pregnancy complications such as gestational diabetes mellitus (GDM),[4] in turn, increasing the risk of adverse pregnancy and neonatal outcomes, as well as future cardiometabolic risk for both the mother and the offspring.[5–11]

Several trials in women with obesity during pregnancy have encouraged dietary changes and/or increases in physical activity. Some achieved modest reductions in GWG, although the majority did not reduce GDM incidence,[12,13] suggesting that limiting GWG may not be sufficient in itself to prevent GDM. In fact, the small number of interventions to date that have been successful in reducing GDM risk had small effect on GWG.[14–18] Instead, the success of these interventions was attributed to intervening at early stages of pregnancy, as well as changes in dietary composition. For example, interventions involving Mediterranean-style diets led to speculation that increased unsaturated fat and polyphenol consumption through liberal intake of olive oil and nuts might improve insulin sensitivity and inflammation.[15,16] However, higher fat and protein consumption in the context of a similar energy intake is also likely to result in a lower carbohydrate intake, which may help control glycemia.

We hypothesized that an intervention which limits total carbohydrate intake from early stages of pregnancy could help prevent GDM. Carbohydrates are major energy-providing nutrients,[19] so reductions may help attenuate GWG, as well as lower blood glucose levels, as shown in people with type 2 diabetes and established GDM.[20,21] To our knowledge, only one previous randomized controlled trial (RCT), the DALI trial, specifically aimed to reduce total carbohydrate intake in women at risk of GDM.[21] However, that trial was not powered to detect effects on GDM incidence. In addition, by 24–28 weeks' gestation, the time point of testing for the presence of GDM, the intervention achieved a small reduction in carbohydrate intake (reduction by <1 portion of carbohydrate food/day) compared to usual care, and a non-significant attenuation of GWG.[22] Moreover, the dietary advice was part of an intensive healthy eating intervention program delivered by lifestyle coaches and may not be viable for delivery at scale and in routine care.

A full-scale RCT to demonstrate if a reduced-carbohydrate approach is effective in reducing GDM risk and improving maternal and neonatal outcomes would require considerable investment,[23] therefore, we aimed to assess whether it is feasible to deliver such a dietary intervention alongside routine antenatal appointments, and whether this leads to successful dietary change, and also to look for early signs of effectiveness by reducing GWG or improving markers of glycemic control.

2 | MATERIALS AND METHODS

2.1 | Study design and participants

This was a two-arm parallel group individually randomized controlled feasibility trial, examining the use of a moderately reduced-carbohydrate dietary intervention, with behavioral support, in pregnant women with obesity (body mass index [BMI] ≥30 kg/m^2) at <20 weeks' gestation. 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.[24]

We recruited participants from the Women's Centre at Oxford University Hospitals NHS Foundation Trust, attending their nuchal scan (typically between 8 and 14 weeks' gestation). A member of the research team assessed eligibility in-person or later over the telephone, based on self-reports. Initially eligible participants who were interested in taking part were booked for a face-to-face baseline visit before 20 weeks' gestation, where consent was obtained, randomization and baseline assessments were conducted, and inclusion was verified after completion of an oral glucose tolerance test (OGTT), which ruled out hyperglycemia.[24] Full inclusion and exclusion criteria are in the published protocol.[24]

2.2 | Randomization

An independent researcher generated the randomization list with 2:1 allocation to intervention: control, using random permuted blocks of 3 and 6. Allocation was only revealed to the recruiter after a participant had enrolled, using online software (Study Randomizer) to ensure allocation concealment.[25] It was not possible to blind participants, clinicians, or the researchers who collected and analyzed the outcome data to the treatment allocation beyond this point.

