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Extended Research Article

Effects of physical activity and diet in pregnancy to prevent gestational diabetes: an individual participant data (IPD) meta-analysis on the differential effects of interventions with economic evaluation

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This article

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Abstract

Background: Physical inactivity and suboptimal diet in pregnancy are important modifiable risk factors for gestational diabetes, a major contributor to pregnancy complications.

Objectives: We aimed to assess the effects of physical activity and/or diet-based lifestyle interventions during pregnancy on gestational diabetes and if these vary by maternal (body mass index, age, parity, ethnicity, education) and intervention characteristics using individual participant data meta-analysis of randomised trials, and a cost-effectiveness analysis.

Data sources International Weight Management in Pregnancy Collaborative Network database was updated by searching major databases from February 2017 to March 2022.

Review methods: The main outcomes were gestational diabetes by any criteria and by the National Institute for Health and Care Excellence. Other outcomes were gestational diabetes as per International Association of Diabetes in Pregnancy Study Group and maternal and perinatal outcomes. We performed a two-stage random-effects individual participant data meta-analysis to obtain summary estimates (odds ratio) with 95% confidence intervals. Study quality of included trials was assessed, and heterogeneity summarised using τ^2. Where possible, we added the aggregate data from non-individual participant data trials to the meta-analysis. We ranked interventions by effectiveness using network meta-analysis and undertook model-based economic evaluation to assess cost-effectiveness. The cost-effectiveness analysis took an NHS cost perspective compared an overall lifestyle intervention versus usual care with a time horizon covering the beginning of pregnancy until the discharge of the mother and infant from the hospital following delivery.

Results: Ninety-two trials (32,284 women) were included; 54 (23,698 women) provided individual participant data. Lifestyle interventions reduced the odds of gestational diabetes (any criteria) by 10% in individual participant data trials (odds ratio 0.90, 95% confidence interval 0.80 to 1.02, 54 studies, 23,361 women), and the findings reached statistical significance when non-individual participant data were included (odds ratio 0.81, 95% confidence interval 0.73 to 0.89, 92 studies, 31,947 women). Physical activity significantly reduced the odds of gestational diabetes by 36% (odds ratio 0.64; 95% confidence interval 0.48 to 0.84), and diet by 19% (odds ratio 0.81; 0.69 to 0.96), but not mixed interventions. Women with middle (odds ratio 0.68, 95% confidence interval 0.51 to 0.90) and high educational level (odds ratio 0.71, 95% confidence interval 0.54 to 0.93) benefited more than those with low educational status, and no differences by maternal body mass index, age, parity or ethnicity. There was no significant reduction in gestational diabetes defined by National Institute for Health and Care Excellence criteria (odds ratio 0.98, 95% confidence interval 0.84 to 1.13) in individual participant data trials. For gestational diabetes defined using International Association of Diabetes in Pregnancy Study Group criteria, interventions reduced gestational diabetes by 14% (odds ratio 0.86, 95% confidence interval 0.75 to 0.97, $\tau^2 = 0.00$, 16 studies, 6174 women) in individual participant data trials and by 17% (odds ratio 0.83, 95% confidence interval 0.72 to 0.95, $\tau^2 = 0.01$, 25 studies, 7883 women) when non-individual participant data trials were added. Overall, physical activity reduced caesarean section (odds ratio 0.83; 0.72 to 0.96), small-for-gestational age (odds ratio 0.72; 0.56 to 0.92) and large-for-gestational age babies (odds ratio 0.81; 0.71 to 0.94); diet-based interventions reduced any preterm birth (odds ratio 0.37; 0.20 to 0.68) compared to controls. No differences were observed for other outcomes. Lifestyle interventions were on average more expensive and more effective at averted gestational diabetes and major outcome averted compared to usual care.

Limitations: We could not identify the specific intervention components and delivery methods associated with improved outcomes, due to variations in reporting.

Conclusion: Lifestyle interventions in pregnancy prevent gestational diabetes, and the effects vary according to the definition of gestational diabetes. Physical activity-based interventions may be the most effective.

Future work: Lifestyle interventions should be implemented and evaluated in routine clinical practice to prevent gestational diabetes, with additional support for women with low socioeconomic status.

Study registration: This study is registered as PROSPERO CRD42020212884. www.crd.york.ac.uk/PROSPERO/view/CRD42020212884

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Supplementary material can be found on the NIHR Journals Library report page (https://doi.org/10.3310/GJST1327).

Supplementary material has been provided by the authors to support the report and any files provided at submission will have been seen by peer reviewers, but not extensively reviewed. Any supplementary material provided at a later stage in the process may not have been peer reviewed.

The supplementary materials (which include but are not limited to related publications, patient information leaflets and questionnaires) are provided to support and contextualise the publication. Every effort has been made to obtain the necessary permissions for reproduction, to credit original sources appropriately, and to respect copyright requirements. However, despite our diligence, we acknowledge the possibility of unintentional omissions or errors and we welcome notifications of any concerns regarding copyright or permissions.

List of abbreviations

BMI	body mass index
CEA	cost-effectiveness analysis
CEAC	cost-effectiveness acceptability curve
DPP	Diabetes Prevention Programme
DSA	deterministic sensitivity analysis
EVPI	expected value of perfect information
EVPPI	expected value of perfect parameter information
GDM	gestational diabetes mellitus
HCHS	Hospital and Community Health Services
HRG	Healthcare Resource Group
IADPSG	International Association of the Diabetes and Pregnancy Study Groups
ICER	incremental cost-effectiveness ratio
IPD	individual participant data
IUD	intrauterine death
i-WIP	International Weight Management in Pregnancy
LGA	large-for-gestational age
MOA	major outcome averted
NICE	National Institute for Health and Care Excellence
NICU	neonatal intensive care unit
NMA	network meta-analysis
NMB	net monetary benefit
OGTT	oral glucose tolerance test
PPI	patient and public involvement
PSA	probabilistic sensitivity analysis
QALY	quality-adjusted life-year
REML	restricted maximum likelihood
SGA	small-for-gestational age
TIDieR	Template for Intervention Description and Replication
WTP	willingness to pay

Plain language summary

During pregnancy, not eating well, not moving enough, and being overweight can lead to a condition called 'gestational diabetes'. It is when mothers have high sugar levels for the first time. This can cause problems for both the mother and the baby during pregnancy and later in life. Being more active and eating healthily could lower the chances of mothers developing 'gestational diabetes'.

However, these changes might help some mothers more than others. It could depend on things like how much they weigh, their age, how many babies they have had before, their ethnicity, and education level.

We wanted to see if improving physical activity and diet – 'lifestyle interventions' – could prevent gestational diabetes, and whether all mothers benefit.

We looked at individual information from almost 24,000 women in different studies from all over the world, that recruited a total of about 32,000 women. Some studies looked at changes in physical activity, some at diet changes and some at both. When we put all this information together, we found that lifestyle interventions could reduce the odds of gestational diabetes by about 10% when considering only studies that shared their data, although some women could see a slight 2% increase in risk. Including information from studies that did not share data, showed greater benefit, reducing the odds by about a fifth.

Lifestyle interventions seemed to work better in mothers who were more educated, so support is needed to make them work for everyone. Physical activity seemed to be the most effective intervention, and reduced caesarean births, having babies who were either too small or too big for their age, and the need for special care after birth. Eating better also lowered the risk of having a baby too early. Although lifestyle intervention was more expensive to the NHS, it lowered the chances of gestational diabetes.

Scientific summary

Background

Gestational diabetes mellitus (GDM) is associated with adverse outcomes for both mothers and babies, and drives rising healthcare costs. Behaviour change interventions such as physical activity and diet could prevent GDM. Any variation in the effect across subgroups of women has implications for clinical management and care provision. Despite many trials and aggregate meta-analyses on the effects of lifestyle interventions, the findings were limited due to varied reporting of aggregate data. To address these limitations, we conducted an individual participant data (IPD) meta-analysis of randomised trials to assess the overall and differential effects of lifestyle interventions (physical activity-based, diet-based, mixed) in preventing GDM and its complications, ranked them by effectiveness, and assessed their cost-effectiveness.

Objectives

Primary

1. To evaluate the effects of lifestyle interventions in pregnancy, across all interventions, and for each type of intervention (physical activity-based, diet-based, and mixed) on gestational diabetes as defined by (1) any criteria and by (2) the National Institute for Health and Care Excellence (NICE).
2. To assess if the effects of lifestyle interventions on GDM vary by maternal characteristics [body mass index (BMI) at booking, age, parity, ethnicity and socioeconomic status].

Secondary

3. To assess the effects of the interventions on GDM as defined by (1) International Association of Diabetes and Pregnancy Study Group (IADPSG) and (2) modified IADPSG criteria, and on fasting and 2-hour post-prandial glucose levels.
4. To evaluate the effects of the interventions on critically important maternal (hypertensive diseases, caesarean section, or preterm birth) and offspring outcomes (stillbirth, large-for-gestational age or admission to the neonatal unit) in (1) all pregnant women in the trials, and in (2) women with GDM in the trials.
5. To categorise interventions by core components and rank their effectiveness using network meta-analysis.
6. To determine the cost-effectiveness of interventions using decision–analytical modelling.

Methods

We undertook IPD meta-analysis using a prospective protocol in line with existing recommendations and used the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines for IPD meta-analysis in reporting our work. The International Weight Management in Pregnancy Collaborative (i-WIP) Network has the largest database of IPD from randomised trials on physical activity and diet in pregnancy identified through a systematic literature search. We updated our current search on MEDLINE, EMBASE, Bioscience Information Service, Latin American and Caribbean Health Sciences Literature, PASCAL, Science Citation Index, Cochrane Database of Systematic Reviews, Cochrane Central Register of Controlled Trials, Database of Abstracts of Reviews of Effects and Health Technology Assessment Database to identify relevant trials up to March 2022 without language restrictions. Randomised trials that assessed the effects of diet, physical activity or a mixed-approach intervention in pregnancy were included. Mixed approach provided overall guidance on both physical activity and diet-based interventions, with varying levels of intensity and structure. Trials including women with GDM at baseline were excluded. Primary researchers were invited to join the i-WIP Network and share their IPD. The primary outcomes were GDM as defined by any established criteria and by NICE.

We performed a two-stage random-effects IPD meta-analysis for all interventions analysed together, and by each intervention type (physical activity-based, diet-based, and mixed approach) to obtain summary intervention effects on GDM using odds ratios (ORs) with 95% confidence intervals (CIs) and summary treatment–covariate interactions. We summarised heterogeneity using τ^2 and 95% prediction intervals (PIs). Quality assessment of each trial was assessed using the Cochrane Risk of Bias tool. Publication and availability bias were also assessed by examining small study effects. We categorise interventions by core components and ranked their effectiveness using network meta-analysis, and quantified the differences in fasting and 2-hour post-prandial glucose levels between the groups. A model-based economic analysis was done to assess the cost-effectiveness of the interventions to prevent GDM and its complications compared with usual care.

Results

Of the 92 eligible studies (32,284 women), 54 trials (23,698 women) contributed data to the IPD meta-analysis.

Effects of interventions on gestational diabetes (any criteria)

Overall lifestyle interventions compared to usual care, reduced the odds of GDM by 10% on average (OR 0.90, 95 CI 0.80 to 1.02, τ^2 = 0.04, 54 studies, 23,361 women) in IPD trials, and by 19% (OR 0.81, 95% CI 0.73 to 0.89, τ^2 = 0.07, 92 studies, 31,947 women) when all available aggregate data (38 studies, 8586 women) from studies that did not share IPD were added.

Physical activity-based interventions were associated with a 36% lower odds of GDM (OR 0.64, 95% CI 0.48 to 0.84, τ^2 = 0.04, 18 studies, 4435 women), and diet-based interventions showed a 19% reduction (OR 0.81; 0.69 to 0.96, τ^2 = 0.00, 8 studies, 2974 women) in odds of GDM compared to the control group. There was no reduction in the odds of GDM for studies with mixed interventions (OR 1.05, 95% CI 0.91 to 1.21, τ^2 = 0.02, 28 studies, 15,952 women). When aggregate data from studies that did not share IPD were added to the IPD meta-analyses for each intervention type, the results remained statistically significant for both physical activity (OR 0.63, 95% CI 0.53 to 0.75, τ^2 = 0.02, 33 studies, 8347 women) and diet-based interventions (OR 0.77, 95% CI 0.60 to 0.98, τ^2 = 0.00, 11 studies, 3384 women). We did not find a statistically significant reduction in the odds of GDM for mixed interventions (OR 0.92, 95% CI 0.82 to 1.04, τ^2 = 0.05, 48 studies, 20,216 women).

When the analysis was limited to IPD studies at low risk of, we observed a non-significant reduction with overall lifestyle interventions (OR 0.94, 95% CI 0.82 to 1.08, τ^2 = 0.03, 33 studies, 15,547 women). The findings were statistically significant for physical activity-based interventions (OR 0.59, 95% CI 0.43 to 0.82, τ^2 = 0.00, 11 studies, 2993 women), but not for diet-based (OR 0.89, 95% CI 0.69 to 1.16, τ^2 = 0.00, 5 studies, 1930 women) or mixed interventions (OR 1.14, 95% CI 1.01 to 1.29, τ^2 = 0.00, 17 studies, 10,624 women).

Effects of interventions on gestational diabetes (National Institute for Health and Care Excellence criteria)

When using NICE criteria, lifestyle interventions showed reduced odds of GDM by 2% which was not statistically significant (OR 0.98, 95% CI 0.84 to 1.13, τ^2 = 0.02, 22 studies, 11,990 women). Physical activity (OR 0.65, 95% CI 0.18 to 2.31, τ^2 = 0.60, 5 studies, 977 women) and diet-based interventions (OR 0.71, 95% CI 0.33 to 1.49, τ^2 = 0.00, 3 studies, 1812 women) showed similar non-significant reductions in the odds of GDM. There were no significant differences observed for mixed interventions compared to control (OR 1.10, 95% CI 0.98 to 1.23, τ^2 = 0.00, 14 studies, 9367 women).

Differential effects of interventions by maternal characteristics

Across the potential effect modifiers examined, we found a statistically significant interaction effect of lifestyle interventions on GDM (defined using any criteria) for mothers' educational status. When compared with mothers with low educational status, we found a 32% (OR 0.68, 95% CI 0.51 to 0.90, τ^2 = 0.00) and a 29% (OR 0.71, 95% CI 0.54 to 0.93, τ^2 = 0.00) reduction in the odds of GDM with overall lifestyle interventions in mothers with middle and high education levels, respectively. This differential effect in the observed benefit persisted in the 95% PIs. There was no interaction effect per unit increase in age or BMI (OR 1, 95% CI 0.98 to 1.02). When defined by NICE criteria, there

were no statistically significant intervention–covariate interaction effects on GDM for any of the potential effect modifiers examined.

Effect of interventions on gestational diabetes (International Association of Diabetes and Pregnancy Study Group and modified International Association of Diabetes and Pregnancy Study Group)

When defined by IADPSG criteria, lifestyle interventions were associated with a 14% reduction in the odds of GDM (OR 0.86, 95% CI 0.75 to 0.97, $\tau^2 = 0.00$, 16 studies, 6174 women) compared to control, when GDM was defined by IADPSG criteria. Including aggregate data from the 9 eligible trials (1709 women) that did not share IPD to the meta-analysis (total of 25 trials, 7883 women) showed a 17% reduction (OR 0.83, 95% CI 0.72 to 0.95, $\tau^2 = 0.14$, 25 studies, 7883 women) in the odds of GDM.

No significant reduction in GDM defined by IADPSG was observed in the meta-analysis of IPD trials for any individual intervention. Significant reductions were observed for mixed interventions when aggregate data were included (OR 0.85, 95% CI 0.74 to 0.99, 15 studies, 5754 women).

We did not observe a significant reduction in the odds of GDM when defined by modified IADPSG criteria across all interventions overall (OR 0.92, 95% CI 0.78 to 1.10, $\tau^2 = 0.07$, 24 studies, 13,186), or for physical activity-based (OR 0.88, 95% CI 0.70 to 1.09, $\tau^2 = 0.00$, 7 studies, 1940 women), diet-based (OR 0.64, 95% CI 0.32 to 1.30, $\tau^2 = 0.00$, 3 studies, 1891 women), or mixed interventions (OR 1.08 95% CI 0.89 to 1.31, $\tau^2 = 0.04$, 14 studies, 9355 women).

Effect of the intervention on fasting and 2-hour post-prandial glucose levels

There were non-statistically significant reductions of fasting glucose levels with overall lifestyle interventions at < 24 weeks gestation [mean difference (MD) −0.005, 95% CI −0. 04 to 0.03, $\tau^2 = 0.00$, 26 studies, 16,622 women], 24–30 weeks' gestation (MD −0.01, 95% CI −0.05 to 0.02, $\tau^2 = 0.00$, 16 studies, 8225 women), and at > 30 weeks' gestation (MD −0.01, 95% CI −0.05 to 0.03, $\tau^2 = 0.00$, 8 studies, 4437 women) compared to control. The 2-hour post-prandial glucose level was significantly reduced with overall lifestyle interventions at 24–30 weeks gestation (MD −0.07, 95% CI −0.12 to −0.01, $\tau^2 = 0.00$, 18 studies, 8749 women) compared to control, but not at < 24 weeks (MD −0.01, 95% CI −0.08 to 0.06, $\tau^2 = 0.01$, 26 studies, 17,558 women) or > 30 weeks' gestation (MD −0.03, 95% CI −0.22 to 0.16, $\tau^2 = 0.01$, 7 studies, 4282 women).

Effects of the intervention on pregnancy outcomes

Across all women, there were no significant differences with overall lifestyle interventions compared to control in the odds of preterm delivery caesarean section, stillbirth, small-for-gestational age and large-for-gestational age babies. Among the intervention types, physical activity reduced caesarean section (OR 0.83, 0.72 to 0.96, $\tau^2 = 0.00$, 17 studies, 4527 women), small-for-gestational age (OR 0.72, 0.56 to 0.92, $\tau^2 = 0.00$, 17 studies, 4594 women) and large-for gestational age babies (OR 0.81, 0.71 to 0.94, $\tau^2 = 0.00$, 17 studies, 4594 women) in all pregnant women; no differences were observed for other outcomes. Diet-based interventions reduced the odds of preterm birth (OR 0.37, 0.20 to 0.68, $\tau^2 = 0.0$, 6 studies, 1464 women) compared to controls, and no reductions were observed for other outcomes. There were no differences observed for any outcome for mixed interventions.

In women who received lifestyle interventions in pregnancy and went on to develop GDM as defined by any criteria, there were no significant differences in the odds of hypertensive disease, small-for-gestational age and large-for-gestational age babies compared to controls who developed GDM. There was an increase in the odds of hypertensive disease (OR 1.78, 95% CI 1.25 to 2.51, $\tau^2 = 0.00$, 13 studies, 276 women), preterm birth (OR 2.28, 95% CI 1.24 to 4.22, $\tau^2 = 0.00$, 11 studies, 251 women) and small-for-gestational age fetus (OR 1.60, 95% CI 1.15 to 2.22, $\tau^2 = 0.00$, 13 studies, 274 women) with physical activity-based interventions. Diet-based interventions reduced the odds of large-for-gestational age fetus (OR 0.25, 95% CI 0.13 to 0.48, $\tau^2 = 0.00$, 6 studies, 241 women) and preterm birth (OR 0.36 95% CI 0.18 to 0.74, $\tau^2 = 0.00$, 6 studies, 246 women) compared to controls who developed GDM.

Effects by intervention core components and network meta-analysis

For GDM defined by any criteria, our subgroup analysis by TIDieR components found a significant difference based on structure and prior training with overall lifestyle interventions. Delivery of lifestyle intervention in group format (OR 0.81, 95% CI 0.68 to 0.97; $p = 0.048$) was associated with a greater reduction in the odds of GDM compared with

individual delivery format (OR 1.02, 95% CI 0.89 to 1.17). There was a greater reduction in the odds of GDM when no prior intervention-specific training was given to providers (OR 0.82, 95% CI 0.69 to 0.96; p = 0.031), compared to when training is given (OR 1.04, 95% CI 0.90 to 1.20). There were no significant differences in GDM by intervention core component subgroups for physical activity-based, diet-based or mixed interventions alone in the IPD.

The network meta-analysis showed that physical activity had the highest probability (89%) of being the most effective intervention (mean rank 1.1, 95% CI 1 to 2) in preventing GDM defined by any criteria. Indirect intervention effects from the network meta-analysis showed that only the physical activity versus mixed-approach comparison was statistically significant, with a reduction in the odds of GDM by 39% on average (OR 0.61, 95% CI 0.46 to 0.83) with physical activity-based interventions compared to mixed interventions.

Cost-effectiveness of physical activity and/or diet-based interventions

Overall lifestyle intervention costed £223 more on average than control in the base-case analysis (£5768 vs. £5545), and the difference in the mean effect of avoiding GDM was 0.0072 (95% CI 0.0071 to 0.0073), indicating that the intervention led to a 0.7% decrease in the number of women who developed GDM compared to control. The incremental cost-effectiveness ratio of avoiding a case of GDM was £31,084. Physical activity or diet-based interventions alone led to a cost difference of £41.70 (95% CI: £40.53 to £42.87) and £16.94 (95% CI: £15.62 to £18.26), respectively, and a 2.9% and 2.8% decrease in the number of GDM cases in the intervention group compared to the control group. The intervention was more cost-effective in women with an obese BMI (1.1%) compared to those with a BMI in the normal (0.7%) or overweight (0.1%) ranges.

Conclusion

Lifestyle interventions reduce the risk of GDM defined by any criteria and IADPSG criteria, but not NICE criteria. The benefits appear to be greater in women with middle and high education level than lower level. Among the intervention types, physical activity appears to be the most effective in preventing GDM. Individual interventions may have some benefits in preventing pregnancy complications like caesarean section, small-for-gestational age, large-for gestational age babies and preterm birth. Overall lifestyle intervention in pregnancy was more cost-effective in women with obesity.

Recommendations for future research

Further exploration of systemic, behavioural and social factors is needed to implement the intervention. The impact of interventions in pregnancy on long-term offspring and maternal (e.g. type 2 diabetes and cardiovascular diseases) outcomes needs evaluation.

Study registration

This study is registered as PROSPERO CRD42020212884. www.crd.york.ac.uk/PROSPERO/view/CRD42020212884

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Chapter 1 Background

Gestational diabetes mellitus (GDM), defined as glucose intolerance first diagnosed in pregnancy, is one of the commonest complications in pregnancy.[1,2] In the UK, at least 40,000 women are diagnosed with GDM every year.[2] Sedentary behaviour, poor diet and obesity contribute to the increasing rates of GDM, affecting between 7% and 38% of pregnancies globally.[3] Women with GDM and their babies are susceptible to complications both in the short and long term. During pregnancy, women diagnosed with GDM are at an increased risk of pre-eclampsia, traumatic vaginal birth, caesarean section, major postpartum haemorrhage and preterm birth.[4] The risks for the babies include stillbirth, birth injury, congenital anomalies, shoulder dystocia, large for gestational age (LGA), hyperbilirubinaemia and admission to neonatal intensive care.[5] In the long term, women with a history of GDM have a 10-fold higher risk of cardiovascular disease, impairment in their carbohydrate metabolism post partum and type 2 diabetes mellitus in the first 5–10 years after birth.[6,7] The infants of women with GDM have a high likelihood of type 2 diabetes and obesity in later life, potentially affecting their life expectancy.[8,9]

In addition to adverse maternal and perinatal outcomes associated with GDM, the maternal healthcare cost of women with GDM is set to increase by 34–95% compared with women without GDM.[10,11] The NHS spend on type 2 diabetes is expected to increase from £8.8B to more than £13B annually in the next 25 years – with GDM remaining one of the major contributory factors.[12] This highlights the need to implement effective and safe interventions to prevent GDM and its complications, to reduce the financial burden on the NHS.

Despite publication of over 70 randomised trials on the effectiveness of physical activity and diet-based interventions on GDM, the following limitations have hindered the implementation of such interventions into clinical practice recommendations, guidelines and policy documents.[13,14] Firstly, aggregate data meta-analysis of studies showing the beneficial effect of behaviour change interventions on GDM has varied in the population, intervention and outcome definitions of included studies.[15] Aggregate data analysis is also limited by its inability to explain the heterogeneity of the effects of these interventions on important maternal and fetal outcomes. Secondly, we do not know if the beneficial effects of diet and physical activity apply to all pregnant women or to only a subgroup of women with risk factors such as high body mass index (BMI), high maternal age, ethnic minority origin and low socioeconomic status, because the participant-level information and subgroup effects (treatment–covariate interactions) are not reported in sufficient detail in published trials. Lastly, the lack of published detail on the type, intensity and setting of effective interventions and the cost-effectiveness of the interventions prevents the implementation of behaviour change interventions in a scalable way.

We have previously established the International Weight Management in Pregnancy (i-WIP) Collaborative Group, which hosts the largest living global database on physical activity and diet-based interventions in pregnancy, with access to cleaned, formatted and standardised data from 36 trials.[13] To address these limitations, we undertook an individual participant data (IPD) meta-analysis of randomised trials, to assess the effects of lifestyle interventions (physical activity-based, diet-based, mixed) on GDM, and assess if the overall effects varied according to maternal characteristics, including age, BMI, parity, ethnicity and socioeconomic status using educational attainment. We also assessed the effect of these interventions on maternal and offspring outcomes in all pregnant women and in those with GDM, and evaluated the cost-effectiveness of the interventions.

Chapter 2 Objectives

Primary

1. To evaluate the effects of lifestyle interventions in pregnancy, across all interventions, and for each type of intervention (physical activity-based, diet-based and mixed) on GDM as defined by any criteria and by the National Institute for Health and Care Excellence (NICE).[16]
2. To assess if the effects of lifestyle interventions on GDM vary by maternal characteristics (BMI at booking, age, parity, ethnicity and socioeconomic status).

Secondary

3. To assess the effects of the interventions on GDM as defined by (1) International Association of Diabetes and Pregnancy Study Group (IADPSG)[17] and (2) modified IADPSG criteria,[18,19] and (3) on fasting and 2-hour post-prandial glucose levels.
4. To evaluate the effects of the interventions on critically important maternal (hypertensive diseases, caesarean section, or preterm birth) and offspring outcomes [stillbirth, LGA or admission to the neonatal intensive care unit (NICU)] in (1) all pregnant women in the trials and in (2) women with GDM.
5. To categorise interventions by core components and rank their effectiveness using network meta-analysis (NMA).
6. To determine the cost-effectiveness of interventions using decision–analytical modelling.

Chapter 3 Methods

Our IPD meta-analysis was performed using a prospective protocol registered with PROSPERO (CRD42020212884),[20] and reported in line with recommendations of the Preferred Reporting Items for Systematic Reviews and Meta-Analyses of IPD guidelines.[21]

Establishment and consolidation of the International Weight Management in Pregnancy network and database

The i-WIP Collaborative group, established in 2013, brings together researchers of primary trials on physical activity and diet in pregnancy who shared IPD from their trials towards the collaborative group database. The i-WIP database is the largest living global database on physical activity-based and diet-based interventions in pregnancy.[20] Relevant trials were identified by a systematic review, and methods on how authors were contacted, data shared, quality checked, recoded and harmonised have previously been reported.[13]

Updating the search

We updated our previous literature search using our existing search strategy to identify new trials published since completion of our previous review.[22] We searched MEDLINE, EMBASE, Bioscience Information Service, Latin American and Caribbean Health Sciences Literature, PASCAL, Science Citation Index, Cochrane Database of Systematic Reviews, Cochrane Central Register of Controlled Trials, Database of Abstracts of Reviews of Effects and Health Technology Assessment Database without language restrictions up to January 2024.

Study selection

We carried out a two-stage study selection process. The abstracts of all citations were evaluated for their eligibility in the first stage. We then studied the identified studies in detail before their inclusion. Two independent reviewers (DC and AB) performed the study selection process by appraising all studies. In case of a disagreement, the opinion of a third reviewer (JA) was obtained.

We included lifestyle intervention trials with random allocation (individual or cluster) on physical activity-based, diet-based and mixed-approach interventions in pregnancy compared to standard antenatal care. We excluded trials which included women at baseline with GDM or evaluated weight loss interventions such as surgery or pharmacotherapy. We excluded pregnant women who had a known diagnosis of GDM at baseline, and only included pregnant women with a BMI of $\geq 18.5\,kg/m^2$ in early pregnancy to exclude those who were underweight. We evaluated three main interventions for GDM prevention: (1) physical activity-based interventions that involved moderate exercise such as dance-based exercise programmes, water-based physical activity, stationary cycling, light-intensity resistance training or enhanced routine daily activity, including walking; (2) diet-based interventions that included different types of diets such as Mediterranean-style diets, low-calorie diets and low glycaemic index diets offered by clinicians, dietitians, physiotherapists, or commercial companies in primary and secondary care settings; and (3) the mixed approach that provided overall guidance on both physical activity and diet-based interventions, with varying levels of intensity and structure.

Data collection process

The authors of relevant studies were invited to join the i-WIP network and share their primary IPD in any format, along with data dictionaries or descriptions. In case of no response, three reminders were sent to each author. For studies that did not provide IPD and for those with which contact was not made, we extracted the published aggregate data. The anonymised IPD was deposited in a custom-built database, formatted, cleaned and harmonised. The final meta-data

set was securely transferred to the World Health Organization Collaborating Centre for Global Women's Health at the University of Birmingham for final data checks and analysis.

Outcome measures

The primary outcomes were GDM as defined by any criteria and by NICE.[16] The secondary outcomes were other definitions of GDM (IADPSG[17] and modified IADPSG[18,19]), maternal and offspring complications such as pregnancy-induced hypertension, pre-eclampsia, preterm birth, caesarean section and need for pharmacological therapy for hyperglycaemia, shoulder dystocia, respiratory distress syndrome, neonatal hypoglycaemia, stillbirth, neonatal death, perinatal death, Apgar score at 1 and 5 minutes, birthweight, gestational age at birth, small-for-gestational age (SGA)/LGA and admission to the NICU. Studies that assessed both GDM and pregnancy outcomes were included in the analysis of secondary outcomes. Components of the structured question are presented in *Table 1*.

Intervention characteristics of physical activity and/or diet-based interventions

We used the Template for Intervention Description and Replication (TIDieR) framework[23] to map and categorise the core components of physical activity and/or diet-based interventions associated with GDM prevention.[24] We extracted data on characteristics of the intervention such as whether the intervention was theory-based, resources provided to the intervention group, who facilitators of the intervention were (e.g. allied health professionals, medical staff, or researcher) and whether training was provided; the mode (e.g. face-to-face, or remote), structure (e.g. individually or in a group), and setting of delivery (hospital/antenatal clinic, or exercise centre); the number [low (1–5 sessions), moderate (6–10 sessions), or high (≥ 11 sessions)] and duration of intervention [low (0–12 weeks), moderate (13–24 weeks), or high (≥ 25 weeks)]; and the gestational age at the start of intervention (< 20 weeks or ≥ 20 weeks).

TABLE 1 Structured research question for IPD meta-analysis of physical activity and/or diet-based interventions to prevent GDM

Question components	Description
Population	Pregnant women with a BMI of ≥ 18.5 kg/m^2 in early pregnancy.
Interventions	Physical activity-based.
	Diet-based.
	Mixed-approach: complex interventions on diet and physical activity with a behavioural change component.
Comparison	No intervention or routine antenatal care.
Outcomes	Primary outcomes.
	Gestational diabetes as defined within the study by the study authors
	Gestational diabetes defined as per NICE 2015 criteria (fasting glucose 5.6 mmol/l or above, and 2-hour glucose 7.8 mmol/l or above after a 75 g oral glucose tolerance test).[16]
	Secondary outcomes
	Gestational diabetes as defined specifically using IADPSG[17] and the modified IADPSG criteria.[18,19]
	Maternal: hypertensive diseases including pre-eclampsia or pregnancy-induced hypertension, caesarean section, preterm birth and need for pharmacological therapy for hyperglycaemia.
	Offspring: shoulder dystocia, respiratory distress syndrome, neonatal hypoglycaemia, stillbirth, neonatal death, perinatal death, Apgar score at 1 and 5 minutes, birthweight, gestational age at birth, SGA/LGA and admission to the neonatal unit.
	Cost-effectiveness of interventions using decision–analytical modelling.
Study design of included studies	Randomised controlled trials (RCTs).

Risk-of-bias assessment in individual studies

We used the Cochrane risk of bias tool 2 to assess the risk of bias in individual studies by considering six domains: sequence generation, allocation concealment, blinding, incomplete outcome data, selective outcome reporting and other potential sources of bias.[25] A study was classified overall as having a high risk of bias if it was assessed as high risk in any one of the following domains: randomisation, allocation concealment, blinding of outcome assessment and incomplete outcome data. In trials that shared IPD, assessment for selection bias was informed by assessing baseline imbalances of key prognostic factor between the groups, and completeness of outcome data for each woman in the trial informed attrition bias assessment.

Sample size considerations

Although no formal sample size requirements are necessary for the meta-analysis, we considered the potential power of our IPD meta-analysis compared to single trials in this field to detect clinically important effects in each subgroup separately (i.e. interaction effect). Evidence suggests that the sample size required to detect an interaction with the same size as the overall treatment should be about four times the size of a single trial.[26] Assuming an interaction between covariate and treatment effect that corresponds to an odds ratio (OR) of 0.70, with 20,000 women,[20] we will have more than 90% power to detect an interaction for the covariates of interest (ethnicity, parity and socioeconomic status).

Data analysis

All analyses were carried out using Stata MP Version 18.0 (StataCorp LP, College Station, TX, USA).

Overall effect and subtypes of intervention

For each definition of GDM (by any criteria, NICE, IADPSG and IADPSG modified), and each intervention type (all interventions, physical activity-based, diet-based and mixed approach), we separately performed a two-stage IPD meta-analysis to obtain summary estimates and 95% confidence intervals (CIs) for the intervention effects (ORs) and the intervention effects modifiers (statistical interactions) of interest. All participants were analysed according to the group they were randomised to. We used a two-stage random-effects meta-analysis approach, which allows for between-study heterogeneity in intervention effect (and interaction effect). In any two-stage meta-analysis, the clustering of participants within trials is accounted for by analysing each trial separately in the first stage before pooling in the second stage.

First stage of individual participant data meta-analysis

All analyses were performed on complete cases for whom the outcome and relevant baseline adjustment covariates were measured and were adjusted for age and BMI where available. For the primary outcomes of GDM defined by any criteria and by NICE, logistic regression models were fit in each trial separately with intervention included as a covariate. For cluster trials, we included a random effect for the unit of randomisation to account for clustering. All primary analyses assessed both the combined intervention effect and type of intervention (physical activity, diet and mixed interventions).

Second stage of individual participant data meta-analysis

We pooled intervention and interaction effect estimates from each trial using a random-effects meta-analysis model [fitted using restricted maximum likelihood (REML)] to produce a summary effect estimate for the average effect across trials. A random-effects model was prespecified to allow for anticipated between-study heterogeneity. CIs for the summary effect were inflated using the Hartung–Knapp correction to account for uncertainty in variance estimates. Heterogeneity was summarised using the estimated between-study variance (τ^2), and its associated 95% CI. To assess the impact of heterogeneity further, we also calculated approximate 95% prediction intervals (PIs) for the intervention (or interaction) effect in a new study similar to one of those included in the meta-analysis.[27] Forest plots were generated to display the study-specific and pooled results.

Differential effect by subgroups (treatment–covariate interactions)

When examining whether the interventions had varying effects based on a woman's age, BMI, parity, ethnicity and socioeconomic status, we extended the models to include and summarise treatment–covariate interaction terms. Intervention effect modifiers were assessed for the combined intervention effect only. A two-stage approach was used as before, with coefficients calculated within studies in the first stage and then synthesised in the second stage. Continuous covariates of interest were analysed on their continuous scale and at prespecified clinically defined categorical values. We adjusted for the prognostic effects of the covariate in addition to age and BMI (as above), and effects were presented within the subgroups defined by the interactions.

Examining potential sources of bias

For each analysis containing 10 or more studies, small study effects were investigated through the construction of contour-enhanced funnel plots which were assessed visually for asymmetry, that is the tendency for smaller studies to provide more positive findings than large ones. For all studies in which IPD were not available, we extracted aggregate data from the publication and, when possible, incorporated these into the second stage of the two-step meta-analysis framework, to combine the IPD trials with the aggregate data from other trials for the outcome of gestational diabetes.[28] This allowed us to examine whether or not conclusions (on summary results) were changed by including additional non-IPD trials.

Sensitivity analysis

We investigated sources of bias by performing sensitivity analyses to exclude IPD from studies at high risk of bias as assessed by the Cochrane risk of bias tool 2 to assess the robustness of the meta-analysis results to study quality. Sensitivity analyses based on risk of bias were restricted to only those studies providing IPD, and to the primary analyses of intervention effect on GDM defined by any criteria and by NICE.

Secondary analyses

Intervention effects on alternative definitions of gestational diabetes

We investigated the effects of combined and individual lifestyle interventions on GDM as defined by (1) IADPSG and (2) modified IADPSG criteria. We performed a two-stage IPD meta-analysis as described above for the primary analyses to obtain summary estimates and 95% CIs for the intervention effects (OR). All analyses adjusted for baseline age and BMI as before. We did not consider intervention effect modifiers for these secondary definitions of GDM. We used the two-stage random-effects meta-analysis approach for synthesis as previously described.

Intervention effects on continuous fasting and 2-hour post-prandial glucose levels

As glucose levels are a continuous variable, we fit linear regression models within each study separately allowing for both timing of glucose measurement and gestational age at testing. As before, cluster trials were analysed allowing for clustering effect. All analyses adjusted for baseline age and BMI. In the second stage of the approach, we synthesised effect estimates using a random-effects meta-analysis model as before to estimate a pooled mean difference (MD) in glucose levels. Analysis was restricted to only those studies providing IPD.

Intervention effects on maternal and offspring outcomes

We evaluated whether intervention impacted maternal and offspring complications in all pregnant women, and in women with GDM defined by any criteria. All analyses were adjusted for baseline age and BMI. For each outcome separately, we fit a logistic regression model in the first stage and a random-effects meta-analysis model in the second stage as described for primary analyses above. Analysis was restricted to only those studies providing IPD.

Metaregression of intervention characteristics of physical activity and/or diet-based interventions

We performed metaregression analysis to explore whether the effect of lifestyle intervention overall and for each intervention type (i.e. physical activity-based, diet-based, mixed) differs according to components of the TIDieR framework. The measure of effect was the OR, adjusted by age and BMI. Analysis was performed stratified by intervention types. The absolute effect of the intervention for the subgroups was provided with a 95% CI. When more

than one groups are compared, the reference group for comparison was the one with the most frequent category overall in the trials. Analysis was restricted to only those studies providing IPD.

Network meta-analysis

A NMA was conducted for the GDM outcome as defined by any criteria (as this definition provided the largest evidence base). A multivariate random-effects meta-analysis framework was used via the network module in Stata using REML estimation. The NMA allowed both direct and indirect evidence to contribute towards each intervention effect (contrast) using the consistency assumption. A common between-study variance was assumed for all intervention contrasts in the network (thus implying a +0.5 between-study correlation for each pair of intervention effects).[29] Sensitivity to relaxing this assumption was examined using model fit statistics. Summary effect estimates for each pair of interventions in the network, with corresponding 95% CIs, were calculated.

