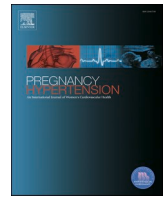




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Evidence of lifestyle interventions in a pregnant population with chronic hypertension and/or pre-existing diabetes: A systematic review and narrative synthesis

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ABSTRACT

Background: Pregnant people with chronic hypertension, pre-existing diabetes or both are at high risk of developing cardiovascular disease. Lifestyle interventions play an important role in disease management in non-pregnant populations.

Aim: To review the existing evidence of randomised controlled trials (RCTs) that examine lifestyle interventions in pregnant people with chronic hypertension and/or pre-existing diabetes.

Methods: A systematic review and narrative synthesis was conducted. Five electronic databases were searched from inception to April 2021 for RCTs evaluating antenatal lifestyle interventions in people with chronic hypertension and/or pre-existing diabetes with outcomes to include weight or blood pressure change.

Results: Nine randomised controlled trials including 7438 pregnant women were eligible. Eight studies were mixed pregnant populations that included women with chronic hypertension and/or pre-existing diabetes. One study included only pregnant women with pre-existing diabetes. Intervention characteristics and procedures varied and targeted diet, physical activity and/or gestational weight. All studies reported weight and one study reported blood pressure change. Outcome data were frequently unavailable for the subset of women of interest, including subgroup data on important pregnancy and birth complications. Eligibility criteria were often ambiguous and baseline data on chronic hypertension was often omitted.

Conclusion: A lack of primary interventional trials examining the effect of lifestyle interventions on weight and blood pressure outcomes in pregnant populations with chronic hypertension and/or pre-existing diabetes was evident. Lifestyle modification has the potential to alter disease progression. Future trials should address the ambiguity and frequent exclusion of these important populations.

1. Introduction

Chronic hypertension (CH) complicates $\leq 5\%$ of pregnancies and those entering pregnancy with a pre-existing diagnosis of type 1 diabetes mellitus (DM) or type 2 diabetes mellitus (T2DM) has a global prevalence of between 0.5 % and 2.6 % [1–3]. Prevalence of these conditions has increased substantially over recent decades and both continue to rise; influenced by advances in maternal age and increasing rates of obesity that often precede these conditions [1,2,4]. Women with CH are nearly eight times more likely to develop superimposed pre-eclampsia than those in the general population are to develop pre-eclampsia [5].

Additionally, they are at least twice as likely to experience an adverse neonatal outcome compared with the general pregnant population [5]. Those with pre-existing diabetes are four times more likely than those who do not have diabetes to experience a fetal death and as well as these obstetric and neonatal complications, both groups have a lifelong cardiovascular disease (CVD) risk [1,5–7]. These data spotlight the importance of examining these populations to improve disease management during pregnancy and to reduce the associated short and long-term risks.

Weight management and more specifically, weight loss is recommended to hypertensive and diabetic populations for disease

Abbreviations: BCT, Behaviour Change Technique; BMI, Body Mass Index; BP, Blood Pressure; CH, Chronic hypertension; CVD, Cardiovascular disease; DM, Type 1 diabetes mellitus; GWG, Gestational Weight Gain; IPD, Individual Participant Data; RCT, Randomised Controlled Trial; T2DM, Type 2 diabetes mellitus.

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management [8–10]. Whilst weight loss is not advocated in pregnancy, avoiding excessive gestational weight gain (GWG) is important for all pregnant women, irrespective of body mass index (BMI), as this can lead to an increased risk of adverse pregnancy outcomes [11,12]. Evidence suggests that for pregnant women with existing risk factors such as hypertension or diabetes additional support may be needed to help reduce excessive weight gain during pregnancy [13–15]. This is to address both the health of the pregnancy and their CVD risk where weight is a modifiable risk factor.

Lifestyle interventions in non-pregnant populations improve blood pressure control and the quality of life in hypertensive populations [16–18]. A review of 105 trials including 6805 participants found statistically and clinically significant reductions in systolic blood pressure following improved dietary intake [17]. Avoiding elevated blood pressure is of utmost importance for the health of the pregnancy but to our knowledge, the effect of lifestyle interventions on blood pressure in a pregnant population with chronic hypertension or pre-existing diabetes is unclear.

Pregnancy is often cited as a powerful ‘teachable moment’ where women are motivated to adopt risk-reducing health behaviours [19]. Systematic reviews of interventions designed to exploit this have examined the effect of lifestyle interventions in the general pregnant population [20–22] or those with overweight or obesity [23] rather than those with pre-existing conditions. An individual participant data (IPD) meta-analysis that included 12,526 women from 36 randomised controlled trials (RCT), found diet and physical activity interventions successfully reduced GWG but found no convincing evidence that interventions improve maternal and fetal outcomes. This was also observed in a subgroup analysis of 128 women with existing hypertension or diabetes. However, the focus of the review, and thus the included studies, was not pregnant women with existing conditions. Such women may benefit the most from lifestyle modification. Additionally, the effect of weight changes on blood pressure was not investigated.

This systematic review aimed to collate the evidence around lifestyle interventions during pregnancy for women with chronic hypertension and/or pre-existing diabetes (DM and T2DM), two clinically well-defined, long-term conditions. Identifying the ‘active’ components of interventions that lead to behaviour change is vital to build knowledge, allow for accurate replication of effective interventions and subsequently, implementation into practice [24,25]. Owing to this importance, the behaviour change techniques (BCT) utilised within the included studies were identified.