2.3 | Interventions

The RECORD study (REduced-Carbohydrate intervention for managing Obesity and Reduction of gestational Diabetes) is described in detail elsewhere.[24] In brief, the dietary advice aimed at providing 130–150 g total carbohydrate/day, with no specific advice to change protein or fat intake, for approximately 6 months (<20 weeks' gestation until delivery). It focused on three main principles (3Rs): 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. A research dietitian (Moscho Michalopoulou) delivered a 30-min one-off consultation, explaining the diet principles, and providing support and motivation, including advice on goal setting, self-monitoring, and problem solving. The consultation was combined with a structured self-help booklet detailing how to apply the 3Rs, and providing general healthy eating advice, meal and snack ideas, and guidance on food labels. Participants also received recipes and materials to help with behavioural control (diet-related goal setting, and diet- and weight-related self-monitoring booklet and charts). Throughout pregnancy until delivery, the dietitian offered up to six 10–15-min telephone sessions, and participants were instructed to weigh themselves once a week. All women received routine antenatal care, which, according to

national guidance, should include one-off face-to-face routine care NHS healthy eating and food safety advice, during the booking appointment with a midwife, prior to randomization in the study. Where given, participants allocated to the control group received no additional advice beyond this.

2.4 | Procedures

Participants attended two study visits, one at baseline (<20 weeks' gestation) and one for follow-up at 24–28 weeks' gestation. The second visit replaced a routine OGTT visit that all participants would have been invited to attend as part of their antenatal care.[26] Each study visit lasted approximately 2.5 h. Height was measured at baseline, and all other assessments were completed at both visits. A digital scale (Active Era, BS-03S) was used to measure weight. Blood pressure was measured twice after 1 min of seated rest, and the mean was taken. A self-completed online questionnaire assessed participants' carbohydrate intake as part of a broader assessment of their dietary intake over the preceding 24 h,[27] and paper questionnaires recorded self-reported highest education level, employment status, ethnicity, and quality of life.[28] A fasting venous blood sample was collected to measure glucose, glycated hemoglobin (HbA1c), and insulin. Participants were then asked to consume a 75-g glucose drink (Polycal Liquid; Nutricia). Further venous blood samples were collected 1- and 2-h post-drink, to measure glucose concentrations. Participants in the intervention group proceeded to receive the dietary consultation, which advised them to reduce their carbohydrate intake until delivery. Intervention sessions were audio-recorded for assessment of the intervention fidelity.

The National Institute for Health and Care Excellence (NICE) recommends that women with GDM in a previous pregnancy are offered an earlier extra OGTT at 16 weeks' gestation, in addition to the one at 24–28 weeks' gestation. Therefore, we offered participants with previous GDM the flexibility to complete OGTTs with their clinical or the study team as they preferred, and for those choosing their clinical team, the opportunity to complete the study assessments via email. Remote participants weighed themselves at home using digital scales, their height was accessed from their booking appointment, and they emailed the most recent blood pressure measurement taken during a clinical appointment. Remote participants assigned to the intervention group received the intervention materials in the post, and the dietary consultation over the phone. Importantly, for these participants, HbA1c, 1-h glucose and fasting insulin were not available as they are not taken as part of routine OGTTs.

All participants were provided with a Bluetooth-enabled blood glucose and ketone monitoring kit connected to a mobile application (Diabetes: M, Sirma Medical Systems), and were instructed to take a fasting capillary glucose and ketone measurement twice a week for the duration of the study. Moscho Michalopoulou reviewed those measurements through a secure central web portal and escalated to a clinician (Lucy H. MacKillop or Jane E. Hirst) when needed. Participants in the intervention group only were instructed to weigh themselves once a week at home using digital scales and logged the measurements manually onto the mobile application.

Participants in the intervention group who were diagnosed with GDM at 24–28 weeks' gestation were advised to continue following the RECORD diet until delivery, at the discretion of their clinical team, since the principles were similar to local standard medical advice that recommends women moderately reduce their carbohydrate intake, choose lower-glycemic-index foods, limit weight gain, and engage in 150 min of moderate-intensity activity/week. Women from the control group diagnosed with GDM also received routine reduced-carbohydrate advice at this stage.

At 36 weeks' gestation, all women were expected to be weighed during a midwife appointment as per routine practice, and digital scales were used for this. After the second study visit, but before delivery, we conducted individual semi-structured interviews with participants from the intervention group, to explore their experience of the intervention and the study. Recruitment for the qualitative interviews stopped when data saturation was reached. After delivery, we extracted maternal and neonatal outcomes from the electronic medical records.