Based on the results, the ranking of intervention types was calculated using resampling methods based on the (approximate) posterior distribution of intervention effect, and quantified by the probabilities of being ranked first, second,. . ., last, together with the mean rank and its 95% CI. Network diagrams and rankograms were used to graphically display the network set-up and rankings.

The consistency assumption (that direct and indirect evidence are consistent with each other on average) was examined for each intervention comparison where there was direct and indirect evidence (seen as a closed loop within the network plot). This involved estimating direct and indirect evidence, and comparing the two using Wald tests, with a global test across all evidence indicating inconsistency if the $p < 0.05$.

Impact of TIDieR intervention components described above was examined by extending the standard NMA to a network metaregression, with components of interventions included one by one as a study-level categorical covariates, to quantify if intervention effects varied according to their components.

Chapter 4 Characteristics and quality of studies included in the individual participant data meta-analysis

Study selection

Our previous search to February 2017 identified 103 randomised trials, of which 72 were eligible for inclusion in this meta-analysis (42 trials which provided IPD and 30 non-IPD trials with GDM data).[20] Our updated search to March 2022 identified 7040 citations, with 136 retained for full-text screening. From 16 eligible trials with GDM data identified in our updated search, 12 trials shared their IPD. Four trials with GDM data were identified after the IPD acquisition timeline (March 2021–March 2022). The final analysis included 92 trials (32,284 women) of lifestyle interventions in pregnancy on GDM, of which 54 (23,698 women) were trials that shared IPD, and 38 trials (8586 women) were from aggregate data only (*Figure 1*).

Characteristics of the studies included overall and in individual participant data

Fifty-four RCTs contributed IPD to this project. Fifty-one trials were randomised trials with individual participant allocation, while three were cluster RCTs.[30–32] Thirty-three trials were conducted in Europe, nine in North America, eight in Australia and four in South America. The sample size of the trials ranged from 12 to 4631 women. Eleven studies included only women with obesity,[18,33–42] 10 included both overweight and women with obesity,[43–52] 4 studies included only overweight women[31,53–55] and 29 included women of any BMI.[30,32,56–82] Eighteen trials evaluated physical activity-based interventions,[33,35,44,50,51,58–60,62,63,69,73,74,76,78,81–83] 8 trials assessed diet-based interventions[39,42,52,56,65,70,79,80] and 28 trials adopted a mixed approach (physical activity, diet, behaviour-changing techniques).[18,30–32,34,36–38,40,41,43,45–49,53–55,57,64,66–68,71,72,75,77] Three trials had a three-arm design (two interventions and routine care arm), in which interventions belonged to the same type, either different types of counselling/diet or different exercise routines.[34,37,39] IPD were available to assess the effects of lifestyle interventions on GDM according to any diagnostic criteria (54 studies, 23,361 women), NICE (22 studies, 11,990 women),[16] IADPSG (16 studies, 6174 women)[17] and modified IADPSG (24 studies, 13,186 women) diagnostic criteria.[16–19] The number of studies reporting rates of GDM outcomes and of individual maternal and fetal/neonatal outcomes is listed in *Table 2*.

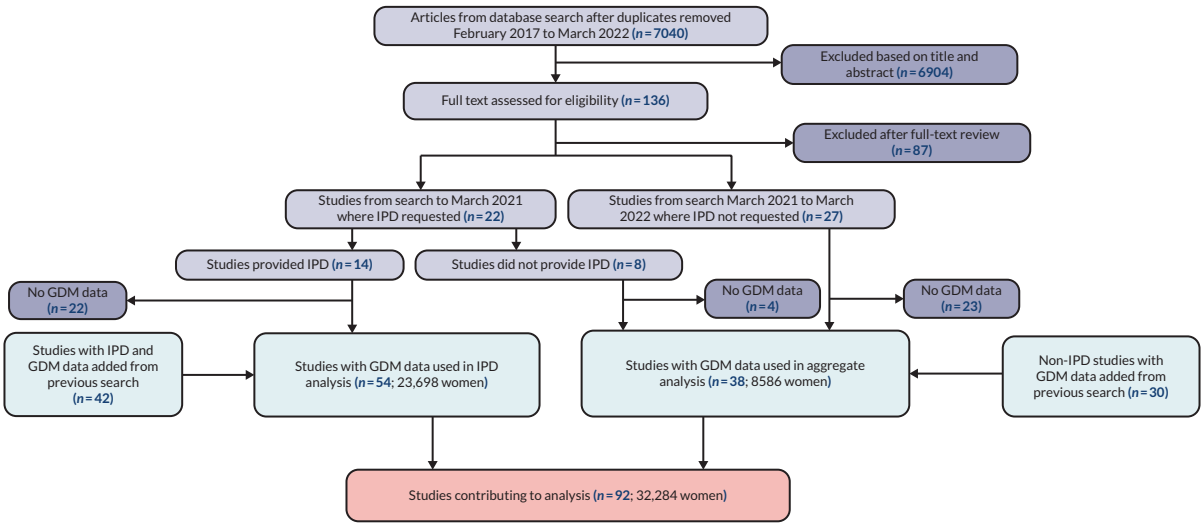

FIGURE 1 Identification and selection of studies included in the IPD meta-analysis of lifestyle interventions on GDM.

TABLE 2 Brief characteristics of trials available and unavailable for the i-WIP GDM IPD meta-analysis

Characteristics	Availability of IPD	
	Available (*n* = 54 studies; 23,698 women)	Unavailable (*n* = 38 studies; 8586 women)
Population		
Any BMI category	29	NA
Obese or overweight BMI	25	NA
Intervention type		
Physical activity-based	18	18
Diet-based	8	5
Mixed approach	28	15
Outcomes		
GDM (by study authors)	54	38
GDM (NICE)	24	0
GDM (IADPSG)	24	6
GDM (modified IADPSG)	24	0
Hypertensive diseases	45	NA
Caesarean section	43	NA
Preterm birth	40	NA
SGA	34	NA
LGA	36	NA
NICU admission	26	NA
Stillbirth	22	NA
Country		
High income	50	35
Low and middle income	4	3

NA, not applicable for the IPD meta-analysis.

Overall, 38 eligible trials (41%, 38/92) comprising 8586 women did not contribute to IPD (see *Report Supplementary Material 1*). Out of these, 15 evaluated physical activity-based interventions,[61,84–97] 3 assessed diet-based interventions[98–100] and 20 trials used a mixed approach.[101–120] The size of the studies ranged from 31 to 1196 women. Thirty-seven trials were randomised trials with individual participant allocation,[61,84–91,93–109,111–121] while one was a cluster RCT.[110] Thirteen trials were conducted in North America, 10 in Europe, 8 in Asia, 2 each in South America, Australia and New Zealand and 1 in Africa. Five studies included only women with obesity,[87,100,114,117,121] 13[89,95,97–99,105,107–109,111,113,115,118] included both overweight and women with obesity,[43–52] 2 studies included only overweight women[31,53–55] and 18 included women with any BMI.[61,84–86,88,90,91,94,96,101–104,106,112,116,119,120] *Table 2* compares the characteristics of studies that shared IPD and those that did not share their IPD for the meta-analysis. Detailed descriptions of all trials are provided in *Appendix 1*, *Table 32* for IPD studies and *Appendix 1*, *Table 33* for non-IPD studies.

Characteristics of the individual participants in the individual participant data meta-analysis

The average age of participants in both trial arms was 29 years, with over 80% of participants being of White ethnicity. Half the participants were nulliparous (50%, 10,767/21,561 women) and held a higher degree (49%, 5754/11,719

women), while 10% (576/5802 women) of participants had a diagnosis of GDM in a previous pregnancy. A detailed comparison of baseline characteristics in both arms of the studies that contributed to the IPD is shown in *Table 3*.

All studies contributed to the outcome of GDM as defined by any criteria (54 trials, 23,361 women). Twenty-four trials contributed to GDM outcome as defined by NICE (13,156 women), IADPSG (12,938 women) and modified IADPSG (13,407 women). Among all pregnant women included in the IPD meta-analysis, the most common outcomes available

TABLE 3 Baseline characteristics of participants in studies that contributed to the IPD meta-analysis

Baseline characteristics	Number of studies	Number of women	Study arm, mean (SD) or %	
			Control	Intervention
			N = 11,160	*N* = 12,538
Age (years)	53	23,607	29.5 (6.0)	29.4 (6.0)
Height (cm)	51	21,560	163.3 (7.1)	163.5 (7.0)
Weight (kg)	38	15,977	78.6 (18.4)	78.2 (18.2)
BMI	54	23,698	28.0 (6.2)	27.9 (6.2)
Race/ethnicity	35	12,649		
White			4995 (80.7%)	5294 (81.9%)
Asian			497 (8.0%)	488 (7.6%)
Black			407 (6.6%)	398 (6.2%)
Central/South American			87 (1.4.%)	77 (1.2%)
Middle East			79 (1.3%)	75 (1.2%)
Other			122 (2.0%)	130 (2.0%)
Educational status of the mother	35	11,719		
Low			1108 (19.5%)	997 (16.5%)
Middle			1881 (33.2%)	1979 (32.7%)
High			2682 (47.3%)	3072 (50.8%)
Smoking status				
Current smoker	44	18,330	842 (9.6%)	851 (8.9%)
Ex-smoker (pre-pregnancy)	24	9969	1494 (32.3%)	1624 (30.4%)
Parity	45	21,561		
0			4931 (48.7%)	5836 (50.6%)
1			3317 (33.1%)	3704 (32.1%)
2			1180 (11.8%)	1328 (11.5%)
3			376 (3.7%)	429 (3.7%)
> 4			231 (2.3%)	229 (2.0%)
Underlying medical condition				
Previous GDM	19	5802	289 (9.9%)	287 (10.0%).
Previous hypertension in pregnancy	41	17,926	914 (10.8%)	1015 (10.8%)
Chronic hypertension	41	5654	50 (2.1%)	76 (2.4%)

in studies that provided IPD were hypertensive disorders in pregnancy (23,698 women, 54 studies), preterm birth (20,769 women, 45 studies), caesarean section (20,534 women, 49 studies), SGA (17,514 women, 43 studies), LGA (17,280 women, 42 studies) and stillbirth (9894 women, 28 studies). Twenty-six studies (6584 women) contributed IPD towards the overall effect of interventions on fasting and 2-hour post-prandial glucose levels (*Table 4*). Among women with GDM, the most common outcomes available were hypertensive disease (2830 women, 45 studies), caesarean section (2693 women, 43 studies), preterm birth (2446 women, 40 studies), LGA (2029 women, 36 studies), SGA (1750 women, 34 studies), NICU admission (1626 women, 26 studies) and stillbirth (1260 women, 22 studies) (see *Table 4*).

TIDieR intervention characteristics of individual participant data studies

Overall, most interventions were not theory-based (65%, 35/54)[30,33,35,36,39,40,42,47,50–52,55–60,62,63,66–71,73,74,76–83] and were delivered in an individual format (51%, 28/54),[18,30–33,35,39,40,42,43,45–48,50,52–55,57,64,65,68,70–72,75,79] using face-to-face delivery method (83%, 45/54),[30–35,37,39–42,44–52,54–60,62–65,68–71,73–76,78–83] with no additional support provided to participants as part of

TABLE 4 Details of outcome measures for all pregnant women and in women with GDM reported in all eligible studies that contributed to the IPD

Outcomes	Number of studies	Number of women
All pregnant women		
Hypertensive disease	54	23,698
Preterm birth	45	20,769
Caesarean section	49	20,534
Stillbirth	28	9894
SGA	43	17,514
LGA	42	17,280
OGTT status		
Fasting OGTT at < 24 weeks	26	6157
2 hours post-prandial OGTT at < 24 weeks	26	6584
Fasting OGTT at 24–30 weeks	16	2907
2 hours post-prandial OGTT at 24–30 weeks	18	3166
Fasting OGTT at > 30 weeks	8	624
2 hours post-prandial OGTT at > 30 weeks	7	590
Women with gestational diabetes (defined by any criteria)		
Hypertensive disease	45	2830
Preterm birth	40	2446
Caesarean section	43	2693
Stillbirth	22	1260
SGA	34	1750
LGA	36	2029
NICU admission	26	1626

OGTT, oral glucose tolerance test.

the intervention (68%, 36/54).[30,32–34,37,40–42,44,45,47,48,50,51,54–59,62,63,66–71,73,74,76,78–83] Facilitators who delivered the intervention were mostly allied health staff (72%, 39/54),[19,30,33,35,37–39,41–45,47–51,53–56,58–60,62–64,66,67,70,74–78,80–83] who did not receive training to deliver the intervention or this was not reported in the studies (65%, 34/54).[33,35,39–41,44,45,47,49,52–59,62–64,66–70,72–76,78–83] Most interventions were started in early pregnancy (< 20 weeks gestation) (72%, 39/54),[18,19,30,31,33–37,39–47,49,54–56,58,59,62,63,68,70,71,73–76,80–83] and delivered in the hospital or antenatal clinics (76%, 40/54).[18,30–35,37–53,55,56,58–60,62–71,74,76–83] Summary intervention characteristics according to TIDieR framework for the included IPD studies are provided in *Appendix 2*, *Table 34*.

Risk of bias within eligible studies

Most of the included eligible trials were rated as having a low risk of bias for random sequence generation (86%, 79/92) and complete outcome data reporting (86%, 79/92). More than half of the studies had a low risk of bias for allocation concealment (61%, 56/92) and selective reporting of outcomes (61%, 56/92). In all but one of the studies, the risk of bias for blinding of participants was rated as either unclear (40%, 37/92) or high (59%, 54/92). Most studies were rated as having either an unclear (42%, 39/92) or low (40%, 37/92) risk of bias for blinding of outcome assessors. Overall, the global risk of bias was low in about two-thirds of all eligible studies (64%, 59/92). *Figure 2* summarises the risk of bias rating by domain for all eligible studies.

Studies that provided IPD were found to have a low risk of bias for random sequence generation (91% compared to 79% in studies where IPD was not available), blinding of outcome assessment (41% compared to 39%) and completeness of outcome data (89% compared to 82%). Both IPD and non-IPD studies had similar low risk-of-bias ratings for allocation concealment (61%), selective reporting of outcomes (61%) and blinding of outcome assessors (41%) (*Table 5*). Detailed assessment of the risk of bias of all eligible studies is provided in *Appendix 3*, *Table 35* for IPD and *Appendix 3*, *Table 36* for non-IPD studies.

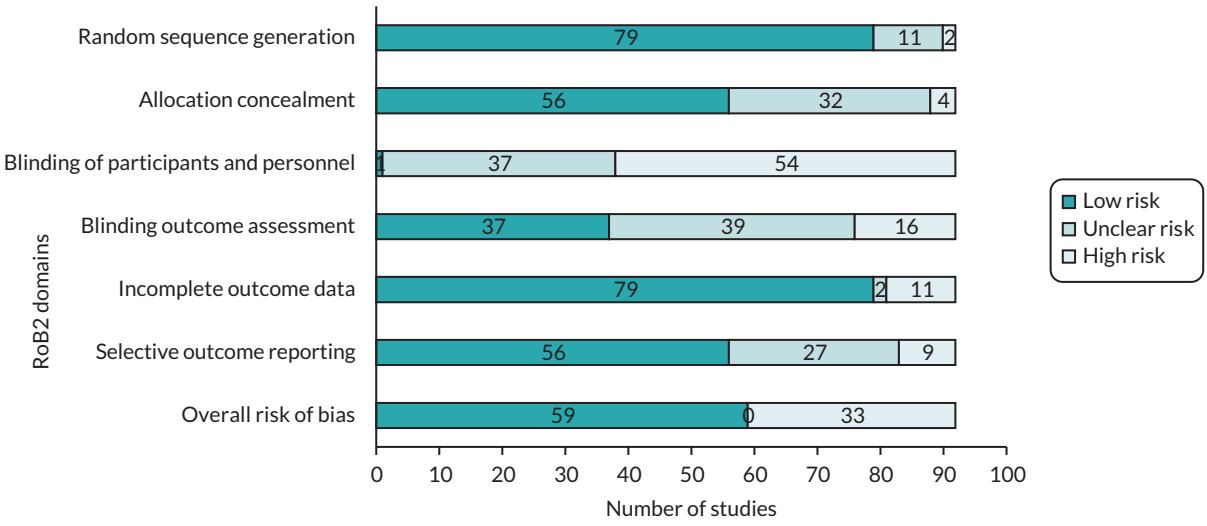

FIGURE 2 Summary of the risk-of-bias rating for all eligible studies (*n* = 92).

TABLE 5 Risk-of-bias assessment in IPD studies compared with non-IPD

	Risk-of-bias rating, *n* (%)					
	Low		Unclear		High	
Items	IPD	Non-IPD	IPD	Non-IPD	IPD	Non-IPD
Random sequence generation	49 (91%)	30 (79%)	5 (9%)	6 (16%)	0	2 (5%)
Allocation concealment	33 (61%)	23 (61%)	18 (33%)	14 (37%)	3 (6%)	1 (3%)
Blinding of participants and personnel	1 (2%)	0	19 (35%)	18 (47%)	34 (63%)	20 (53%)
Blinding outcome assessment	22 (41%)	15 (39%)	18 (33%)	21 (55%)	14 (26%)	2 (5%)
Incomplete outcome data	48 (89%)	31 (82%)	0	2 (5%)	6 (11%)	5 (13%)
Selective outcome reporting	33 (61%)	23 (61%)	13 (24%)	14 (37%)	8 (15%)	1 (3%)
Overall risk of bias	33 (61%)	26 (68%)	0	0	21 (39%)	12 (32%)
Total number of studies	54	38	54	38	54	38

Chapter 5 Effects of lifestyle interventions in pregnancy on gestational diabetes

Effects of interventions on gestational diabetes (any criteria)

Fifty-four trials (23,361 women) contributed IPD towards the effect of interventions on GDM as defined by study authors, including 18 trials (4435 women) on physical activity-based interventions, 8 trials (2974 women) on diet-based and 28 trials (15,952 women) on mixed interventions.

Overall, lifestyle interventions reduced the odds of GDM by 10% on average (OR 0.90, 95% CI 0.80 to 1.02, $\tau^2 = 0.04$, 54 studies, 23,361 women), which was not statistically significant (*Table 6* and *Figure 3*), with 95% PI of 0.59 to 1.38. When we included all available aggregate data from the 38 eligible trials (8586 women) that did not share IPD to the meta-analyses (total of 92 trials, 31,947 women), we found a statistically significant reduction in the odds of GDM by 19% (OR 0.81, 95% CI 0.73 to 0.89, $\tau^2 = 0.07$, 92 studies, 31,947 women) (see *Table 6*). However, the 95% PI (0.48 to 1.36) indicates the potential for the interventions to have no effect in some populations. We observed a greater degree of heterogeneity in the studies which only contributed aggregate data, compared with those which provided IPD. This introduced an additional level of heterogeneity into the analyses combining IPD and aggregate data studies ($\tau^2 = 0.06$).

Among the intervention types, we found a significant reduction in the odds of GDM by 36% with physical activity (OR 0.64, 95% CI 0.48 to 0.84, $\tau^2 = 0.04$, 18 studies, 4435 women), and by 19% with diet-based (OR 0.81, 95% CI 0.69 to 0.96, $\tau^2 = 0.00$, 8 studies, 2974 women) interventions. For studies with mixed interventions, we did not find a reduction in GDM (OR 1.05, 95% CI 0.91 to 1.21, $\tau^2 = 0.02$, 28 studies, 15,952 women).

When aggregate data from studies that did not share IPD were added to the IPD meta-analyses, we observed a consistent reduction in GDM for both physical activity-based (OR 0.63, 95% CI 0.53 to 0.75, $\tau^2 = 0.02$, 33 studies, 8347 women) and diet-based interventions (OR 0.77, 95% CI 0.60 to 0.98, $\tau^2 = 0.00$, 11 studies, 3384 women). PIs were estimated to be below the null, indicating potential benefit of these interventions in populations similar to the studies included in the meta-analysis. For studies with mixed interventions, we did not find a reduction in GDM (OR 1.05, 95% CI 0.91 to 1.21, $\tau^2 = 0.02$, 28 studies, 15,952 women), which remained so even after inclusion of the aggregate data (OR 0.92, 95% CI 0.82 to 1.04, $\tau^2 = 0.05$, 48 studies, 20,216 women) (see *Table 6* and *Figure 3*).

Sensitivity analysis by excluding studies rated as having a high risk of bias showed consistent significant reduction in GDM for physical activity-based interventions (OR 0.59, 95% CI 0.43 to 0.82, $\tau^2 = 0.00$, 11 studies, 2993 women).

TABLE 6 Effects of lifestyle interventions on GDM (any criteria)

Intervention	Source	Number of studies	Number of women	OR (95% CI)	95% PI	τ^2
Physical activity	IPD only	18	4435	**0.64 (0.48 to 0.84)**	0.39 to 1.05	0.04 (0.00 to 0.43)
	IPD + AD	33	8347	**0.63 (0.53 to 0.75)**	**0.45 to 0.89**	0.02 (0.00 to 0.20)
Diet	IPD only	8	2974	**0.81 (0.69 to 0.96)**	**0.68 to 0.97**	0.00 (0.00 to 0.17)
	IPD + AD	11	3384	**0.77 (0.60 to 0.98)**	**0.60 to 0.98**	0.00 (0.00 to 0.30)
Mixed	IPD only	28	15,952	1.05 (0.91 to 1.21)	0.78 to 1.40	0.02 (0.00 to 0.12)
	IPD + AD	48	20,216	0.92 (0.82 to 1.04)	0.58 to 1.47	0.05 (0.01 to 0.15)
All	IPD only	54	23,361	0.90 (0.80 to 1.02)	0.59 to 1.38	0.04 (0.01 to 0.13)
	IPD + AD	92	31,947	**0.81 (0.73 to 0.89)**	0.48 to 1.36	0.07 (0.02 to 0.14)

AD, aggregate data.
Bold values represent statistically significant results.

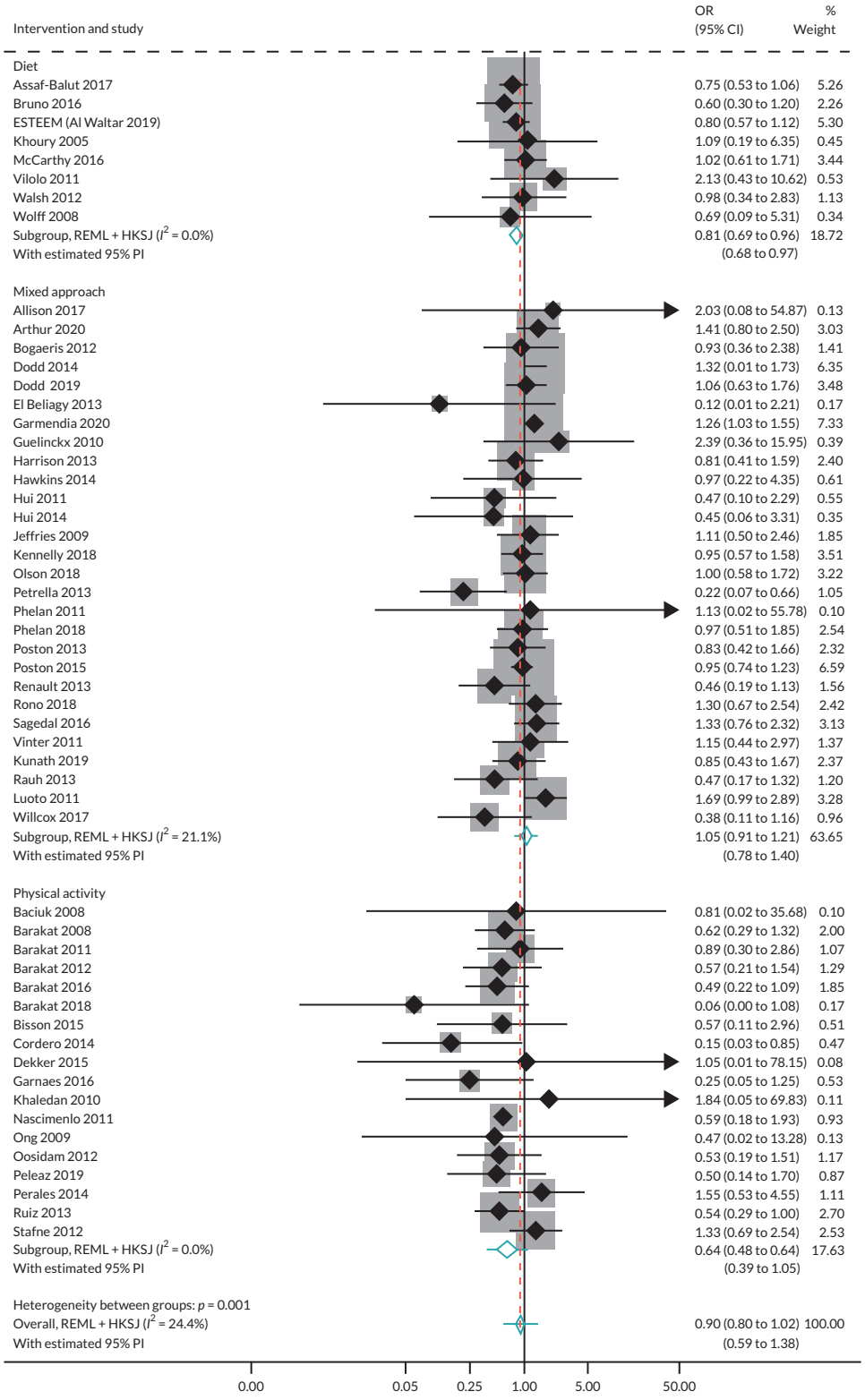

FIGURE 3 Effects of lifestyle interventions on GDM (any criteria) based on IPD only.

Overall lifestyle interventions (OR 0.94, 95% CI 0.82 to 1.08, τ^2 = 0.03, 33 studies, 15,547 women) and diet-based interventions (OR 0.89, 95% CI 0.69 to 1.16, τ^2 = 0.00, 5 studies, 1930 women) reduced the odds of GDM in studies at low or medium risk of bias, but this was not statistically significant. For studies with mixed interventions, there was a statistically significant increase in odds of GDM by 14% (OR 1.14, 95% CI 1.01 to 1.29, τ^2 = 0.00, 17 studies, 10,624 women) in studies at low or medium risk of bias (see *Appendix 4*, *Table 37*).

Effects of interventions on gestational diabetes (National Institute for Health and Care Excellence criteria)

Twenty-two trials (11,990 women) contributed IPD towards analysis of the effect of interventions on GDM as defined by NICE, including 5 trials (997 women) on physical activity-based interventions, 3 trials (1812 women) on diet-based and 14 trials (9201 women) on mixed interventions. Overall, lifestyle interventions reduced the odds of GDM by 2% on average (OR 0.98, 95% CI 0.84 to 1.13, $\tau^2 = 0.02$, 22 studies, 11,990 women) which was not statistically significant (*Table 7* and *Figure 4*)

For types of intervention, we found similar non-statistically significant reductions in the odds of GDM with physical activity (OR 0.65, 95% CI 0.18 to 2.31, $\tau^2 = 0.60$, 5 studies, 977 women) and diet-based interventions (OR 0.71, 95%

TABLE 7 Effects of lifestyle interventions on GDM (NICE definition)

Intervention	Number of studies	Number of women	OR (95% CI)	95% PI	τ^2
Physical activity	5	977	0.65 (0.18 to 2.31)	0.04 to 11.49	0.60 (0.00 to 8.80)
Diet	3	1812	0.71 (0.33 to 1.49)	0.08 to 6.47	0.00 (0.00 to 2.80)
Mixed	14	9201	1.10 (0.98 to 1.23)	0.99 to 1.24	0.00 (0.00 to 0.06)
All	22	11,990	0.98 (0.84 to 1.13)	0.72 to 1.36	0.02 (0.00 to 0.13)

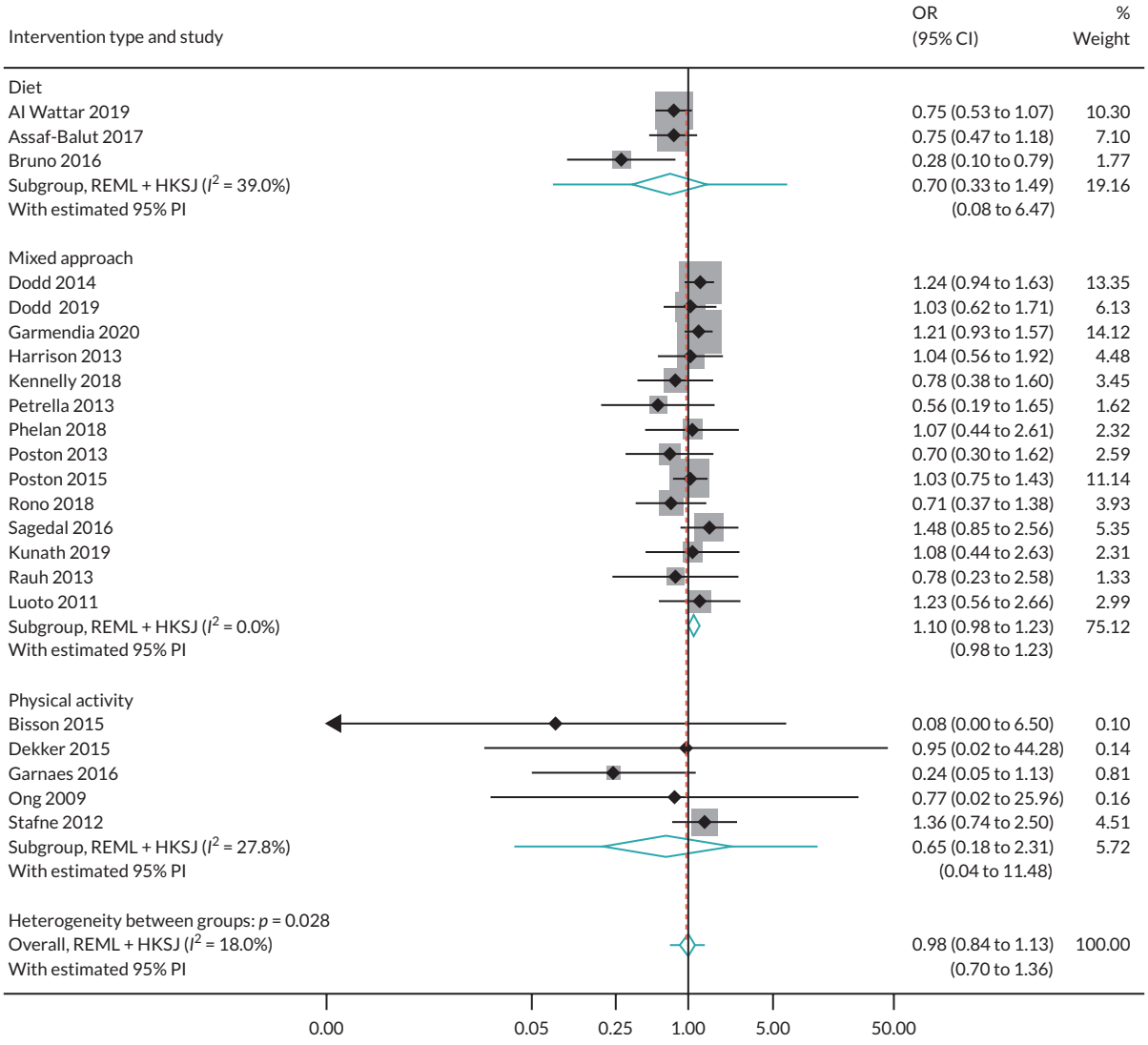

FIGURE 4 Effects of lifestyle interventions on GDM (NICE definition) based on IPD only.

CI 0.33 to 1.49, τ^2 = 0.00, 3 studies, 1812 women). For studies with mixed interventions, we did not find a reduction in GDM compared to controls (OR 1.10, 95% CI 0.98 to 1.23, τ^2 = 0.00, 14 studies, 9201 women) (see *Table 7* and *Figure 4*). There were no aggregate data only studies reporting GDM as defined by NICE criteria.

Sensitivity analyses findings were similar with main findings when GDM was defined according to NICE criteria (see *Appendix 4*, *Table 38*).

Differential effects of interventions by maternal characteristics

Table 8 provides the numbers of trials and IPD that contributed to the analysis to evaluate the differential effect of interventions (treatment–covariate interactions) on GDM as defined by any criteria. Across the potential effect modifiers examined, we found a statistically significant interaction effect only for mothers' educational status. When compared with mothers with low educational status, we found a 32% (OR 0.68, 95% CI 0.51 to 0.90, τ^2 = 0.00) and a 29% (OR 0.71, 95% CI 0.54 to 0.93, τ^2 = 0.00) reduction in the odds of GDM with overall lifestyle interventions in mothers with middle and high education level, respectively. This differential effect in the observed benefit persisted in the 95% PIs (see *Table 8*). There were no statistically significant treatment–covariate interaction effects on GDM for maternal ethnicity, parity, age and BMI. For continuous covariate interactions (BMI, age) for which we assumed a linear effect, we found no interaction effect per unit increase (OR 1, 95% CI 0.98 to 1.02).

Table 9 provides the numbers of trials and IPD that contributed to the analysis to evaluate the differential effect of interventions on GDM as defined by NICE. There were no statistically significant intervention–covariate interactions

TABLE 8 Treatment–covariate interactions for GDM (any criteria)

Intervention	Subgroup	Number of studies	Number of women	Interaction, OR (95% CI)	95% PI	τ^2
Ethnicity	Non-White vs. White	18	8733	0.98 (0.71 to 1.34)	0.71 to 1.34	0.00 (0.00 to 0.41)
Parity	Multiparous vs. nulliparous	40	19,574	0.88 (0.75 to 1.03)	0.75 to 1.03	0.00 (0.00 to 0.17)
Education	Middle vs. low	33	10,887	**0.68 (0.51 to 0.90)**	**0.51 to 0.90**	0.00 (0.00 to 0.49)
	High vs. low	32	10,794	**0.71 (0.54 to 0.93)**	**0.54 to 0.93**	0.00 (0.00 to 0.41)
Age	≥ 20 vs. < 20	24	17,320	1.00 (0.74 to 1.36)	0.74 to 1.36	0.00 (0.00 to 0.79)
	Age (continuous)	52	23,161	1.00 (0.98 to 1.02)	0.98 to 1.02	0.00 (0.00 to 0.00)
BMI	Overweight vs. normal	33	16,711	0.98 (0.74 to 1.29)	0.50 to 1.90	0.09 (0.00 to 0.64)
	Obese vs. normal	48	21,080	0.90 (0.72 to 1.11)	0.72 to 1.12	0.00 (0.00 to 0.37)
	BMI (continuous)	54	23,361	1.00 (0.98 to 1.02)	0.98 to 1.02	0.00 (0.00 to 0.00)

Bold values represent statistically significant results.

TABLE 9 Treatment-covariate interactions for GDM (NICE definition)

Intervention	Subgroup	Number of studies	Number of women	Interaction, OR (95% CI)	95% PI	τ^2
Ethnicity	Non-White vs. White	10	5736	0.73 (0.42 to 1.26)	0.34 to 1.57	0.05 (0.00 to 1.30)
Parity	Multiparous vs. nulliparous	14	9072	0.98 (0.77 to 1.24)	0.77 to 1.25	0.00 (0.00 to 0.37)
Education	Middle vs. low	8	4312	1.30 (0.78 to 2.15)	0.77 to 2.19	0.00 (0.00 to 1.12)
	High vs. low	8	4293	1.15 (0.68 to 1.96)	0.67 to 1.99	0.00 (0.00 to 1.35)
Age	≥ 20 vs. < 20	13	10,461	1.15 (0.87 to 1.51)	0.87 to 1.51	0.00 (0.00 to 0.73)
	Age (continuous)	22	11,990	1.00 (0.99 to 1.02)	0.99 to 1.02	0.00 (0.00 to 0.00)
BMI	Overweight vs. normal	16	7965	1.11 (0.67 to 1.83)	0.34 to 3.56	0.23 (0.00 to 1.43)
	Obese vs. normal	16	9219	1.07 (0.69 to 1.68)	0.40 to 2.87	0.17 (0.00 to 1.19)
	BMI (continuous)	22	9462	1.00 (0.99 to 1.02)	0.99 to 1.02	0.00 (0.00 to 0.00)

on GDM for any of the potential effect modifiers examined. The largest observed effect was an average reduction in the odds of GDM of 27% (OR 0.73, 95% CI 0.42 to 1.26, $\tau^2 = 0.05$) for non-White women compared to those of White ethnicity (see *Table 9*). For the continuous covariate interactions (BMI, age) for which we assumed a linear effect, we found no interaction effect per unit increase (OR 1, 95% CI 0.99 to 1.02, $\tau^2 = 0.00$).

Forest plots for all interaction effects for GDM as defined by any criteria and by NICE are provided in *Appendices 5* and *6*, respectively.

Small study effects

The contour-enhanced funnel plots for GDM as defined by any criteria (*Figure 5*) showed no clear evidence of asymmetry, indicating that smaller studies were unlikely to have differing intervention effects compared with larger studies. Addition of aggregate data from non-IPD studies to the meta-analysis did not alter the symmetry (*Figure 6*).

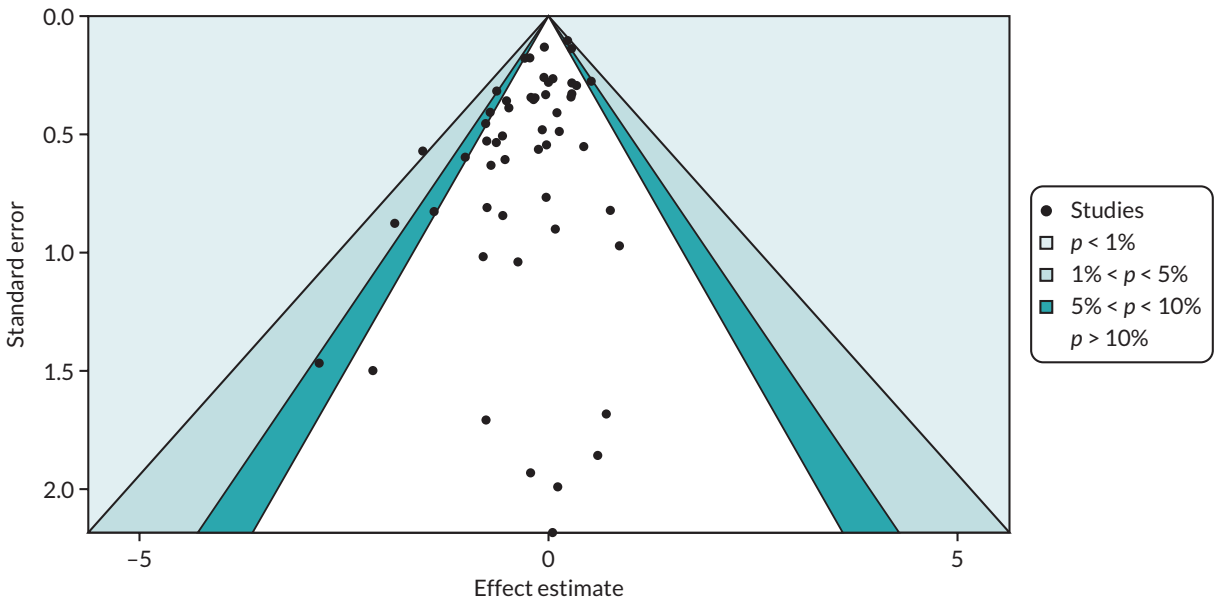

FIGURE 5 Contour-enhanced funnel plot for overall intervention effects on GDM as defined by any criteria (IPD only).