The review set out to answer the following research questions:

1. What evidence exists around lifestyle interventions in pregnancy for those with chronic hypertension and/or pre-existing diabetes and what behaviour change techniques are utilised in these interventions?
2. What effect do lifestyle interventions in pregnancy have on gestational weight in pregnant women with chronic hypertension and/or pre-existing diabetes?
3. What effect do lifestyle interventions in pregnancy have on blood pressure in pregnant women with chronic hypertension and/or pre-existing diabetes?

2. Methods

The protocol was registered prospectively on PROSPERO (CRD42021244694). PRISMA (Preferred Reporting Items for Systematic Reviews and meta-Analyses) and SWiM (Synthesis Without meta-analysis) guidelines were used for reporting [26,27].

2.1. Literature search

Medline, Embase, Web of Science, CINAHL, and PsycINFO were searched from inception to April 2021. LG devised the search strategy

and conducted the search (April 2021) with support from a specialist librarian (Supplementary Table 1). MeSH terms and keywords with all possible synonyms and spellings were used with Boolean operators. No language or time limits were applied. This was complemented by hand searching the reference lists of similar and recent systematic reviews identified through the databases. The references of IPD meta-analysis were preferentially screened as well as recent, high quality systematic reviews [28]. Grey literature was screened and potentially eligible ongoing studies were followed up throughout the review process to assess for inclusion.

2.2. Study selection

Randomised controlled trials (including cluster RCTs), in any setting, that included pregnant women with chronic hypertension and/or those with a pre-existing diagnosis of diabetes (DM or T2DM) were included [8–10].

When it was not clear if the study included women with CH and/or pre-existing diabetes and the study included more than 200 participants, authors were contacted for clarification. In a sample with less than 200 participants, authors were pragmatically contacted if there was estimated to be, based on information available, at least 10 participants with either of these conditions in the sample.

Lifestyle interventions were included if delivered during the antenatal period and aimed to change behaviour or knowledge about diet, physical activity, gestational weight or a combination of these. Interventions that included self-monitoring or self-management were only included if directly influencing a lifestyle behaviour (as opposed to titration of medication or to inform clinical management). Comparator interventions included routine antenatal care (as described by trialists), minimal intervention or an active comparator, for example, provision of a food diary or a visit from an interventionist that was additional to routine care.

2.3. Outcomes

Studies that reported gestational weight and/or blood pressure change were included. Change was considered as the documented weight and blood pressure measurements closest to booking and closest to delivery as reported by authors. Where available, process outcomes including acceptability, feasibility and behavioural outcomes were collected. Important fetal, maternal and neonatal outcomes, as prioritised by an expert consensus, were collected when available [29]. These included the development of preeclampsia and pregnancy induced hypertension (where applicable), gestation diabetes mellitus (where applicable), preterm delivery and caesarean section, intrauterine death, small or large for gestational age, and admission to neonatal unit.

2.4. Data extraction and quality assessment

Two authors independently screened studies using a decision aid to ensure consistency (LG, RP). Discrepancies were resolved through discussion with the wider review team (NMA, KT, RJM) and reasons for exclusions documented.

Following identification of eligible studies, key study characteristics were collected and intervention characteristics were extracted independently and used the Template for Intervention Description and Replication (TIDieR) framework [30] (LG, RP). The BCT taxonomy was used to code the interventions [31]. Protocols and supplementary materials were consulted when coding BCT to provide more detail (Supplementary Table 2). Coding was completed independently by two reviewers (LG, RP), interpretations were compared to ensure consistency, and this was followed by a discussion with the wider members of the review team (KT, NMA).

Studies were judged independently to be at low, unclear or high-risk of bias using the Cochrane risk of bias assessment tool [32] (LG, RP).

This includes four domains: random sequence generation; allocation concealment; blinding of outcome assessment; and incomplete outcome data. Performance bias was not assessed due to the nature of behavioural interventions.

2.5. Analysis

As we anticipated moderate to high heterogeneity, a random effects meta-analysis for change in mean gestational weight and blood pressure was planned. Due to the high clinical heterogeneity in the data retrieved and the lack of available data for the population of interest for this review, a meta-analysis would have been inappropriate and a narrative synthesis was undertaken [33]. Data is presented in tables, structured according to population characteristics, beginning with those that have more directness in relation to the review question (i.e. included only, or a subgroup for those with chronic hypertension and/or pre-existing diabetes). Vote counting assisted in indicating evidence of intervention effect on weight and blood pressure. Microsoft Excel 2016 supported data synthesis.

Intervention characteristics including BCT and intervention intensity, as defined a priori (Supplementary Table 3), were tabulated and discussed narratively.

3. Results

Following de-duplication, 1464 articles were screened for eligibility, 209 full text articles were screened and subsequently, nine studies were included (Fig. 1). Grey literature and hand searching generated no further studies.

Studies were included where authors confirmed inclusion of pregnant women with chronic hypertension and/or pre-existing diabetes

even if no subgroup data was available. This was a deviation from the protocol in order to incorporate all available evidence of interventions that included the population of interest for the review. This aimed to help build the knowledge base and guide and inform further research in this group. Where authors were not able to clarify the inclusion of participants with chronic hypertension or pre-existing diabetes, the studies were excluded.

3.1. Study and participant characteristics

Included studies randomised a total of 7438 pregnant women with the sample size ranging from 20 to 2212 women (Table 1). Seven were standard RCTs [34–40] and two were cluster RCTs [41,42]. The studies were conducted in Australia, Finland, Brazil, the UK and the USA. One study was international and included nine European countries (Table 1).