2.5 | Outcome measures

The primary outcomes were pre-specified feasibility criteria to progress to a full RCT, based on (i) adoption of the diet by the intervention group: mean carbohydrate consumption at 24–28 weeks' gestation, and (ii) retention rate: proportion of all participants who complete a second OGTT at 24–28 weeks' gestation. We used 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; Table 1).

Secondary outcome assessment offered the opportunity to collect some pilot data which could be used to power a definitive RCT in the future. Exploratory outcomes examined further dietary changes, assessed the potential effect of the intervention on maternal and neonatal outcomes, and sought feedback on the acceptability of the intervention and the study. Process outcomes explored procedures, resources, and management issues, to aid the design of a future RCT (Appendix Table S1).

2.6 | Statistical analysis

Sample size was based around the adoption of the reduced-carbohydrate intervention and retention rate, as indicators of feasibility. We wanted to detect a target intake at 130–150 g/day (~140 g/day) at 24–28 weeks' gestation in the intervention group, with 95% confidence intervals (CIs) that do not cross 170 g/day. We also considered that a minimum of 80% of all participants were needed to complete an OGTT at 24–28 weeks' gestation, as in previous trials,[29,30] with 95% CIs that do not cross 70%. Both were satisfied with a sample size of 60 participants allocated in a 2:1 ratio to intervention: control. The study was not powered to detect a statistically significant difference in clinical effectiveness between the trial arms.

TABLE 1 Feasibility progression criteria.

Criteria	Assessment	Indication of success	
Adoption of the diet from the intervention group	Total carbohydrate intake via online 24-h recall diet questionnaire at 24–28 weeks' gestation	Green	Mean intake <170 g/day and 95% CIs that include 140 g/day, but do not include 170 g/day
		Amber	Mean intake ≤170 g/day and 95% CIs that include both 140 g/day and 170 g/day
		Red	Mean intake >170 g/day and 95% CIs that do not include 140 g/day or 170 g/day
Retention of all participants	Mean proportion of all enrolled participants who complete an OGTT at 24–28 weeks' gestation	Green	Retention of ≥80% of recruited participants, with estimated 95% CIs that do not include 70%
		Amber	Retention of ≥70% of recruited participants, with estimated 95% CIs that include both 70% and 80%
		Red	Retention of <70% of recruited participants, with estimated 95% CIs that do not include 70% or 80%

Abbreviations: CIs, confidence intervals; OGTT, oral glucose tolerance test.

The statistical analysis was carried out using the intention-to-treat approach and was based on available data only. Women who were initially randomized but discontinued due to abnormal baseline OGTT were not included in any analysis. 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.[31] We used linear regression models to determine the within- and between-group differences at follow-up in order to explore the potential effect of the intervention on secondary and exploratory continuous outcomes. In most analyses, outcome was the change score, and models were adjusted for baseline maternal age, ethnicity, Index of Multiple Deprivation, baseline BMI, and baseline value of the outcome. For weight, which was measured at baseline and at two follow-up time points (24–28 and 36 weeks' gestation), we used the mean weight measurement at follow-up as the outcome, as well as repeated-measures linear regression models, in which we included as fixed effect the interaction between study visit and randomized group, and instead of baseline BMI, we adjusted for baseline mean weight. All statistical analyses were conducted using Stata 16.0.

The fidelity of intervention delivery, based on six audio-recorded dietary consultations, was assessed by an independent reviewer against pre-specified essential criteria: (i) information about GDM; (ii) 3Rs; (iii) goal setting; and (iv) information on and instruction for self-monitoring of weight. We analysed qualitative data from individual semi-structured interviews with participants from the intervention group, following a descriptive thematic analysis approach, using NVivo (version 11).