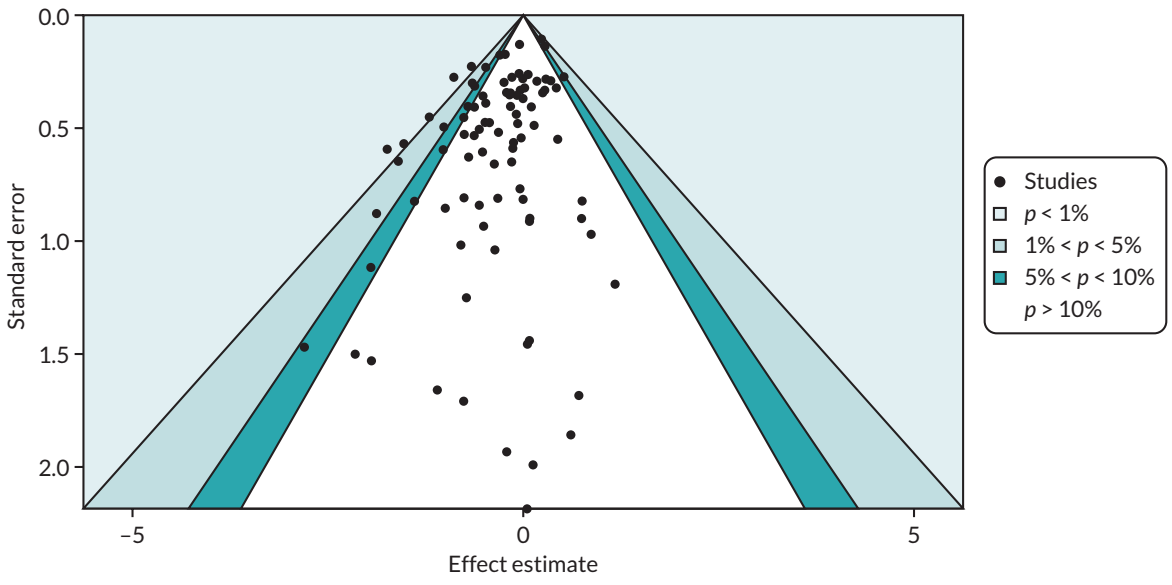

FIGURE 6 Contour-enhanced funnel plot for overall intervention effects on GDM as defined by any criteria (IPD and aggregate data).

Excluding studies rated as being at high risk of bias (*Figure 7*) also did not alter the symmetry. Similar plots were observed for GDM as defined by NICE (*Figure 8*) and studies with low risk of bias (*Figure 9*), although fewer studies contributed to these analyses.

Effects of interventions on gestational diabetes (International Association of the Diabetes and Pregnancy Study Groups criteria)

Sixteen trials (6174 women) contributed IPD towards analysis for the effect of interventions on GDM as defined by IADPSG, including 3 trials (55 women) on physical activity-based interventions, 2 trials (895 women) on diet-based and 11 trials (5224 women) on mixed interventions. Overall, there was a significant reduction with lifestyle interventions in the odds of GDM by 14% on average (OR 0.86, 95% CI 0.75 to 0.97, $\tau^2 = 0.00$, 16 studies, 6174 women) (*Table 10* and *Figure 10*). When we included available aggregate data from the 9 eligible trials (1709 women) that did not share IPD

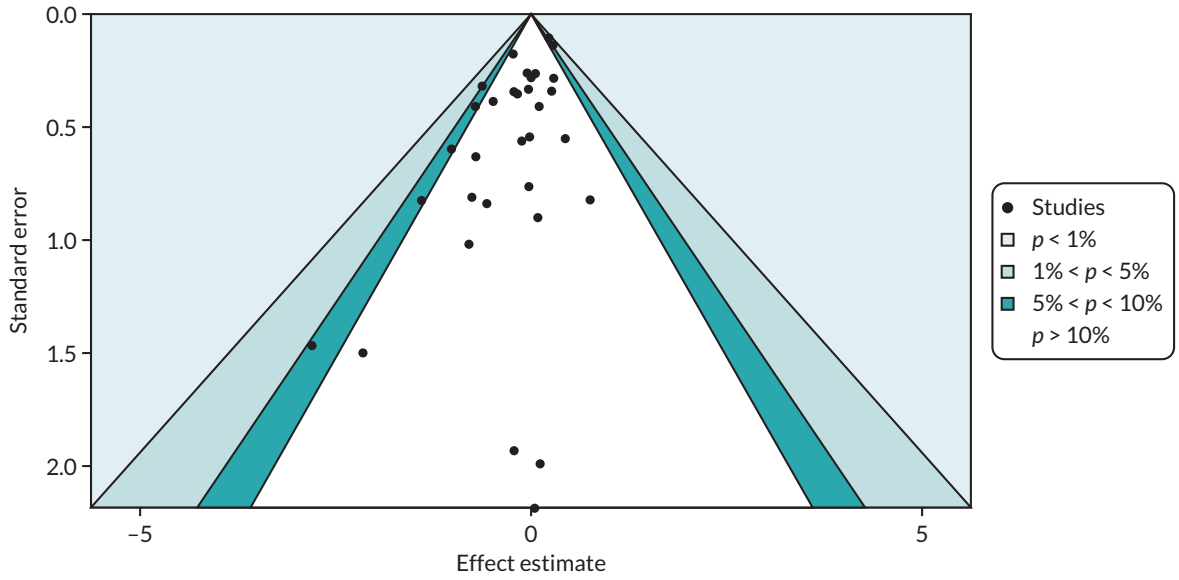

FIGURE 7 Contour-enhanced funnel plot for overall intervention effects on GDM as defined by any criteria (IPD studies classified as low risk of bias).

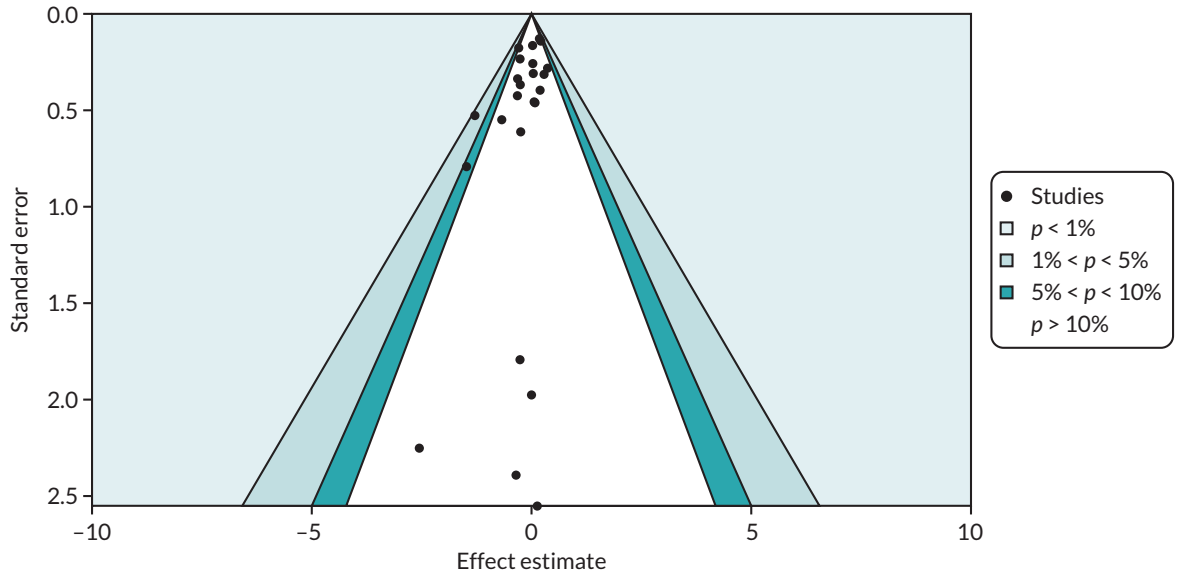

FIGURE 8 Contour-enhanced funnel plot for overall intervention effects on GDM as defined by NICE (IPD only).

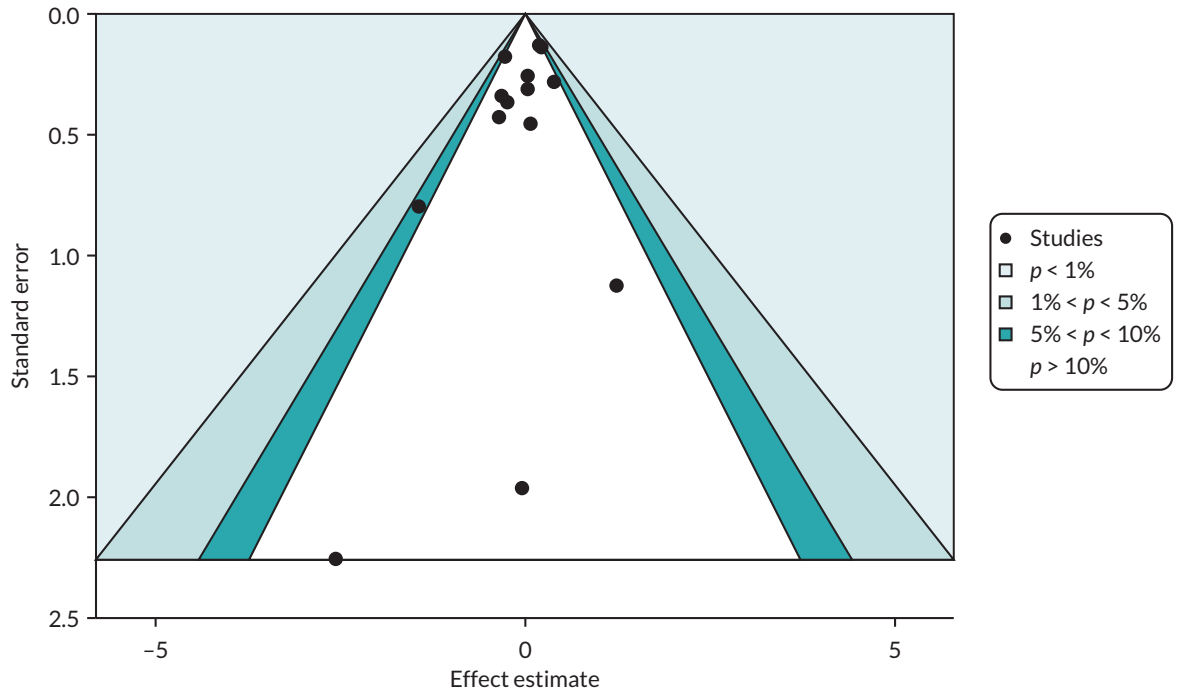

FIGURE 9 Contour-enhanced funnel plot for overall intervention effects on GDM as defined by NICE (IPD studies classified as low risk of bias).

TABLE 10 Effects of lifestyle interventions on GDM (IADPSG definition)

Intervention	Source	Number of studies	Number of women	OR (95% CI)	95% PI	τ^2
Physical activity	IPD only	3	55	0.92 (0.28 to 3.08)	0.03 to 32.47	0.00 (0.00 to 13.85)
	IPD + AD	5	420	0.93 (0.69 to 1.25)	0.66 to 1.31	0.00 (0.00 to 1.44)
Diet	IPD only	2	895	0.71 (0.06 to 7.88)	Undefined	0.00 (0.00 to 14.9)
Mixed	IPD only	11	5224	0.89 (0.76 to 1.03)	0.76 to 1.04	0.00 (0.00 to 0.08)
	IPD + AD	15	5754	**0.85 (0.74 to 0.99)**	**0.73 to 0.99**	0.00 (0.00 to 0.10)
All	IPD only	16	6174	**0.86 (0.75 to 0.97)**	**0.75 to 0.97**	0.00 (0.00 to 0.07)
	IPD + AD	25	7883	**0.83 (0.72 to 0.95)**	0.63 to 1.09	0.14 (0.00 to 0.12)

AD, aggregate data.
Bold values represent statistically significant results.

to the meta-analysis (total of 25 trials, 7883 women), we found the significant reduction in the odds of GDM persisted, with a 17% reduction (OR 0.83, 95% CI 0.72 to 0.95, τ^2 = 0.14, 25 studies, 7883 women) (see *Table 10*).

Among the intervention types, we found non-significant reductions in the odds of GDM with physical activity (OR 0.92, 95% CI 0.28 to 3.08, τ^2 = 0.00, 3 studies, 55 women), diet-based (OR 0.71, 95% CI 0.06 to 7.88, τ^2 = 0.00, 2 studies, 895 women) and mixed interventions (OR 0.89, 95% CI 0.76 to 1.03, τ^2 = 0.00, 11 studies, 5224 women) (see *Figure 10* and *Table 10*). When aggregate data from studies that did not share IPD were added to the IPD meta-analyses, we observed a significant reduction in odds of GDM for mixed interventions only (OR 0.85, 95% CI 0.74 to 0.99, τ^2 = 0.00, 15 studies, 5754 women), with PIs estimated to be below the null indicating potential benefit of this intervention in a new pregnant woman from a similar population to the studies included in the meta-analysis.

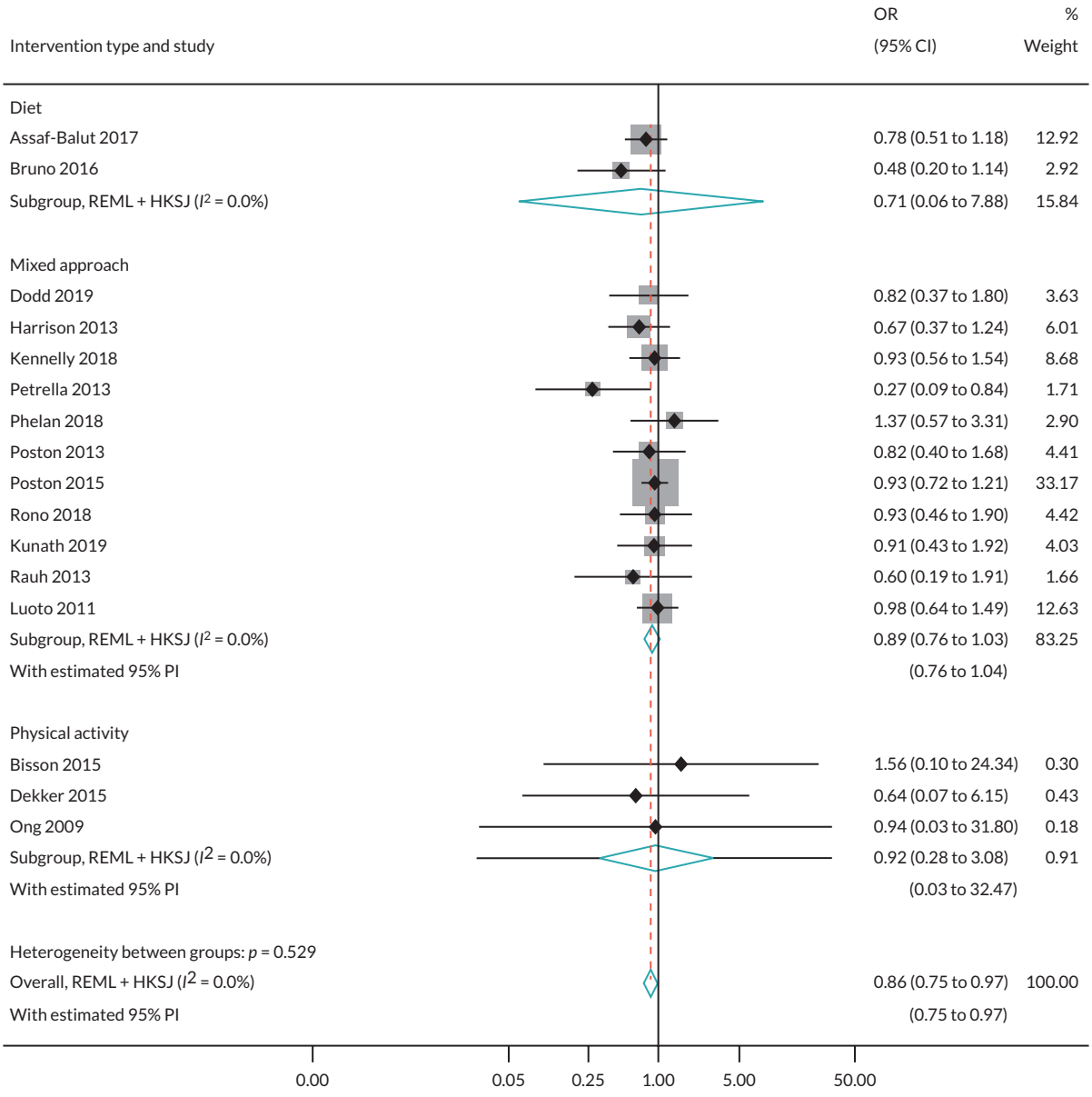

FIGURE 10 Effects of lifestyle interventions on GDM (IADPSG definition) based on IPD only.

Effects of interventions gestational diabetes (modified International Association of the Diabetes and Pregnancy Study Groups criteria)

Twenty-four trials (13,186 women) contributed IPD towards the effect of interventions on GDM as defined by modified IADPSG criteria, including 7 trials (1940 women) on physical activity-based interventions, 3 trials (1891 women) on diet-based and 14 trials (9355 women) on mixed interventions. Overall, lifestyle interventions reduced the odds of GDM by 8% on average (OR 0.92, 95% CI 0.78 to 1.10, τ^2 = 0.07, 24 studies, 13,186), which was not statistically significant (*Table 11* and *Figure 11*).

For type of intervention, there were non-significant reductions in the odds of GDM with physical activity (OR 0.88, 95% CI 0.70 to 1.09, τ^2 = 0.00, 7 studies, 1940 women) and diet-based interventions (OR 0.64, 95% CI 0.32 to 1.30, τ^2 = 0.00, 3 studies, 1891 women). For studies with mixed interventions, we did not find a reduction in GDM (OR 1.08 95% CI 0.89 to 1.31, τ^2 = 0.04, 14 studies, 9355 women). There were no aggregate data only studies reporting GDM defined by modified IADPSG criteria (see *Figure 11* and *Table 11*).

TABLE 11 Effects of lifestyle interventions on GDM (modified IADPSG definition)

Intervention	Source	Number of studies	Number of women	OR (95% CI)	PI	τ^2
Physical activity	IPD	7	1940	0.88 (0.70 to 1.09)	0.70 to 1.10	0.00 (0.00 to 0.53)
Diet	IPD	3	1891	0.64 (0.32 to 1.30)	0.08 to 5.11	0.00 (0.00 to 2.78)
Mixed	IPD	14	9355	1.08 (0.89 to 1.31)	0.68 to 1.72	0.04 (0.00 to 0.21)
All	IPD	24	13,186	0.92 (0.78 to 1.10)	0.52 to 1.64	0.07 (0.02 to 0.23)

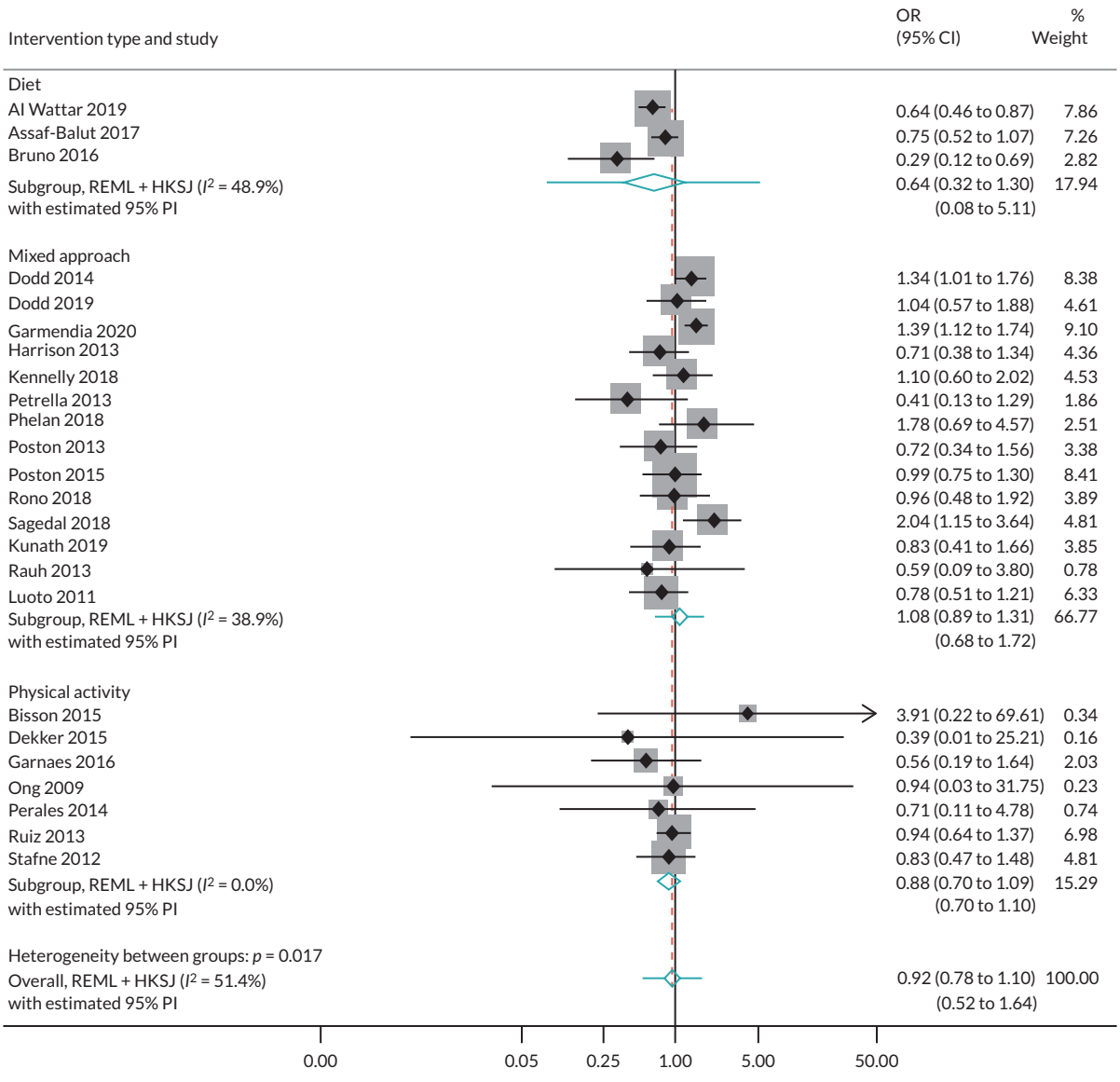

FIGURE 11 Effects of lifestyle interventions on GDM (modified IADPSG definition) based on IPD only.

Effect of the intervention on fasting and 2-hour post-prandial glucose levels

Twenty-six studies (17,558 women) contributed IPD towards the overall effect of interventions on fasting and 2-hour post-prandial glucose levels. At all gestational age categories (< 24 weeks, 24–30 weeks, > 30 weeks), lifestyle interventions reduced fasting and 2-hour post-prandial glucose levels. However, the reductions were not statistically significant except for at 24–30 weeks' gestation where the 2-hour post-prandial glucose levels was reduced by −0.07 mmol/l on average (MD −0.07, 95% CI −0.12 to −0.01, τ^2 = 0.00, 18 studies, 8749 women) (*Table 12*).

TABLE 12 Effects of lifestyle interventions on continuous fasting and 2-hour post-prandial glucose levels

Time	Gestational age	Number of studies	Number of women	MD (95% CI)	PI	τ^2
Fasting	< 24 weeks	26	16,622	−0.0047 (−0.04 to 0.03)	−0.04 to 0.03	0.00 (0.00 to 0.01)
	24–30 weeks	16	8225	−0.01 (−0.05 to 0.02)	−0.05 to 0.02	0.00 (0.00 to 0.01)
	> 30 weeks	8	4437	−0.01 (−0.05 to 0.03)	−0.05 to 0.03	0.00 (0.00 to 0.04)
2-hour post prandial	< 24 weeks	26	17,558	−0.01 (−0.08 to 0.06)	−0.23 to 0.21	0.01 (0.00 to 0.04)
	24–30 weeks	18	8749	**−0.07 (−0.12 to −0.01)**	−0.20 to 0.07	0.00 (0.00 to 0.02)
	> 30 weeks	7	4282	−0.03 (−0.22 to 0.16)	−0.38 to 0.33	0.01 (0.00 to 0.27)

Bold values represent statistically significant results.

Note
Results are on the scale of mmol/l.

Effects of the intervention on pregnancy outcomes

For all pregnant women included in trials that shared IPD, there were no significant differences with overall lifestyle interventions than control in the odds of preterm delivery, caesarean section, stillbirth, SGA and LGA babies (*Table 13*). Among intervention types, physical activity significantly reduced the odds of caesarean section (OR 0.83, 95% CI 0.72 to 0.96, τ^2 = 0.00, 17 studies, 4527 women), SGA (OR 0.72, 95% CI 0.56 to 0.92, τ^2 = 0.00, 17 studies, 4594 women), and LGA babies (OR 0.81, 95% CI 0.71 to 0.94, τ^2 = 0.00, 17 studies, 4594 women) in all pregnant women compared to controls; no differences were observed for other outcomes. Diet-based interventions reduced the odds of preterm delivery (OR 0.37, 95% CI 0.20 to 0.68, τ^2 = 0.0, 6 studies, 1464 women) compared to controls, and no reductions were observed for other outcomes. There were no differences observed for any outcome with mixed interventions (see *Table 13*).

In women who received lifestyle interventions in pregnancy and went on to develop GDM as defined by any criteria, there was no significant reduction in the odds of hypertensive disease, SGA and LGA babies compared to controls who developed GDM (*Table 14*). For the intervention types, we found a significant increase in the odds of hypertensive disease (OR 1.78, 95% CI 1.25 to 2.51, τ^2 = 0.00, 13 studies, 276 women), preterm delivery (OR 2.28, 95% CI 1.24 to 4.22, τ^2 = 0.00, 11 studies, 251 women) and SGA babies (OR 1.60, 95% CI 1.15 to 2.22, τ^2 = 0.00, 13 studies, 274 women) with physical activity-based interventions. Diet-based interventions reduced the odds of LGA (OR 0.25, 95% CI 0.13 to 0.48, τ^2 = 0.00, 6 studies, 241 women) and preterm delivery (OR 0.36 95% CI 0.18 to 0.74, τ^2 = 0.00, 6 studies, 246 women) compared to controls who developed GDM (see *Table 14*).

Effects by TIDieR intervention core components

Appendix 7, *Table 39*, *Appendix 8*, *Table 40*, *Appendix 9*, *Table 41* and *Appendix 10*, *Table 42* summarise the intervention characteristics associated with GDM using IPD meta-analysis. For GDM defined by any criteria, our subgroup analysis by TIDieR components found a significant difference based on structure and prior training with overall lifestyle interventions. Delivery of the intervention in group format (OR 0.81, 95% CI 0.68 to 0.97; p = 0.048) was associated with a greater reduction in the odds of GDM compared with individual delivery format (OR 1.02, 95% CI 0.89 to 1.17). There was a greater reduction in the odds of GDM when no prior intervention-specific training was given to providers (OR 0.82, 95% CI 0.69 to 0.96; p = 0.039), compared to when this training is given (OR 1.04, 95% CI 0.90 to 1.20) (see *Appendix 7*, *Table 39*). There were no significant differences in GDM outcomes for other TIDieR component subgroups or intervention types.

TABLE 13 Effects of lifestyle interventions on pregnancy outcomes in all women included in IPD studies

Outcome	Intervention	Number of studies	Number of women	OR (95% CI)	PI	τ^2
Hypertensive disease	Physical activity	18	4620	0.87 (0.64 to 1.18)	0.42 to 1.79	0.09 (0.00 to 0.86)
	Diet	8	2980	0.81 (0.55 to 1.17)	0.44 to 1.47	0.04 (0.00 to 0.73)
	Mixed	28	16,098	1.10 (0.97 to 1.24)	0.97 to 1.24	0.00 (0.00 to 0.06)
	All	54	23,698	1.03 (0.92 to 1.14)	0.92 to 1.14	0.00 (0.00 to 0.09)
Preterm birth	Physical activity	15	4504	1.02 (0.78 to 1.34)	0.77 to 1.34	0.00 (0.00 to 0.29)
	Diet	6	1464	**0.37 (0.20 to 0.68)**	0.19 to 0.71	0.00 (0.00 to 1.73)
	Mixed	24	14,801	0.95 (0.79 to 1.13)	0.72 to 1.24	0.01 (0.00 to 0.13)
	All	45	20,769	0.93 (0.80 to 1.07)	0.73 to 1.18	0.01 (0.00 to 0.11)
Caesarean section	Physical activity	17	4527	**0.83 (0.72 to 0.96)**	0.72 to 0.96	0.00 (0.00 to 0.11)
	Diet	8	2829	0.93 (0.78 to 1.11)	0.71 to 1.22	0.01 (0.00 to 0.38)
	Mixed	24	13,178	0.99 (0.88 to 1.10)	0.71 to 1.37	0.02 (0.00 to 0.09)
	All	49	20,534	0.93 (0.86 to 1.01)	0.73 to 1.19	0.01 (0.00 to 0.05)
Stillbirth	Physical activity	7	1218	1.39 (0.86 to 2.25)	0.83 to 2.30	0.00 (0.00 to 3.57)
	Diet	4	1576	0.65 (0.25 to 1.66)	0.18 to 2.32	0.00 (0.00 to 8.09)
	Mixed	17	7100	0.75 (0.57 to 1.01)	0.56 to 1.01	0.00 (0.00 to 0.68)
	All	28	9894	0.80 (0.64 to 1.01)	0.64 to 1.01	0.00 (0.00 to 0.42)
SGA	Physical activity	17	4594	**0.72 (0.56 to 0.92)**	0.56 to 0.92	0.00 (0.00 to 0.27)
	Diet	6	1450	0.89 (0.17 to 4.74)	0.02 to 48.57	1.65 (0.09 to 11.83)
	Mixed	20	11,470	1.06 (0.94 to 1.20)	0.93 to 1.20	0.00 (0.00 to 0.08)
	All	43	17,514	0.94 (0.82 to 1.09)	0.82 to 1.09	0.00 (0.00 to 0.18)
LGA	Physical activity	17	4594	**0.81 (0.71 to 0.94)**	0.69 to 0.97	0.00 (0.00 to 0.11)
	Diet	6	1450	0.72 (0.46 to 1.14)	0.44 to 1.18	0.00 (0.00 to 0.94)
	Mixed	19	11,236	1.03 (0.92 to 1.16)	0.92 to 1.16	0.00 (0.00 to 0.05)
	All	42	17,280	0.93 (0.85 to 1.02)	0.85 to 1.02	0.00 (0.00 to 0.05)

Bold values represent statistically significant results.

TABLE 14 Effects of lifestyle interventions on pregnancy outcomes in women with GDM (any criteria)

Outcome	Intervention	Number of studies	Number of women	OR (95% CI)	PI	τ^2
Hypertensive disease	Physical activity	13	276	**1.78 (1.25 to 2.51)**	**1.25 to 2.52**	0.00 (0.00 to 1.32)
	Diet	8	475	0.89 (0.46 to 1.75)	0.45 to 1.79	0.00 (0.00 to 2.72)
	Mixed	24	2079	1.06 (0.83 to 1.35)	0.83 to 1.35	0.00 (0.00 to 0.39)
	All	45	2830	1.09 (0.90 to 1.31)	0.90 to 1.31	0.00 (0.00 to 0.23)
Preterm birth	Physical activity	11	251	**2.28 (1.24 to 4.22)**	**1.23 to 4.25**	0.00 (0.00 to 1.72)
	Diet	6	246	**0.36 (0.18 to 0.74)**	**0.17 to 0.78**	0.00 (0.00 to 5.01)
	Mixed	22	1932	0.78 (0.57 to 1.06)	0.57 to 1.06	0.00 (0.00 to 0.51)
	All	40	2446	0.88 (0.67 to 1.17)	0.67 to 1.17	0.00 (0.00 to 0.50)
Caesarean section	Physical activity	13	274	0.82 (0.45 to 1.48)	0.45 to 1.49	0.00 (0.00 to 1.31)
	Diet	8	438	1.13 (0.93 to 1.38)	0.92 to 1.39	0.00 (0.00 to 1.13)
	Mixed	22	1981	0.98 (0.80 to 1.19)	0.77 to 1.25	0.00 (0.00 to 0.19)
	All	43	2693	0.98 (0.85 to 1.13)	0.85 to 1.13	0.00 (0.00 to 0.12)
Stillbirth	Physical activity	4	79	1.43 (0.60 to 3.39)	0.44 to 4.60	0.00 (0.00 to 11.32)
	Diet	4	177	0.71 (0.29 to 1.78)	0.21 to 2.46	0.00 (0.00 to 18.27)
	Mixed	14	1004	0.91 (0.78 to 1.06)	0.78 to 1.07	0.00 (0.00 to 1.45)
	All	22	1260	0.95 (0.78 to 1.14)	0.78 to 1.14	0.00 (0.00 to 0.86)
SGA	Physical activity	13	274	**1.60 (1.15 to 2.22)**	**1.15 to 2.23**	0.00 (0.00 to 1.26)
	Diet	6	241	0.89 (0.18 to 4.35)	0.03 to 26.97	1.13 (0.00 to 13.99)
	Mixed	15	1235	1.19 (0.93 to 1.51)	0.93 to 1.52	0.00 (0.00 to 0.71)
	All	34	1750	1.17 (0.92 to 1.49)	0.92 to 1.49	0.00 (0.00 to 0.51)
LGA	Physical activity	13	274	0.96 (0.56 to 1.66)	0.56 to 1.67	0.00 (0.00 to 1.29)
	Diet	6	241	**0.25 (0.13 to 0.48)**	**0.12 to 0.51**	0.00 (0.00 to 2.89)
	Mixed	17	1514	1.11 (0.86 to 1.44)	0.86 to 1.44	0.00 (0.00 to 0.21)
	All	36	2029	1.01 (0.80 to 1.28)	0.80 to 1.28	0.00 (0.00 to 0.22)
NICU admission	Physical activity	3	56	0.64 (0.12 to 3.52)	0.00 to 97.41	0.00 (0.00 to 27.36)
	Diet	5	365	0.68 (0.40 to 1.16)	0.37 to 1.25	0.00 (0.00 to 4.36)
	Mixed	18	1205	1.07 (0.81 to 1.43)	0.81 to 1.43	0.00 (0.00 to 0.44)
	All	26	1626	0.98 (0.78 to 1.24)	0.78 to 1.24	0.00 (0.00 to 0.32)

Bold values represent statistically significant results.

Network meta-analysis of interventions

A connected network was formed for GDM defined by any established criteria (54 studies and 4 interventions) (*Figure 12*). Eighteen studies compared control with physical activity-based interventions, 8 studies provided comparisons between control and diet-based interventions, and 28 studies compared control with mixed interventions.

The consistency assumption could not be assessed as there were no closed loops within the network (see *Figure 12*). Between-study heterogeneity was estimated to be non-zero, indicating some degree of heterogeneity between studies

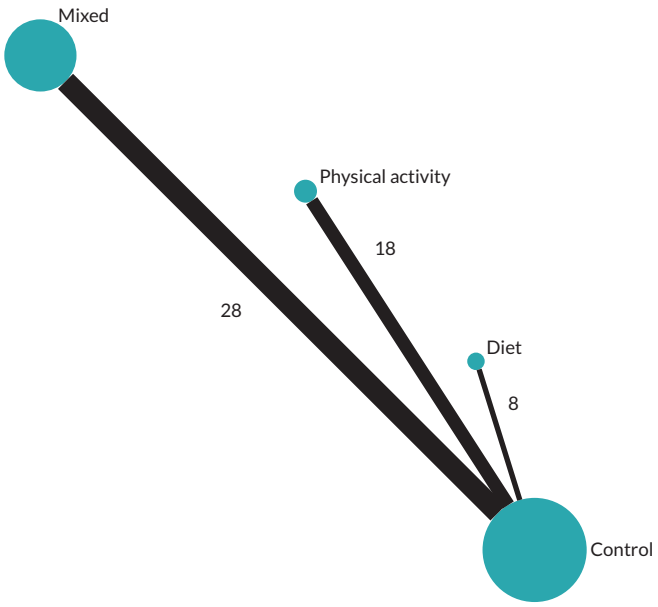

FIGURE 12 Network graph of included studies for GDM defined by any criteria, with thickness of lines and size of circles proportional to the number of studies and number of women, respectively.

included in the network ($\tau^2 = 0.10$). Summary effect estimates for comparisons for which there was direct evidence were consistent with the findings from univariate IPD meta-analyses. Indirect intervention effects were estimated for all other comparisons in the network (*Table 15*). Only the physical activity versus mixed-approach comparison was found to be statistically significant, showing a reduction in the odds of GDM by 39% on average (OR 0.61, 95% CI 0.46 to 0.83). All other indirect comparisons had 95% CI's overlapping the null value of one indicating the potential for no difference in effectiveness between interventions.

Table 16 gives the probability of each intervention being ranked from best to worst, as well as the mean rank with an estimate of uncertainty (95% CI) obtained from simulations. Physical activity had the highest mean rank (1.1, 95% CI 1 to 2) and highest probability of being ranked best intervention (89%). Mixed interventions had the lowest mean rank (3.8, 95% CI 3 to 4) and highest probability of being ranked worst intervention (78.6%). Diet and control interventions were less certainty in their mean ranking, with 95% CIs spread across three ranks. The uncertainty in the mean rankings indicates that for any particular ranking position it is somewhat uncertain which intervention is superior. Given the evidence from the univariate IPD meta-analysis above and the NMA here, there appears to be evidence that physical activity-based interventions may be beneficial in reducing the odds of GDM compared to other interventions examined here.

Network metaregression models were fitted including study-level characteristics describing the components of interventions. The consistency assumption remained valid for all network metaregression models (global Wald test *p*-values were all > 0.45). Between-study variance remained small, but non-zero (τ range 0.069 to 0.132). Some component effects could not be estimated due to collinearity. Where component effects could be estimated, the effects were estimated with uncertainty reflected in wide 95% CIs covering both potentially beneficial and harmful effects. No components of interventions were found to have a statistically significant effect on the overall intervention effect.