Eight studies were mixed pregnant populations that included pregnant women with chronic hypertension and/or pre-existing diabetes [34–38,40–42]. One study included a pregnant population with pre-existing diabetes [39]. All but two studies [38,39] excluded pregnant women with pre-existing diabetes.

3.2. Risk of bias

Eight studies were judged as low risk of bias [34–38,40–42] and one judged as unclear risk [39] because of the limited information provided by authors (Table 2). Authors judgement for each domain is available in Supplementary Table 4.

3.3. Intervention characteristics

Intervention procedures varied including the primary target

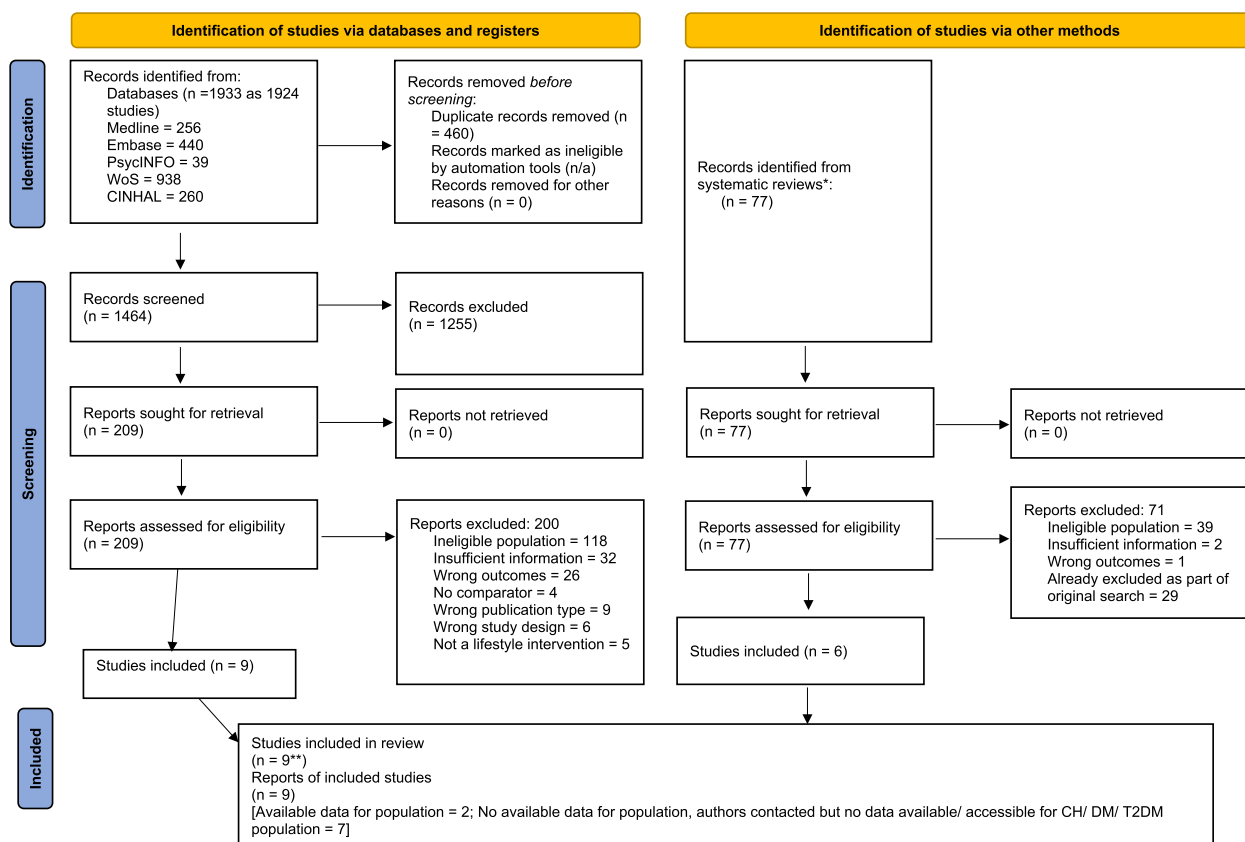


Fig. 1. PRISMA flow diagram of the systematic search and selection of relevant studies. Adapted from: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. *BMJ* 2021;372:n71. doi: 10.1136/bmj.n71. *systematic reviews identified in search, narrowed to IPD, most recent and most recent Cochrane review. **Complete overlap with studies identified via other methods.

Table 1

Overview of randomised controlled trials included in review.