2.7 | Patient and public involvement

We convened two focus groups of women affected by GDM, recruited from a local antenatal clinic, a national GDM support website, and a social media forum, prior to ethical submission. The first group helped to prioritize and refine the research question. The second group was provided with an outline of the study protocol and they were 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 moderating starchy foods in their diet during pregnancy. A patient representative with previous GDM provided feedback on the intervention materials and the behavioural support components, and joined the trial management group.

3 | RESULTS

Participants were recruited between 14 May 2021, and 31 March 2022. Of 1660 women approached, 385 (23%) had a BMI ≥30 kg/m^2. Fifty-five women (3.3% of the approached sample, and 14% of those with eligible BMI) attended a baseline study visit and were randomly allocated to the RECORD program ($n = 34$) or usual care ($n = 17$). Four randomized participants, all assigned to the intervention group, had an abnormal baseline OGTT and were discontinued from the study, leaving 51 enrolled participants (Figure 1). Participants were mainly in their 30s, of White ethnic background, and highly educated (Table 2). Recruitment stopped at 51 participants due to a slow recruitment rate and delay to the start of the study caused by the COVID-19 pandemic. However, both progression criteria were satisfied with this smaller sample (Appendix S1). Six participants were offered an early OGTT, as part of their routine care (five due to previous GDM, and one deemed at high risk by their clinical team, due to comorbidities and older age, despite no history of GDM). These six participants chose to undergo both OGTTs with their clinical team, and therefore completed all study assessments remotely. At follow-up (24–28 weeks' gestation), two more participants (no history of GDM)