TABLE 15 Network meta-analysis results for all possible comparisons

Intervention 1	Intervention 2	OR	95% CI
Control	Physical activity	**1.55**	**(1.18 to 2.02)**
	Diet	1.23	(0.98 to 1.55)
	Mixed	0.95	(0.83 to 1.09)
Physical activity	Control	**0.65**	**(0.50 to 0.85)**
	Diet	0.80	(0.56 to 1.13)
	Mixed	**0.61**	**(0.46 to 0.83)**
Diet	Control	0.81	(0.65 to 1.03)
	Physical activity	1.26	(0.88 to 1.79)
	Mixed	0.77	(0.59 to 1.01)
Mixed	Control	1.06	(0.92 to 1.21)
	Physical activity	**1.63**	**(1.21 to 2.20)**
	Diet	1.30	(0.99 to 1.71)

Bold values represent statistically significant results.
Note
OR < 1 favours intervention 1, OR > 1 favours intervention 2.

TABLE 16 Estimated probabilities (%) of each intervention having each rank and the mean rank with 95% CIs for each intervention

	Intervention			
Rank (%)	Physical activity	Diet	Control	Mixed
Best	89	11	0	0
2nd	11	83.1	3.4	2.5
3rd	0	3.1	78	18.9
Worst	0	2.8	18.6	78.6
Mean rank (95% CI)	1.1 (1 to 2)	2 (1 to 3)	3.2 (2 to 4)	3.8 (3 to 4)

Chapter 6 Cost-effectiveness of lifestyle interventions to prevent gestational diabetes

Introduction

This chapter reports the economic evaluation carried out within the i-WIP project. The primary objective of the economic analysis was to determine the relative cost-effectiveness of overall lifestyle intervention (physical activity-based, diet-based, mixed) compared with usual care to prevent GDM and its complications in women with a BMI of ≥ 18.5 kg/m^2 in early pregnancy. We have defined these three main intervention types in Chapter 3 above. For our economic analysis, we used the study authors' definition of GDM within the study to define glucose intolerance with onset or first recognition during pregnancy.[122]

A secondary objective was to conduct cost-effectiveness analyses using either physical activity-based or diet-based as the sole intervention. An additional objective was to undertake subgroup analyses based on pre-specified maternal characteristics including BMI, age, parity and ethnicity.

Method

The main economic analysis was a cost-effectiveness analysis (CEA) using a decision-analytic model as this was considered the most suitable approach for presenting alternative pathways and collating the data for analysis. In a decision-analytic model, events are expressed as probabilities, weighted against costs and outcomes to calculate an expected value for each alternative option.[123] A decision tree model was deemed appropriate for this study due to the short-term nature of the decision problem.[123]

The study population was women whose pre-pregnancy BMI were classed as normal, overweight or obese. Underweight women (with a BMI < 18.5) were not included. The base-case analysis was derived from available data from the IPD meta-analysis conducted for the i-WIP project.[20] The CEA adopted the perspective of the UK NHS; hence only direct health costs were reported. The time horizon adopted for the base-case analyses was from the beginning of pregnancy until the discharge of the mother and infant from the hospital following delivery. Given that this duration is typically < 1 year, discounting was not required for the base-case analysis.

The analysis compared the use of lifestyle interventions versus usual care for the prevention of GDM. Usual care in this context refers to care as usual by their midwife or obstetrician without any behavioural interventions. The IPD meta-analysis provides a composite outcome which includes various maternal and fetal outcomes. The primary economic evaluation results are reported in terms of the additional cost per case of GDM avoided. Maternal and fetal outcomes such as the number of caesarean sections avoided, the number of stillbirths and the number of neonatal admissions to NICU as well as the major outcome averted (MOA) were also reported.

There is no cost-effectiveness threshold for results in natural units such as adverse maternal and neonatal outcomes. Hence, we considered that the intervention was cost-effective or dominant if the decision-makers' willingness to pay (WTP) for a case of GDM avoided is zero for the GDM avoided analysis. For the MOA analysis, we considered that the intervention was cost-effective or dominant if the decision-makers' WTP for a case of MOA is zero.

Model structure

A decision tree model (*Figure 13*) was constructed using TreeAge Pro software (TreeAge Software, Inc., Williamstown, MA, USA) (TREEAGE Software Williamstown MA. TreeAge Pro 2023. R1 Healthcare; 2023). The model structure was informed by the objectives of the study, NICE guidelines on the management of diabetes in pregnant women[16,124] as well as the approaches used in published model-based studies that are relevant to the study.[13,125] The pathways of the

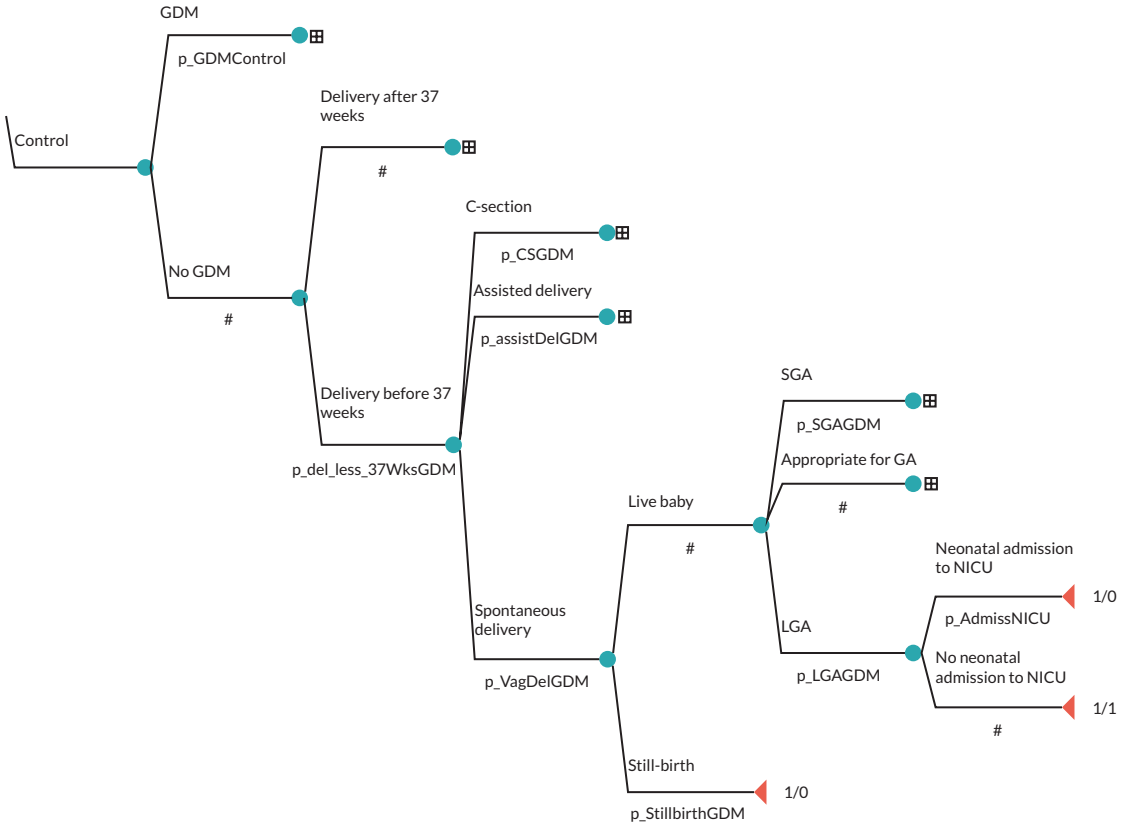

FIGURE 13 International Weight Management in Pregnancy GDM model structure.

model were finalised using expert opinion from within the research study team and represent, as far as possible, the clinical steps carried out in a UK hospital in the event of GDM.

Within the model the intervention (physical activity-based, diet-based, and mixed) and usual care (control) were directly compared. The model was parameterised using data from the i-WIP IPD meta-analysis, supplemented by published literature as well as expert opinion from within the research study team. Square boxes depict decision nodes, for which a choice is made between strategies (intervention and usual care). Circles represent chance nodes, and here, several subsequent events could happen with each event assigned a probability of occurring. Triangles represent terminal nodes and signify the final possible outcomes in the model.

Women with a BMI of ≥ 18.5 kg/m^2 in early pregnancy entered the model at randomisation to receive either the intervention (diet, physical activity or mixed) or usual care (control). All women were assumed to follow one of two alternative clinical pathways based on whether they developed GDM or not (see *Figure 13*). We focused on the interventions effect on reducing GDM only and did not consider the interventions effect on hypertensive diseases. We also used effectiveness data solely from the IPD meta-analysis and thus did not look at outcomes following birth. Each pathway included appropriate maternal and fetal outcomes as detailed below. The final outcomes were assessed on discharge from the hospital following delivery.

We acknowledge that a possible pathway following randomisation could include fetal demise (defined as the loss of pregnancy following randomisation and before a diagnosis of GDM or no GDM arms) and maternal death. However, these events occur for only a very small proportion of patients, with the literature reporting a risk of 0.00088[126] and 0.01[127] for maternal death and fetal demise, respectively. We have, however, excluded both events as it is a chance finding not related to the model intervention.

Following a diagnosis of GDM or no GDM, women could experience either a preterm birth defined as birth before 37 gestational weeks or a birth at term. The modes of birth included in the model were spontaneous birth, assisted birth

and caesarean section. The outcome of the delivery was either a live baby or a stillbirth [or intrauterine death (IUD)]. Stillbirth was defined as a baby born with no signs of life after 24 weeks of completed pregnancy and IUD as a baby with no signs of life in utero.[128] Women who experienced stillbirth or IUD were assumed to have received appropriate antenatal care for any condition they were recorded as developing during the trial. Additional costs associated with investigations and counselling were included in the total costs for these women.[129]

As the focus of the intervention was on GDM prevention, we did not consider the interventions effect on hypertensive diseases. As much as possible, for the base-case analysis, we only included pathways for which data were available from the i-WIP meta-analysis; thus, events such as maternal admissions to intensive care unit following childbirth were not included in the analysis.

Model pathways

The model was built on the predefined assumption that the mother and baby are one; hence the maternal and fetal outcomes were not separated. In this model, the women either get GDM or do not. Other pregnancy complications were not considered in the model. We focused on GDM, and only GDM complications were considered.

Model assumptions

To develop a workable model, some further pragmatic assumptions were required. All assumptions were agreed with the clinical team before the model-based analysis was undertaken. These are summarised below and divided into two categories: model pathways and model inputs.

Model inputs

We assumed that women who developed GDM would receive the most resource-intensive pathway (based on clinical expert opinion). Based on NICE guidelines,[16] we assumed that women who developed GDM incurred additional antenatal healthcare costs related to testing and treatment. These costs, taken from an economic model informing the guidelines, included an initial treatment to control blood glucose levels using diet with subsequent treatment using insulin or metformin if adequate control of blood glucose was not achieved after 10 days. This initial treatment comprised 0.5 hours of a dietitian's time, 0.5 hours of a nurse's time on blood glucose self-monitoring training and 10 days of four daily blood glucose readings. Patients achieving adequate control using diet continued on diet for 80 days and the additional resource use were two daily blood glucose readings. For patients who did not achieve blood glucose control after 10 days, we assumed an even split went to insulin or metformin. Insulin analogue comprised an initial 0.75 hours of a nurse time on training, and twice-daily insulin injections for 80 days. For patients who are put on metformin, they had a daily 15 mg treatment dose and two daily blood glucose readings for 80 days. Patients had a risk of severe hypoglycaemia requiring hospital admission with insulin analogue (1%) or metformin (0.1%).

Since all participants in the model received routine antenatal care at onset, and the economic evaluations were used to examine the differences in costs and outcomes between alternative courses of action,[130] the costs of routine antenatal care were not included in the model as they would be identical for each arm.

The cost of delivery of the baby was based on the NHS Reference costs schedule.[131] For those women who had a diagnosis of GDM, all delivery options had a complications and comorbidities score of 1–2 plus (comorbidities scores range from 0 to 4 with a higher score denoting severity). For women without GDM, it was assumed that women would not have any complications and that their delivery would have a complications and comorbidities score of 0–1. The onset of labour (which could be spontaneous or induced) was not included in the model as within the NHS cost schedule these costs were not explicitly separated from the delivery costs. Hence, for the base-case analysis, we assumed that the delivery cost included the cost of the mode of labour onset.

Model parameters

The main clinical data used to populate the model were drawn from the IPD meta-analyses. Resource use was obtained from the published sources and unit costs were based on established sources such as the National Schedule of Reference Costs[131] and the Unit Costs of Health and Social Care.[132]

Effectiveness data

The primary focus of the economic evaluation was the effect of the intervention on maternal and fetal outcomes. The maternal outcomes included the development of GDM as well as outcomes relating to the timing and mode of delivery (preterm delivery and caesarean section). Fetal outcomes included stillbirth/IUD or livebirth with either SGA babies or LGA babies. The terminal outcome was neonatal admission to the NICU or no neonatal admission to the NICU.

Maternal outcomes

The estimates of baseline risk and the effect of the intervention on the development of GDM were drawn from the IPD meta-analysis (*Table 17*). For the intervention effect, data from the IPD meta-analysis were used to estimate pooled effect ORs for the development of GDM. The baseline risk for the usual care group was based on pooled data for the control groups included in the trials.

To derive the baseline effect values, a multilevel mixed-effects logistic regression (melogit) on GDM was run adjusting only for the allocation variable (random effects on studies). Then the intercept (alpha) was used to calculate the baseline risk for GDM for the control group (p) as p = exp(alpha)/(1 + exp(alpha)). For the intervention group, the beta was calculated, where beta = alpha + log OR (OR for developing GDM and no GDM, obtained previously from the IPD). Now, the baseline risk for GDM for the intervention group (q) is q = exp(beta)/[1 + exp(beta)].

For all other variables, there was no adjustment for the allocation variable when running the logistic regression. So, the base-case values for these variables were based on all the women in the i-WIP IPD, irrespective of whether they were in the control arm or the intervention arm. Maternal outcomes were not considered when they were already observed at baseline, that is, we did not count the presence of GDM in women who had DM or GDM at baseline.

The IPD meta-analysis also considered maternal outcomes related to the timing and type of delivery (*Table 18*). These included preterm delivery, normal delivery, assisted delivery and caesarean section. Delivery-related outcomes were estimated for all women irrespective of whether they received the intervention or care as usual.

Fetal outcomes

The IPD meta-analysis data provided estimates of fetal and infant outcomes for all women. *Table 19* shows fetal outcomes for women with and without GDM.

Costs

The cost inputs for the model were estimated from the perspective of the UK NHS. Unit costs for each resource item (*Table 20*) were identified from published national sources. The majority of the costs were obtained from the National Schedule of NHS Costs 2020–1[131] while some costs were also obtained from previous literature.[13,129]

TABLE 17 Baseline risk and intervention effect

Description	Base-case value	Distribution	Alpha	Beta	Source
Baseline risk of GDM (control)	0.125865	Beta	1379	9579	IPD
Baseline risk of no GDM (control)[a]	0.874135	N/A	N/A	N/A	IPD
Baseline risk of GDM (intervention)	0.1186281	Beta	1471	10,932	IPD
Baseline risk of no GDM (intervention)[a]	0.8813719	N/A	N/A	N/A	IPD

N/A, not applicable.
a Calculated as the remainder of 1 Baseline Risk of GDM.

Note
Values of α and β are given for beta distributions. The base-case values were used to produce deterministic results.
The distributions were used to undertake probabilistic sensitivity analysis, produce the probabilistic results and produce the incremental cost-effectiveness scatterplots.

TABLE 18 Timing and mode of birth for women

Description	Base-case value	Distribution	Alpha	Beta	Source
GDM					
Preterm birth (birth before 37 weeks)	0.1160	Beta	285	2172	IPD
C-section	0.3159	Dirichlet	$\alpha_1 = 854$	N/A	IPD
Assisted birth	0.1239	Dirichlet	$\alpha_2 = 335$	N/A	IPD
Spontaneous birth	0.5601	Dirichlet	$\alpha_3 = 1514$	N/A	IPD
No GDM					
Preterm delivery (birth before 37 weeks)	0.0914	Beta	1649	16,386	IPD
C-section	0.2517	Dirichlet	$\alpha_1 = 4892$	N/A	IPD
Assisted birth	0.1096	Dirichlet	$\alpha_2 = 2130$	N/A	IPD
Spontaneous birth	0.6387	Dirichlet	$\alpha_3 = 12416$	N/A	IPD

N/A, not applicable.

Note
Values of α and β are given for beta distributions. The base-case values were used to produce deterministic results. The distributions were used to undertake probabilistic sensitivity analysis, produce the probabilistic results and produce the incremental cost-effectiveness scatterplots.

TABLE 19 Fetal outcomes

Description	Base-case value	Distribution	Alpha	Beta	Source
GDM					
Stillbirth	0.0369	Beta	50	1306	IPD
LGA	0.1958	Beta	399	1639	IPD
SGA	0.0599	Beta	123	1932	IPD
Appropriate for gestational age[a]	0.7444	N/A	N/A	N/A	IPD
Infant admission to the NICU	0.1222	Beta	202	1451	IPD
No GDM					
Stillbirth	0.0184	Beta	165	8825	IPD
LGA	0.1396	Beta	2086	12,853	IPD
SGA	0.0719	Beta	1089	14,067	IPD
Appropriate for gestational age[a]	0.7885	NA	NA	NA	IPD
Infant admission to the NICU	0.0775	Beta	899	10,707	IPD

N/A, not applicable.
a Calculated as the remainder of 1 – LGA proportion–SGA proportion.

Note
Values of α and β are given for beta distributions. The base-case values were used to produce deterministic results.
The distributions were used to undertake probabilistic sensitivity analysis, produce the probabilistic results and produce the incremental cost-effectiveness scatterplots.

TABLE 20 Unit costs of resource items (prices in £2022–3)

Description	Unit cost (£)	Standard error	Distribution	Source
Intervention (physical activity and diet-based intervention)	245	49	Gamma	(Rogozińska *et al.*, 2017)
Additional cost of stillbirth (core-recommended investigations and care immediately following a miscarriage)	1403	281	Gamma	(Rogozińska *et al.*, 2017, Mistry *et al.*, 2013)
Additional antenatal care for GDM	177	35	Gamma	(NICE, 2015)
Preterm birth with CCs (CC Score 2 +) NZ17A	1266	253	Gamma	NHS Cost Schedule 2020/21
Preterm birth without CCs (CC Score 0–1) NZ17B	845	169	Gamma	NHS Cost Schedule 2020/21
Spontaneous birth with CCs (normal delivery with CC score 1–2 +) NZ30A, NZ30B	3175	635	Gamma	NHS Cost Schedule 2020/21
Spontaneous birth without CCs (normal birth with CC score 0) NZ30C	2597	519	Gamma	NHS Cost Schedule 2020/21
Assisted birth with CCs. (assisted birth with CC score 1–2 +) NZ40A, NZ40B	4169	834	Gamma	NHS Cost Schedule 2020/21
Assisted birth without CCs. (assisted birth with CC score 0) NZ40C	3318	664	Gamma	NHS Cost Schedule 2020/21
C-section with CCs (planned or emergency caesarean section with CC Score 2–3) NZ50B, NZ51B	7064	1413	Gamma	NHS Cost Schedule 2020/21
C-section without CCs (planned or emergency caesarean section with CC Score 0–1) NZ50C, NZ51C	6188	1238	Gamma	NHS Cost Schedule 2020/21
Neonatal admission to NICU, XA01Z	1866	373	Gamma	NHS Cost Schedule 2020/21
Routine postnatal care (postnatal disorders with CC Score 0–1) NZ26B	1369	274	Gamma	NHS Cost Schedule 2020/21
Postnatal care: women with GDM (postnatal disorders with CC Score 2 +) NZ26C	2146	429	Gamma	NHS Cost Schedule 2020/21

All costs were expressed in 2021–2 Great British pound values. Cost estimates from earlier years were inflated to 2021–2 prices using the Hospital and Community Health Services (HCHS) pay and prices index.[132] The HCHS pay and price inflation is a weighted average of two separate inflation indices – the pay cost index and the health service cost index. In cases where there are different categories associated with resource use, weighted averages were used (see *Table 20*).

The cost of the intervention was obtained from a previous study for the i-WIP project[13] which used a cost based on a systematic review by the authors.[13] This cost was the median value of pregnancy weight management interventions studies reporting an intervention cost;[13] the median value corresponds to a Netherlands study where the intervention comprised twice weekly 1 hour exercise group programme by a trained physiotherapist for the remainder of the pregnancy.[133] The intervention cost was inflated using Dutch Consumer Price Index and then converted into a UK equivalent using Purchase Power Parity ratios.[134] The additional cost of antenatal care for women with GDM was obtained from the 2015 NICE guidelines on the management of diabetes in pregnancy.[16,124] The standard error was assumed to be 20% of the mean cost where it was not reported.

Analysis

The model-based CEA evaluated the costs and outcomes of diet and physical activity-based interventions compared to usual care in preventing GDM for pregnant women with a BMI of ≥ 18.5 kg/m^2 at the start of pregnancy. The base-case

analysis explored a hypothetical cohort of 10,000 pregnant women based on the findings of the IPD meta-analysis for all women. Additional analyses were carried out using either physical activity or diet-based interventions only (*Table 21*).

To explore if the intervention when administered to a specific group was more effective, pre-defined subgroup analyses were conducted on women based on their pre-pregnancy BMI categories. Three BMI categories were assessed – normal weight (pre-pregnancy BMI of 18.5–24.9 kg/m^2), overweight (pre-pregnancy BMI 25–29.9 kg/m^2) or obese (pre-pregnancy BMI of ≥ 30 kg/m^2). A series of subgroup analyses were also carried out on other maternal characteristics including age (< 20 years and ≥ 20 years), parity (nulliparous and multiparous), ethnicity (White and non-White) and educational level (low, middle and high).

The relative cost-effectiveness was calculated using estimates of effect size from the IPD meta-analysis. The results were reported in terms of an incremental cost-effectiveness ratio (ICER) of cost per MOA measured as clinical outcomes. These outcomes included GDM, caesarean section, pre-term birth, SGA, LGA and admission to NICU. The IPD meta-analysis provided various outcomes, which included maternal and fetal complications.

Sensitivity analysis

To quantify the inherent uncertainty associated with the model assumptions and ultimately assess the generalisability of the results, a series of deterministic and probabilistic sensitivity analyses were carried out. Deterministic sensitivity analysis (DSA) comprises the variation of one or more parameters while keeping the others at their baseline value. A DSA can identify the model inputs relevant to a decision and also identify threshold values.[123]

A probabilistic sensitivity analysis (PSA) was also undertaken to allow a comprehensive representation of the uncertainty of the model input data. For each uncertain parameter, probability distributions were assigned, from which a value was randomly drawn. Ten thousand (10,000) Monte Carlo simulations were subsequently computed, by simultaneously varying all relevant parameters to generate paired mean cost and effectiveness estimates. These estimates were used jointly to form an empirical distribution of the differences in both the cost and effectiveness of interventions. Beta distributions were applied to probabilities where only two outcomes were possible and gamma distributions were for costs.[135] Ninety-five per cent PIs illustrate the variability around the model mean output predictions.

The paired estimates of costs and effectiveness generated by the simulations were plotted as scatterplot dots in a cost-effectiveness plane.[123,136] A cost-effectiveness plane is made up of four quadrants: north-east, north-west, south-east and south-west. Based on the location of the scatterplot dots on the quadrant, an intervention may be deemed more effective and more costly (north-east), more effective and less costly (south-east), less effective and less costly (south-west) or less effective and more costly (north-west) than the alternative intervention.

Using the net monetary benefit (NMB) for each of the simulations, the proportion of times the intervention had the highest NMB was calculated for a range of threshold values for the maximum WTP for a GDM avoided. These values were summarised graphically using a cost-effectiveness acceptability curve (CEAC) to show the uncertainty surrounding the cost-effectiveness of the intervention, for a range of thresholds for cost-effectiveness.

TABLE 21 Baseline risk and intervention effect for physical activity and diet-based interventions

Description	Base-case value	Distribution	Alpha	Beta	Source
Physical activity-based interventions only					
Baseline risk of GDM (control)	0.0788	Beta	175	2047	IPD
Baseline risk of GDM (physical activity)	0.0484	Beta	110	2163	IPD
Diet-based interventions only					
Baseline risk of GDM (control)	0.1732	Beta	265	1265	IPD
Baseline risk of GDM (diet)	0.1476	Beta	210	1212	IPD

Value of information analysis has been undertaken to inform and prioritise future research. First, the expected value of perfect information (EVPI) was estimated. The EVPI measures the additional value of resolving all decision uncertainty compared to the current level of decision uncertainty within the model-based economic evaluation.[137] Second, the expected value of perfect parameter information (EVPPI)[137,138] was carried out to assess the value in removing the uncertainty in the following groups of parameters:

1. baseline risk of GDM in intervention and usual care
2. cost of the intervention
3. mode of delivery for GDM and non-GDM patients.

Expected value of perfect parameter information was calculated using a double-loop Monte Carlo simulation. The inner loop was run for 10,000 samples, and the outer loop was run with 1000 samples.[138]

Deterministic sensitivity analysis

A range of DSAs was carried out for the primary and secondary analyses. This sensitivity analysis involves varying input values one at a time across a plausible range while holding the remaining values at their baseline values.[139]

Varying the cost of the intervention – the cost of the intervention used for this research was from a previous study conducted as part of the i-WIP project.[13] We varied the costs to reflect the minimum (£154) and maximum (£1156) costs identified from the literature.[13]

Threshold analysis – the UK NICE recommends a cost-effectiveness threshold range of £20,000–30,000 per quality-adjusted life-year (QALY) gained. However, there is no cost-effectiveness threshold for results in natural units such as adverse maternal and neonatal outcomes. Hence, we conducted a threshold analysis to identify when the intervention would be dominant or where the intervention would be selected if the decision-makers' WTP for a case of GDM avoided is zero. The threshold analysis was performed in a deterministic manner, with the cost of the intervention varied while other inputs remained fixed.

The onset of labour – the onset of labour was not included in the base-case analysis. However, for the sensitivity analysis, we assumed that the onset of labour for women who developed GDM was by induction. This involved changing the cost of spontaneous delivery from £3175 to £4181 and the cost of assisted delivery from £4169 to £5215.

Caesarean section – for the base case we assumed a cc score of 0–1 for women without GDM and 2–3 for women with GDM. For the sensitivity analysis, we explored the impact of the highest cc score (four plus) for women with GDM. Hence, we changed the cost of a caesarean section for women with GDM from £7064 to £8540.

Results

Primary analysis

The results of the primary analysis are provided in *Table 22*. At the end of pregnancy for the primary outcome (cases of GDM avoided), the control arm was cheaper with an average cost of £5422 compared to the i-WIP intervention arm with a cost of £5652 with a cost difference of £230. However, women in the intervention arm avoided more cases of GDM (0.8814) than those in the control arm (0.8741) with an effect difference of 0.0072. The difference in cost and effectiveness resulted in an ICER of £31,827 per GDM avoided. This means that there is an additional cost of £66,520 for every additional GDM avoided following the intervention pathway compared to the control.

An additional base-case analysis was performed in terms of cost per MOA (see *Table 22*). Overall, 35 fewer women experienced any major outcome in the intervention arm. Again, the intervention was more costly but more effective with an ICER of £66,520 per MOA compared to the control.

The base-case point estimate results of the individual maternal and fetal outcomes evaluated are presented in *Table 23*. The intervention led to 17 fewer cases of LGA and 2 fewer preterm delivery cases. Similarly, the intervention led to

TABLE 22 Average costs (£) for the intervention group compared with usual care (point estimate)

Group allocation	Total cost (£)	Cost difference (£)	Total effect	Effect difference	Cases avoided difference in 10,000 women	ICER (£)
Primary analysis (GDM avoided)						
Control	5422		0.8741			
Intervention	5652	230	0.8814	0.0072	72	31,827
MOA						
Control	5422		0.4182			
Intervention	5652	230	0.4217	0.0035	35	66,520

TABLE 23 Results for primary base-case analysis for a cohort of 10,000 women (point estimates)

Outcome	Outcomes avoided		Women experiencing outcomes		Outcomes avoided difference	Cost per outcomes avoided (£)
	Intervention	Control	Intervention	Control		
Preterm birth	9008	9007	992	993	2	1,273,062
Caesarean section	7422	7418	2578	2582	5	485,902
IUD/stillbirth	9781	9780	219	220	1	1,591,328
SGA	9316	9317	684	683	−1	Dominated
LGA	8483	8465	1517	1535	17	131,779
NICU admissions	9194	9191	806	809	3	774,327

minimal reductions in stillbirths, caesarean sections and admissions to the NICU. However, one additional woman gave birth to a SGA baby in the intervention arm.

The ICERs show that there was an additional cost of £1,273,062 for each preterm delivery avoided, £485,902 for each caesarean section avoided, £131,779 for each LGA avoided and £774,327 for each NICU admission avoided. Thus, if the outcome of interest is a reduction in the number of NICU admissions, an additional £774,327 is required for each additional woman who avoids this complication compared with usual care.

The results of the PSA (*Table 24*) provide an assessment of the parameter uncertainty in the cost and effectiveness for both arms using 10,000 Monte Carlo simulations. These results show that the intervention on average to be more costly and more effective with an effect difference than usual care. At a zero WTP threshold for outcomes averted, usual care was associated with a higher average NMB.

This is further illustrated by *Figure 14*. The graph plots the result of the PSA iterations on the cost-effectiveness plane. The plane shows the joint density of differences in cost and effectiveness between the two model arms. Most of the plots are in the northeast quadrant showing that the intervention is more costly and more effective.

The CEAC is presented in *Figure 15*. The CEAC shows that the probability that the intervention is cost-effective increases as the WTP for the cases of GDM averted increases. At a zero WTP for an additional case of GDM avoided threshold, the intervention was not cost-effective across the PSA iterations. As the WTP threshold for an additional case of GDM avoided increases, the number of PSA iterations where the intervention was cost-effective increases. The highest level of uncertainty on which option is the most cost-effective, that is where the probability for either strategy is 50%, is where the WTP threshold for an additional case of GDM avoided is set at £32,000. Beyond this WTP threshold, the probability of the intervention being cost-effective is higher than the probability of the control being cost-effective.

TABLE 24 Results of the PSA (GDM avoided)

Group	Mean cost (£) (95% PI)	Effect (95% PI)	Cases avoided difference in 10,000 women (95% PI)	NMB
Intervention	5652 (5627 to 5677)	0.8814 (0.8814 to 0.8815)	8814 (8814 to 8815)	−5652 (−5677 to −5627)
Control	5422 (5398 to 5447)	0.8741 (0.8741 to 0.8742)	8741 (8741 to 8742)	−5422 (−5447 to −5398)

Note
NMB calculated assuming WTP of zero per GDM case avoided.

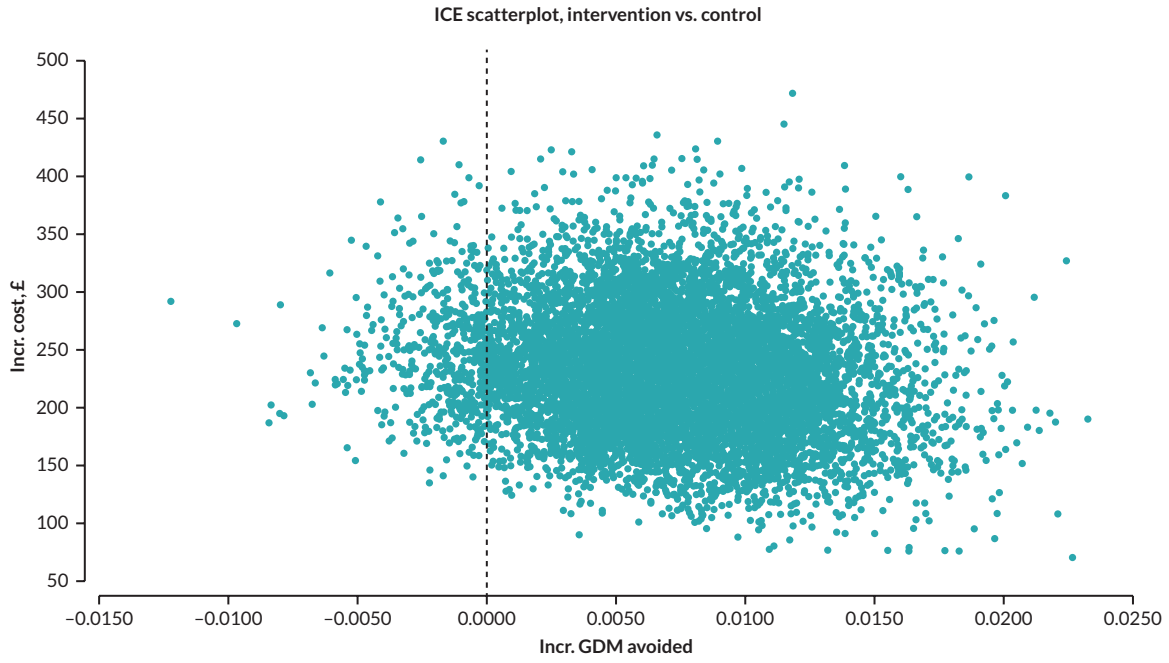

FIGURE 14 Cost-effectiveness plane for base-case analysis (GDM avoided).

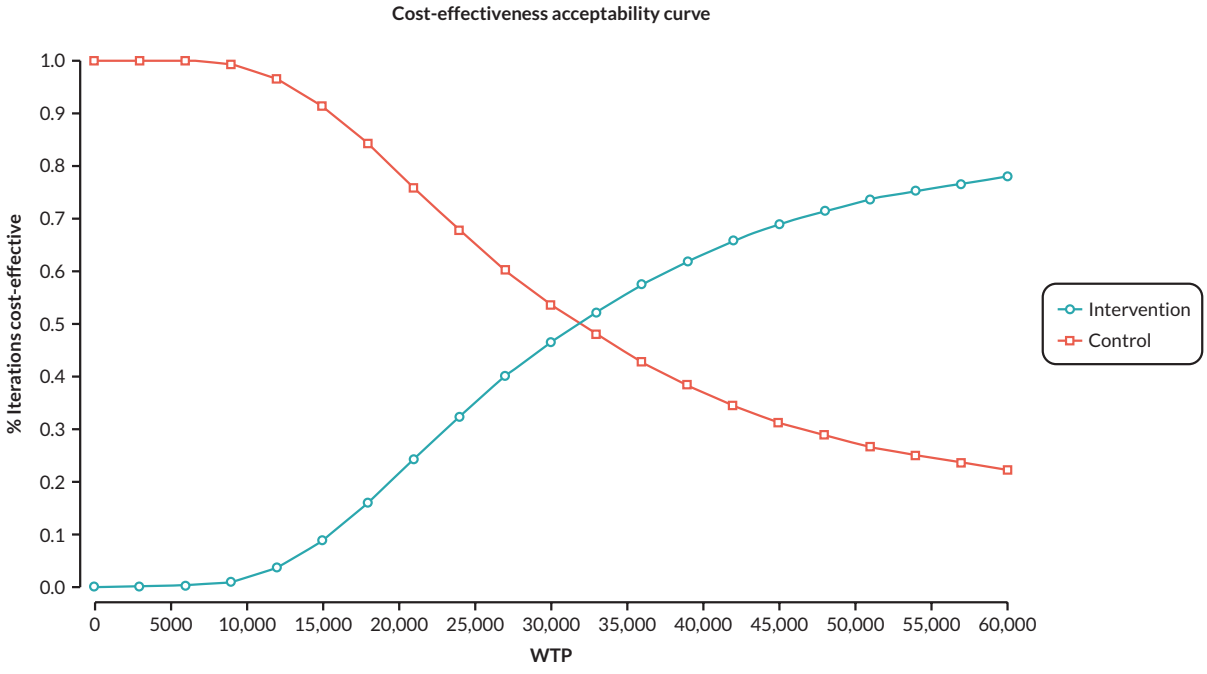

FIGURE 15 Cost-effectiveness acceptability curve for base-case analysis (GDM avoided).

The EVPI increases as the WTP threshold increases until it peaks around the £33,000 threshold and then decreases at subsequent higher WTP thresholds. This peak is £58 per woman to eliminate all decision uncertainty (*Figure 16*).

A PSA was carried out for all the outcome measures including GDM, preterm delivery, caesarean sections, stillbirths, LGA, SGA and NICU admissions avoided. The mean results across the PSA iterations (*Table 25*) show that the intervention remained more costly but more effective than usual care. This result is further illustrated in *Figures 17* and *18*. The intervention was always more costly than usual care but was not always more effective across all the PSA iterations (see *Figure 17*).

The CEAC for MOA (see *Figure 18*) shows that the crossover point where uncertainty is highest is at the £67,000 WTP threshold for MOA.

The EVPI for MOA followed a similar pattern as the GDM EVPI graph with increases in per-patient EVPI as the WTP threshold increases until a certain point and then decreases in EVPI for WTP thresholds thereafter (*Figure 19*). The highest per-patient EVPI was £57 at a WTP threshold of £65,000 per major outcome avoided.

The EVPPI results for GDM avoided and MOA are shown in *Table 26*. There was no value in eliminating the decision uncertainty on mode of delivery at any of the WTP thresholds examined. Baseline GDM risk was associated with the highest value out of the parameters examined and peaked at WTP thresholds near the respective deterministic ICERs for GDM avoided and MOA.

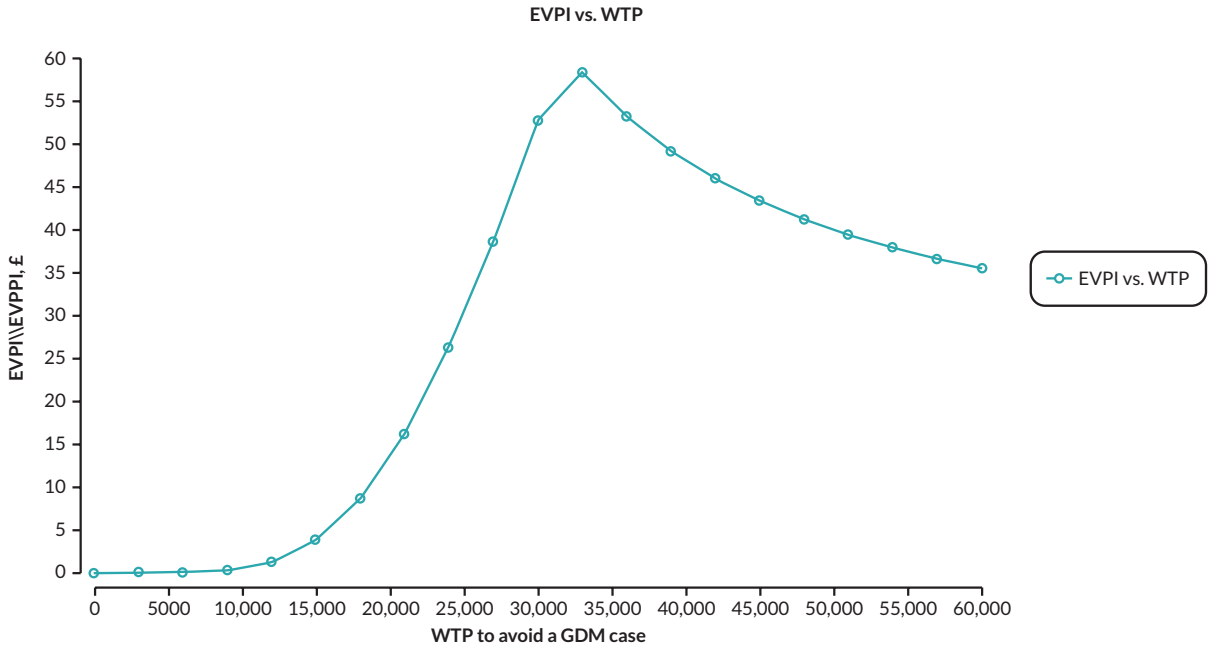

FIGURE 16 Expected value of perfect information: GDM avoided.