Study (Author, Year)	Country, year, design	Population	Study groups	Primary outcomes	Aim of trial and authors conclusion on weight and blood pressure (for total study population)
Studies that provide data on pregnant women with chronic hypertension and/or pre-existing diabetes					
<i>Simmons et al., (2017) [40]</i>	9 European countries 2012–2015 RCT	436 pregnant women. 41 women with chronic hypertension. Women with pre-existing diabetes excluded.	Healthy eating and/or physical activity (3 intervention arms) Usual care	GWG at 35 to 37 weeks, fasting glucose and HOMA-IR (Homeostatic Model Assessment for Insulin Resistance) at 24 to 28 weeks.	Test the effect of 3 lifestyle interventions in reducing GDM. Gestational weight change – Positive – the intervention (HE + PA) was effective compared to control in limiting GWG. See Table 4 for weight change in participants with chronic hypertension. Systolic and diastolic blood pressure change – Not an outcome.
<i>Ney, 1982 [39]</i>	USA Dates not stated. RCT.	20 pregnant women. 10 women with type 1 diabetes. 10 women with type 2 diabetes. No information on chronic hypertension.	HCF (High carb, high fibre diet) Control diet (Usual care for diabetes management)	Diabetic control.	Compared diets on various quantitative criteria of diabetic control. Gestational weight change - Positive – GWG was significantly lower in intervention arm compared to control. See Table 4 for weight change in participants with existing diabetes. Systolic and diastolic blood pressure change – Not an outcome.
Studies that provide data on the number of participants with chronic hypertension and/or pre-existing diabetes but no outcome data available					
<i>Watter et al., (2019) [36]</i>	UK 2014–2016 RCT	1252 pregnant women. 58 women with chronic hypertension. Women with pre-existing diabetes excluded.	ESTEEM (Effect of Simple, Targeted Diet in Pregnant Women With Metabolic Risk Factors on Pregnancy Outcomes) intervention Usual care	A composite outcome combining gestational diabetes or preeclampsia and a composite outcome combining stillbirth, SGA or admission to neonatal unit.	Assessed whether a Med diet reduces adverse outcomes in high-risk women. Gestational weight change – Positive – women allocated to the intervention gained less gestational weight. Systolic and diastolic blood pressure change – Not an outcome.
<i>Nascimento et al., 2011 [38]</i>	Brazil 2008–2010 RCT	82 women pregnant. ~23 women with pre-existing diabetes (Not exact number (only % given). ~37 women with chronic hypertension (Not exact number (only % given).	Study group Usual care	GWG during the programme and excessive maternal weight gain.	To evaluate the effectiveness and safety of physical exercise on outcomes and quality of life on maternal/perinatal outcomes. Gestational weight change – Positive when stratified by BMI group – overweight women from the study group (n = 9) gained less gestational weight than the control group (n = 5). There was no significant difference in GWG between groups when data was analysed as a whole. Systolic and diastolic blood pressure change – No effect - The intervention did not affect systolic or diastolic arterial blood pressure.
Studies that include women with chronic hypertension but provide no further detail on these participants (pre-existing diabetes excluded from these studies)					
<i>Dodd et al., (2014) [35]</i>	Australia 2008–2011 RCT	2212 pregnant women. Women with chronic hypertension included but no data collected. Women with pre-existing diabetes excluded.	Lifestyle advice Usual care	Incidence of infants born large for gestational age.	To assess whether dietary and lifestyle advice to limit GWG in overweight and obese women improves maternal, fetal and infant outcomes. Gestational weight change – No effect – There was no difference in total GWG between the groups. Systolic and diastolic blood pressure change – Not an outcome.
<i>Dodd et al., (2019) [34]</i>	Australia 2014–2017 RCT	641 pregnant women. Women with chronic hypertension included but no data collected. Women with pre-	Lifestyle advice Usual care	Proportion of infants with birth weight > 4 kg.	To evaluate the effect of dietary and exercise advice among pregnant women of normal BMI, on pregnancy and birth outcomes. Gestational weight change – No effect –

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Table 1 (continued)

Study (Author, Year)	Country, year, design	Population	Study groups	Primary outcomes	Aim of trial and authors conclusion on weight and blood pressure (for total study population)
		existing diabetes excluded.			There were no differences between the groups for total GWG. Systolic and diastolic blood pressure change – Not an outcome.
Hedderston et al., (2018) [41]	USA 2011–2012 Cluster RCT	2014 pregnant women with gestational diabetes. Women with chronic hypertension included but no data collected. Women with pre-existing diabetes excluded.	Tailored letter Usual care for gestational diabetes management	The proportion of women meeting the IOM guidelines for second and third trimester appropriate weekly rate of weight gain from gestational diabetes diagnosis to delivery. <i>To note: this study evaluated one element of a larger trial that involved a postnatal intervention with a primary goal of reducing postpartum weight retention.</i>	To evaluate if a tailored letter improves GWG among women with gestational diabetes. Gestational weight change (note: authors report % meeting IOM guidelines for appropriate weekly rate of GWG) – Positive - The intervention group had a statistically significant 8 % increased likelihood of meeting the IOM guidelines for appropriate weekly rate of GWG. Systolic and diastolic blood pressure change – Not an outcome.
Luoto et al., (2011) [42]	Finland 2007–2009 Cluster RCT	399 pregnant women. Women with chronic hypertension included but no data collected. Women with pre-existing diabetes excluded.	Intervention group Usual care	Proportion of women with gestational diabetes and new-borns birthweight.	To evaluate whether intensive lifestyle counselling could prevent the development of gestational diabetes and large for gestational age. Gestational weight change – No effect – Total GWG did not differ significantly between the groups. Systolic and diastolic blood pressure change – Not an outcome.
McCarthy et al., (2016) [37]	Australia 2011–2012 RCT	382 pregnant women. Women with chronic hypertension included but no data collected. Women with pre-existing diabetes excluded.	Serial self-weighing and simple dietary advice Usual care	A composite of one or more obstetric complication (gestational diabetes, pregnancy induced hypertension, Mode of Delivery other than spontaneous vaginal delivery, postpartum haemorrhage, 3rd/4th degree tear, admission to intensive care unit, high dependency unit stay > 6 h, maternal death).	To determine the effect of the intervention on obstetric outcomes. Gestational weight change – No effect – Mean GWG was not significantly different between groups. Systolic and diastolic blood pressure change – Not an outcome.

Abbreviations: HE, Healthy Eating; PA, Physical Activity; GWG, Gestational Weight Gain; BMI, Body Mass Index; IOM, Institute of Medicine.

Table 2

Risk of bias of included studies.