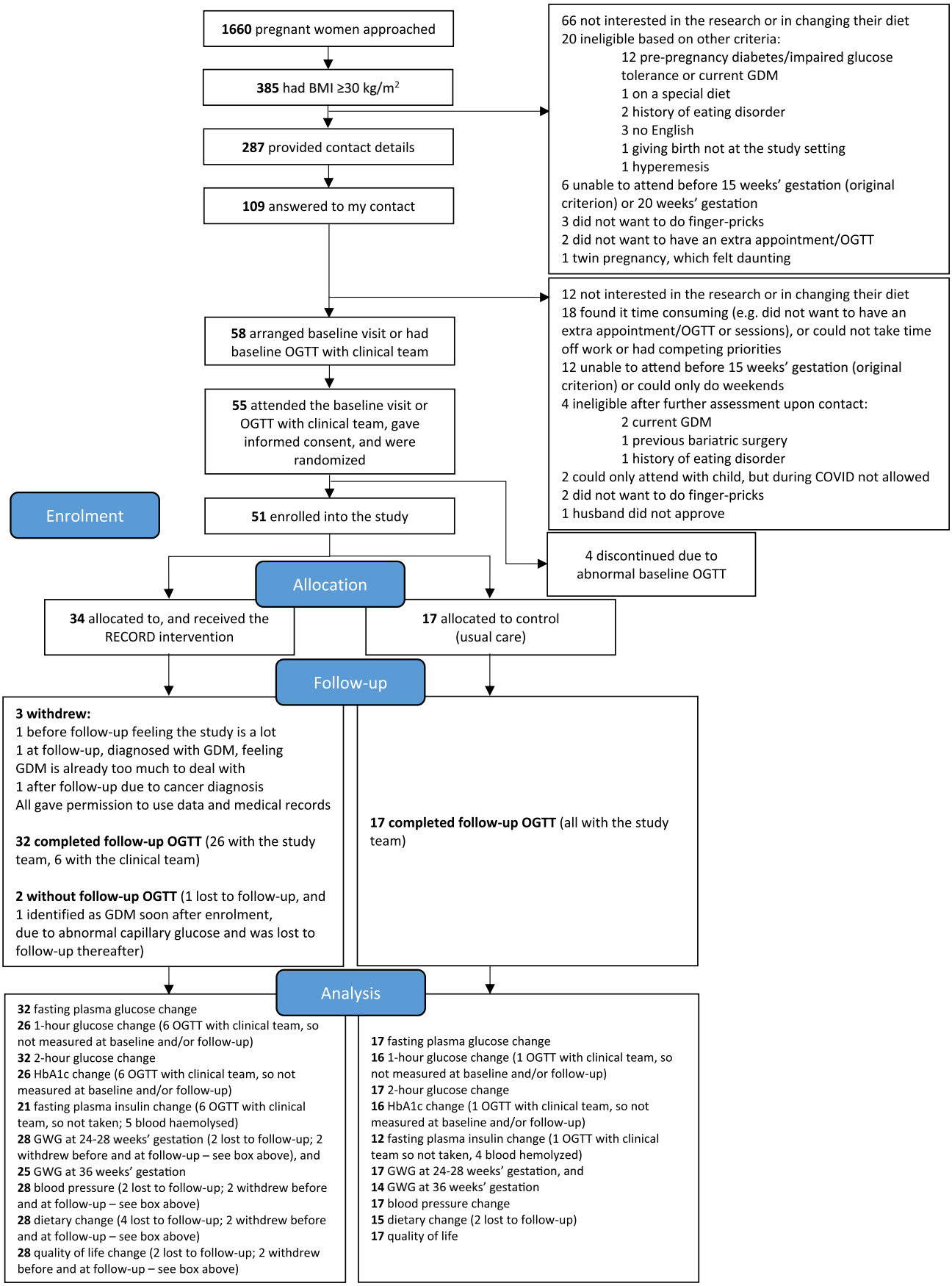

FIGURE 1 Trial flow diagram, BMI, body mass index; GWG, gestational weight gain; HbA1c, glycated hemoglobin; OGTT, oral glucose tolerance test.

chose to have their OGTT with their clinical team for convenience, and completed study assessments remotely. Eventually, dietary data at follow-up were available for 28 intervention participants, but the adoption progression criterion was also still satisfied (Appendix S1). All pregnancies were singleton, and all participants had live births. Their clinical outcomes were extracted after delivery from medical records. Follow-up finished immediately after delivery for each participant, with the latest delivery on 15 September 2022.

3.1 | Progression criteria

Mean total carbohydrate intake in the intervention group at 24–28 weeks' gestation was 190.4 (95% CI 162.5 to 215.6) g/day, an adjusted reduction of −24.6 (95% CI −51.5 to 2.4) g/day since baseline (Table 2), not satisfying the adoption criterion (red light). Forty-nine of 51 participants attended the second OGTT, a retention rate of 96% (95% CI 86.8–98.9; green light). One participant with previous GDM, assigned to the intervention group, had a normal baseline OGTT, but presented with consistently high fasting capillary glucose measurements when self-monitoring at home, shortly after randomization. Based on these measurements, the diabetes team at the hospital advised that the participant should receive treatment for GDM. Therefore, this participant did not undergo a second OGTT, which led to a retention rate among women who were expected to have a second OGTT of 98% (49/50).

3.2 | Secondary and exploratory outcomes

Process measures are shown in Appendix Table S2. Attendance at the intervention delivery sessions and study follow-up was satisfactory, and participants had good engagement in regular self-monitoring of glucose, ketones and weight.

As this was a feasibility study, it was not powered to detect changes in secondary and exploratory measurements, or clinical outcomes. Changes in markers of glycaemic control were more favourable for the intervention compared to control group (Table 3). Average fasting capillary glucose and ketone levels during pregnancy were similar in the two groups. Ketone levels remained low throughout pregnancy in both groups (Table 3). Only one participant from the intervention group developed high ketones (>4 mmol/L) over 3 days, but this was deemed unrelated. There was a notable decrease in blood pressure favoring the intervention (Table 3). GDM incidence was 17.6% in the intervention and 5.9% in the control group, based on the NICE criteria.[26] However, some women had elevated 1-h 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. In total, 20.5% of participants in the intervention group and 17.6% of the control group were treated for GDM (Table 4).

The intervention group gained less weight compared to the control group, both at 24–28 and at 36 weeks' gestation; adjusted between-group difference of −2.0 (95% CI −4.8–0.8) kg and −1.4

TABLE 2 Baseline characteristics of participants assigned to the RECORD programme or usual care.