TABLE 25 Probabilistic sensitivity analysis for all outcomes (MOA)

Group	Mean cost (£) (95% PI)	Effect (95% PI)	Cases avoided difference in 10,000 women (95% PI)	NMB (£)
Intervention	5652 (5627 to 5677)	0.4208 (0.4207 to 0.4208)	4208 (4207 to 4208)	−5652 (−5677 to −5627)
Control	5422 (5398 to 5447)	0.4173 (0.4172 to 0.4174)	4173 (4172 to 4174)	−5422 (−5447 to −5398)

Note
NMB calculated assuming WTP of zero per MOA.

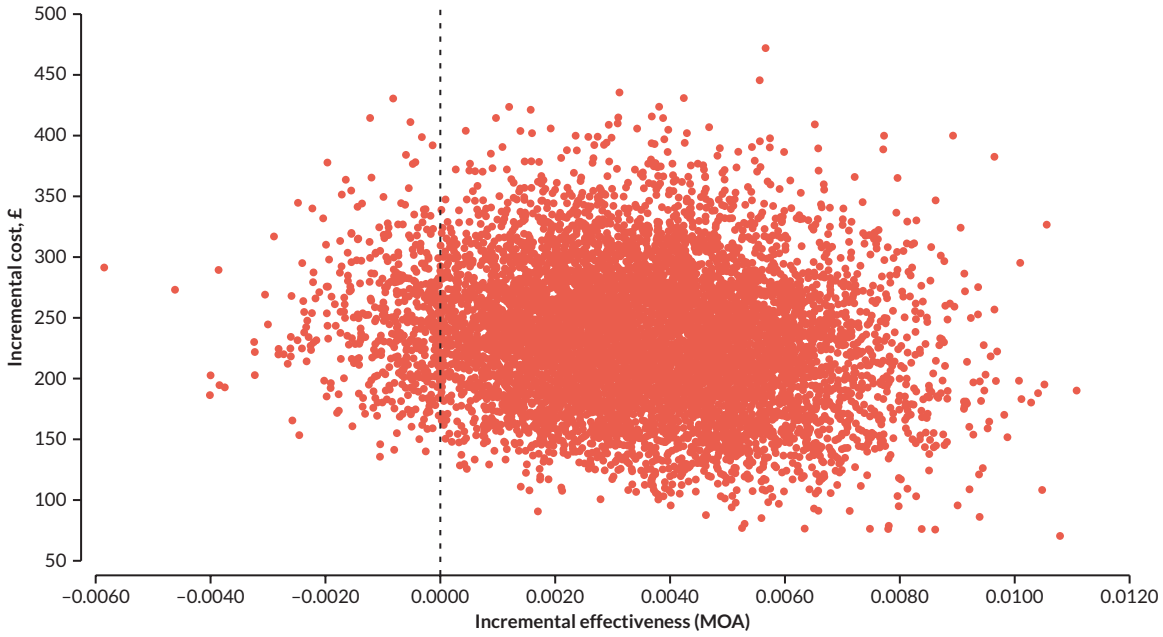

FIGURE 17 Cost-effectiveness plane (MOA).

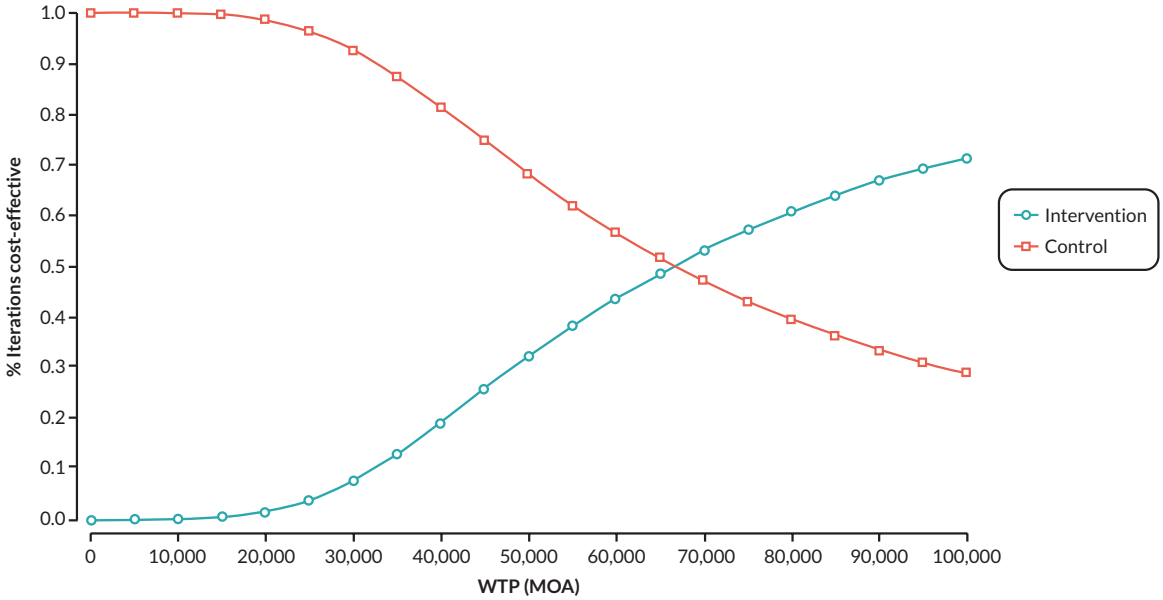

FIGURE 18 Cost-effectiveness acceptability curve (MOA).

Secondary analysis

Physical activity and diet-based interventions

Additional analyses were conducted to assess the relative cost-effectiveness of physical activity-based and diet-based interventions only compared to usual care in preventing adverse maternal and neonatal outcomes. Using cost values derived from a previous study conducted within the i-WIP project,[125] the cost of diet-based interventions was estimated as £100 while the cost of physical activity-based interventions was £130.

The PSA results averaged across 10,000 iterations (*Table 27*) showed that the use of either diet or physical activity-based interventions alone was more costly and more effective than usual care. The impact of diet or physical activity is further highlighted by the cost-effectiveness planes and the CEACs presented in *Figures 20–23*.

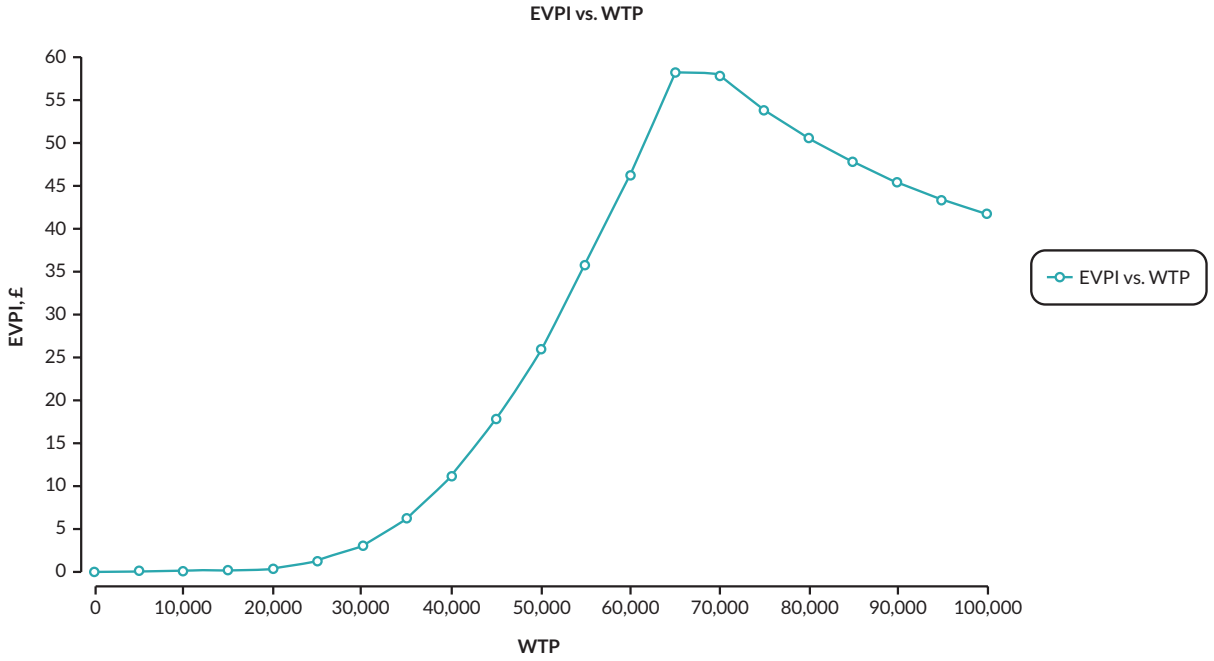

FIGURE 19 Expected value of perfect information: MOA.

TABLE 26 Expected value of perfect parameter information

	GDM avoided			Major outcomes averted		
WTP (£)	GDM baseline risk (£)	Intervention cost (£)	Mode of delivery (£)	GDM baseline risk (£)	Intervention cost (£)	Mode of delivery (£)
0	0.00	0.00	0.00	0.00	0.00	0.00
5000	0.00	0.00	0.00	0.00	0.00	0.00
10,000	0.05	0.00	0.00	0.00	0.00	0.00
15,000	1.64	0.01	0.00	0.00	0.00	0.00
20,000	9.51	0.69	0.00	0.02	0.00	0.00
25,000	25.59	4.11	0.00	0.26	0.00	0.00
30,000	48.37	15.20	0.00	1.15	0.00	0.00
35,000	49.63	10.40	0.00	3.55	0.08	0.00
40,000	43.23	3.28	0.00	7.47	0.43	0.00
45,000	38.41	0.65	0.00	13.45	1.27	0.00
50,000	35.06	0.11	0.00	21.31	2.91	0.00
55,000	32.58	0.00	0.00	30.84	5.99	0.00
60,000	30.74	0.00	0.00	41.71	11.14	0.00
65,000	29.26	0.00	0.00	53.66	18.80	0.00
70,000	28.11	0.00	0.00	52.17	14.14	0.00
75,000	27.28	0.00	0.00	48.45	8.81	0.00
80,000	26.70	0.00	0.00	45.34	5.17	0.00
85,000	26.23	0.00	0.00	42.61	2.79	0.00
90,000	25.87	0.00	0.00	40.17	1.32	0.00
95,000	25.60	0.00	0.00	38.13	0.57	0.00
100,000	25.39	0.00	0.00	36.45	0.26	0.00

TABLE 27 Secondary analysis (GDM avoided)

Group allocation	Mean cost (£) (95% PI)	Effect (95% PI)	Mean cases avoided in 10,000 women (95% PI)	NMB (95% PI)
Physical activity				
Intervention	5364 (5338 to 5391)	0.9516 (0.9515 to 0.9517)	9516 (9515 to 9517)	−5364 (−5391 to −5338)
Control	5327 (5301 to 5352)	0.9213 (0.9212 to 0.9214)	9213 (9212 to 9214)	−5327 (−5352 to −5301)
Diet				
Intervention	5597 (5573 to 5621)	0.8523 (0.8521 to 0.8525)	8523 (8521 to 8525)	−5597 (−5621 to −5573)
Control	5518 (5495 to 5541)	0.8269 (0.8267 to 0.8271)	8269 (8267 to 8271)	−5518 (−5541 to −5495)

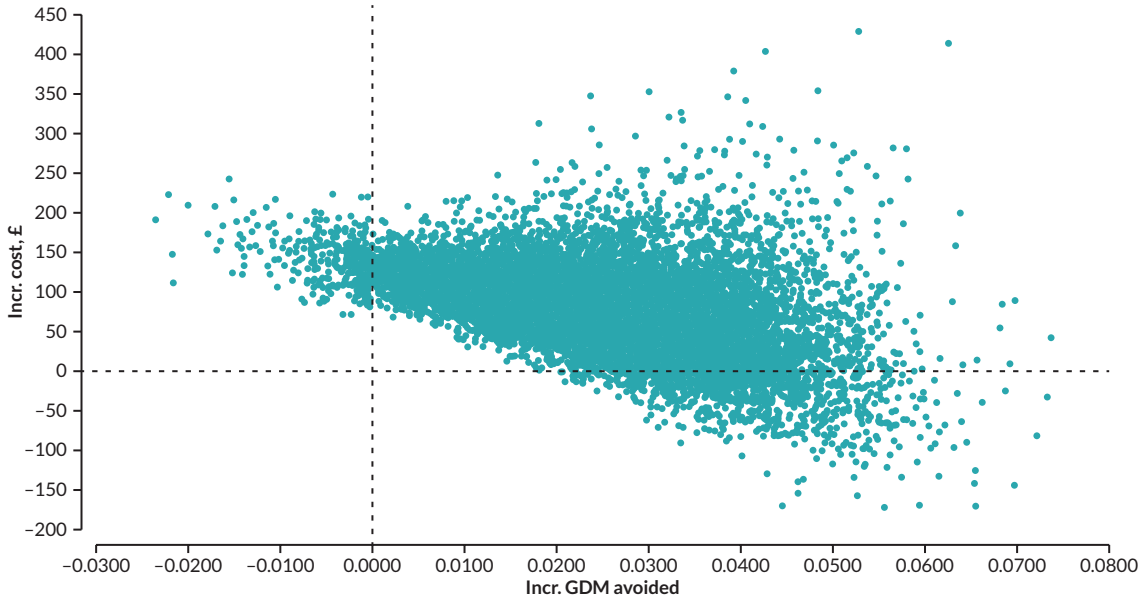

FIGURE 20 Cost-effectiveness plane (diet-based interventions).

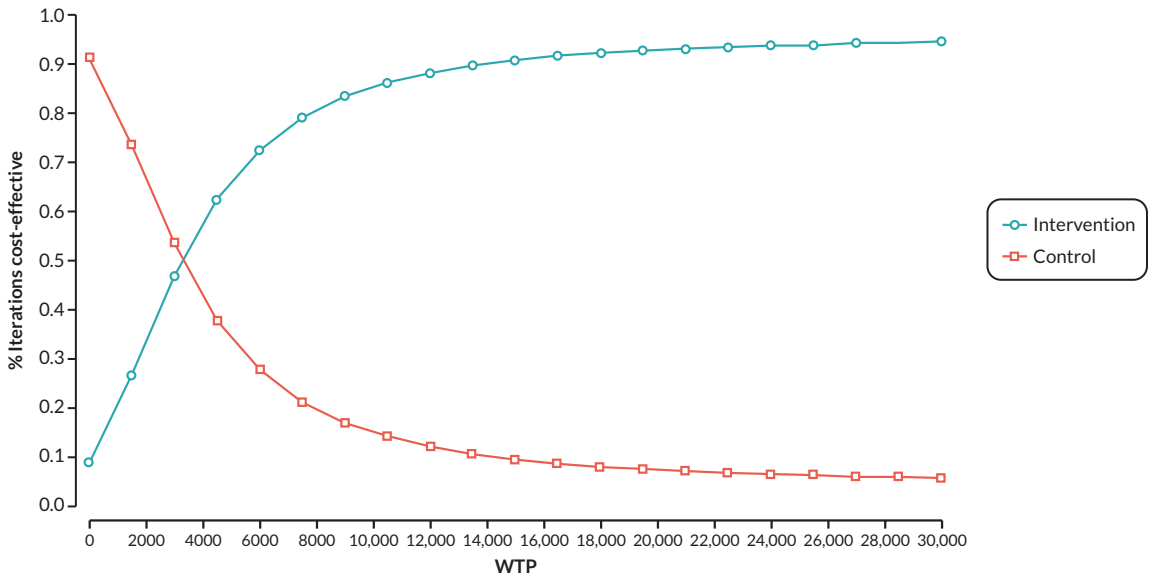

FIGURE 21 Cost-effectiveness acceptability curve (diet-based interventions).

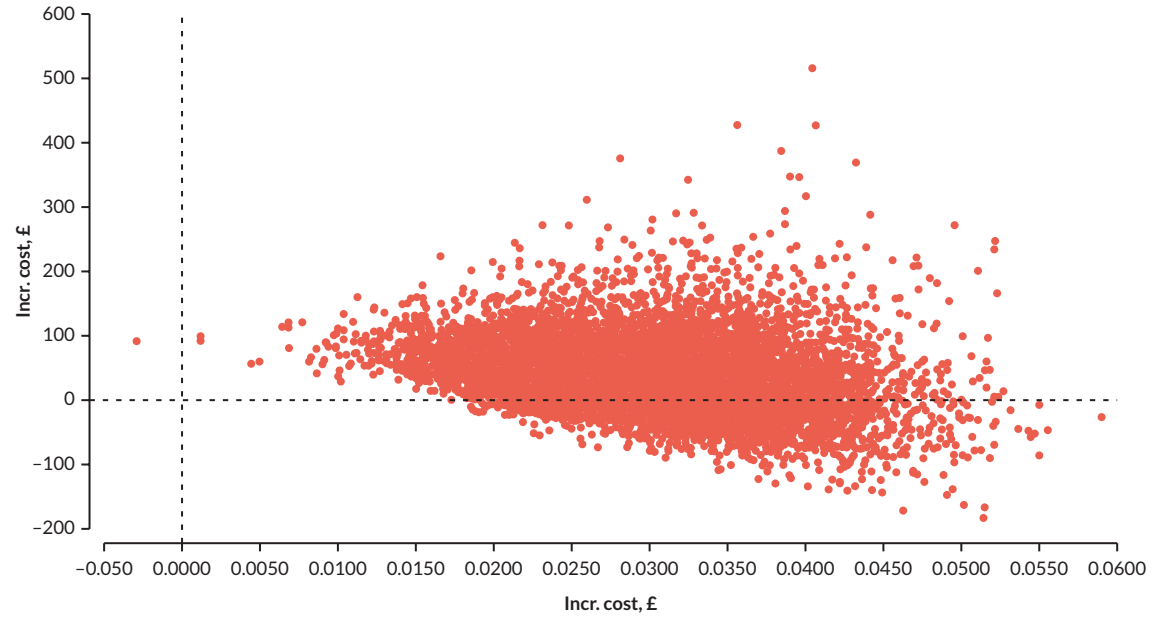

FIGURE 22 Cost-effectiveness plane (physical activity-based interventions).

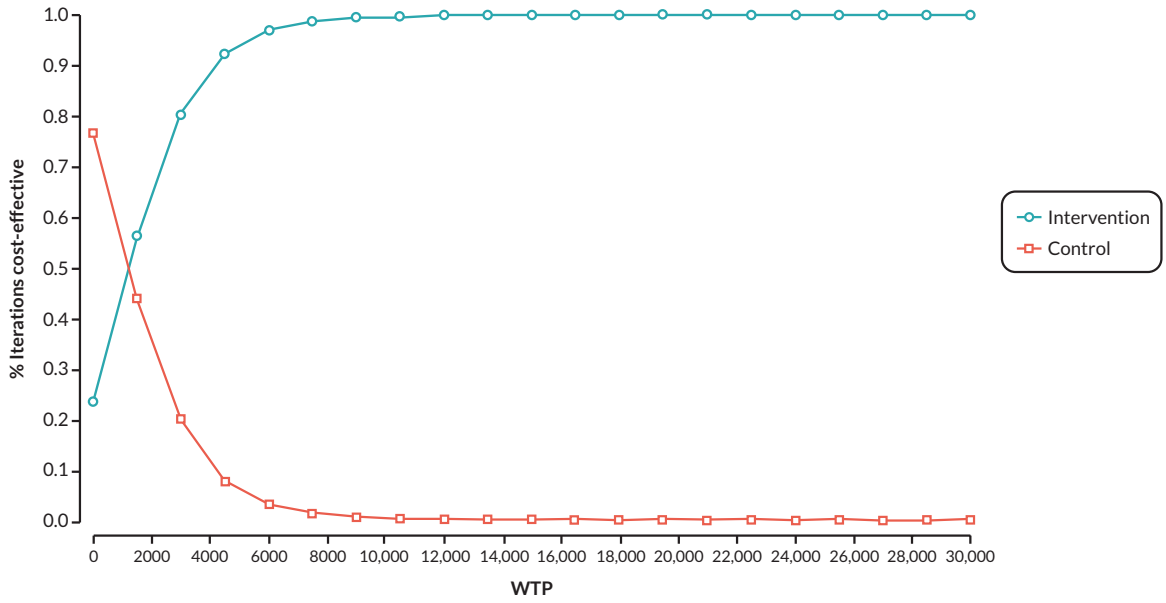

FIGURE 23 Cost-effectiveness acceptability curve (physical activity-based intervention).

From the cost-effectiveness plane for diet-based interventions (see *Figure 20*), the PSA iterations spanned three quadrants. The intervention was more effective than usual care with most of the plots in the northeast and southeast quadrants.

The CEAC for diet (see *Figure 21*) shows that the crossover point where the decision uncertainty is highest is when the WTP is around £3250 per GDM case avoided.

The cost-effectiveness plane for physical activity-based interventions is presented in *Figure 22*. This shows that the intervention is more costly but more effective than the control. The CEAC (see *Figure 23*) shows the crossover point at a WTP of £1500. Thereafter, the intervention has a higher probability of cost-effectiveness as the WTP threshold increases with the curve plateauing near 100% for WTP thresholds above £10,000.

Subgroups

The subgroup analysis results are presented in *Table 28*. Overall, for all the subgroups (except the low education level), the intervention was costlier but more effective than the care-as-usual arm. For every 10,000 women, the intervention led to the avoidance of GDM in 107 White women versus 189 non-White women. Regarding parity, the intervention was more effective in nulliparous women than in multiparous women with 124 cases of GDM avoided in nulliparous and 40 cases of GDM avoided in multiparous women per 10,000 women.

For the subgroup of women categorised by education level, the intervention was most effective among the middle level (322 additional GDM cases averted) and least effective among the low level (29 additional GDM cases) compared to the control (usual care). Women aged 20 years and above benefited more from the intervention with an 85 fewer cases of GDM compared to women < 20 years among whom there was a 22 fewer GDM cases. The intervention led to a 104, 69 and 61 fewer GDM cases in women with obesity, normal and overweight BMIs, respectively.

Deterministic sensitivity analysis

The results of the DSA are presented in *Tables 29–31*. For the first DSA, we varied the cost of the intervention to reflect the minimum (£154) and maximum (£1156) costs identified from a literature review within the i-WIP study.[13]

TABLE 28 Subgroup analysis (per GDM avoided)

Subgroup	Intervention, mean cost (£)	Control, mean cost (£)	Cost difference (£)	Intervention, mean	Control, mean	Effect difference	Cases avoided difference in 10,000 women	ICER (£)
Ethnicity								
White	5652	5429	223	0.8815	0.8708	0.0107	107	20,851
Non-White	5789	5582	207	0.8142	0.7953	0.0189	189	10,938
Parity								
Nulliparous	5703	5483	220	0.8565	0.8441	0.0124	124	17,786
Multiparous	5611	5374	237	0.9017	0.8977	0.0040	40	59,740
Education								
Low	5719	5468	251	0.8487	0.8516	−0.0029	−29	Dominated
Middle	5610	5430	180	0.9025	0.8703	0.0322	322	£5573
High	5591	5381	210	0.9117	0.8947	0.0170	170	12,355
Age								
< 20 years	5571	5330	241	0.9217	0.9195	0.0022	22	110,409
> 20 years	5658	5430	228	0.8787	0.8702	0.0085	85	26,836
BMI								
Normal	5546	5315	231	0.9338	0.9269	0.0069	69	33,486
Overweight	5648	5415	233	0.8837	0.8776	0.0061	61	38,373
Obesity	5762	5538	224	0.8272	0.8168	0.0104	104	21,495

TABLE 29 Sensitivity analysis – varying intervention costs

Scenario	Cost of the intervention (£)	Total cost of intervention arm (£)	Cost per GDM avoided (£)	Cost per MOA (£)
Base case	245	5652	31,827	66,520
Lower cost	154	5561	19,252	40,238
Higher cost	1156	6563	157,709	329,623

TABLE 30 Threshold analysis

Group allocation	Total cost (£)	Difference in cost (£)	Total effect (GDM avoided)	Effect difference	ICER
Threshold analysis (GDM avoided)					
Intervention	5422	0.00	0.8841	0.0072	Dominant
Control	5422		0.8737		
Threshold analysis (MOA)					
Intervention	5422		0.4217	0.0035	Dominant
Control	5422	0.00	0.4182		

TABLE 31 Sensitivity analysis – mode of labour onset and CC4 + for c/s (£)

Variable	Control cost (£)	Intervention cost (£)	Cost difference (£)	ICER (£)	Outcome
Inclusion of labour onset (induction control)	5509	5735	225	31,133	GDM avoided
				65,070	MOA avoided
Varying the cost of C/s with complications (CCs 4 +)	5481	5708	227	31,361	GDM avoided
				65,546	MOA avoided

The findings (see *Table 31*) showed that when varying the cost of the intervention, the average cost of the intervention arm ranged from £5652 to £6563. At the highest cost of £1156, the ICER increased to £157,709 and £329,623, respectively, per GDM avoided and major outcome avoided.

A threshold analysis (see *Table 30* and *Figure 24*) was conducted to determine the cost for the intervention at which the intervention becomes cost-effective. Cost-effective here is the point at which the intervention strategy costs the same as the control strategy and the decision-makers' WTP for a case of GDM avoided or MOA was assumed to be zero. The minimum cost of the intervention rendered to achieve a cost-effective result is £15. At this value, the intervention was dominant. This minimum cost is £230 (£245–15) less than the base-case intervention cost of £245.

Additional sensitivity analyses were carried out and reported in *Table 31*. For all scenarios, the intervention remained more costly than the control with a similar cost difference.

Discussion

Principal findings

A CEA was undertaken to assess the effect of lifestyle interventions in preventing the development of GDM and its complications in women with a BMI of ≥ 18.5 kg/m^2 in early pregnancy. The result of the base-case analysis shows that overall the overall intervention is more costly, but it is also slightly more effective. The ICER from the deterministic analysis was estimated as £31,827 per case of GDM avoided compared with care as usual. The intervention led to a slight reduction in the other complications evaluated including preterm delivery, caesarean sections, stillbirths and admissions into the NICU. However, the ICERs for some of these outcomes were high which is expected, given the minimal effect differences.

In contrast to the acceptable threshold that exists for results in terms of QALYs of £20,000–30,000 per QALY, there is no standard cost-effectiveness threshold for outcomes reported in natural units such as major outcomes or cases of GDM avoided. Had the outcomes been cost saving (i.e. less costly, and more effective), the decision that the

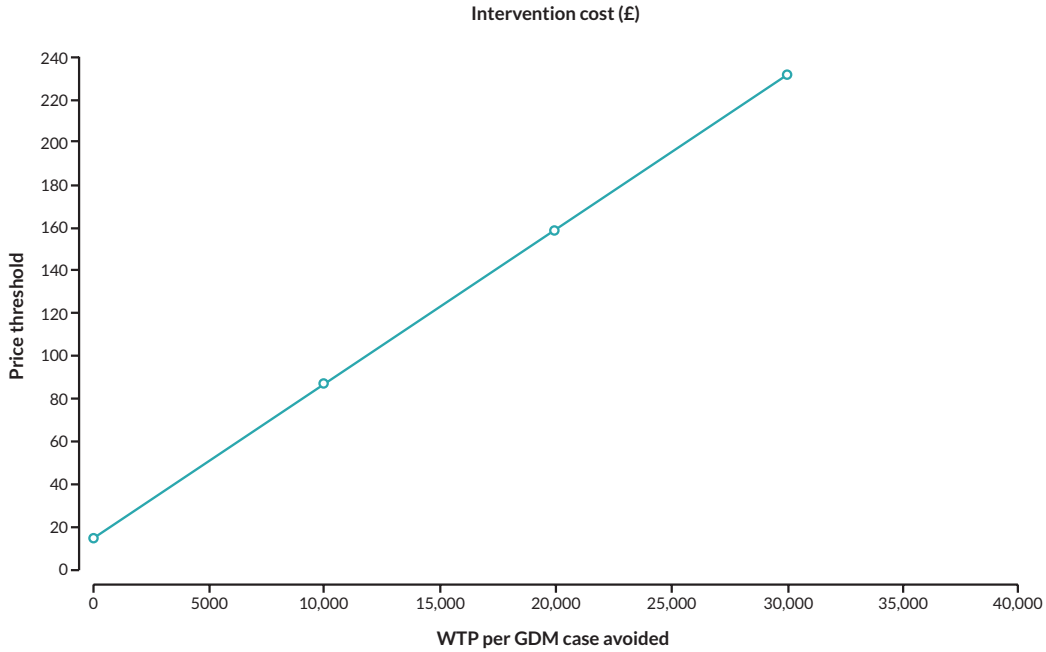

FIGURE 24 Threshold analysis for GDM avoided.

intervention provides good value for money would have been easier. However, using the threshold for QALYs provides a useful metric for interpreting the cost-effectiveness results. Using the additional cost difference of £230 and assuming that the intervention does not affect the patients underlying utility score, the QALY decrement for the additional GDM cases would have to exceed the maximum possible score of 1 for the intervention to be cost-effective at the higher cost-effectiveness threshold of £30,000 per QALY. Thus, the economic evaluation would be unlikely to be cost-effective for the specified 12-month time horizon.[140–143] We did not consider longer-term outcomes in the model-based economic evaluation. This may lead to an underestimation of the costs associated with GDM. A case of GDM leads to an increased risk of infant admission to the NICU[140,141] with findings in Australia showing that infants born to mothers with GDM are 80% more likely to require admission to NICU compared to mothers without GDM.[142] There is also the long-term maternal impact which is the development of type 2 diabetes. Studies show that 50–60% of women who had GDM develop type 2 diabetes within 5–10 years of delivery.[143] Hence, a decision on the cost-effectiveness would include how much decision-makers are willing to pay to avoid these longer-term outcomes.

The use of physical activity or diet-based interventions alone was also more costly and more effective compared to usual care. Notably, the average effectiveness for physical activity-based interventions alone or diet-based interventions alone was higher compared to the use of physical activity and/or diet-based interventions.

The subgroup analyses carried out showed that, generally, the intervention was more costly but more effective. Three BMI categories (normal, overweight and obese) were assessed, and the study found that the intervention was most effective in women who had obesity in early pregnancy. The intervention was also more effective in nulliparous women compared to women who have had one or more previous pregnancies lasting> 24 weeks gestation (multiparous). The intervention however led to an increase in GDM among women who were classed as having a low level of education.

Strengths and limitations of the economic analysis

A key strength of the economic evaluation is that it was based on data from a large IPD meta-analysis with over 100 studies on antenatal lifestyle interventions and thus provided a comprehensive analysis of cost-effectiveness. As much as possible, the outcomes and resource use included in the model followed the clinical pathway that is typical practice in the UK. Unit costs for resource use were drawn from established national sources. In cases where variables were not depicted by Healthcare Resource Groups (HRGs), we liaised with the clinical team to decide on the most appropriate HRG, therefore enhancing the generalisability of the study. The model-based analysis also benefited from the robustness of the main analyses and the sensitivity analyses.

The limitations include first, that there was inadequate evidence available for the resource use associated with maternal deaths and admissions following childbirth. Given that the incidence of maternal death associated with the intervention is negligible, we did not include this in our analysis. It is uncommon (0.024% in 2015–6),[144] it has a higher incidence among those with GDM (crude odd ratio of 2.04 for those with gestational or pre-existing diabetes)[144] and its inclusion would have increased the associated cost of GDM and thus marginally improved the cost-effectiveness of the GDM prevention intervention.

Another limitation of the model is the failure to explore the effect of a longer time horizon and the impact of the wider societal costs on the participants. GDM has a longer-term impact on maternal (including diabetes, heart disease and obesity) and child's health. Given this, the model would have been strengthened by extending the time horizon and incorporating the development of diabetes from GDM cases to quantify the long-term costs and consequences of a GDM prevention strategy. We were also unable to disaggregate further the non-White ethnic minority group to explore in more detail cost-effectiveness of the interventions in those subgroups, which is of particular importance given the disproportionate GDM and obesity-related risk in some ethnic groups.

Comparison with other studies

To our knowledge, this is the first UK model-based economic evaluation to investigate the cost-effectiveness of behavioural interventions in avoiding GDM and averting negative maternal and neonatal outcomes using the i-WIP meta-analysis data. Two previous studies in Australia by the same authors have conducted similar analyses using the IPD meta-analysis data and a model-based approach.[125,145] The earlier study[125] focused on GDM and hypertensive disease in pregnancy and reported that the intervention group was 2.25% less likely to develop GDM and/or hypertensive disease compared to the control group. However, this study did not explore maternal outcomes such as preterm delivery or neonatal outcomes such as LGA, SGA or admissions to the NICU. The later study[145] explored the impact of physical activity and diet on maternal and neonatal outcomes. The authors reported that physical activity-based interventions, diet-based interventions and mixed interventions decreased adverse maternal events by 4.2%, 3.5% and 2.9%, respectively, in the intervention group compared with standard care. The study included just one neonatal outcome – admissions to the NICUs. Hence, compared to these studies, the current study included a broader range of outcomes. However, like our study, both these studies used a time horizon of < 1 year.

Implication for policy

The global risk of developing GDM is 5–25.5%,[146] and in the UK, 1 in 20 (5%) pregnancies are affected.[16] The results of the model-based economic analysis suggest that the short-term model results do not suggest that the use of diet and physical activity-based interventions is likely to be cost-effective for the prevention of GDM in women with a BMI of ≥ 18.5 kg/m^2 in early pregnancy.

Recommendation for future research

Future research could explore the economic effect over a longer period. This would enable a more robust analysis of the long-term costs and outcomes of the intervention in both the women and their children. It is also relevant for future research to assess the broader impact by adopting the societal perspective.

Summary of health economics findings

For the deterministic base-case analysis, the mean total cost was higher in the intervention group (£5652) than in the control group (£5422), with an additional cost of £230. The additional difference in the mean effect of avoiding GDM was 0.0072, indicating that the intervention led to a 72 fewer GDM cases in a 10,000-cohort size. The base-case analysis found an ICER of £31,084 per case of GDM avoided. A value of information analysis suggests that reducing the decision uncertainty on the baseline risk of GDM parameter comprises most of the value of removing all decision uncertainty.

The use of physical activity or diet-based interventions alone had a narrower mean cost difference and a higher mean effectiveness difference than the primary analysis comparison. Subgroup analyses found more GDM averted among women whose BMI category at early pregnancy was obese (104 fewer cases) compared to women with BMI classified as normal (69 fewer cases) and overweight (61 fewer cases).

Chapter 7 Stakeholders workshop

Introduction

At the end of the project, a workshop bringing together key stakeholders was held to obtain their views on the integration of lifestyle interventions to prevent GDM into routine care, if these were found to be effective from the i-WIP IPD. The workshop also served to obtain stakeholder views on any barriers and facilitators to integration, resource requirements, and how the interventions could be adapted to local needs. The workshop was held on 26 September 2023 at The Exchange, Birmingham, UK.

Objectives

The workshop aimed to:

1. Present findings from the i-WIP GDM IPD meta-analysis and economic evaluation on lifestyle interventions to prevent GDM.
2. Obtain stakeholder perspectives on policy and practice implications.
3. Develop recommendations to guide implementation of physical activity and/or diet-based interventions for GDM prevention.

Attendees

The workshop brought together 22 participants representing: obstetrics, midwifery, researchers, endocrinology, nutrition, exercise physiology, policy-makers, health economists, patient advocates and women with previous history of GDM. A list of attendees is included in *Report Supplementary Material 2*.

Format of the day

The workshop was divided into three sessions. The first session involved presentation of study findings from the i-WIP GDM project. The second and third sessions involved facilitated breakout group discussions. At the first of the breakout group session, we sought to identify implications of the research findings on clinical practice and policy by asking; (1) what was the key message of the study findings, (2) how does this fit with current knowledge and (3) what is the significance and main implication?

At the second breakout group session, we sought to inform the development of recommendations and steps to their integration. We asked (1) how the results can inform policy and guidelines, (2) what resources are needed for implementation, (3) what local adaptations are needed for implementation, (4) what barriers and facilitators are present and (5) what metric should be used to measure success of any initiative? An artist graphical sketch summarising the day is provided in *Report Supplementary Material 3*.

Recommendations

Following the workshop, the below five key recommendations were made:

1. Lifestyle interventions, especially physical activity-based interventions, should be recommended to all pregnant women to prevent GDM. Campaign phrases suggested by patient and public involvement and engagement attendees included '***is the baby moving, are you moving***', and '***count the kicks, count the steps***'.
2. Physical activity or diet-based interventions should be initiated early in pregnancy to maximise their effectiveness.
3. Physical activity or diet-based interventions should be tailored to the individual needs of each woman, considering her medical history and socioeconomic and cultural background.

4. Resources and programmes that empower pregnant women with information on the importance of physical activity in pregnancy should be developed, along with ongoing support throughout pregnancy.
5. Active advocacy for policy changes that foster the integration of physical activity or diet-based interventions into routine maternity care settings to prevent GDM is urgently needed.

Conclusion

The i-WIP GDM meta-analysis provided strong evidence that physical activity or diet-based interventions in pregnancy can prevent GDM. The stakeholder workshop helped translate these findings into actionable recommendations to guide clinical practice and policy aimed at reducing the burden of GDM. Workshop attendees agreed that interventions, especially physical activity, can be an effective way to prevent GDM and should be recommended to all pregnant women. The attendees also agreed that interventions should be tailored to the individual needs of each woman. The recommendations made at the workshop will inform a position paper on lifestyle interventions in pregnancy to prevent GDM.

Chapter 8 Discussion

Summary of findings

Lifestyle interventions in pregnancy can significantly reduce the risk of developing GDM. The effect size was consistently greater in physical activity-based interventions irrespective of the definition of GDM, when aggregate data are included, and when studies at high risk of bias are excluded. The NMA showed that physical activity-based interventions had the highest probability of being the most effective intervention compared. Mixed interventions were generally less effective in reducing GDM risk, and this may be due to the burden of simultaneous engagement across behaviour change interventions which may affect adherence and compliance with intervention. The overall intervention effect was similar in pregnant women irrespective of maternal ethnicity, parity, age and BMI at booking. However, the intervention effects were greater in women who had middle and higher educational level than those with low education level. There was a significant difference in GDM outcomes based on structure and prior training according to TIDieR component subgroups. There is no strong evidence that the interventions reduce the risk of maternal and offspring outcomes, except a reduction in caesarean section, LGA babies and SGA babies with physical activity-based interventions and a decrease in preterm delivery with diet-based interventions. Women in the physical activity group who went on to develop GDM appear to be at increased risk of hypertensive disease, preterm birth and SGA babies compared to control women with GDM. Lifestyle interventions cost £230 more than control and results in 72 fewer women developing GDM. Physical activity-based interventions alone or diet-based interventions alone were also associated with higher mean costs and higher cases avoided compared to the control group.