Risk of bias domain	Number of studies (n = 9)		
	Low risk	Unclear risk	High-risk
Overall risk of bias	8	1	0
Random sequence generation (selection bias)	8	1	0
Allocation concealment from person randomising participants (selection bias)	7	2	0
Blinding of outcome assessment (detection bias)	5	4	0
Incomplete outcome data (attrition bias)	9	0	0
Selective reporting (reporting bias)	9	0	0
Other bias	7	2	0

behaviour or focus of the intervention (i.e. diet, physical activity, weight or a combination of these), delivery method, number, frequency and duration of intervention sessions, delivery personnel, intervention intensity and inclusion or absence of a theoretical underpinning (Table 3).

Comparators were described as usual or standard care that reflected current clinical practice and guidelines but were minimally described by most authors. Generally, comparators either did not include dietary, physical activity, or GWG guidance or only minimal advice. Two studies included usual care for a diabetic population that included monitoring blood sugars and dietary advice.

3.4. Gestational weight change

All studies reported gestational weight change as an outcome. One study presented this as the proportion of women meeting the Institute of Medicine guidelines for weekly rate of GWG [41]. Two studies provided subgroup data on the target population [39,40]. Simmons et al., (2017) found women with chronic hypertension in the intervention groups gained less gestational weight overall than those in the control group [40]. The least weight was gained in the intervention arm that included both the diet and physical activity component (Table 4). Ney et al., (1982) found that the participants (pregnant women with pre-existing diabetes) gained less gestational weight in the dietary intervention group [39] (Table 4).

The remaining studies reported outcomes for the total, i.e. mixed populations, and are summarised as having 'no effect' (i.e. no difference between the groups) or a 'positive' effect (Table 1). Two studies [36,41] reported a positive effect of the intervention on GWG and four studies [34,35,37,42] found no effect of the intervention on attenuation of GWG. Nascimento et al., (2011) found a positive effect for women who were overweight ($n = 9$) when data were stratified by BMI but when data was analysed as a whole, no effect was observed [38].

3.5. Blood pressure change

Nascimento et al., (2011) reported systolic and diastolic blood

Table 3
Intervention characteristics of included studies using TIDIER framework.

Study	Groups	Interventions							Sessions		
	Comparator Intervention	Underlying theory (why)	Content (what)	Provider (including training if provided)	Mode (How)	Location (where)	Duration/ Gestation at recruitment	Intensity	Number/ Frequency	When or at what gestation	Length per session
Studies that provide data on pregnant women with chronic hypertension and/or pre-existing diabetes											
Simmons et al., (2017) [40]	Usual care	N/A	Usual care	Midwife or obstetrician	N/A	Hospital or maternity practice	Recruited < 19 + 6/40	N/A	N/A	N/A	N/A
	Healthy eating (HE)	Patient empowerment	HE - lower carbohydrate, lower fat, and higher protein diet. Focus on portion size to limit calories.	Health coach –training program included observed session.	F2F (individual)		Intervention complete by 35/ 40.	3	5 F2F sessions ≤4 phone calls	Participants preference and availability of coach	30–45 min
	Physical activity (PA)	Cognitive behavioural technique	GWG of 5 kg. Handbook, educational materials and scales provided	Standardisation sessions every 6 months.	Telephone				Mail contacts (no. undefined)		≤20 min
	Healthy eating and physical activity (HE and PA)	Motivational interviewing	PA - aerobic and anaerobic PA promoted. GWG of 5 kg. Materials as per HE plus pedometer/Dyna-bands. HE and PA – above two interventions combined.	Selected on natural ability to be emphatic, background in either behavioural change, HE and/or PA. Training on MI technique	Mail						N/A
65 Ney, 1982 [39]	Control diet (usual care for women with diabetes)	N/A	Encouraged a diet commonly prescribed in pregnancy Caloric intake based on weight gain and activity levels and a GWG of 20- 30lbs. Personal counselling and management according to lab and clinical data.	Usual diabetic team reviewed lab tests and clinical data.	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	High carb, high fibre diet	None described.	As above but nutrition counselling to encourage a daily intake of 60 g-70 g of dietary fibre and 65 % calories from available carbohydrates. Unprocessed wheat bran and/or muffins provided to have 3x a day.	Usual diabetic team reviewed lab tests and clinical data. Interventionist unclear.	F2F (individual) Telephone	Clinical research centre and High-risk obstetric clinic	Mean 16 ± 2.3 weeks	3	Undefined	Weekly Regular phone contact	Undefined
Studies that provide data on the number of participants with chronic hypertension and/or pre-existing diabetes but no outcome data available											
Watter et al., (2019) [36]	Current clinical practice	N/A	Dietary advice as per UK national recommendations for antenatal care and weight management	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Mediterranean- style diet	Social cognitive theory	Supported to follow the diet. Personalised SMART goals. Mixed nuts, extra virgin olive oil provided. Culturally adapted recipes	Trial dietician and trained researchers/ allied health professionals.	F2F (1 individual and 2 group) Telephone	Unclear	From 18 weeks gestation Endpoint unclear.	3	3 F2F 2 phone calls	18/40 20/40 28/40 24/40 32/40	Unclear

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Table 3 (continued)