	Control ($n = 17$)	Intervention ($n = 34$)	All ($N = 51$)
Maternal age, years[a]	34.1 (±5.5)	33.2 (±3.5)	33.5 (±4.2)
BMI, kg/m^2[a]	35.5 (±4.6)	35.6 (±4.7)	35.5 (±4.6)
Gestational age at baseline[a]			
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[b]			
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[b]			
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[c]	9.0 (3.0)	9.0 (4.0)	9.0 (3.0)
Primigravida	4 (23.5)	11 (32.4)	15 (29.4)
Previous GDM[b]	0 (0.0)	5 (14.7)	5 (9.8)

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

TABLE 3 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[a] at follow-up	Change adjusted[a] at 36 weeks' gestation	Adjusted[a] 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)
Glycaemic markers								
Fasting plasma glucose, mmol/L								
Intervention	4.4 (±0.4), $n = 34$	4.6 (±0.4), $n = 32$[c]	-	0.2 (0.1 to 0.3), $n = 32$[c]	-	0.2 (0.1 to 0.3), $n = 32$[c]	-	0.1 (−0.1 to 0.3)
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-h glucose, mmol/L								
Intervention	6.7 (±1.4), $n = 27$[e]	7.6 (±1.6), $n = 26$[c]	-	1.0 (0.5 to 1.5), $n = 26$[c]	-	0.9 (0.4 to 1.4), $n = 26$[c]	-	−0.3 (−1.1 to 0.5)
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-h glucose, mmol/L								
Intervention	5.5 (±1.2), $n = 33$[e]	5.9 (±1.3), $n = 32$[c]	-	0.4 (−0.1 to 0.9), $n = 32$[c]	-	0.5 (0.0 to 1.0), $n = 32$[c]	-	−0.1 (−0.9 to 0.7)
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), $n = 17$	-	-
HbA1c, mmol/mol[d]								
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)
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[d,f], 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)
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[d,f]								
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)
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), $n = 12$	-	-

(Continues)

TABLE 3 (Continued)

Fasting capillary glucose, mmol/L								
Intervention				4.8 (±0.5), $n = 33$				0.05 (−0.2 to 0.3)
Control				4.8 (±0.5), $n = 17$				-
Fasting capillary ketones, mmol/L								
Intervention				0.1 (±0.1), $n = 33$				0.03 (−0.01 to 0.1)
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)[b], $n = 28$	7.3 (5.1 to 9.4)[b], $n = 25$	24–28 weeks' gestation: −2.0 (−4.8 to 0.8)[b] 36 weeks' gestation: −1.4 (−4.5 to 1.6)[b]
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)[b], $n = 17$	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), $n = 17$	-	-	-	-	-	-
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)
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)
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)
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 3 (Continued)

Total carbohydrate, 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)
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 carbohydrate								
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)
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 carbohydrate, 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)
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), $n = 15$	-	-
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)
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)
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)
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), $n = 15$	-	-
% 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)
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), $n = 15$	-	-

(Continues)

TABLE 3 (Continued)

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)
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)
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), $n = 15$	-	-
% 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)
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)
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)
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), $n = 17$)	-	-

Abbreviations: AOAC, Association of Analytical Chemists; BMI, body mass index; HbA1c, glycated haemoglobin; HOMA-IR, homeostatic model assessment of insulin resistance; IOM, Institute of Medicine; EQ-5D, EuroQol-5D.

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

[b]Adjusted for: age, ethnicity, Index of Multiple Deprivation, and baseline weight.

[c]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 gestational diabetes before 24–28 weeks' gestation due to consistently high fasting capillary glucose measurements taken as part of the study, and therefore, did not have an OGTT at 24–28 weeks' gestation.

[d]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.

[e]Baseline 1-h and 2-h 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 not included in the analysis. However, it was clinical decision that this participant could still enrol into the study.

[f]For some participants, insulin levels may be missing because the blood was haemolysed.