Strengths and limitations

Our IPD meta-analysis is the largest to date and is based on over 23,000 women, enhancing precision and reliability over aggregate data.[15] By accessing the raw participant data, the IPD approach allowed us to standardise variables, including harmonising adjustment variables and outcome definitions, subgroup categories, and addressing missing data more effectively, thereby enhancing the reliability of our results.[147] The large sample size for our IPD allowed us to carry out detailed evaluation of differential subgroup effects not possible in smaller individual trials or in aggregate data, where participant-level information is not available and subgroup effects (treatment–covariate interactions) rarely reported in sufficient detail. The consistency in findings on the positive effect of lifestyle interventions to prevent GDM – especially with physical activity-based interventions, across sensitivity analysis and high-quality studies – strengthens the robustness of our results. By incorporating a NMA, we were able to provide a comparative assessment of intervention efficacy, which is important for guiding health policy and prioritising interventions based on their potential impact on GDM prevention.

Our study had some limitations. Not all aggregate data meeting the inclusion criteria could be obtained within the IPD project timeline, including recently published studies, and this may have affected precision of the results. However, the proportion of IPD not shared was much less than that included in our IPD meta-analysis. While our analysis explored different GDM diagnostic criteria, including those defined by NICE, IADPSG, and modified IADPSG, the raw oral glucose tolerance test (OGTT) results were not available for every time point required for redefining GDM diagnosis for the various diagnostic criteria within all the included IPDs, which in turn affected the number of IPDs that contributed to analysis of GDM outcomes based on other GDM diagnostic criteria. Addition of these test data to our work may have improved the precision in our estimates for other GDM outcome definitions. This highlights the importance GDM diagnostic criteria has on the potential impact of any intervention to prevent GDM. Future trials should report binary GDM outcomes, but also collect the raw individual OGTT test results which would be important for future IPD meta-analysis studies.[148] The interventions varied in the duration, intensity, timing and provider. We were only able to broadly define them as predominantly physical activity-based, diet-based or mixed interventions. The mixed interventions group was very heterogeneous, with many trials having unstructured interventions. A third of trials that shared IPD did not report ethnicity in the data, and for those that did, the population were mostly White. As a result, we were unable to explore the effects of ethnicity in detailed subcategories in the non-White group because of the wide variation in

definitions of race and ethnicity in individual studies. Disaggregated ethnicity data should be collected and reported in individual studies to better explore generalisability of findings and ensure interventions do not widen the inequality gap. The lack of cost-effectiveness thresholds for natural units made interpretation challenging on whether any GDM prevention strategies could be cost-effective. Finally, the IPD obtained in our study were insufficient to determine optimal intervention components and delivery methods, and the variation in intervention components and delivery across studies may have contributed to heterogeneity in these findings.

Comparison to existing evidence

There are currently no national or international guidelines on recommended interventions to prevent GDM, likely due to uncertainty in the effectiveness of lifestyle interventions for preventing GDM.[149] Our findings are consistent with previous IPD and aggregate data meta-analysis that found that lifestyle interventions in pregnancy – especially physical activity-based interventions – can reduce the risk of GDM, with greater benefits when physical activity is started early in pregnancy.[13,20,150] Meta-analyses of dietary interventions for GDM prevention have also reported reduced risk, with greater benefits for overweight and women with obesity.[151] Unlike IPD, these aggregate data meta-analysis were unable to account for baseline prognostic factors in assessing the effects of intervention, which can affect the magnitude of effects estimated. These aggregate data studies also do not quantify the expected benefit in subgroups of women with risk factors such as those with high BMI, high maternal age, ethnic minority origin and low socioeconomic status.[152] The quality of evidence from the reviews were found to be low due to variations in the definitions, small sample sizes with imprecise estimates, and statistical heterogeneity due to use of aggregate data.[14]

Based on the findings of our IPD meta-analysis, we were able to provide robust estimates for GDM based on various diagnostic criteria, and with minimal heterogeneity that limited previously published reviews. We did not observe a beneficial effect in GDM prevention with the mixed approach, which was consistent with previously published reviews.[15] Women with middle to high education levels experienced a substantial reduction in GDM odds compared to those with lower education status, suggesting a potential social gradient in intervention effectiveness. This is a common finding in individually focused interventions and an issue of concern for behavioural science.[153,154] This finding underscores the need for tailored approaches that consider socioeconomic determinants in designing and implementing preventive strategies. We found a significant difference in GDM outcomes based on structure and prior training according to TIDieR component subgroups, where intervention delivered in group format resulted in a greater reduction in the odds of GDM compared with individual format delivery. This may be due to the social support and shared learning experience from peers which can motivate behaviour change in a group setting.[155] The social dynamic may introduce positive peer pressure which further promotes adherence to the intervention. There was also a greater reduction in the odds of GDM when no prior intervention-specific training was given to providers compared to when this training is given. Untrained providers may have implemented the intervention more flexibly, adapting them to individual needs of the women. This flexibility may have improved engagement and adherence with the intervention.[156,157]

Relevance to clinical practice

There are currently no widespread practice-level protocols or policy-level guidance targeting pregnancy or GDM prevention; the focus instead remains on screening and treatment of diagnosed cases. The Diabetes Prevention Programme (DPP) in the UK does not include prevention of GDM in its programme.[158] Our IPD meta-analysis provides evidence on GDM reduction through physical activity and diet-based interventions, delivered during antenatal care. Women should be encouraged to follow any lifestyle intervention that is convenient and available, especially regarding physical activity since this showed the greatest benefit in GDM risk reduction. The observed substantial risk reduction in GDM with physical activity-based intervention may be partially attributed to the contrast between typically more sedentary usual care control groups versus the active intervention arm. Compared to non-pregnant state, pregnant women tend to experience declined physical activity levels,[150] thus emphasising the importance of physical activity in preventing GDM. Given the high prevalence of GDM and associated risks of complications in both mother and babies, shifting the population distribution even slightly could have substantial public health impacts if widely implemented.

The research spotlight must now shift to implementation of science approaches, which can inform translation into equitable, culturally appropriate, scalable interventions embedded within supportive health systems and policy environments. While our study found that physical activity-based interventions help prevent GDM, the risks of certain outcomes such as hypertensive disease, preterm delivery and SGA babies were paradoxically higher in women who still went on to develop GDM. This could be due to differences in intervention adherence and post-diagnosis management, which we were unable to account for in our study and may vary across settings. Such clinical management, while aiming to reduce complications, could also inadvertently increase risks like preterm birth.[159]

Research recommendations

While this IPD meta-analysis confirms lifestyle interventions can significantly reduce GDM risk, enhanced benefits were seen in women from higher socioeconomic groups compared to those from lower socioeconomic group. This is despite those from more disadvantaged backgrounds being more likely to have higher baseline risk linked to higher incidence of obesity,[160] inadequate access to healthy foods and reduced access to recreational facilities such as gyms.[161] Understanding behavioural, social and structural factors influencing intervention engagement and compliance is critical to advance health equity. This can help inform tailoring of programmes to increase uptake of interventions and maximise benefits across the socioeconomic spectrum. While our subgroup analysis on effect of socioeconomic status on the interventions was limited to maternal education, there are other factors important to socioeconomic status we were unable to explore due to data availability. Further research can explore these factors such as deprivation deciles to provide a more holistic overview on how to ensure interventions support women from lower socioeconomic strata, improve GDM outcomes, and life course health implications for them and their children. Future studies are needed on the barriers and facilitators at individual, interpersonal, community, organisational and policy levels, to help guide adaptations to optimise engagement and outcomes across diverse populations. Research is also needed to assess intersections between socioeconomic status and race/ethnicity to help identify specific cultural factors affecting intervention effectiveness which can be leveraged in future programmes. Studies evaluating personalised lifestyle interventions based on socioeconomic factors and individual risk profiles may also enhance the precision of preventive strategies based on these interventions. Use of technology in delivery of lifestyle interventions is gaining popularity and may bring down the cost of delivering interventions at scale.[162] However, the effectiveness and acceptability of technology-enabled solutions will need to be rigorously assessed once developed and deployed.

Gestational diabetes confers lifelong metabolic risk with intergenerational impact, but exploring lifestyle intervention effects on longer-term maternal and offspring outcomes was beyond the scope of this study. Physical activity and dietary modifications that lower GDM rates could potentially exert protective effects against obesity, impaired glucose tolerance, metabolic syndrome and type 2 diabetes over the child's life course, countering rising population trends. Well-designed observational follow-up studies could help quantify these potential multi-generational benefits. There is a need for these longer-term outcomes to be then included in model-based economic evaluations to comprehensively assess the cost-effectiveness of GDM prevention. The i-WIP Collaborative Network has provided a platform for researchers in this field to prioritise outcomes, standardise variables, plan future studies and influence public policies.[13]

Patient and public involvement

Patient and public involvement (PPI) members provided input on the running of the project via participation in the steering committee and project management groups. The Katie's Team www.elly.org.uk/copy-of-research PPI Advisory Group, which includes mothers, pregnant women, carers and family members with an interest in improving the quality of research within women's health, provided feedback on what they consider to be important outcomes and fine-tuning of the primary outcomes. Ngawai Moss, a Katie's Team member, was co-applicant on the grant. Our stakeholder workshop (see Chapter 7) involved women and family members, and their contribution helped with interpretation of the findings. Dissemination of findings will be done in collaboration with Katies team, the Hilda's www.dhlnetwork.com/hildas PPI group and other interested charities.

Equality, diversity and inclusion

Our research on lifestyle interventions for preventing GDM aimed to assess their impact across diverse populations. We recognise that maternal health outcomes are influenced by social, economic and structural factors, and our analysis has sought to assess differences in intervention effects based on ethnicity, socioeconomic status and other key demographic variables. While we found no differences in intervention effects by ethnicity, women with higher educational levels benefited more, highlighting socioeconomic disparity. Barriers such as financial constraints, limited access to green spaces and cultural or social perceptions of physical activity during pregnancy may affect engagement, particularly for marginalised groups.

To ensure inclusivity, we engaged with stakeholders, including PPI groups and healthcare professionals. Our collaboration with the Hilda's women's health PPI group and a stakeholder workshop involving obstetricians, midwives, policymakers and women with lived experience of gestational diabetes helped integrate lived experiences into the research, ensuring that the perspectives of those affected by GDM were represented. These discussions emphasised the need for early initiation of lifestyle interventions, tailored approaches based on individual needs, and better support for pregnant women through accessible information and resources. We also aimed for diversity in our research team, which includes individuals at various career stages and with different disciplinary and demographic backgrounds. Findings will be disseminated through stakeholder events and adapted into accessible formats for patients and the wider public to support informed decision-making and policy development. The recommendations from our stakeholder engagement will also contribute to a position paper guiding the integration of lifestyle interventions into routine antenatal care.

Impact and learning

Our research has been designed with a strong focus on ensuring that findings translate into real-world impact. A key component of this effort was a stakeholder workshop (see Chapter 7) that brought together obstetricians, midwives, policy-makers, researchers, health economists and women with lived experience of GDM. This workshop facilitated discussions on how lifestyle interventions can be integrated into routine maternity care, identifying both barriers and facilitators to implementation. To maximise dissemination, findings will be shared through stakeholder engagement events, policy briefs, and accessible formats for healthcare professionals and pregnant women. Collaborations with maternity care providers and public health organisations will support the integration of physical activity and diet-based interventions into antenatal care. Additionally, recommendations from the workshop will inform a position paper advocating for policy changes to incorporate lifestyle interventions into national guidelines.

Future efforts will focus on implementation of science approaches to ensure interventions are scalable and culturally appropriate. By fostering partnerships with key stakeholders, we aim to bridge the gap between research and practice, ensuring that the benefits of lifestyle interventions reach all pregnant women, particularly those from underserved communities.

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Patient and public involvement

Patient and public involvement members provided input to the running of the project via participation in the steering committee and project management groups. Our stakeholder workshop (see *Chapter 7*) involved women and family members, and their contribution helped with interpretation of the findings. Dissemination of findings will be done in collaboration with Katies team www.elly.og.uk/copy-of-research, the Hilda's www.dhlnetwork.com/hildas PPI group and other interested charities.

Data-sharing statement

All data requests should be submitted to the corresponding author. Access to available anonymised data may be granted following review and appropriate agreements being in place.

Ethics statement

Ethics approval was not required because the IPD meta-analysis involved secondary analysis of existing anonymised data.

Information governance statement

University of Birmingham is committed to handling all personal information in line with the UK Data Protection Act (2018) and the General Data Protection Regulation (EU GDPR) 2016/679. Under Data Protection legislation, University of Birmingham is the Data Processor, and you can find out more about how we handle personal data, including how to exercise your individual rights and the contact details for our Data Protection Officer here www.birmingham.ac.uk/privacy

Disclosure of interests

Full disclosure of interests: Completed ICMJE forms for all authors, including all related interests, are available in the toolkit on the NIHR Journals Library report publication page at https://doi.org/10.3310/GJST1327.

Primary conflicts of interest: Sharon A Simpson has been a member of HTA Clinical Evaluations and Trials Committee (20 July 2016–30 November 2020), Commissioning Panel for the National Institute of Health Research (NIHR) Policy Research Programme (2019–22) Membership of Chief Scientist Office HIPS committee 2018–23.

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Publications

Full list of publications, conference papers, seminars etc., resulting from this study

Coomar D, Hazlehurst JM, Austin F, Foster C, Hitman GA, Heslehurst N, *et al.*; International Weight Management in Pregnancy (i-WIP) Collaborative Group. Diet and physical activity in pregnancy to prevent gestational diabetes: a protocol for an individual participant data (IPD) meta-analysis on the differential effects of interventions with economic evaluation. *BMJ Open* 2021;**11**:e048119. https://doi.org/10.1136/bmjopen-2020-048119

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Royal College of Obstetrics and Gynaecology World Congress 2023: Oral presentation Dyuti Coomar

Perinatal Society of Australia and New Zealand 2024 Congress: Oral presentation John Allotey

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Appendix 1 Clinical characteristics of included randomised controlled trials

TABLE 32 Individual participant data trials

Arthur, 2020;[57] English (Australia)	**Method of randomisation:** The lead researcher generated the random allocation sequence	**Inclusion criteria:**	Women allocated to the treatment group were provided with the same information as controls but were additionally provided with a set of digital scales and a weight diary with instruction to record their weight each day. However, these scales were provided as an incentive to join the trial only and were not standardised.	The women allocated to the control group (CG) received written and verbal information regarding appropriate weight gain in pregnancy. The Institute of Medicine (IOM) guidelines regarding weight gain in pregnancy are explicitly displayed in the standardised Queensland Health pregnancy handheld health record provided to all women undertaking public hospital led antenatal care in Queensland and these were discussed with the women enrolled.	**Primary outcome:**
	Allocation concealment: Sequentially numbered opaque envelopes were used	Women in the second trimester of a singleton pregnancy booking in to deliver in an outer metropolitan hospital in Queensland (Radcliffe Hospital).			• Percentage weight change above target range (as defined by the IOM guidelines)
	Blinding: Non-blinded study	**Exclusion criteria:** • Poor English proficiency • Multiple pregnancies • Previous bariatric surgery • Pre-existing medical disease (including diabetes hypertension or renal disease and smoking)			**Secondary outcomes:** • Gestational weight gain (GWG) **Maternal clinical characteristics:** • GDM • Hypertension or pre-eclampsia (PE)
		Number of participants: Intervention, *n* = 197 Control, *n* = 199			• Gestational age at delivery • Method of delivery • Estimated blood loss
		Type of intervention: Mixed			**Perinatal clinical characteristics:** • Weight

TABLE 32 Individual participant data trials (*continued*)

					• Length • Head circumference • Apgar 1 minute • Apgar 5 minutes • Admission to special Care Nursery (SCN) • Length of stay in SCN • Fetal distress
Assaf-Balut, 2017;[56] English (Spain)	**Method of randomisation:** Stratified randomisation with permutated block randomisation, stratified by age (18–29, 30–34 and ≥ 35), pregestational BMI (< 25, 25–29.9 and ≥ 30 kg/m^2), parity (1 or > 1), and ethnicity (White, Hispanic and other), in an allocation ratio of (1 : 1) in blocks of 4–6	**Inclusion criteria:**	Both the intervention group (IG) and CG were given the same basic MedDiet recommendations: ≥ 2 servings/day of vegetables, ≥ 3 servings/day of fruit (avoiding juices), 3 servings/day of skimmed dairy products, wholegrain cereals, 2–3 servings of legumes/week, moderate to high consumption of fish; a low consumption of red and processed meat, avoidance of refined grains, processed baked goods, pre-sliced bread, soft drinks and fresh juices, fast foods and precooked meals.	All recommendations same as the intervention arm except, controls were advised by midwives to restrict consumption of dietary fat, including EVOO and nuts. These recommendations are provided in local antenatal clinics as part of the available guidelines in pregnancy standard care.	**Primary outcome:**
	Allocation concealment: Not reported	• Women attending their first gestational visit at 8 ± 12 GW (Visit 0) with fasting blood glucose (FBG) < 92 mg/dL.	They were also recommended to walk ≥ 30 minutes/day. These recommendations were given to women by different parties, depending on the group they were allocated to. In one hand, participants allocated to IG received lifestyle guidance from dietitians 1 week after inclusion in a unique 1-hour group session. The key IG recommendation was a daily consumption of at least 40 ml of EVOO and a handful (25–30 g) of pistachios. To ensure the consumption of the minimum amount recommended, women were provided at Visit 1 and 2 with 10 l of EVOO and 2 kg of roasted pistachios each. This way, they had available 1l of EVOO and 150 g of roasted pistachios weekly, throughout the pregnancy.		• GDM

continued

TABLE 32 Individual participant data trials (*continued*)

	Blinding: Participants, staff and the dietitian were aware of the allocation assignments. Statistician and research assistant blinded	• 18 years old • Single gestation **Exclusion criteria:** • Gestational age at entry > 14 GW • Intolerance to nuts or extra virgin olive oil (EVOO) • Medical conditions or pharmacological therapy **Number of participants:** Intervention, *n* = 500 Control, *n* = 500 **Type of intervention:** Diet	The number of visits for the study was alike in both groups. All women were followed up at first ultrasound visit (Visit 1), at 24 ± 28 GW (Visit 2), third trimester evaluation at 36 ± 38 GW (Visit 3) and at delivery. Nutritional guidance was reinforced at each visit for both groups. Dietary recommendations were individualised at each visit depending on GWG (according to first trimester BMI), in the context of usual recommendations. These recommendations were given in aims to reduce the caloric content of their diet when GWG exceeded the goal, by either the dietitian (IG) or the midwife (CG).	**Secondary outcomes:** • GWG • Pregnancy-induced hypertension • Caesarean section (CS) • Perineal trauma • Shoulder dystocia • Preterm delivery (< 37 GW) • Neonates SGA (< 10 percentile) and LGA (> 90 percentile) according to national charts • Admissions to the NICU

TABLE 32 Individual participant data trials (*continued*)

Baciuk, 2008;[58] English (Brazil)	**Method of randomisation**: Computer-generated randomisation list of numbers. Volunteers were enrolled sequentially and randomised to one of the two study groups **Allocation concealment**: Each sequential number corresponded to a sealed opaque envelope containing the information on the randomisation group. **Blinding:** Outcome assessors	**Inclusion criteria:** • Pregnant women of < 20 weeks of pregnancy Singleton pregnancy • No gestational risk factors • Received prenatal care at the research institution and intended to give birth there **Exclusion criteria:** • Practising regular physical exercise • Two or more CSs	The counsellors were trained for the study by recording conversations with 10 pregnant women, followed by feedback on performance by other members of the research team. Physical activity (water aerobics): the intervention was the regular, moderate practice of water aerobics for 50 minutes three times a week in an indoor swimming pool with water warmed at 28–30 °C. Water aerobics was initiated following the first physical evaluation and continued up to delivery. The moderate intensity of exercises during the sessions was assured by monitoring patients' heart rate (HR) using a HR monitor and kept around 70% of one's predicted maximum HR.	No intervention	**Outcomes**: • GDM • Request for analgesia • CS • Apgar score at 1 minute of ≥ 7 vaginal delivery • Preterm birth (< 37 weeks) • Low birthweight (< 2500 g), adequacy of neonatal weight to gestational age

continued

TABLE 32 Individual participant data trials (*continued*)

		• Clinical and/or laboratory diagnoses (neurological, cardiovascular, pulmonary, musculoskeletal or endocrine disorders any disorder that could represent a risk to the woman's health, such as morbid obesity, severe anaemia or vaginal bleeding during pregnancy) **Number of participants:** Intervention, *n* = 34 Control, *n* = 37 **Type of intervention:** Physical activity			• Length of labour (minutes), birthweight, gestational age, weight gain • Body fat (%) • Fat-free mass (%) BMI
Barakat, 2008;[60] English (Spain)	**Method of randomisation:** Not reported	**Inclusion criteria:**	The programme consisted of 35- to 40-minute sessions thrice weekly from 12 to 13 weeks of gestation to end of pregnancy (38–39 weeks), with an estimated average of 80 sessions per participant. They were supervised by a trained fitness specialist with each group consisting of 10–12 women. The venue was spacious and well-lit with favourable conditions (altitude 600 m, temperature 19–21 °C and humidity 50–60%). The sessions were accompanied by music. The exercise activity was of light to moderate intensity with a target HR of ≤ 80% of maximum predicted HR for age (220–age). All participants were provided with HR monitors. Each session included a warm-up (8 minutes), a core session (20 minutes) and a cool-down period (8 minutes). Warm-up and cool-down components involved light stretching exercises for limbs, neck and trunk. In addition, the cool-down period included relaxation exercises. The core	The women were asked to maintain their level of activity.	**Outcomes:**

TABLE 32 Individual participant data trials (*continued*)

			portion involved toning and very mild resistance exercises. Toning included shoulder shrugs and rotations, arm elevations and leg lateral elevations, pelvic rocks and tilts. The resistance exercises included one set of 10–12 repetitions of each of (1) abdominal curls and (2) the below exercises using barbells (3 kg/exercise) or low to medium resistance bands: bicep curls, arm side lifts and extensions, shoulder elevations, bench press, seated lateral row, leg circles and lateral leg elevations, knee (hamstring) curls and extensions, ankle flexions and extensions. Exercises such as jumping, ballistics, extreme stretching and joint overextension were avoided	
Allocation concealment: The investigator responsible for randomly assigning participants did not know in advance which group the next person would be allocated to, and was not part of the assessment	• Singleton and uncomplicated pregnancy			• GDM
Blinding: Outcomes assessors	• Not at high risk for preterm delivery (no history of recurrent spontaneous preterm birth, i.e. number of previous preterm deliveries ≤ 1) • Aged 25–35 years • Sedentary before gestation (not exercising > 20 minutes on > 3 days/week)			• GWG • Preterm deliveries • Birthweight

continued

TABLE 32 Individual participant data trials (*continued*)

		Exclusion criteria: • Not under medical follow-up throughout the entire pregnancy period • Women not planning to give birth in the same obstetrics hospital associated with the study • Women with any serious medical condition preventing them from exercising safely **Number of participants:** Intervention, *n* = 80 Control, *n* = 80 **Type of intervention:** Physical activity			• Macrosomia • Birth length • Head circumference • Ponderal index • Apgar score at 1 minute • Apgar score at 5 minutes
Barakat, 2011;[81] English (Spain)	**Method of randomisation**: Use of a random number table	**Inclusion criteria:**	The programme consisted of 35- to 45-minute sessions thrice weekly from 6 to 9 weeks of gestation to the end of pregnancy (38–39 weeks), with an estimated average of 85 sessions per participant. The participants were supervised by a trained fitness specialist with each group consisting of 10–12 women. The venue was spacious and well-lit with favourable conditions (altitude 600 m, temperature 19–21 °C and humidity 50–60%). High room temperatures and humid environment were avoided. The sessions were accompanied by music. The exercise activity was of light to moderate intensity with a target HR of ≤ 70% of maximum predicted HR for age (220–age).	Standard care	**Outcomes:**

TABLE 32 Individual participant data trials (*continued*)

Allocation concealment: Not reported	• Pregnant women in first trimester attending the hospital associated with the study	All participants were provided with HR monitors. Each session included a warm-up (7–8 minutes), a core session (25 minutes) and a cool-down period (7–8 minutes).	• GDM
Blinding: Not reported	**Exclusion criteria:**	Warm-up and cool-down components involved light stretching exercises for limbs, neck and trunk. In addition, the cool-down period included relaxation and pelvic floor exercises. The core portion involved toning and very mild resistance exercises. Toning included shoulder shrugs and rotations, arm elevations and leg lateral elevations, pelvic rocks and tilts. The resistance exercises included one set of 10–12 repetitions of each of (1) abdominal curls and (2) the below exercises using barbells (3 kg/exercise) or low- to medium-resistance bands: bicep curls, arm side lifts and extensions, shoulder elevations, bench press, seated lateral row, leg circles and lateral leg elevations, knee (hamstring) curls and extensions, ankle flexions and extensions. Exercises such as jumping, ballistics, extreme stretching and joint overextension were avoided. Supine exercises were limited to 2 minutes and exercises involving the Valsalva manoeuvre were avoided. Care was taken to ensure adequate nutrition prior to exercise sessions.	• GWG
	• Not planning to deliver in the same department		• Gestational age at delivery
	• Not receiving medical follow-up throughout the pregnancy		• Type of delivery (normal, instrumental, caesarean)
	• Absolute contraindication to aerobic activity in pregnancy		• Delivery lacerations type

continued

TABLE 32 Individual participant data trials (*continued*)

		• Haemodynamically significant heart disease • Restrictive lung disease • Recent pulmonary embolism (previous 5 years) • Cervical incompetence/ cerclage • Multiple pregnancy • Risk of premature labour • Pregnancy-induced hypertension (PIH)/PE • Thrombophlebitis • Acquired infectious disease • Intrauterine growth restriction • Major blood disorders • Absence of prenatal control **Number of participants:** Intervention, *n* = 40 Control, *n* = 40 **Intervention type:** Physical activity		• Systolic and diastolic blood pressure • 1-hour glucose level • Birthweight • Macrosomia • Apgar score at 1 minute • Apgar score at 5 minutes
Barakat, 2012a;[59] English (Spain)	**Method of randomisation:** Computer-generated list of random numbers	**Inclusion criteria:**	The programme consisted of 40- to 45-minute sessions thrice weekly from 6 to 9 weeks of gestation to end of pregnancy (38–39 weeks), with an estimated average of 85 sessions per participant. The participants were supervised by a trained fitness specialist with each group consisting of 10–12 women. The venue was spacious and well-lit with favourable	Standard Care	**Outcomes:**

TABLE 32 Individual participant data trials (*continued*)

		conditions (altitude 600 m, temperature 19–21 °C and humidity 50–60%). The sessions were accompanied by music The exercise activity was of light to moderate intensity with a target HR of ≤ 70% of maximum predicted HR for age (220–age). All participants were provided with HR monitors. Each session included a warm-up (7–8 minutes), a core session (25 minutes) and a cool-down period (7–8 minutes). Warm-up and cool-down components involved light stretching exercises for limbs, neck and trunk. The core portion included exercises for arms and abdomen, and aerobic dance to improve posture, strengthen muscles of labour and pelvic floor and prevent lower back pain.	
Allocation concealment: Not reported **Blinding:** Randomisation procedure including sequence generation, allocation concealment, and implementation was made for three different authors to facilitate blinding.	• Healthy uncomplicated singleton pregnancy **Exclusion criteria:** • Absolute obstetrical contraindication to exercise [as per American College of Obstetricians and Gynecologists (ACOG) (2002)] • Plans to deliver baby elsewhere		• GDM • GWG • Type of delivery (normal, instrumental, caesarean) • Gestational age at delivery

continued

TABLE 32 Individual participant data trials (*continued*)

		• Not receiving antenatal care throughout the pregnancy, participating in another physical activity programme, regular exercise before pregnancy (four or more times per week) **Number of participants:** Intervention, *n* = 138 Control, *n* = 152 **Type of intervention:** Physical activity			• Preterm delivery (< 37 weeks) • Blood pressure • 1-hour glucose tolerance test • Birthweight/length • pH of the umbilical cord blood • Apgar score
Barakat, 2016;[62] English (Spain)	**Method of randomisation:** The randomisation list was obtained by computer-generated random allocation with a 1 : 1 ratio	**Inclusion criteria:**	During pregnancy, women in the IG trained for 3 days a week with sessions lasting 50–55 minutes. The training started from weeks 9 to 11 of pregnancy and continued until the end of the third trimester (weeks 38–39). The programme included aerobic exercise, aerobic dance, muscular strength, and flexibility, and met the standards set by ACOG. Women used a HR monitor to ensure HR remained below 70% of the age-predicted maximum. Each session had a gradual warm-up and cool-down period lasting 10–12 minutes, with the main exercise session lasting 25–30 minutes. One set (10–12 reps) was performed using barbells or low-to-medium resistance bands. Exercises in the supine position were not performed for more than 2 minutes.	Women in the CG received general advice from their healthcare provider about the benefits of physical activity. The CG participants had the same number of visits with their healthcare providers as the exercise group during their pregnancy.	**Primary outcome**:
	Allocation concealment: The allocations were sealed in numbered white envelopes, which were kept in the midwifery facility.	• Women with singleton and uncomplicated pregnancies (no type 1, 2 diabetes or GDM at baseline)			• PIH

TABLE 32 Individual participant data trials (*continued*)

	Blinding: Not reported	• Without history or risk of preterm delivery **Exclusion criteria:** • Women not planning to give birth in the same obstetric hospital • Women having any serious medical conditions (contraindications) • Women not under medical follow-up throughout pregnancy. **Number of participants:** Intervention, *n* = 420 Control, *n* = 420 **Type of intervention:** Physical activity			**Secondary outcomes:** • GDM • GWG • Birthweight • Macrosomia (birthweight was > 4000 g) • Low birthweight was defined as < 2500 g.
Barakat *et al.*, 2018;[83] English (Spain)	**Method of randomisation:** A computer-generated list of random numbers was used to allocate the participants into the study groups.	**Inclusion criteria:**	Pregnant women in the IG participated in a supervised moderate exercise programme 3 days per week (55–60 minutes per session) from the 9th to 11th week to the end of the third trimester. Each participant was expected to attend 83–85 group training sessions and used a HR monitor to ensure their HR was under 70% of the age-predicted maximum. The exercise programme met the standards set by the American Congress of Obstetricians and Gynecologists and included sections such as warm-up, aerobic resistance, muscle strengthening, balance exercises, stretching, pelvic floor strengthening, and relaxation. Exercises were performed using barbells or elastic bands, and exercises in the supine position were not performed for more than 2 minutes.	The women in the CG received standard care during their pregnancy. They had scheduled visits with their obstetricians and midwives every 4–5 weeks until the 36th–38th week of pregnancy, and then weekly until delivery, as per hospital protocol. They were given general nutrition and physical activity advice by their healthcare providers. The women were not discouraged from exercising on their own during pregnancy. However, the CG women were asked about their exercise habits once each trimester using a 'Decision Algorithm' over the phone, similar to our previous studies.	**Primary outcome:**

continued

TABLE 32 Individual participant data trials (*continued*)

	Allocation concealment: The researcher who was in charge of randomly assigning participants to each group did not know in advance which treatment the next person would receive.	• Women with singleton and uncomplicated pregnancies (no type 1, 2 diabetes or GDM at baseline)	Question#1: Since the beginning of pregnancy, have you exercised in your leisure time, in a supervised programme or on your own?	• Data corresponding to labour and delivery
	Blinding: The randomisation blinded process (sequence generation, allocation concealment and implementation) was performed by three different authors.	• With no history or risk of preterm delivery (i.e. one previous preterm delivery)	a Answer: No.	• Duration of stages, spontaneous/assisted vaginal delivery
		• Not participating in any other trial	b Answer: Yes.	• Use of epidural
		Exclusion criteria:	Question #2: (If the previous response was 'b'): Given 7 days a week, how many days per week did you exercise?	**Secondary outcomes:**
		• Women with severe medical conditions (contraindications) that prevent them from exercising safely.	a Answer: < 3 days.	• GDM
		• Women not planning to give birth in the same obstetric hospital	b Answer: 3 days or more.	• GWG
		• With no medical follow-up throughout pregnancy.	Question #3: (If the previous response was 'b'): Taking into account the total duration of physical exercise continuously, how long did you exercise every day?	• Maternal gestational age
		Number of participants:	a Answer: < 20 minutes each day.	• Birthweight
		Intervention, *n* = 227	b Answer: 20 minutes or more each day.	• Apgar scores

TABLE 32 Individual participant data trials (*continued*)

		Control, *n* = 202 **Type of intervention:** Physical activity		Interpretation of the 'Decision Algorithm': Pregnant women in the CG who reached level b of these three questions, were excluded from the study.	• pH of the umbilical cord blood
Bisson, 2015;[33] English (Canada)	**Method of randomisation:** Randomisation was stratified according to parity and based on a computer-generated random numbers table.	**Inclusion criteria:**	The exercise group was offered a supervised exercise programme starting at the 15th week of gestation with free membership in a hospital-based conditioning centre, where kinesiologists were always available for counselling. Participants were individually supervised once a week and invited to complete 2 more sessions/week. Exercise prescription consisted of 3 weekly 1-hour sessions, for a total of 36 prescribed sessions over 12 weeks. Each session included a 5–10 minutes warm-up on a stationary ergo cycle, a 15–30- minute treadmill walk, a 20- minute muscular workout and a cool-down period.	The CG was told to continue usual activities without being restrained from doing physical activity. Both groups were given a pamphlet about the benefits of physical activity and appropriate exercises for pregnant women.	**Primary outcome:**
	Allocation concealment: Sealed envelopes were kept in a secure place by a research assistant not involved in the study and provided to a kinesiologist at the time of allocation.	• Women recruited before the end of the 14th week of gestation at family practice obstetrical and ultrasound clinics and in the community.	Duration of the cardiovascular training increased progressively from 15 minutes during the first week to 30 minutes by the end of the first month. The muscular workout included dynamic exercises for both lower and upper limbs using the participant's own body weight, small weights, exercising balls and strength equipment with selective charges. Participants started with 1 set of 10–15 repetitions per exercise and progressed to 2 sets of 15 repetitions, with intensity adjusted to their tolerance level. To enhance motivation, the muscular workout was modified every 4 weeks (twice during the		• Time spent at moderate and vigorous physical activity (MVPA) at 36 weeks of gestation.

continued

TABLE 32 Individual participant data trials (*continued*)

			intervention period). Exercise intensity was self-monitored with HR monitors (Polar FT4, Polar Electro, Finland) and the modified Borg Scale, with targets at 70% of peak HR (measured during the fitness test), and/or at a perceived exertion score of 3–5/10. Participants recorded duration and mean HR of each session from their monitors on their exercise log. On non-training days, women were advised to be as active as possible.	
Blinding: Due to the nature of the intervention, kinesiologists in charge of training and participants were not blinded to group assignment. However, all assessors and research assistants in charge of data entry and analyses were blinded to participants' allocation.	• Pre-pregnancy BMI ≥ 30.0 kg/m^2 • Regardless of previous physical activity levels 18 years or older • Singleton pregnancy planning to deliver in participating hospitals **Exclusion criteria:** • Women with diabetes or chronic hypertension before pregnancy **Number of participants:** Intervention, *n* = 25			• Number of accelerometery counts/day (reflecting total activity) • Daily time spent at MVPA in periods ≥ 10 minutes • Physical activity in the previous month was measured at each visit using the Pregnancy Physical Activity Questionnaire (PPAQ) • Adherence to exercise **Maternal outcomes:** • GDM • GWG

TABLE 32 Individual participant data trials (*continued*)

		Control, *n* = 25 **Type of intervention:** Physical activity			• Gestational age at delivery (weeks) • Caesarean delivery • Gestational hypertension **Newborn outcomes:** • Birthweight, g • Placental weight, g • Birthweight *z*-score • LGA • SGA • Birth length, cm • Head circumference, cm
Bogaerts, 2012;[34] English (Belgium)	**Method of randomisation:** Women were randomly assigned to three groups **Allocation concealment:** Opaque envelopes	**Inclusion criteria:** • Pregnant women with a BMI of ≥ 29 kg/m^2 (classified as obese)	Brochure group: a study-specific brochure containing information on diet and physical activity during pregnancy including tips to limit excessive GWG was provided. Lifestyle IG: this group received the same brochure but additionally had four antenatal lifestyle intervention sessions. The sessions included a group of up to three women led by a midwife trained in motivational intervention techniques. Each session lasted 1.5–2 hours and occurred: before 15 weeks of pregnancy between 18 and 22 weeks between 24 and 28 weeks between 30 and 34 weeks. The sessions focused on energy balance and energy expenditure, physical activity and other issues and queries related to pregnancy. The suggested dietary composition was based on national	Routine antenatal care as per national guideline 'prenatal care'.	**Outcomes:** • GDM

continued

TABLE 32 Individual participant data trials (*continued*)

		recommendations and included 50–55% carbohydrates, 30–35% fat and 9–11% protein intake. The lifestyle and dietary habits in relation to the participants' 7-day food diaries were discussed, including topics such as reading food labels and shopping methods. The intervention was based on the concept of motivational interviewing and the behaviour change model of Prochaska and others. The communication was directive and focused on intrinsic motivation to resolve discrepancies and conflicts about making changes without undue pressure. After each session, the women were asked to set personal goals and identify behaviours that need changing. Positive reinforcement was provided to increase self-confidence by identifying and dealing with barriers to behavioural change.	
Blinding: Not reported	**Exclusion criteria:** • Gestational age of > 15 weeks • Pre-existing type 1 diabetes mellitus (DM) • Multiple pregnancy primary need for nutritional advice • Incomplete knowledge of Dutch language		• GWG (weight at delivery minus self-reported pre-pregnancy weight) • GWG at first trimester (weight at 14 weeks minus pre-pregnancy weight) • GWG at second trimester (weight at 22 weeks minus pre-pregnancy weight) • GWG at third trimester (weight at 34 weeks minus pre-pregnancy weight) • Anxiety (State and Trait Anxiety Inventory)

TABLE 32 Individual participant data trials (*continued*)