Study	Groups	Interventions							Sessions		
		Underlying theory (why)	Content (what)	Provider (including training if provided)	Mode (How)	Location (where)	Duration/ Gestation at recruitment	Intensity	Number/ Frequency	When or at what gestation	Length per session
			and grocery list. Group sessions, partners involved. Educational materials.								
Nascimento et al., 2011 [38]	Control group	N/A	Routine prenatal advice (standardised nutritional counselling).	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Study group (Exercise counselling)	None described.	Counselling and education on recommended GWG and PA. Exercise journal and home exercises.	Trained physical therapist.	F2F (individual and group).	Unclear	Mean duration 12.3 weeks	2	Weekly Home exercise 5x/wk	Weekly	40 min classes
Studies that include women with chronic hypertension but provide no further detail on these participants (pre-existing diabetes excluded from these studies)											
Dodd et al., (2014) [35]	Standard care	N/A	State wide perinatal practice (no routine provision of diet, exercise or GWG advice).	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Lifestyle advice	Stage theories of health decision making	Dietary advice consistent with Australian standard, individualised information on meal plans, healthy recipes, simple food substitutions, snacking, eating out, food preparation. Encouraged to increase walking and incidental activity. Workbook to monitor progress.	Trained research assistants and research dietician.	F2F (individual) Telephone	Unclear	Recruited between 10 and 20/40	3	3 F2F 3 phone calls	Initial session within 2 weeks of randomisation 28, 36/40 22, 24, 32/40 phone calls	Unclear
Dodd et al., (2019) [34]	Standard care	N/A	Standard care (no routine provision of advice related to diet, exercise or GWG).	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Lifestyle advice	Stage theories of health decision making	Dietary advice consistent with Australian guidelines emphasising balance, reduce energy dense foods and increase fibre. SMART goals, significant other involved.	Trained research assistants and research dietician	F2F (individual) Telephone	Unclear	Recruited between 10 and 20/40	3	3 F2F 3 phone calls	Initial session shortly after trial entry then at 28, 36/40 20, 24, 32 weeks follow up phone calls.	Unclear
Hedderson et al., (2018) [41]	Usual care for women with GDM	N/A	Health education materials as per usual care. Up to two calls/week to review blood glucose and lifestyle advice. Nurses and dieticians available by phone. No advice on GWG.	Nurse	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Tailored letter			N/A	Postal letter	N/A		1			N/A

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Table 3 (continued)

Study	Groups	Interventions							Sessions		
		Underlying theory (why)	Content (what)	Provider (including training if provided)	Mode (How)	Location (where)	Duration/ Gestation at recruitment	Intensity	Number/ Frequency	When or at what gestation	Length per session
		None described. (To note: this was one element of an intervention, the postnatal component involved counselling and has a theoretical basis)	A tailored letter with 6 messages: weight history, goal GWG specific to BMI, pregnancy weight goal, weight management recommendation, lifestyle tips, risk information on weight gain.				After GDM diagnosis		1 mailed letter	Shortly after GDM diagnosis	
Luoto et al., (2011) [42]	Usual care group	N/A	Usual care (some dietary counselling and follow up of GW but little PA advice).	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Intensive counselling	PRECEDE-PROCEED and Stages of Change	Counselling on BMI-specific GWG to meet and to increase/maintain/adjust leisure time PA. Counselling to achieve a healthy diet based on Finnish guidelines and diabetes prevention research. Discussed barriers, opportunities for change. Notebooks to monitor behaviours objectives. Optional group exercise sessions.	Nurses and physiotherapists.	F2F, messages, telephone	Maternity clinics of primary healthcare centres.	8–12/40 until 37–39/40.	3	5 counselling sessions. Monthly (optional) group sessions	8–12/40 16–18/40 22–24/40 32–34/40 36–37/40	First session = 20–30 min then 10–15 min 2 h group sessions
McCarthy et al., (2016) [37]	Standard care	N/A	Information card with booking BMI and advice on target GWG. No regular weighing.	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Serial self-weighing and simple dietary advice	None described.	Information card with booking BMI and advice on target GWG. Card included weight management advice based on the Australian Guide. Dietary advice given, encouraged serial self-weighing. Stickers on AN notes to encourage discussion about weight with care providers.	Research midwife.	F2F (individual).	Unclear	From 14/40 until delivery.	2	1	Unclear	30 min
Summary		Underlying theory	Focus/content of intervention	Providers	Mode of delivery	Location	Duration	Intensity	–	–	–
		5 with a theoretical basis	GWG only = 0 Diet only = 4 PA only = 0 GWG, diet, PA = 3	Research midwives nurses, research assistants, dieticians, physical therapists,	In-person and remote (calls, messages, mail) = 6	Where provided included: healthcare	Most recruited from 8 to 20/40 and sessions (if > 1) often	Level 1 = 1 Level 2			

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Study	Interventions		Sessions								
	Groups	Underlying theory (why)	Content (what)	Provider (including training if provided)	Mode (How)	Location (where)	Duration/ Gestation at recruitment	Intensity	Number/ Frequency	When or at what gestation	Length per session
	Comparator Intervention										
			GWG, diet = 2 GWG, PA = 2 Diet, PA = 0	trained health coaches	In-person only = 2 Remote only (via a posted letter) = 1	facilities (hospital or midwife clinic) and a clinical research centre.	continued until around term.	= 2 Level 3 = 6			

pressure change, for the total population, from 16 weeks gestation to 40 weeks gestation. No statistical data was extractable or available upon request from authors [38]. Authors stated that the intervention did not affect systolic or diastolic arterial blood pressure. The remaining studies did not collect or report blood pressure data as a primary or secondary outcome.