(95% CI −4.5–1.6) kg, respectively (Table 3). Weight before delivery was not measured at the hospital. Therefore, in order to evaluate the proportion of participants meeting the Institute of Medicine recommendations for weight gain during pregnancy, we assessed the weight gain from baseline (<20 weeks' gestation) until 36 weeks' gestation. Thirty-six-week weight data were available from 25 participants in the intervention group and 14 participants in the control group. Twenty-four percent of the intervention group, as opposed to 7% of the control group, gained weight within the recommendations.

Both groups reported lower total carbohydrate intake at follow-up, with greater adjusted reduction in the intervention group (Table 3). Adjusted analysis showed a reduction in starch intake in the intervention group, with no change in the control group at follow-up. Both groups reported slightly reduced sugar intake at follow-up, with greater reduction in the intervention group. Mean fibre intake was similar in the two groups at each time point (Table 3).

3.3 | Serious adverse events

There were a total of four serious adverse events from the start until the closing of the study. One participant in the intervention group was hospitalized for preeclampsia and obstetric cholestasis, and her child was born with an 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 experienced bleeding at approximately 17 weeks' gestation and was hospitalized for monitoring for one night. All these events were judged by the Chief and Principal Investigators, an obstetric physician, and the central study team, as not related to the study.

3.4 | Qualitative findings

We interviewed 16 participants from the intervention group. The key themes of experiences of the intervention are presented in Appendix Table S3, and feedback on study processes is presented in Appendix Table S4. Participants largely found the diet to be acceptable, and reported they planned to continue with the dietary changes beyond pregnancy. Some participants, however, found the diet challenging, especially towards the late stages of pregnancy, and a few could not follow the advice. Engagement with the diet was facilitated by clear, specific messages, structured materials, and use of behavioural strategies. Frequent barriers included competing priorities, physical symptoms, and complex psychological relationships with food. Participants placed high value on the role of social support and accountability to the unborn baby in their motivation and ability to adopt the diet. Concern about developing complications during pregnancy, including GDM, as well as objective successes (e.g., limited GWG), also drove motivation. However, in a few cases, participants reported perceptions denoting that they did not fully realize their increased risk of GDM and its consequences, which reduced their motivation to prioritize attention to their diet. Most participants reported feelings of well-being from following the diet, and of reassurance from receiving extra monitoring and advice in pregnancy, however, a few participants found regular self-weighing uncomfortable because of negative body image and history of dieting.

TABLE 4 Clinical outcomes by group allocation.

	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-h 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 hyperbilirubinemia	1 (2.9)	1 (5.9)
Requiring phototherapy	1 (2.9)	0 (0.0)

Note: Values are count (%) unless otherwise specified.
Abbreviations: GDM, gestational diabetes mellitus; NICE, National Institute for Health and Care Excellence; NICU, neonatal intensive care unit.

4 | DISCUSSION

This randomized feasibility trial met the retention, but not the diet adoption progression criteria. The secondary and exploratory outcomes, indicative of early effectiveness, suggested a potential improvement in 1- and 2-h glucose levels on the OGTT and blood pressure at 24–28 weeks' gestation, as well as in GWG at both 24 to 28 and 36 weeks' gestation, in the intervention group 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, as well as being content with the study processes, including regular monitoring of blood glucose, ketones and weight.

4.1 | Strengths and limitations

This was a theoretically informed intervention developed with input from key stakeholders, making it suitable for delivery alongside routine antenatal appointments. Participants welcomed the clear specific messages, and usefulness of structured materials. Together, these suggest that it is possible for generalists to deliver this intervention at scale without detailed nutritional knowledge. This is also the first study to report regular blood glucose and ketone levels from early or mid-pregnancy through to delivery, which can provide clinicians with insight into expected values for pregnancy.

The study took place in one hospital site in Oxford, with low ethnic diversity and socioeconomic deprivation, which limits the generalizability of the results. As in previous studies,[15,29] large numbers of women had to be approached, and recruitment stopped at a smaller sample size than originally planned. Some women mentioned reluctance to change their diet during pregnancy, or competing priorities, but for most women not taking part, the reasons were unknown as they did not respond to our contact. It was also impossible to blind participants to this behavioral intervention, which may have resulted in the observed potential contamination in the control group.