		Number of participants: Intervention 1 (Brochure group), *n* = 58 Intervention 2 (Lifestyle group), *n* = 76 Control, *n* = 63 **Type of intervention:** Mixed			• Depression (10-item Edinburgh Postnatal Depression Scale) • PIH • PE • Induction of labour • Method of delivery (vaginal, vacuum/forceps, elective CS and emergency CS) • Birthweight • Apgar score at 1 minute • Apgar score at 5 minutes
Bruno, 2016;[47] English (Italy)	**Method of randomisation:** The randomisation list was obtained by computer-generated random allocation with a 1 : 1 ratio **Allocation concealment:** The allocations were sealed in numbered white envelopes, which were kept in the midwifery facility.	**Inclusion criteria:** • Pregnant women with a pre-pregnancy BMI ≥ 25 kg/m^2	Dietary intervention During enrolment, women attended a session with a dietitian lasting about an hour. The IG received a personalised diet (I) with a daily intake of 1500 kcal/day. The prescribed diet included plant foods, cereals, legumes and fish, with olive oil as the primary source of fat and moderate to no consumption of red wine. The diet provided three main meals and three snacks, with a target macronutrient composition of 55% carbohydrates, 20% protein and 25% fat. The dietary intervention aimed to reduce the consumption of foods with a high glycaemic index and high saturated fat content while substituting them with healthier alternatives that were based on the taste and preferences of the women.	All women in the CG received standard physical activity recommendations. Women were asked about their adherence to the suggested lifestyle.	**Maternal outcomes:** • GDM

continued

TABLE 32 Individual participant data trials (*continued*)

	Blinding: Not reported.	• Age > 18 years • Singleton pregnancy **Exclusion criteria:** • Chronic diseases (including diabetes mellitus) • Previous GDM • Smoking habits (≥ 5 cigarettes per day), hypertension • Medical conditions or dietary supplements that might affect body weight (i.e. thyroid diseases). Previous bariatric surgery, contraindications to exercise and intent to deliver outside of our hospital. **Number of participants:** Intervention, *n* = 69 Control, *n* = 62 **Type of intervention:** Mixed	Physical intervention The physical intervention encouraged pregnant women to engage in moderate-intensity activity for at least 30 minutes, three times a week. The 'talk test' was used to monitor the intensity of the exercise. Follow-up appointments were scheduled at weeks 16, 20, 28 and 36 of pregnancy with both the gynaecologist and the dietitian. At each follow-up, weight was measured, and dietary habits were assessed.	• PIH, preterm birth • Gestational age at delivery (days) • Induction of labour • Caesarean delivery **Neonatal outcomes:** • Birthweight (g) • LGA infants (≥ 90th centile) • Macrosomia (> 4000 g) • SGA infants (≤ 10th centile)

TABLE 32 Individual participant data trials (*continued*)

Chao, 2017;[43] English (USA)	**Method of randomisation:** Women were randomly allocated to the CG and the IG	**Inclusion criteria:**	Participants received weekly 20-minute telephone counselling sessions with a dietitian trained in behavioural weight-loss treatment. The sessions took place between weeks 16 and 36 of gestation or until delivery. A treatment manual based on Look AHEAD trial was adapted to create a programme focusing on appropriate weight gain during pregnancy.	The CG received standard counselling during their obstetrics visits on nutrition, exercise and weight-gain goals. They did not receive the telephone and WiFi weighing intervention or specific feedback on weight-gain progress during pregnancy from study staff. All participants completed monthly 24-hour food recalls using an online system.	**Outcomes:**
	Allocation concealment: Not reported	• Women up to 16 weeks pregnant were recruited from two obstetrics clinics in Philadelphia, PA, USA.	The programme focused on weight management through nutrition, exercise and lifestyle changes, aiming to improve adherence to the diet and activity plan, prevent disordered eating and reduce environmental food cues. Participants maintained food records and aimed for a calorie increase of only 300 per day above pre-pregnancy levels. Weight-gain goals were 0.6 lbs/week for overweight and 0.5 lbs/week for obese women in the second and third trimesters. The programme also emphasised on improving mood and reducing stress. The women were required to weigh themselves weekly with a WiFi scale.		• GDM
	Blinding: Not reported	• Self-reported pre-pregnancy BMI between 25 and 50 kg/m^2	The WiFi scales sent data to personalised weight charts accessible online for remote weight monitoring and feedback. The study dietitian reviewed treatment sessions weekly and provided customised feedback based on weights, food records and adherence issues.		• GWG
		• 18 and 40 years of age			
		• Ability to read and understand English			

continued

TABLE 32 Individual participant data trials (*continued*)

		Exclusion criteria: • DM • History of gestational diabetes • Twins or other multiples • HIV • Chronic steroid use **Number of participants:** Intervention, *n* = 20 Control, *n* = 21 **Type of intervention:** Mixed			
Cordero, 2014;[63] English (Spain)	**Method of randomisation:** Women were randomly allocated to the CG and the IG **Allocation concealment**: Not reported **Blinding**: Not reported	**Inclusion criteria:** • Pregnant women living in the healthcare area of Hospital Puerta de Hierro, Madrid, Spain • Age, 33.24 (± 4.3 years)	Physical Activity Programme The physical activity programme for pregnant women in the IG lasted from weeks 10 to 14, with exercise sessions lasting 50–60 minutes three times a week. The sessions consisted of two on-land sessions in a gym hall and one aquatic water-based activity in small and large pool tanks. The exercise intensity was set using Borg's scale and maternal HR was monitored to ensure it did not exceed 60% of the calculated HR reserve. A fitness specialist and an obstetrician supervised all sessions to ensure patient safety and adherence to the training programme. On-land session.	The women in the CG remained inactive.	**Primary outcome:** • GDM (The National Diabetes Data Group criteria) **Secondary outcomes:**

TABLE 32 Individual participant data trials (*continued*)

	• Women without medical obstetric contraindications	Land sessions were divided into two parts: phase 1 included activation, physical and psychological preparation, and various exercises such as locomotive games, articular movement and light stretches. Phase 2 consisted of low-impact aerobics, including aerobics, fitness, modern dance, Latin dance, cardio boxing, rhythm and percussion.	• GWG
	• Women having medical clearance for physical exercise	In the next phase, the body was toned through targeted muscular exercises that engaged almost all muscle groups. However, exercises that focused on the abdominal muscles were avoided. To tone different muscle groups, a programme of two sets of 15 repetitions was completed. For biceps and triceps, dumbbells weighing 2 kg were used, while lunges were used for quadriceps stimulation. Gluteal work was done on all fours using the body weight. Exercises that involved extreme stretching, the Valsalva manoeuvre, ballistic movements, joint overextension and jumping were specifically avoided. Additionally, the exercises were performed supine for no longer than 2 minutes.	• Gestational age at delivery
	Exclusion criteria:	The pelvic floor exercise block began with identifying the affected areas, then progressed to practising slow and fast contractions in different positions. The final phase focused on improving flexibility in the affected muscle groups. The block also included relaxation and visualisation exercises, self-massage and pair massage.	• Type of delivery

continued

TABLE 32 Individual participant data trials (*continued*)

	• Not listed	Sessions included various exercises accompanied by music with different tempos. The exercises used materials such as foam rubber balls, elastic bands, dumbbells, Swiss balls and mats. Aquatic activities included upper and lower body movements.	• Birthweight
	Number of participants:	The central part of the work was divided between (1) displacements while swimming (except butterfly style) and (2) strength exercises and aquatic activities (propulsion exercises).	• Length
	Intervention, *n* = 101	In the final part of the routine, we did flexibility exercises, relaxation and breathing in the small pool tank. We used aquatic materials like foam rubber balls, swimming accessories and weights for resistance. Water temperature was 28.5–29 °C. Timing of sessions.	
	Control, *n* = 156	Aerobic sessions on land: 10-minute warm-up, 20-minute choreography, 12-minute resistance exercises, 10-minute pelvic floor exercises, 8-minute stretching.	
	Type of intervention: Physical activity	Aquatic activities: 10-minute warm-up, 30-minute core session (swimming laps, step climbs, lunges, strength exercises in water), 10-minute stretching. All sessions were supervised by a qualified fitness specialist (group size: 10–12 women).	

TABLE 32 Individual participant data trials (*continued*)

Dekker, 2015;[35] English (Australia)	**Method of randomisation:** Randomisation was done using number allocation through an external service. Stratification of the randomisation was based on BMI (≤ 40 or > 40 kg/m^2) and parity (0 or ≥ 1).	**Inclusion criteria:**	At 12-weeks' gestation, all participants attended a group education session where written information on exercise, nutrition and adequate GWG was provided. The exercise intervention consisted of an individualised exercise plan meeting the specified energy expenditure requirements based on personal preferences and ability, monthly face-to-face exercise advice by physiotherapists and paper-based diaries for self-monitoring of activity. Women not meeting the specified energy expenditure requirements were offered additional face-to-face support to identify barriers and alterations to the exercise plan.	At 12-weeks' gestation, all participants attended a group education session where written information on exercise, nutrition and adequate GWG was provided.	**Maternal outcomes:**
	Allocation concealment: Not reported	• Aged 18–45			• GDM
	Blinding: Not reported	• BMI 30 kg/m^2 or greater			• GWG (kg)
		• Pregnancy care at the Royal Brisbane and Women's Hospital			• BMI (kg/m^2)
		• Willing and able to be randomised to an exercise intervention			• Fasting glucose (mmol/l)
		• Able to provide informed consent			**Neonatal outcomes:**
		Exclusion criteria:			• Gestational age delivery (days)
		• Non-English speaking			• Five-minute Apgar score
		• Medical or obstetric contraindication to exercise including hemodynamically significant heart disease			• CS (*n*) (% of group)
		• Restrictive lung disease			• Birthweight (g)

continued

TABLE 32 Individual participant data trials (*continued*)

		• Incompetent cervix (cerclage) • Multiple gestation • Severe anaemia • Chronic bronchitis • Type 1 diabetes • Orthopaedic limitations • Poorly controlled seizure disorder, poorly controlled hyperthyroidism, or a heavy smoker **Number of participants:** Intervention, *n* = 19 Control, *n* = 16 **Type of intervention:** Physical activity			• Length (cm) • Head circumference (cm) • Abdominal circumference (cm) • Mid upper arm circumference (cm)
Dodd, 2014;[48] English (Australia)	**Method of randomisation:** Randomisation was done by telephoning the central randomisation service, using a computer-generated schedule with balanced variable blocks. Stratification occurred for parity (0 v ≥ 1), BMI at antenatal booking (25–29.9 v ≥ 30	**Inclusion criteria:**	Pregnant women who received Lifestyle Advice underwent a comprehensive dietary and lifestyle intervention. The intervention included a range of strategies such as dietary modifications, exercise routines and behavioural changes, which were delivered by a research dietitian and trained research assistants. The dietary advice provided to the women was in line with the current Australian standards, which advocated for a balanced intake of carbohydrates, fats and proteins. The women were advised to reduce their consumption of foods high in refined carbohydrates and saturated fats, increase their intake of fibre and consume two servings of fruits, five servings of vegetables and three servings of dairy daily. To increase physical activity, the women were encouraged to increase their walking and incidental activity.	Women receiving standard care followed local hospital guidelines without routine advice on diet, exercise or gestational weight.	**Outcome:**

TABLE 32 Individual participant data trials (*continued*)

	Allocation concealment: Not reported **Blinding:** Outcome assessors	• Women with a BMI of 25 kg/m^2 or greater • Singleton pregnancy between 10 and 20 weeks gestation **Exclusion criteria:** • Women with multiple pregnancies • Type 1 or 2 diabetes diagnosed • Prior to pregnancy **Number of participants:** Intervention, *n* = 1075 Control, *n* = 1067 **Type of intervention:** Mixed			• GDM **Primary neonatal outcomes:** • The incidence of infants born LGA (birthweight ≥ 90th centile for gestational age and infant sex) and with birthweight above 4 kg **Secondary neonatal outcomes:** • Gestational age at birth • Apgar score of 7 or above at 5 minutes of age • Need for resuscitation at birth; birthweight above 4.5 kg or below 2.5 kg • Birthweight (and *z*-scores) • Birth length (and *z*-scores) Head circumference (and *z*-scores) • Admission to NICU • Admission to special care baby unit
Dodd, 2019;[64] English (Australia)	**Method of randomisation:** A computer-based randomisation service in the Discipline of Obstetrics and Gynaecology, The University of Adelaide was used.	**Inclusion criteria:**	Women randomised to the Lifestyle Advice Group received an intervention consisting of six sessions throughout their pregnancy. The intervention included three face-to-face sessions with a dietitian, one shortly after trial entry, another at 28 weeks' gestation, and a third	Women who were randomised to the standard care group received their antenatal care according to hospital guidelines, which did not include information relating to dietary intake, physical activity or weight gain during pregnancy. Women in the standard care group	**Primary outcome:**

continued

TABLE 32 Individual participant data trials (*continued*)

		provided by a research assistant at 36 weeks' gestation. Additionally, women received three telephone calls from the research assistant at 20, 24 and 32 weeks' gestation.	received antenatal care without dietary, activity, or weight-gain information.	
Allocation concealment: Not reported.	• Women with a BMI of 18.5–24.9 kg/m^2	Dietary advice aligned with Australian guidelines. Balance carbs, fats and proteins. Reduce energy-dense, non-core foods high in carbs and fats. Increase fibre, 2 fruits, 5 vegetables, 3 dairy daily.		• Proportion of infants with birthweight > 4 kg
Blinding: Blinding of participants was not possible given the nature of the intervention, but where possible, antenatal care-providers, outcome assessors and data analysts were blinded to treatment allocation	• A singleton pregnancy between 10 and 20 weeks	The intervention was tailored using health decision-making stage theories. Women were given written dietary and activity info, individual diet and activity plan, recipe book and menu plans in first session with a research dietitian.		**Secondary Infant Outcomes:**
	Exclusion criteria:	Women were encouraged to set realistic goals for diet and exercise, supported to make changes and monitor progress using the SMART goals approach – Specific, Measurable, Achievable, Relevant, and Time-Specific criteria to increase success. These principles were reinforced at subsequent contacts with research staff.		• Preterm birth before 37 weeks' gestation
	• Women with multiple pregnancies			• Perinatal mortality
	• Women with diabetes (type 1 or type 2) diagnosed before pregnancy			• Infant death
	Number of participants:			• LGA
	Intervention, *n* = 319			• SGA
	Control, *n* = 322			• Admission to NICU or special care baby unit

TABLE 32 Individual participant data trials (*continued*)

		Type of intervention: Mixed			• Hyperbilirubinaemia • Nerve palsy • Fracture • Birth trauma • Shoulder dystocia **Maternal outcomes:** • GDM • GWG • Hypertension • PE • Need for and length of antenatal hospital
ESTEEM (Al Wattar, 2019[19]); English (UK)	**Method of randomisation:** 1 : 1 ratio via a password-protected online data management system. Used minimisation to balance the groups for maternal BMI, parity and ethnicity.	**Inclusion criteria:**	ESTEEM intervention was based on a Mediterranean-style diet: provided participants in the intervention arm with mixed nuts (30 g/day of walnuts, hazelnuts and almonds) and extra virgin olive oil (0.5 l/week) as the main sources of cooking fat. The trial dietitian and trained researchers delivered the intervention over 3 face-to-face sessions, which included a personalised one-on-one session at 18 weeks' gestation, and 2 further group sessions at 20 and 28 weeks using pre-piloted presentations. In the first visit, the 24-hour food recall technique was used to identify any changes that were needed in the participants' diet to follow a Mediterranean-style pattern. The intervention was made culturally sensitive by providing cooking advice through a bespoke recipe book. Instead, incorporated elements of the Mediterranean diet into the local cuisine by code	Received dietary advice as per UK national recommendations for antenatal care and weight management in pregnancy	**Maternal outcomes:**

continued

TABLE 32 Individual participant data trials (*continued*)

		signing the recipes with community teams (food-academy.co.uk). Where possible, we involved women's partners to participate in these sessions. In between the face-to-face sessions, women were followed up twice with phone calls at 24 and 32 weeks' gestation to reinforce the dietary goals and to assess their general health. Adherence was marked by the number of sessions attended.	
Allocation concealment: Random elements allocated to ensure allocation concealment	• Pregnant women ≥ 16 years		• GDM
Blinding: Not reported	• < 18 weeks' gestation		• GWG
	• Singleton pregnancy		• PE
	• Able to consume nuts and olive oil		• Maternal admission to high dependency or intensive care unit
	• Proficient in written and spoken English		• Antepartum haemorrhage
	Exclusion criteria:		• Mode of delivery
			• Preterm delivery
	• History of pre-existing diabetes		• Maternal anaemia
	• GDM		**Neonatal outcomes:**
	• Chronic renal disease		• Stillbirths
	• Autoimmune disease		• Neonatal deaths
	• If they were taking lipid-altering drugs such as statins at the time of booking		• SGA fetus (< 10th percentile)
	Number of participants:		• Admission to the neonatal care unit

TABLE 32 Individual participant data trials (*continued*)

		Intervention, *n* = 627 Control, *n* = 625 **Type of intervention:** Diet			• Birthweight • Hypoxic ischaemia • Encephalopathy
El Beltagy, 2013; English	**Method of randomisation:** Not reported. **Allocation concealment:** Not reported. **Blinding:** Not reported.	**Inclusion criteria:** Obese women at risk of gestational diabetes **Exclusion criteria:** Not reported **Number of participants:** Intervention, *n* = 48 Control, *n* = 48 **Type of intervention:** Mixed	Mild physical activity programme and diet modification for 12 weeks	No details	**Outcomes** • GDM • GWG
Garmendia, 2020;[30] English (Chile)	**Method of randomisation:** The cluster units were randomly allocated to: (1) enhanced implementation of nutritional healthcare standards (IG), or (2) routine care (CG). **Allocation concealment:** Not reported	**Inclusion criteria:** • < 15 weeks of gestation, Between 16 and 40 years of age	CHiMINCs is an intervention that helps primary healthcare centres implement evidence-based guidelines. It involves training healthcare professionals on nutrition, counselling pregnant women on diet and physical activity, providing a physical activity programme, and referring patients to dietitians as needed. Based on gestational weight-gain recommendations, the intervention aims to improve communication skills of PHCC professionals. For more information, please refer to the source. At each PHCC visit, midwives provided pregnant women with specific recommendations for their GWG, based on a computer chart following IoM 2009 guidelines. They also gave advice	The participants in the CG were provided with routine antenatal care and nutritional counselling in accordance with national guidelines. The nutritional status of pregnant women was evaluated based on BMI increases according to gestational age, using Atalah's chart. While the Chilean guidelines included GWG recommendations based on nutritional status, no further advice was given during each prenatal appointment to achieve adequate GWG. Dietary recommendations were provided, including an additional consumption of 350 calories per day during the second and third trimesters.	**Primary outcomes:** • GWG

continued

TABLE 32 Individual participant data trials (*continued*)

			on healthy nutrition and physical activity, including the benefits of breastfeeding, avoiding sugary drinks, limiting bread, choosing lean meats and fish, and eating a lot of vegetables and fruits. Women were invited to attend 1-hour physical activity classes, supervised by trainers three times a week, to achieve moderate-intensity activity.	
Blinding: Not reported	• Residence within catchment areas of selected Public Health Care Centers (PHCCs) • No plans to move for the following 2 years **Exclusion criteria:** • High-risk pregnancies indicated by any of the following guidelines of the Chilean Ministry of Health • Prior history of abortion (> 2), children with low birthweight (< 2500 g) • Prematurity or perinatal death • Current multiple gestation • Uterine scar • Chronic diseases	Midwives referred pregnant women to dietitians based on specific criteria: gaining over 3 kg in the first trimester, and over 3 kg/month for normal weight women, 2 kg/month for overweight women, and 1.5 kg/month for obese women in the second and third trimesters.	• Adequate birthweight • Birth length • Macrosomia • LGA **Secondary outcomes:** • GDM • Birth (< 37 weeks) • Infants with low birthweight (birthweight < 2500 g) • Infant born SGA (birthweight ≤ 10th percentile for gestational age according to Alarcón-Pittaluga curves)	

TABLE 32 Individual participant data trials (*continued*)

		• Currently underweight (BMI < 18.5 kg/m²) **Number of participants:** Intervention, *n* = 2565 Control, *n* = 2066 **Type of intervention:** Mixed			• Low score at 1 minute and at 5 minutes on the Apgar score test (score below 7).
Garnaes, 2016;[44] English (Norway)	**Method of randomisation:** Women were randomly allocated to the CG and the IG **Allocation concealment:** Not reported. **Blinding:** Not reported.	**Inclusion criteria:** • Pre-pregnancy BMI ≥ 28 kg/m² • Age ≥ 18-year-old • Gestational week < 18 Carrying a singleton live fetus at 11–14 weeks ultrasound scan.	The exercise group received exercise sessions at the hospital three times weekly, supervised by a physical therapist following guidelines from the ACOG. Sessions included 35 minutes of treadmill walking/jogging and 25 minutes of resistance training. Exercises were adjusted based on each woman's strength level and included pelvic floor exercises. Participants also followed a 50-minute home exercise programme once a week, including 35 minutes of endurance training and 15 minutes of strength exercises, and did daily pelvic floor muscle exercises. They were given a weight-gain curve and encouraged to compare their weight gain with it. Participants attended one motivational interview session during the intervention period.	The CG received standard maternity care from their healthcare providers, following Norwegian guidelines for healthy pregnant women. They were encouraged to continue their regular activities, including exercise.	**Primary outcome:** • GWG **Secondary outcomes:** • GDM

continued

TABLE 32 Individual participant data trials (*continued*)

		• The participants had to be able to come to St Olavs Hospital for assessments and exercise classes **Exclusion criteria:** • High risk for preterm labour, diseases that could interfere with participation, and habitual exercise training (twice or more weekly) in the period before inclusion. **Number of participants:** Intervention, *n* = 46 Control, *n* = 45 **Type of intervention:** Physical activity			• BMI • Body composition • Physical activity level • Skinfold thickness • Blood pressure • Incidence of maternal hypertension in late pregnancy
\Guelinckx, 2010;[37] English (Belgium)	**Method of randomisation:** Women were randomly assigned to three different groups **Allocation concealment:** Not reported	**Inclusion criteria:** • Obese (BMI of > 29.0 kg/m^2, IoM criteria)	Lifestyle intervention based on a brochure or on active education Passive group: provided with a brochure containing information on diet, physical activity and tips to limit GWG at the first antenatal consultation. Active group: received same brochure and also actively counselled by a trained nutritionist in three group sessions at 15, 20 and 32 weeks of gestation. The sessions had up to five women and lasted 1 hour each. Counselling on balanced diet was based on the official national dietary recommendations (energy intake: 9–11%, proteins; 30–35%, fat; 50–55%, carbohydrates). Aim was to limit intake of energy-dense foods, replacing with healthier alternatives such as fruits, increasing wholewheat	No intervention	**Outcomes:** • GDM

TABLE 32 Individual participant data trials (*continued*)

		grains and low-fat dairy products, and reducing saturated fatty acids. General topics such as energy balance, body composition, food labels and physical activity were discussed. Tips for behavioural modification to reduce emotional eating and binge eating were provided. Total energy intake was not restricted in any group but aimed to do so indirectly by limiting the intake of energy-dense foods. Nutritional data were obtained from 7-day dietary records. A physical activity score was calculated for each trimester of the pregnancy by using the Baecke questionnaire	
Blinding: None	• White women with gestational age < 15 weeks consecutively attending the antenatal clinic **Exclusion criteria:** • Pre-existing diabetes or developing GDM • Multiple pregnancy gestational age of > 15 weeks • Premature labour (< 37 weeks) • Special nutritional needs such as metabolic disorder, allergic conditions, kidney problems and Crohn's disease • Suboptimal knowledge of Dutch language **Number of participants:** Intervention (active), *n* = 65 Intervention (passive), *n* = 65		• PIH • PE • Chronic hypertension • GWG • Gestational age at delivery • Induction of labour • CS • Birthweight/length • Macrosomia (birthweight > 4000 g) • Total physical activity score

continued

TABLE 32 Individual participant data trials (*continued*)

		Control, *n* = 65 **Type of intervention:** Mixed			
Harrison, 2013;[45] English (Australia)	**Method of randomisation:** Computer-generated randomisation	**Inclusion criteria:**	Individual four-session behaviour change lifestyle intervention in antenatal clinic setting at 14–16, 20, 24 and 28 weeks of gestation. The intervention was based on the social cognitive theory, adapted from the study group's earlier lifestyle intervention programme (HeLP-her).The sessions were delivered by a health coach (exercise physiologist). Healthy eating and physical activity were encouraged along with specific dietary advice in pregnancy. Behavioural change strategies were aimed at identifying short-term goals and promoting self-efficacy and self-monitoring. Goals included lifestyle changes such as reducing high-fat or convenience foods, increasing fruit/vegetable intake and increasing frequency of physical activity. Participants themselves set goals. Pedometers and weight-gain charts based on IoM recommendations were provided to monitor the progress. Written Australian dietary and physical activity guidelines and other resources to encourage optimal health, GWG and lifestyle were provided	A single brief education session based on Australian Dietary and Physical Activity Guidelines were provided along with written versions of guidelines. GWG was not discussed	**Primary outcome:**
	Allocation concealment: Sealed opaque envelopes	• Gestational age of 12–15 weeks			• GWG (weight was measured at baseline; 12, 16 and 28 weeks of gestation)
	Blinding: Care providers, researchers and outcome assessors were blinded to group allocation	• Overweight [BMI of ≥ 25 or ≥ 23 kg/m^2 if high-risk ethnicity (Polynesian, Asian and African populations) or obese (BMI of ≥ 30 kg/m^2)] increased risk of GDM as per a validated risk prediction tool			**Secondary outcome:**

TABLE 32 Individual participant data trials (*continued*)

		• Willing to complete an OGTT at 28 weeks of gestation instead of the standard glucose challenge test at GDM screening **Exclusion criteria:** • Multiple pregnancies • Type 1 or 2 diabetes • BMI of ≥ 45 kg/m^2 • Pre-existing chronic medical conditions • Non-English-speaking **Number of participants:** Intervention, *n* = 121 Control, *n* = 107 **Type of intervention:** Mixed			• GDM
Hawkins, 2014;[46] English (USA)	**Method of randomisation:** Randomisation was stratified by age (< 30 years, ≥ 30 years) and pre-pregnancy BMI (25–30 kg/m^2, ≥ 30 kg/m^2 with a block size of 4.	**Inclusion criteria:**	The lifestyle intervention involved 6-monthly in-person counselling sessions and five telephone-delivered booster sessions by bilingual educators. The tailored approach was developed from the transtheoretical Model and Social Cognitive Theory and included motivationally targeted materials, tip sheets and strategies for overcoming barriers to physical activity. The overall goal of the exercise component was to encourage pregnant women to achieve the ACOG guidelines for physical activity during pregnancy (≥ 30 minutes of moderate-intensity activity on most days of the week) through increasing walking and developing a more active lifestyle. Personalised physical activity goals were established. Participants tracked	Standard care	**Primary outcomes:**

continued

TABLE 32 Individual participant data trials (*continued*)

		progress using a digital pedometer and a physical activity log. The dietary component aimed to decrease intake of foods high in saturated fat and increase dietary fibre. Participants received a low-literacy pictured-based food guide. Health educators assessed the participants' readiness for change and helped them set dietary goals. They provided a low-literacy pictured-based food guide and self-monitoring logs. Booster sessions were conducted to review logs, troubleshoot challenges, introduce new materials and set new goals. Subsequent sessions included a review of logs, problem-solving, new tailored materials and goal setting. The intervention was developed using a culturally sensitive approach to better meet the needs of the Hispanic population.	
Allocation concealment: Not reported **Blinding:** Not reported	• Hispanic women aged 18–40 years • Gestational age of < 18 weeks • Overweight or obese (pre-pregnancy BMI ≥ 25 kg/m^2). Self-reported participating in < 30 minutes of moderate-intensity activity per week. **Exclusion criteria:** • History of type 2 diabetes, hypertension, heart disease or chronic renal disease	Intervention fidelity Health educators received extensive training to ensure consistent delivery of the intervention. This included a three-session interviewer training course, booster training sessions and monthly quality assurance reviews.	• Physical activity • Diet **Secondary outcomes:** • GDM • GWG

TABLE 32 Individual participant data trials (*continued*)

		• Current medications that adversely influence glucose tolerance Not planning to continue the pregnancy to term • Contraindications to participating in moderate-intensity physical activity or a low-fat/high-fibre diet • Self-reported participation in ≥ 30 minutes of moderate-intensity exercise on ≥ 3 days/week or ≥ 20 minutes of vigorous-intensity exercise on ≥ 1 day/week • Multiple gestation (e.g. twins) **Number of participants:** Intervention, *n* = 33 Control, *n* = 35 **Type of intervention:** Mixed			Infant birthweight, g Gestational age at delivery, weeks
Hui, 2011 (2012);[67] English (Canada)	**Method of randomisation:** Computer-generated randomisation allocation table performed by a staff member without involvement in the study design	**Inclusion criteria:**	Exercise component: a community-based exercise programme – recommended exercise included walking, mild to moderate aerobic, stretching and strength exercises (3–5 times per week for 30–45 minutes/session). The programme started around 20–26 weeks of gestation and finished at 36 weeks. The group exercise sessions were held in air-conditioned gymnasia in community centres. Group floor aerobic, stretching and strength exercises were led by licensed fitness trainers. Participants were instructed to record daily physical activities in activity logs	Standard prenatal care recommended according to the Society of Obstetricians and Gynaecologists of Canada were given to the CG. Exercise instruction and dietary intervention were not provided to participants in the CG	**Outcomes:**

continued

TABLE 32 Individual participant data trials (*continued*)

	Allocation concealment: Sealed and labelled envelope	• No pre-existing GDM	Dietary component: interviews and counselling were provided twice in pregnancy by registered dietitians (at enrolment and 2 months after enrolment). Dietitians provided personalised dietary counselling to participants based on their food choice map (FCM) interview results, pregnancy week, weight gain and the Health Canada guidelines for food intake in pregnancy.		• GDM
	Blinding: Participants and study staff were not blinded	**Exclusion criteria:** • Medical, obstetric Skeletal or muscular disorders that could contraindicate physical exercise during pregnancy **Number of participants:** Intervention, *n* = 102 Control, *n* = 88 **Type of intervention:** Mixed			• GWG • LGA • Birthweight
Hui, 2014;[66] English (Canada)	**Method of randomisation:** Randomisation was performed using a computer-generated randomisation allocation table.	**Inclusion criteria:**	Participants in the IG received a weekly community-based exercise programme, including aerobic exercise, stretching and strength exercises. The programme was delivered in weekly group exercise classes or via a DVD format for home use. Participants exercised for 30–45 minutes, 3–5 times a week, from 20–26 gestational weeks to 36 gestational weeks. They recorded their exercise activities in a logbook. Attendance < 3 times in group exercise, no interest in exercising at home, or no record in the logbook were considered as withdrawal from the study.	CG participants did not receive exercise or dietary interventions. They received standard prenatal care and a package of information on healthy habits during pregnancy from Health Canada.	**Outcomes:**

TABLE 32 Individual participant data trials (*continued*)

	Allocation concealment: Participants received a sealed envelope labelled with the assigned randomisation number, which contained instructions for participants	• Women with < 20 weeks of pregnancy	Dietary intervention	• GDM
	Blinding: The nature of the study meant that participants and study staff were not blinded to the types of interventions.	• No existing diabetes during pregnancy and signed consent form.	IG participants received two individualised dietary consultations using the FCM software, a proven tool for assessing dietary intake. During the consultation, participants and dietitians marked food stickers on a magnetic board to recall food intake. Nutritional information on the stickers was scanned into a computer, and daily calorie intake and macronutrients were analysed instantly. Nutritional recommendations were based on the dietary intake analysis and Health Canada guidelines for food intake during pregnancy, while considering personal food preferences, beliefs and budgeting. The FCM software helped identify factors relevant to participants' food choices and intake, providing a complete weekly intake and reasons behind food choices.	• GWG
		Exclusion criteria:	Our unique approach involves creating a personalised, achievable dietary plan that considers participants' food choices. We provide them with a copy of the FCM as their diet plan, and reinforce recommendations at a follow-up consultation 2 months later.	• Birthweight (g)
		• Not listed		• Large-for-gestational age
		Number of participants:		• CS

continued

TABLE 32 Individual participant data trials (*continued*)

		Intervention, *n* = 57 Control, *n* = 56 **Type of intervention:** Mixed			
Jeffries, 2009;[68] English (Australia)	**Method of randomisation:** A computer random number generator was used to randomly assign women to the intervention and CG. **Allocation concealment**: Number cards allocating women to the two groups were placed in opaque, sequentially numbered envelopes **Blinding:** Patients	**Inclusion criteria:** • Pregnant women with gestational age of ≤ 14 weeks **Exclusion criteria:** • Aged < 18 or > 45 years • Non-English speaking • Multiple pregnancy • Type 1 or 2 diabetes **Number of participants:** Intervention, *n* = 148 Control, *n* = 138 **Type of intervention:** Mixed	Women allocated to the IG were given personalized weight measurement card including information on optimal GWG (based on their BMI at the time of recruitment and the US IoM guidelines) and were asked to record their weight at 16, 20, 24, 28, 30, 32 and 34 weeks of gestation. The patient was allowed to choose to measure weight at hospital or at home	No intervention	**Outcomes:** • GDM • GWG • Birthweight SGA and LGA (weight < 10 centile and > 90 centile) • Preterm delivery • Instrumental delivery • Caesarean delivery • PE • PIH • Apgar score at 5 minutes of < 7 • Hypoglycaemia • Shoulder dystocia

TABLE 32 Individual participant data trials (*continued*)

					• Gestational age at delivery
Kennelly, 2018;[49] English (Ireland)	**Method of randomisation:** Randomisation was performed using a computer-generated sequence in a ratio of one to one.	**Inclusion criteria:**	Participants allocated to the IG received standard antenatal care plus a 'Healthy Lifestyle Package'. The 'Healthy Lifestyle Package' began with a single face-to-face education session conducted individually or in pairs. The information provided during the education session is reinforced through various delivery channels, such as a smartphone application, e-mails sent every 2 weeks by the research team, and two follow-up hospital visits at 28 and 34 weeks of gestation. The e-mails are standardised to cover a specific theme every 2 weeks, with some discourse between researchers and participants when individuals have specific inquiries.	Women in the CG received standard antenatal care, which in Ireland does not include uniform advice on diet, exercise, or weight gain during pregnancy.	**Primary outcome:**
	Allocation concealment: The biostatistician prepared sequentially numbered, sealed opaque envelopes, which were opened at the first study visit.	• Singleton pregnant women between 10 and 15 weeks of gestation			• GDM
	Blinding: As a result of the nature of the intervention, neither participants nor researchers were blinded to the intervention or outcomes.	• BMIs between 25.0 and 39.9 in possession of a smartphone			**Secondary outcome:**
		Exclusion criteria:			• GWG
		• Not listed			• PE or PIH
		Number of participants:			• Onset of labour
		Intervention, *n* = 278			• Caesarean delivery as primary procedure

continued

TABLE 32 Individual participant data trials (*continued*)

		Control, *n* = 287 **Type of intervention:** Mixed			• Duration of labour (min) • Epidural • 3rd-degree tear • Mode of delivery (spontaneous vaginal, instrumental, elective caesarean, emergency caesarean)
Khaledan, 2010;[69] English (Iran)	**Method of randomisation:** Random sampling was performed with matching BMI, number of pregnancies, gestational age and socioeconomic status of participants. **Allocation concealment:** Not reported **Blinding:** Not reported	**Inclusion criteria:** • A singleton pregnancy, with intact fetal membrane. **Exclusion criteria:**	The study required pregnant women in the experimental group to do exercise three times a week for 2 months. The programme used in the study was a modified Clapp programme, consisting of three sessions per week for 8 weeks, with each session lasting for half an hour up to 45 minutes. Each session began with 15 minutes of stretching and flexibility exercises to make the muscles and joints soft and flexible. Then, the aerobic stage was performed to continue with the rhythm, where the person took a slow walk, and the HR was maintained within 60% of the maximum HR. This step started with a 5-minute duration in the first session, and then 1 minute was added to the duration in each subsequent session until the 18th session, where the duration was reached to 15 minutes, and it remained constant until the end of the meeting. The intensity of the exercise was determined based on 60% of the maximal HR for each person, which was calculated through the formula 220−age × 60/100. The HR was recorded about three times during the aerobic exercise by the subjects' carotid pulse (beginning, middle and end of rally).	Pregnant women in the CG received diet based on Food Pyramid guidelines recommended by the America Agricultural Department. In addition, an iron and folic acid tablets under a routine pregnancy care was also provided.	**Primary outcome** • GDM **Secondary outcomes**

TABLE 32 Individual participant data trials (*continued*)

	• Heart disease • Chronic pulmonary disease • Cervical insufficiency or correction of cervical insufficiency • Multiple pregnancy • Permanent vaginal bleeding at second and third trimester of pregnancy • Placenta previa after 20 weeks and six of pregnancy • The risk of preterm delivery in the current pregnancy • Rupture of fetal membranes • Presence of hypertension during pregnancy • Severe anaemia • Unchecked arrhythmia on mother • Chronic inflammation of airways • Type 1 diabetes with poor control • Extreme morbid obesity • Very low maternal weight • History of completely sedentary lifestyle • Fetal growth restriction in current pregnancy • Uncontrolled hypertension	After the aerobic phase, all participants consumed fluids like water or juice. Then, a cooling stage for 10–15 minutes with light stretching was done in a sitting position.	• Pregnancy induced-hypertension • Preterm birth

continued

TABLE 32 Individual participant data trials (*continued*)

		• Skeletal and structural limitations • Seizure disorders • Uncontrolled hyperthyroidism • Heavy smokers **Number of participants:** Intervention, *n* = 20 Control, *n* = 24 **Type of intervention:** Physical activity			
Khoury, 2005;[70] English (Norway)	**Method of randomisation:** The randomisation list was generated from a table of random numbers drawn up by the investigator who had no contact with the participants	**Inclusion criteria:**	Diet/dietary advice: cholesterol-lowering diet from gestational week 17–20 to birth. Dietitian visits were arranged at inclusion, and at 24, 30 and 36 weeks of gestation. Aims of dietary intervention were to: limit dietary cholesterol to 150 mg/day reduce the intake of saturated fat to 8% of dietary energy target total fat 32% of total energy intake (including 8–9% of energy from polyunsaturated fat and 16–17% from monounsaturated fat), protein 16–17% of energy, and carbohydrates 50–51% of energy tailor energy intake for target at a weight gain of 8–14 kg from pre-pregnancy levels encourage the intake of fatty fish, vegetable oils, mainly olive oil and rapeseed oil, nuts, nut butters, margarine based on olive oil or rapeseed oil at least six-a-day of fresh fruits and vegetables was advised prefer low-fat dairy products Subjects were advised to have meat for a main meal twice a week and use legumes, fatty fish, poultry, etc. on other days. Cooking lessons were arranged for special foods. Coffee was limited to two cups/day.	The CG was advised to consume their usual diet, not to introduce more oils, low-fat meat and dairy products than usual. Target weight gain was 8–14 kg and energy intake breakdown of fats, carbohydrate and proteins was same as IG.	**Outcomes:**

TABLE 32 Individual participant data trials (*continued*)