Eight studies gave sufficient information to code the BCTs in the interventions [34–38,40–42]. The 93 BCT's were collated into 14 domains to present more consolidated results [31]. Studies included between five and eight different behaviour change categories (Supplementary Table 5). The most common techniques, used in all eight of the coded interventions, were 'Goals and Planning', 'Shaping knowledge' and 'Comparison of outcomes' (Fig. 2). 'Feedback and monitoring' was coded in seven interventions. Four domains, 'Reward and threat', 'Regulation', 'Scheduled consequences' and 'Covert learning', were not identified in any of the coded studies.

Simmons et al., (2017) reported data on retention rates and found that 78 women withdrew before the final oral glucose tolerance test of which 21 % had chronic hypertension ($p = 0.02$) [40]. Process outcomes were reported in the remaining eight studies but no detail about the characteristics of women (i.e. whether they had hypertension or diabetes) were described and therefore not reported here.

Whilst all studies targeted changes in diet or physical activity, none of the included studies reported the changes in dietary intake and physical activity levels for women with chronic hypertension and/or pre-existing diabetes.

Watter et al., (2019) reported maternal and fetal outcomes for women with chronic hypertension including pre-eclampsia, gestational diabetes, small for gestational age and admission to neonatal unit (Supplementary Table 6) [36]. No differences between the groups were found. The remaining included studies reported some or all of the pre-specified maternal and fetal outcomes to be collected in the review but data was available only for the total participant population and therefore not reported here.

4.1. Principle findings

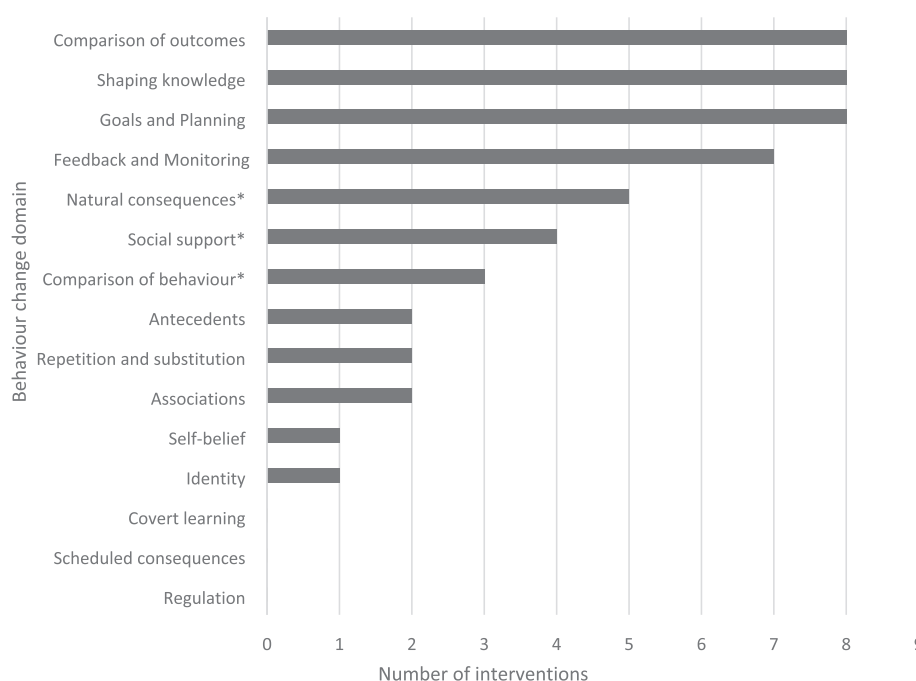
68

Table 4

Gestational weight change for included studies that included analysis of participants with chronic hypertension and/or pre-existing diabetes.

Study ID (Author, year)	No. participants	GWG end points	Control group (kg) Mean \pm SD	Intervention group(s) (kg) Mean \pm SD		
Ney <i>et al.</i> , (1982) [39]	20 participants type 1 or type 2 diabetes.	Maternal weight gain during pregnancy. End points not defined.	Control group (n = 9) 15.9 \pm NR	High carb, high fibre diet (n = 11) 11.8 \pm NR		
Simmons <i>et al.</i> , (2017) [40]	436 randomised in total 41 women randomised with chronic hypertension	Weight at baseline (study entry) and weight between 35 and 37 weeks.	Usual care (n = 9) 11.2 \pm 5.4	Health eating and physical activity intervention (n = 12) 4.9 \pm 3.9	Healthy eating intervention (n = 9) 8.4 \pm 5.0	Physical activity intervention (n = 11) 7.7 \pm 4.7

Abbreviations: NR = Not reported. GWG = Gestational weight gain.

**Fig. 2.** Frequency of use of each behaviour change domain. Note: *Includes one study with the related BCT offered in the optional group session.

4.2. Comparison with literature

Previous reviews have established that interventions that incorporate components of diet and physical activity have a modest effect on GWG in the general pregnant population or those who start pregnancy overweight or with obesity [20,22,23]. A review conducted by the i-WIP collaboration also found few studies included or provided information on those with pre-existing conditions and the interventions were not specifically designed for this population. Perhaps due to their different inclusion criteria to this review or ability to access additional data, the i-WIP group conducted a subgroup analysis on women with pre-existing hypertension and diabetes in an attempt to determine, the currently unknown, intervention effects in this population. One-hundred and twenty-eight women (2.9 % of women in the subgroup analysis) were included in this analysis and no differential intervention effects were found, i.e. those in the intervention group gained less gestational weight than the control. Combining the findings of both reviews, we can confidently say that there is a lack of focus on pregnant women with these pre-existing conditions, who may benefit the most from lifestyle interventions.