4.2 | Comparison with other studies

Previous preventative interventions for GDM employed general healthy eating advice or a Mediterranean-style diet. The RECORD study differs in that it specifically focused on reducing the total amount of carbohydrate, rather than changing the total dietary pattern. It was intended to be simple for general practitioners to deliver in routine consultations and for women to adopt, recognizing this is a time of life when they have other priorities, and maybe less opportunity to focus on complex dietary change. However, RECORD resulted in only a small reduction of approximately one portion of carbohydrate foods/day in the intervention group, and this was not significantly greater than the decrease in the control group, similarly to previous interventions in women with and without GDM.[22,32] There was a small change in intake of sugars, and no evidence of change in fibre intake, despite explicit messages to remove sugary foods and replace refined carbohydrates with unrefined or wholegrain alternatives. Similarly, in the UPBEAT trial, which primarily promoted a lower-glycemic-index diet, fibre intake increased minimally in the intervention compared to the control group (between-group adjusted mean difference: 0.83 g/day, 95% CI 0.17–1.48). It is therefore unclear whether a substantial reduction in total carbohydrate intake is feasible in women with overweight or obesity during pregnancy, and a full trial to test this specific approach is not warranted based on current evidence.

This was a feasibility trial that was not powered to detect differences in clinical outcomes. However, we collected this information to inform power calculations for future studies, and to generate new hypotheses. The duration of active intervention and follow-up, from an average of 15 weeks' gestation at enrolment, until 24–28 weeks' gestation, was short, yet there was notable difference in weight gain between groups that persisted to 36 weeks' gestation, which exceeds that seen in some higher-intensity programs.[13] The reasons for this are unclear. It may be that participants did employ reduced-carbohydrate strategies in ways that were not detected in the 24-h recall dietary assessment method, which is notoriously imprecise and prone to reporting errors, and may not have reflected habitual intake.[33,34] Alternatively, the weekly self-weighing may have prompted a self-regulatory response,[35] leading to other changes in dietary intake that were not detected in the dietary assessment, or to an increase in physical activity which we did not measure. With regards to self-weighing specifically, previous trials testing its effectiveness on limiting GWG have been unsuccessful in engaging women in regularly measuring their weight during pregnancy,[36,37] which could stem from negative emotional responses elicited by regular weighing in the absence of appropriate support and guidance.[36] An exception is the intervention by McCarthy et al.,[38] which similarly to RECORD, provided simple dietary advice on top of self-weighing and achieved 53% completion of at least five self-measurements over 6 months. In the same timeline, RECORD achieved 55% completion of all and 65% completion of half of the required measurements. The better engagement observed in these two studies could be due to providing GWG guidelines along with feedback and support with action plans to maximize the opportunity to harness the full potential of self-regulation.

In conclusion, women who chose to take part in this study found the intervention acceptable and follow-up rates were good, suggesting trials of this kind are feasible to conduct during pregnancy. However, according to the pre-specified criteria, the intervention did not lead to a meaningful reduction in total carbohydrate intake in women with obesity at risk of GDM. In its present form, there is no justification to continue to a definitive trial, although the secondary and exploratory analyses suggested that this intervention may be worth refining and retesting in a future feasibility trial. Such a trial would target women at the highest risk of GDM. To improve adherence to the reduced-carbohydrate regimen, the immediate care team would deliver the intervention as part of a woman's care package, and we would develop materials that would be culturally appropriate, to increase diversity and facilitate incorporation into everyday life. A

future trial could also employ continuous glucose monitoring alongside current measures, which, despite the cost involved, could increase the acceptability of the intervention.

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CONFLICT OF INTEREST STATEMENT

Lucy H. MacKillop is a part-time employee of EMIS Group plc.

PEER REVIEW

The peer review history for this article is available at https://www.webofscience.com/api/gateway/wos/peer-review/10.1111/dom.15442.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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