The Mediterranean diet is known to reduce blood pressure in high-

risk groups outside of pregnancy [43]. The ESTEEM trial, included in the review, investigated the effect of a Mediterranean style diet [36]. In their sample of pregnant women with metabolic risk factors, authors found mothers in the intervention group gained less gestational weight than the control (MD -1.2 kg, 95 % CI -2.2 to -0.2) and it reduced the odds of gestational diabetes (aOR 0.65, 95 % CI 0.47–0.91). The intervention had no significant effect on preeclampsia or any individual components of the composite offspring outcome. These data were not included in the current review as analysis included the total participant population. As well as the Mediterranean diet, authors are increasingly exploring the effect of other dietary patterns in both low and high-risk pregnant populations on various clinical and metabolic outcomes [44–48]. Studies indicate that diet during pregnancy has a role in promoting cardiovascular health where adherence to certain diets has the potential to improve maternal and offspring outcomes, support gestational weight management, glycaemic control and reduce blood pressure. As there continues to be evidence for the positive effect of specific dietary patterns that modify risk factors and support disease management, the current review now indicates that it is pertinent to test and understand the effect of these on important subgroups where there is potential to delay disease progression.

Understanding and describing key behaviour change techniques used within interventions is an important step in developing future effective interventions. Two existing systematic reviews examined the effectiveness of BCT on GWG [49,50]. There is cross-over with the most frequently identified BCT found in the current review. Although, unlike these reviews, we were unable to determine the effectiveness of the techniques, we further the existing evidence-base by presenting the most frequently utilised techniques that should continue to be tested so that the core active components can be determined and, in turn, ensure the implementation of effective interventions into practice.

5. Strengths and limitations

This is the first systematic review to examine the effect of lifestyle interventions in a high-risk pregnant population who have chronic hypertension and/or pre-existing diabetes. Although studies of mixed populations were included, the focused review has helped identify significant gaps in this area of research. The review offers new insights and a new angle in which researchers should consider in future work in this area.

Robust methods were used including duplicate screening and data extraction with regular discussions on discrepancies to improve reliability. Authors were contacted pragmatically and grey literature and the reference lists of recent and similar systematic reviews were searched. Risk of bias was assessed independently and the majority of studies were classified as low risk of bias therefore any bias present was unlikely to alter the conclusions made.

Insufficient reporting of inclusion and exclusion criteria in many studies created challenges during the review process and required reviewers to make several assumptions based on the available data. Unlike women with pre-existing diabetes, it was not always clear if women with chronic hypertension were included or excluded in the sample despite contacting authors hence assumptions had to be made. Future authors should provide greater clarity in eligibility criteria for this population.

Pregnant women with chronic hypertension and/or pre-existing diabetes were included in the review. Although these populations share similar characteristics, differences exist. However, insights from diabetes research are often translated to hypertensive populations, perhaps because lifestyle modification is important in the management of both and is recommended first line treatment in general practice. This suggests that including populations with pre-existing conditions in one review, and acknowledging the relationship between them, is a reasonable approach and has been noted in other studies [20,51–53]. Furthermore, transparency in our reporting shows clearly the inclusion or exclusion of each of the two populations in each study and data has not been aggregated; reducing misinterpretation of the review findings.

There was insufficient data to perform a random effects meta-analysis and a narrative synthesis was more appropriate to address the review question. Transparency in reporting the findings helped avoid over-interpretation of included studies that had less directness in answering the review question (i.e. being explicit about studies that included mixed pregnant population). This narrative synthesis has provided a useful presentation of the evidence-base; vital in advancing the research field.

5.1. Implications for future research

Authors should attempt to collect and publish baseline data on important pre-pregnancy medical conditions, including hypertension and where they are excluded this should be clear in the eligibility criteria. If women with chronic medical conditions are included, authors should be encouraged to publish the necessary data to perform additional subgroup analysis to support the collation of evidence on these small, but important, groups. Blood pressure is an important and routinely collected clinical parameter. Collecting this data could help in determining how improvements in diet and physical activity levels may

affect blood pressure during pregnancy and into the postnatal period. Development of isolated interventions in pregnancy that consider individual conditions appears limited. Further consideration to conduct primary studies examining the effect of lifestyle interventions in important subgroups, by harnessing the knowledge from non-pregnant high-risk populations, is warranted.

6. Conclusion

The findings of this systematic review have indicated that there is a shortage of primary interventional studies examining the effect of lifestyle interventions in high-risk pregnant populations who enter pregnancy with chronic conditions. Regular exclusion of this important group, or omission of this detail in describing participant characteristics, hinders the ability to understand what is most effective for women who may benefit the most from lifestyle modification to reduce the risk of adverse pregnancy outcomes as well as improve long-term cardiovascular health.

7. Contributors

LG, NMA, KT and RJM contributed to creating the research question and parameters of the review, including the search strategy. LG conducted the search with assistance from a specialist librarian, Nia Roberts. LG and RP reviewed the titles, abstracts and full text of articles identified during screening. Disagreement on reviewed articles were resolved by consensus or discussion with KT, NMA and RJM. Data extraction was completed by LG and RP. Narrative synthesis was conducted by LG and reviewed by NMA, KT and RJM. Drafting the manuscript was led by LG with critical revisions by all authors. LG is the guarantor for this research.

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Declaration of Competing Interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: Richard J. McManus has received BP monitors for research use from Omron and is working with them to develop a telemonitoring system for use in primary care. He receives no personal payment for such work. All other authors declare no competing interests.

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Availability of data

Available upon reasonable request from the corresponding author.

Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.preghy.2022.12.004>.

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