	Allocation concealment: Consecutively numbered, sealed, opaque envelopes provided to dietitian delivering intervention	• Aged 21–38 years	• GDM
	Blinding: investigators/clinicians and outcomes assessors	• BMI of 19–32 kg/m^2	• GWG
		• Non-smokers or ex-smokers (quit ≥ 5 years ago)	• Gestational age at delivery
		• Not immigrants to Norway from non-Western countries	• Preterm delivery
		• Single healthy fetus at 17–20 weeks' gestation on ultrasound	• Preterm stillbirth
		• No previous pregnancy complications first, second or third pregnancy	• Intrauterine growth restriction
		• Not vegetarian or following a Mediterranean-type diet	• Hypertensive complications (PIH/PE)
		Exclusion criteria:	• Fetal distress
		• High-risk pregnancies caused by diabetes	• Birthweight
		• Endocrine disease	• Maternal and neonatal lipid profile
		• Hypertension	
		• Drug abuse	
		• Thromboembolic disease or significant cardiac	
		• Gastrointestinal (GI)	
		• Pulmonary or haematological disease	
		History of neonatal death, stillbirth	

continued

TABLE 32 Individual participant data trials (*continued*)

		• Preterm delivery or recurrent abortion (more than three previous spontaneous abortions) • Ongoing hyperemesis gravidarum or bleeding after gestational age of 12 weeks in the current pregnancy **Number of participants:** Intervention, *n* = 141 Control, *n* = 149 **Type of intervention:** Diet			
Kunath, 2019;[71] English (Germany)	**Method of randomisation:** Women were randomly assigned to the intervention and to the CG. **Allocation concealment:** Not reported.	**Inclusion criteria:** • Women with a pre-pregnancy BMI of between ≥ 18.5 and ≤ 40.0 kg/m^2	As part of a study, pregnant women in the IG received three individual face-to-face counselling sessions during their pregnancy, and one session after delivery. The sessions were conducted by trained midwives, gynaecologists, or medical assistants from the participating gynaecological practices. The counselling sessions were scheduled alongside routine pre- and postnatal visits to ensure consistency in counselling practice and content. The counselling sessions lasted 30–45 minutes and aimed to encourage pregnant women to consume a balanced diet, engage in physical activity and self-monitor weight gain. Women received a weight-gain chart according to their baseline BMI category, which depicted weight development during the course of pregnancy as recommended by the IoM. The lifestyle counsellors received a presentation binder with easily understandable material for each counselling session and checklists for scheduling and documentation of sessions to ensure consistency in counselling practice and content.	Participants in the CG received information leaflets on healthy pregnancy lifestyle and attended routine prenatal care.	**Maternal outcomes:** • GDM

TABLE 32 Individual participant data trials (*continued*)

	Blinding: Not reported.	• A singleton pregnancy, ≤ 12th week of gestation, • Aged between 18 and 43 years • Sufficient German language skills **Exclusion criteria:** • Women with a multiple or complicated pregnancy • Women with severe pre-existing illnesses **Number of participants:** Intervention, *n* = 1139 Control, *n* = 1122	In addition to general information, individual feedback on dietary habits and physical activity, as assessed at study entry via questionnaires, was provided. Women were advised to achieve 150 minutes of moderate physical activity per week, and to facilitate adherence to physical activity recommendations, women received a brochure giving examples for appropriate exercise, a list of local prenatal exercise programmes and a pedometer to enable self-monitoring of daily physical activity. More details of the lifestyle programme are given in the published study protocol. As a measure of process evaluation, several medical and midwifery practices were monitored to check if the intervention programme was performed as intended. A sample of lifestyle counselling sessions were supervised by a member of the study team who assessed the duration and delivery of content, as well as the use of study materials.	• Hypertension • PE/HELLP syndrome • Bleeding • Preterm labour **Obstetric outcomes**: • Birth mode • Spontaneous birth • Elective CS • Emergency CS

continued

TABLE 32 Individual participant data trials (*continued*)

		Type of intervention: Mixed			• Instrumental vaginal delivery • Induction of labour • Anaesthesia • Weight retention, kg (6–8 weeks postpartum) **Neonatal outcomes:** • Birthweight, g • Birth length, cm • Head circumference, cm • LGA (> 90th percentile) • SGA (< 10th percentile) • Macrosomia (weight > 4500 g) • Preterm birth • Neonatal complications at birth
Luoto, 2011;[31] English (Finland)	**Method of randomisation:** Cluster randomisation of paired municipalities based on number of births, population size, socioeconomic status and type (rural/urban). The municipalities, not participants, were randomised into intervention and study groups	**Inclusion criteria:**	Five counselling sessions at 8–12 weeks, 16–18 weeks, 22–24 weeks, 32–34 weeks and 36–37 weeks. One primary session each for physical activity and diet followed by booster sessions. The primary session was 20–30 minutes long, but the booster sessions lasted for 10–15 minutes. The interventions were based on PRECEDE–PROCEED and stages of change models. GWG: IoM recommendations were discussed. A BMI-specific weight-gain chart was included. Physical activity: the aim was to increase leisure time	Routine care including usual dietary and physical activity counselling	**Outcomes:**

TABLE 32 Individual participant data trials (*continued*)

		physical activity to meet recommendations or maintain it if they had already reached it. The weekly action plan was agreed with each participant and the recommended minimum weekly leisure time physical activity dose was 800 MET minutes. Monthly 2-hour thematic meetings including group exercises were offered and these were led by physiotherapists Diet: advised as per Finnish dietary recommendations – saturated fat ≤ 10%, polyunsaturated fat 5–10% and total fat 25–30% (includes saturated, monounsaturated, polyunsaturated, and *trans*-fatty acids) of total energy intake and fibre 25–35 g/day. They were encouraged to include high-fibre bread, five portions of fruits/vegetables, low-fat dairy products, fish twice weekly, only moderate amounts of spread/oil and restrict sugar containing snacks/drink. The nurse checked if the written objectives were met at each booster visit.	
Allocation concealment: Not reported **Blinding:** Not reported	At least one of the following risk factors: • BMI of ≥ 25 kg/m^2 • GDM • Any signs of glucose intolerance • Macrosomic baby (≥ 4500 g) in any prior pregnancy • Family history of type 1 or 2 diabetes in first- or second-degree relatives • Aged ≥ 40 years		• GDM • Weight of the newborn infant adjusted for gestational age	

continued

TABLE 32 Individual participant data trials (*continued*)

		Exclusion criteria: At least one of the following: • Abnormal baseline OGTT at 8–12 weeks' gestation (fasting glucose > 5.3 mmol/l, 1-hour glucose > 10.0 mmol/l or 2-hour > 8.6 mmol/l) • Abnormal baseline OGTT at 8–12 weeks' gestation (fasting glucose > 5.3 mmol/l, 1-hour glucose > 10.0 mmol/l or 2-hour > 8.6 mmol/l) • Abnormal baseline OGTT at 8–12 weeks' gestation (fasting glucose > 5.3 mmol/l, 1-hour glucose > 10.0 mmol/l or 2-hour > 8.6 mmol/l) • Could not speak Finnish aged < 18 years • Twin pregnancy contraindications to physical activity substance abuse, treatment psychiatric illness **Number of participants:** Intervention, seven municipalities, *n* = 196 Control, seven municipalities, *n* = 246 **Type of intervention:** Mixed			
McCarthy, 2016;[52] English (Australia)	**Method of randomisation:** A computer-generated random number table with balanced variable blocks of 4, 6 or 8 was used to randomise treatment allocation.	**Inclusion criteria:**	Women who participated in the study were randomly assigned to receive serial self-weighing and basic dietary advice as an intervention. They were given a card that listed their booking BMI and provided guidance on their target gestational weight gain according to the IOM GWG guidelines. The	Women randomised to standard care were given a card that listed their booking BMI and advised their target gestational weight gain, while no other changes were made to routine care. Regular weighing was not included.	**Primary outcomes:**

TABLE 32 Individual participant data trials (*continued*)

		card also had space to chart their serial weights. On the reverse side of the card, there were seven general points of weight management advice based on The Australian Guide to Healthy Eating. The research midwife then provided an individual session of approximately 30 minutes to offer simple dietary advice, encourage serial weighing, and discuss weight gain with doctors and/or midwives at subsequent antenatal appointments.	
Allocation concealment: Opaque, sequentially numbered sealed envelopes were filled with allocation to standard care or serial self-weighing (intervention).	• Overweight or obese (booking or early pregnancy BMI of ≥ 25.0)	Additionally, adhesive reminder messages were placed in antenatal progress notes of overweight women stating, 'I'm in the current study aiming to gain 7–11 kg. Please talk to me about my weight'. Obese women were given a similar adhesive reminder note recommending a target weight gain of 5–9 kg in their progress notes.	• GDM
Blinding: Researchers assessing these outcomes were blinded to treatment allocation.	• Gestation < 20 weeks		• PIH
	• Aged at least 18 years		• PE
	• Singleton pregnancy		• Mode of birth other than spontaneous vertex (including elective and emergency CS, vacuum and forceps delivery)
	• English-speaking		• Postpartum haemorrhage (PPH)
	Exclusion criteria:		• Perineal trauma of 3rd or 4th degree
	• Women with pre-existing diabetes		• Admission to adult intensive care high dependency unit

continued

TABLE 32 Individual participant data trials (*continued*)

		• Known major fetal abnormality **Number of participants:** Intervention, *n* = 190 Control, *n* = 192 **Type of intervention:** Diet			• Postnatal stay on birth suite of > 6 hours • Maternal death. **Secondary outcomes:** • GWG • C-reactive protein • Leptin • Adiponectin • Quality of life [as assessed by the World Health Organization (WHO) Quality of Life WHOQOL-BREF]
Nascimento, 2011;[51] English (Brazil)	**Method of randomisation**: List of random numbers generated by SAS version 9.1 statistical program (SAS Institute Inc., Cary, NC, USA) **Allocation concealment:** Sealed sequentially numbered opaque envelopes	**Inclusion criteria:** • Pre-pregnancy overweight (BMI of 26.0–29.9 kg/m^2) or obesity (BMI of ≥ 30.0 kg/m^2)	Exercise protocol: women performed exercise weekly under the guidance of a trained physical therapist. The exercises were light- to moderate-intensity exercises, with HR s not exceeding 140 beats per minute. (ACOG recommendations). Standardised research protocol consisting of a 22-exercise sequence was followed. Group or individual exercises lasted 40 minutes with 10 minutes of general stretching, 22 minutes of exercises to strengthen the limb muscles, and 10 minutes of guided relaxation. Home exercise counselling. Women were counselled on home exercise to be done five times/week, with exercises from the protocol or walking. They were required to note the details of daily exercise in a monthly exercise book.	Routine antenatal advice and standard nutritional counselling. They were not provided physical activity counselling	**Primary outcomes:** • GDM

TABLE 32 Individual participant data trials (*continued*)

	Blinding: Not blinded	• Aged ≥ 18 years • Gestational age of 14–24 weeks **Exclusion criteria:** • Multiple pregnancy Exercising regularly • Contraindications for exercise, such as cervical incompetence • Severe hypertension • Diabetes • Vascular complications and risk of abortion **Number of participants:** Intervention, *n* = 39 Control, *n* = 41 **Type of intervention:** Physical activity			• GWG **Secondary outcome:** • Increased blood pressure **Perinatal outcomes:** • CS • Newborn infant weight, • Gestational age at delivery • Preterm birth • Apgar scores at 1 and 5 minutes • LGA • SGA Quality of life (WHOQOL – BREF questionnaire)
Olson, 2018;[72] English (USA)	**Method of randomisation:** Women were randomly assigned to the intervention and the CG.	**Inclusion criteria:**	Participants who were assigned to the IG were granted access to a password-protected intervention website. This self-directed intervention was designed using the Integrative Model of Behaviour Prediction and the Behaviour Model for Persuasive Design and was based on formative research undertaken with the target population. The intervention was developed on the basis of a successful non-electronic pregnancy lifestyle intervention for low-income women. Women in the IG had access to three	Women in the placebo CG had access to a password-protected control website. They did not have access to weight-gain tracker and diet/physical activity tools as these were believed to be active intervention components.	**Primary outcome:**

continued

TABLE 32 Individual participant data trials (*continued*)

			behaviour change tools, including a weight-gain tracker, a goal-setting and self-monitoring tool for diet and physical activity, as well as health information such as tips, articles, information about local pregnancy and parenting-related resources, a blogging tool and an event and appointment reminder.		
	Allocation concealment: Not reported **Blinding:** Not reported.	• Age 18–35 years • Gestational age ≤ 20 weeks at time of enrolment. **Exclusion criteria:** • BMI < 18.5 and ≥ 35 kg/m^2, multiple gestation • Weight-affecting medical or psychiatric conditions • No e-mail addresses **Number of participants:** CG, *n* = 563 (received treatment, *n* = 500) Pregnancy intervention and post partum control, *n* = 563 (received treatment, *n* = 497) Pregnancy and post partum intervention, *n* = 563 (received treatment, *n* = 495) **Type of intervention:** Mixed			• GWG **Secondary outcomes:** • GDM • Adherence to the treatment protocol
Ong, 2008;[73] English (Australia)	**Method of randomisation:** Not reported	**Inclusion criteria:**	Physical activity: home-based exercise programme beginning at week18 of gestation; three sessions per week of stationary cycling (home-based) supervised exercise. Exercise training was performed at home on an upright stationary cycle ergometer provided to each participant for the study period. Each session	No intervention	**Outcomes:**

TABLE 32 Individual participant data trials (*continued*)

			consisted of a 10-minute warm-up followed by one or two 15-minute bouts of cycling (with rest periods if necessary). Exercise intensity was controlled by HR initially aimed at 50–60% of maximum HR and later increased to 60–70% of maximum HR. The duration was later increased to 40–45 minutes. Sessions ended with a 10-minute cool-down period of slow pedalling		
	Allocation concealment: Not reported **Blinding:** Not reported	• Singleton pregnancy • Normal 18-week anatomy scan • No evidence of cardiovascular disease • No pre-existing diabetes **Exclusion criteria:** • Not listed **Number of participants:** Intervention, *n* = 6 Control, *n* = 6 **Type of intervention:** Physical activity			• GDM • GWG • Post-intervention glucose • Insulin levels on OGTT
Oostdam, 2012;[50] English (The Netherlands)	**Method of randomisation:** Computer-generated randomised allocation schedule stratified to the centre where the participants will be followed up. Within each centre, participants were randomly allocated to the study or CG. Block randomisation in blocks of four performed	**Inclusion criteria:**	Exercise programme of aerobic and strength training twice weekly under supervision of a trained physiotherapist from recruitment through to remainder of pregnancy. Each session lasted for 60 minutes. Aerobic training provided using cycle ergometers, treadmills, cross-trainers and rowing machines. Strength and aerobic training tailored to individual participants, taking into consideration predicted maximum muscle strength, aerobic capacity and target HR. ACOG recommendations were used as a guidance.	Usual care by midwives and obstetricians	**Primary outcomes:**

continued

TABLE 32 Individual participant data trials (*continued*)

	Allocation concealment: Only the programmer of central database knew key of coding related to group assignment	• Obese (BMI of ≥ 30 kg/m^2) or overweight (BMI of ≥ 25 kg/m^2) with at least one of the following:	• Fasting plasma glucose
	Blinding: Independent examiners assessing outcomes blinded but participants and researchers could not be blinded	• History of macrosomia (birthweight > 97th percentile of gestational age)	• Relative increase in insulin resistance in mother
		• History of abnormal glucose tolerance during previous pregnancy	• Neonatal birthweight
		• Family history of type 2 diabetes in first-degree relative	**Secondary outcomes:**
		• Gestational age of 14–20 weeks	• GDM
		• Aged > 18 years	• GWG
		• Sufficiently fluent in Dutch	• Maternal serum triglycerides
		• Capable of moderately physical activity	• High-density lipoprotein
		• Willing to give consent	• Cholesterol
		Exclusion criteria:	• Glycated haemoglobin (HbA1c)
		• GDM diagnosis before randomisation	• Maternal physical activity level
		• Hypertension (systolic > 160 mmHg and/or diastolic > 100 mmHg) alcohol abuse (i.e. two glasses of alcohol or more per day)	• Fetal growth
		• Drug abuse (except for incidental analgesic agents)	• Changes in healthcare and non-healthcare costs

TABLE 32 Individual participant data trials (*continued*)

		• Use of medication affecting insulin secretion/sensitivity (antiviral, corticosteroids, antihypertensive drugs) • Serious pulmonary (chronic obstructive pulmonary disease, exercise-induced asthma) • Cardiac, hepatic or renal (serum creatinine level of < 150 µmol/l) • Impairment malignant disease serious mental or physical impairment impacting on ability to participate in the study **Number of participants:** Intervention, *n* = 62 Control, *n* = 59 **Type of intervention:** Physical activity			
Pelaez, 2019;[74] English (Spain)	**Method of randomisation:** A statistical randomisation computer was used to perform a simple randomisation to allocate women to each group.	**Inclusion criteria:**	Each session began with an 8-minute warm-up that included walking, movement games, light dancing and gentle dynamic stretching. The 35-minute core section of the training session included low-impact aerobics such as aerobic dance, Latin dance, and adapted cardio-boxing, as well as 10 minutes of resistance training focused on major muscle groups like the core muscles, gluteus, pectoralis, quadriceps, calves and back muscles. Resistance training incorporated barbells, elastic bands, fitball, and body weight dynamic exercises like squats, lunges, bench press, biceps curl, wall push-ups, lateral leg elevations, ankle extensions and flexions.	The women in the standard care group were provided with basic care, which involved being monitored by midwives and obstetricians. They also received general nutrition and physical activity counselling from healthcare professionals. The counselling mainly consisted of verbal and written instructions, such as increasing the consumption of milk, fibre and other dairy products (up to a litre equivalent in cheese or yoghurt) while reducing the intake of fats and sugars. The healthcare professionals recommended moderate-intensity physical activities such as walking or swimming and advised against any activity that may cause harm or risk of falling. The women in this group were not discouraged from exercising on their own.	**Primary outcome:**

continued

TABLE 32 Individual participant data trials (*continued*)

	Allocation concealment: Not reported. **Blinding:** Not reported.	• Healthy women with singleton and uncomplicated gestation • Not participating in other exercise programme • Spanish communication skills **Exclusion criteria:** • Women not planning to give birth at Hospital Universitario de Fuenlabrada • Having any contraindications according to the ACOG guidelines **Number of participants:** Intervention, *n* = 115 Control, *n* = 230 **Type of intervention:** Physical activity	The cool-down period lasted 15 minutes and included pelvic floor muscle training, static stretching, and relaxation exercises. Supine position, ballistic movements and high-impact exercises were avoided. Group dynamics were used to enhance motivation and adherence. These included games, exercises in pairs or groups, and social networks such as Facebook (Facebook, Inc., Menlo Park, CA, USA) and WhatsApp (WhatsApp LLC, Menlo Park, CA, USA). Talking about needs and feelings was allowed and encouraged. The programme was designed and conducted by a physical activity and sports sciences PhD student.	• GWG **Secondary outcomes:** • GDM • Fetal macrosomia • Type of delivery • Macrosomia (birthweight > 4000 g)

TABLE 32 Individual participant data trials (*continued*)

Perales, 2014;[82] English (Spain)	**Method of randomisation:** Computer-generated list of random numbers was used **Allocation concealment:** Not reported	**Inclusion criteria:** • Pregnant women living in Madrid, Spain, who underwent ultrasound examination within 12 weeks of gestation	The programme consisted of three 55- to 60-minute sessions thrice weekly from 9 to 12 weeks of gestation to the end of pregnancy (39–40 weeks of gestation). Each session consisted of warm-up (5–8 minutes), aerobic dance and resistance exercises for muscle groups of legs, buttocks and abdomen to stabilise the lower back (25 minutes), balancing exercises (10 minutes), pelvic floor muscle training (10 minutes) and a cool-down period (5–8 minutes). Exercises in supine position were limited to 2 minutes and extreme stretching, jumping, ballistic movements, overextension of joints and exercises involving Valsalva manoeuvre were specifically avoided. The exercise intensity was light to moderate and was guided by the target HR (55–60% of maximum HR) for each participant displayed on a poster. All participants wore HR monitors during exercise sessions. Karvonen's formula based on trimester, physical condition and age was used to calculate maximum HR. Borg scale ratings were also used to adjust the intensity of exercise. Sessions had groups of 10–12 women and were supervised by a qualified fitness specialist and assisted by an obstetrician. The venue was a spacious well-lit room in a hospital (altitude 600 m, temperature 19–21 °C, and humidity 50–60%) and sessions were accompanied by music. Care was taken to ensure adequate nutrition prior to exercise sessions.	Standard Care	**Outcomes:** • GDM

continued

TABLE 32 Individual participant data trials (*continued*)

	Blinding: Researchers and outcome assessors were blinded. Randomisation procedure including sequence generation, allocation concealment, and implementation was made for three different authors to facilitate blinding. Blinding of participants was not possible	**Exclusion criteria:** • Absolute obstetrical contraindication to exercise [as per ACOG (2002)] • Plans to deliver baby elsewhere • Not receiving antenatal care throughout the pregnancy • Participating in another physical activity programme regular exercise before pregnancy (four or more times per week) **Number of participants:** Intervention, *n* = 101 Control, *n* = 83 **Type of intervention:** Physical activity	• GWG • Percentage of women with excessive weight gain (as per IoM guidelines) • Percentage of women with adequate weight gain (as per IoM guidelines) • Gestation age at delivery • Mode of delivery (normal, instrumental, CS) • Birthweight • Length of the baby at birth • Head circumference • Apgar score at 1 minute • Apgar score at 5 minutes

TABLE 32 Individual participant data trials (*continued*)

Petrella, 2013;[55] English (Italy)	**Method of randomisation:** Computer program that generated random allocation in blocks of three	**Inclusion criteria:**	Diet: the IG diet was initiated at randomisation by a gynaecologist and a dietitian who provided a further 1-hour counselling on recommended weight gain in pregnancy for each BMI category. The calorie allowance was 1500 kcal/day with an extra 200 kcal/day for obese women and 300 kcal/day for overweight women to account for physical activity programme. The target diet composition was 55% carbohydrate (80% complex low glycaemic index), 20% protein (50% animal and 50% vegetable) and 25% fat (12% monounsaturated, 7% polyunsaturated and 6% saturated fat) given as three main meals and three snacks. The last snack was 2 hours after dinner to prevent overnight hypoglycaemia. The minimum recommended intake of carbohydrates was 225 g/day. Urine was examined for ketonuria thrice during pregnancy. Exercise: the exercise intervention was in line with recommendations for the general population. Women were advised 30 minutes of moderate intensity activity for a minimum of 3 days a week. Adherence was checked by a pedometer. Women were advised that the exercise intensity should allow them to maintain a conversation ('talk test').	The CG received a simple nutritional booklet based on Italian guidelines for a healthy diet during pregnancy.	**Primary outcome:**
	Allocation concealment: Sealed numbered white envelopes	• Women with singleton pregnancies			• GWG
	Blinding: Both the gynaecologist and dietitian delivering the interventions knew the allocation of the patient.	• Pre-pregnancy BMI of ≥ 25 kg/m^2			**Secondary outcomes:**

continued

TABLE 32 Individual participant data trials (*continued*)

		• Aged > 18 years were recruited during 12th week of gestation from antenatal clinics **Exclusion criteria:** • Twin pregnancy • Chronic conditions (diabetes, hypertension and untreated thyroid diseases andother medical conditions) known to affect body weight • Previous GDM • Smoking during pregnancy • Previous bariatric surgery • Women who just started regular physical activity, or used herbal products or dietary supplements known to affect body weight • Not intending to deliver at the study centre **Number of participants:** Intervention, *n* = 33 Control, *n* = 30 **Type of intervention:** Mixed			• GDM • Gestational hypertension • Preterm delivery
Phelan, 2011;[75] English (USA)	**Method of randomisation:** Computerised, randomly changing block sizes, stratified as per clinic and BMI category	**Inclusion criteria:**	Standard care plus a behavioural lifestyle intervention ('Fit for Delivery') to avoid excessive weight gain during pregnancy. The intervention was based on the 1990 IoM guidelines for weight and nutrition during pregnancy and used established principles of learning theory to encourage changes in eating and physical activity. The intervention included a face-to-face interview with	Standard scheduled visits, monthly until 28 weeks of gestation, fortnightly between 28 and 36 weeks of gestation, weekly until delivery and at 6 weeks after delivery. Participants were provided standard nutrition counselling by physicians, nutritionists, nurses and counsellors. A brief (15-minute) face-to-face visit	**Primary outcome:**

TABLE 32 Individual participant data trials (*continued*)

		an interventionist at the start of treatment. Discussion focused on appropriate GWG targets, physical activity (30 minutes of walking, most days) and calorie intake (20 kcal/kg). Daily self-monitoring of weight, diet and physical activity was recommended along with emphasis on limiting high-fat foods. Weight scales, food diaries and pedometers were given to facilitate self-monitoring. Postcards promoting healthy lifestyle were mailed weekly. Personalised weight-gain graphs with feedback were provided following each visit.	with the study interventionist was arranged at recruitment. Women were provided with study newsletters containing general information related to pregnancy such as vitamins, at 2-monthly intervals and post partum. Women were weighed regularly but were not given weight graphs.	
Allocation concealment: Opaque envelopes **Blinding:** No blinding	• Aged > 18 years • Singleton pregnancy Gestational age of between 10 and 16 weeks • BMI of between 19.8 and 40 kg/m^2 • Non-smoker • Fluent in English • Access to a telephone **Exclusion criteria:** • Self-reported major health or psychiatric diseases • Weight loss during pregnancy • ≥ 3 miscarriages **Number of participants:**Intervention, *n* = 201			• GWG **Secondary outcomes:** • GDM • Maternal hypertension • PE • Gestational age at delivery • Preterm delivery • CS • Infant birthweight • Low birthweight • Macrosomia

continued

TABLE 32 Individual participant data trials (*continued*)

		Control, *n* = 200 **Type of intervention:** Mixed			
Phelan, 2018[54]; English (USA)	**Method of randomisation:** The randomisation was computer-generated by the study statistician, and women were randomly assigned within the site and by ethnicity (Hispanic or non-Hispanic) to the control and IG.	**Inclusion criteria:**	During the study, participants were encouraged to engage in at least 30 minutes of physical activity on most days of the week. They were given a pedometer and instructed to gradually increase their daily steps until they reached a goal of 10,000 steps per day. Women were also provided with personalised feedback on their weight gain at each visit. Other behavioural strategies included daily tracking of food and drink intake, calorie counting, and physical activity. Stimulus control techniques, problem-solving skills, goal setting, self-reinforcement and daily self-monitoring of weight were also employed. Meal replacement records were reviewed by the interventionist at every visit, and adherence was discussed. Automated postcards promoting healthy habits were mailed weekly to further support the participants.	Participants in the enhanced usual care group received the typical prenatal care offered by their providers, including physicians, nurses, nutritionists and counsellors from the Women, Infants, and Children's Special Supplemental Nutrition Program (WIC).	**Outcomes:**
	Allocation concealment: Not reported.	• Gestational age between 9 and 16 weeks, as assessed by ultrasound			• GDM
	Blinding: Not reported.	• BMI (in kg/m^2) ≥ 25			• GWG
		• English or Spanish speaking			• Preterm delivery (< 36 week)
		• Age ≥ 18 years			• Caesarean delivery
		• Singleton pregnancy			• PE
		Exclusion criteria:			• Maternal hypertension
		• Participants with glycated haemoglobin ≥ 6.5			• Low birthweight (< 2500 g)

TABLE 32 Individual participant data trials (*continued*)

		• Participants with self-reported major health diseases (e.g. heart disease, cancer, renal disease and diabetes) • Current substance abuse • Current treatment for a serious psychological disorder (schizophrenia, bipolar disorder), • Contraindications to aerobic exercises • Participant with repeated no-shows or loss of contact during initial screening and other less frequent criteria **Number of participants:** Intervention, *n* = 132 Control, *n* = 132 **Type of intervention:** Mixed			• Macrosomia (> 4000 g)
Poston, 2013;[38] English (UK)	**Method of randomisation:** Randomisation was performed online. **Allocation concealment:** Not reported **Blinding:** Not reported	**Inclusion criteria:** • BMI ≥ 30 kg/m^2 • Singleton pregnancy	The intervention used psychological models of health behaviour, including control theory and social cognitive theory. We set 'SMART' goals, recorded behaviours in a logbook, and facilitated social support through group sessions. We also delivered the session content via phone or e-mail for those unable to attend. Dietary advice The study aimed to evaluate the effect of a specific diet on several outcomes, including GI, glycaemic load and energy intake from saturated fatty acids. The IG was advised to consume low GI foods, replace sugar-sweetened beverages with low GI alternatives, and reduce saturated fats. The focus was on exchanging high GI foods for low GI foods.	Women in the CG attended data collection appointments with the study midwife at 27 + 0–28 + 6 and 34 + 0–36 + 6 weeks, coinciding with routine antenatal visits.	**Maternal outcomes:** • GDM • GWG

continued

TABLE 32 Individual participant data trials (*continued*)

	• Gestational age > 15 + 0 weeks and < 17 + 6 weeks' gestation	Physical activity advice	• PE
	Exclusion criteria:	During the intervention period, women in the test group were encouraged to increase their daily physical activity gradually. They were asked to set step goals, which were monitored using a pedometer, and to maintain their achieved physical activity level after the intervention period. The recommendations included walking at a moderate intensity level. The intervention was delivered according to these guidelines. The intervention was delivered by health trainers (HTs).	• Mode of delivery
	• Unable or unwilling to give written informed consent	UK HTs do not need specific qualifications, but relevant experience. They receive a manual and training in behaviour modification and group sessions. Women receive a participant handbook, pedometer, logbook and DVD at their first appointment. Group sessions focus on different dietary and activity elements, with goals reviewed and set each week. Discussions include barriers to change and ways to overcome them.	• Blood loss at delivery
	• Gestation < 15 + 0 weeks and > 17 + 6 weeks		• Inpatient nights
	• Pre-existing diabetes		**Neonatal outcomes:**
	• Pre-existing essential hypertension (treated)		• Gestational age at delivery
	• Pre-existing renal disease multiple pregnancy		• Birthweight
	• Systemic lupus erythematosus (SLE)		• Anthropometry
	• Antiphospholipid syndrome		• Inpatient nights

TABLE 32 Individual participant data trials (*continued*)

		• Sickle cell disease; thalassaemia • Celiac disease • Currently prescribed metformin • Thyroid disease • Current psychosis **Number of participants:** Control, *n* = 75 women and neonates *n* = 84 Intervention, *n* = 79 women and neonates *n* = 85 **Type of intervention:** Mixed			
Poston, 2015;[18] English (UK)	**Method of randomisation:** Randomisation was done online using a computer-generated program. The randomisation schedule was minimised according to ethnicity, parity, age, BMI and centre	**Inclusion criteria:**	One-to-one interview at baseline with a HT specifically trained for the study, followed by 8 weekly sessions of 1–1.5 hours each. Women are encouraged to attend all and strongly recommended to attend a minimum of five sessions with other sessions covered by telephone or e-mail. HTs cover specific goal-setting, self-monitoring and feedback on performance, problem-solving and use of social support. Women were provided with handbook, DVD of recommended exercise regime, pedometer, logbook for recording weekly goals and steps achieved through pedometer. Exercise advice: to increase pedometer steps and daily activity incrementally; moderate activity in the form of walking encouraged in line with UK Royal College of Obstetricians and Gynaecologists recommendations, with more options depending on baseline activity	Routine antenatal care, explaining the risks of obesity, advising on a healthy diet and safe levels of physical activity.	**Primary outcomes:**

continued

TABLE 32 Individual participant data trials (*continued*)

Allocation concealment: Sequential study numbers allocated, irrespective of allocation to the intervention or CG **Blinding**: Not reported	• Women with a singleton pregnancy between 15 and 18 + 6 weeks' gestation • BMI of ≥ 30 kg/m^2 at first antenatal appointment **Exclusion criteria:** • No informed consent outside 15–18 + 6 weeks' gestation • Multiple pregnancy • Medical disorders • Hypertension requiring treatment • Pre-existing renal disease • SLE • Sickle cell disease • Antiphospholipid syndrome • Thalassaemia • Celiac disease • Thyroid disease • Current psychosis • On metformin **Number of participants:** Intervention, *n* = 783 Control, *n* = 772 **Type of intervention:** Mixed	Diet: to promote healthier eating with no restriction of calories, substitute low glycaemic index for medium/high glycaemic index food, restrict sugar-sweetened beverages but not fruits and reduce saturated fatty acid intake.	• GDM (according to International Association of the Diabetes and Pregnancy Study Groups criteria) • LGA baby (> 90th weight centile) **Secondary outcomes:** • GWG • PE. • Mode of delivery • Induction of labour • Blood loss at delivery • Inpatient nights • Birthweight of baby • Gestational age at delivery • Neonatal death • Neonatal complications

TABLE 32 Individual participant data trials (*continued*)

Rauh, 2013;[32] English (Germany)	**Method of randomisation:** Computer-generated cluster randomisation of gynaecological practices into intervention or CGs	**Inclusion criteria:**	The IG received two individual counselling modules at 20 and 30 weeks of gestation, the first session lasting 60 minutes and the second 30 minutes. General lifestyle advice including nutrition, physical activity and appropriate GWG was provided. Healthy nutrition and energy balance as per German Nutrition Society were explained. The dietary goals were to reduce the intake of high-fat and energy-dense foods and increase the intake of low-fat foods and fruits, wholegrain foods and vegetables. Women were encouraged to consume more fish and advised regarding appropriate fat/cooking oil/spreads. Physical activity equivalent to 30 minutes of moderate-intensity exercises on most days was recommended. Non-weight-bearing endurance exercises such as walking, swimming, aquatic exercises and cycling were suggested. Women were also provided with information on local antenatal exercise programmes and encouraged to join them. The exercise recommendations were based on the guidelines of ACOG and Society of Obstetricians and Gynecologists of Canada. Women were provided with personalised weight charts as per BMI category including IoM recommendations for that category. They were asked to monitor their weights on a weekly basis. The individual counselling sessions also provided personalised feedback on diet and physical activity based on the 7-day records of diet and physical activity questionnaires.	Routine antenatal care including an information leaflet consisting of 10 general statements on a healthy lifestyle during pregnancy not including advice on diet or gaining weight.[35]	**Primary outcome:**

continued

TABLE 32 Individual participant data trials (*continued*)

	Allocation concealment: Randomisation performed by a researcher not involved in study design **Blinding:** Study design did not permit blinding	• Aged > 18 years • Singleton pregnancy • Gestational age of < 18 weeks • BMI of ≥ 18.5 kg/m^2 • Language skills: 'sufficient' German **Exclusion criteria:** • Contraindication to physical activity, such as cervical incompetence, placenta praevia, or persistent bleeding • Pre-pregnancy diabetes • Uncontrolled chronic diseases affecting weight such as thyroid dysfunction or psychiatric diseases **Number of participants:** Intervention, four practices, *n* = 167 Control, four practices, *n* = 83 **Type of intervention:** Mixed			• GWG **Secondary outcomes:** • GDM • Birthweight • Length of the baby at birth • Impaired glucose tolerance • Mode of delivery (spontaneous, caesarean, vacuum) • Induction of labour • Preterm delivery • LGA • SGA
Renault, 2013;[39] English (Denmark)	**Method of randomisation:** Randomisation was stratified by parity to ensure equal distribution of primiparous women in all groups	**Inclusion criteria:**	All participants (before enrolment) received one consultation with a dietitian after the initial ultrasound scan at 11–14 weeks of gestation. A low-fat low-calorie (1200–1675 kcal/day) Mediterranean-style diet, with preference to fish and oils, was recommended. Dietary advice was as per Danish national guidelines for healthy eating. Only	Standard care including one consultation with a dietitian after the initial ultrasound scan at 11–14 weeks' gestation. Dietary advice was as per Danish national guidelines for healthy eating. Only oral advice was given and women were asked to aim for a GWG of < 5 kg.	**Primary outcome:**

TABLE 32 Individual participant data trials (*continued*)

		oral advice was given and women were asked to aim for a GWG of < 5 kg. Physical activity: a dietitian advised to increase physical activity aiming for a daily step count of 11,000/day, a validated pedometer was provided to the participants. Pedometer data were recorded for a consecutive 7-day period every 4 weeks. Women were reminded through text messages when a recording period started and encouraged to achieve the target. If 11,000 steps were not achievable, they were asked to set their own targets. They were asked to enter the pedometer data and weight into a chart and return it.	
Allocation concealment: A web allocation by an independent agency allowed allocation concealment	• BMI of ≥ 30 kg/m^2	Diet: the women in the physical activity plus diet group also had alternate face-to-face or telephone consultations with an experienced dietitian every 2 weeks (11–13 consultations) during pregnancy. They received feedback, encouragement and specific dietary advice if diet was incorrect or if weight targets were not being achieved.	• GWG
Blinding: Not reported	• Aged > 18 years • Singleton pregnancy • Normal scan at 11–14 weeks' gestation • Gestational age of < 16 weeks at inclusion • Ability to read and speak Danish **Exclusion criteria:**		**Secondary outcomes:** • GDM • Gestational hypertension • PE • Induction of labour • CS (emergency/planned)

continued

TABLE 32 Individual participant data trials (*continued*)

		• Multiple pregnancy • Pre-pregnancy diabetes • Conditions limiting level of physical activity • History of bariatric surgery; alcohol or drug abuse **Number of participants:** Intervention 1 (exercise), *n* = 142 Intervention 2 (diet and exercise), *n* = 142 Control, *n* = 141 **Type of intervention:** Diet			• Gestational age at delivery • Preterm delivery (28–34 weeks and 34–37 weeks) • Fetal birthweight • Relative birthweight • SGA • LGA • Macrosomia • pH of umbilical cord blood • Placental weight
Rono, 2018;[40] English (Finland)	**Method of randomisation:** Computer-generated randomly permuted blocks.	**Inclusion criteria:**	Participants in the study received personalised advice on diet and physical activity from trained nurses. They visited a nurse every 3 months before pregnancy and once each trimester during pregnancy and attended local antenatal clinic visits. The IG was recommended to engage in physical activity for a minimum of 150 minutes per week at moderate intensity and adopt an overall active lifestyle. They were also advised to consume healthy foods and reduce the intake of sugar-rich foods. Women with a BMI ≥ 25 kg/m^2 were recommended to achieve a 5–10% weight loss before pregnancy. For women with a pre-pregnancy BMI ≥ 30 kg/m^2, it was recommended to avoid weight gain during the first two trimesters.	Participants in both intervention and CGs received the same number of visits to the study nurse, completed the same questionnaires and measurements. They were given information leaflets on healthy diet and exercise and received the usual antenatal care provided to all Finnish pregnant women by public primary healthcare centres, including 10–15 visits to a nurse and 2–3 visits to a physician during pregnancy.	**Outcomes:**

TABLE 32 Individual participant data trials (*continued*)

	Allocation concealment: An independent statistician outside the study group created the randomisation sequence and prepared the opaque randomisation envelopes.	• Women aged 18 years or older planning pregnancy within 1 year	• GDM
	Blinding: Not reported	• BMI ≥ 30 kg/m^2	• PE
		• Previous history of GDM	• PIH
		• With no overt diabetes at inclusion	• Hepatogestosis
		Exclusion criteria:	• Birth weight (g)
		• Women on medications that influence glucose metabolism (such as continuous oral corticosteroids or metformin), multiple pregnancies	• Birth weight *z*-score (SD) Respiratory distress or transient tachypnea of newborn
		• Physical disability	• Congenital malformation.
		• Current substance abuse	
		• Severe psychiatric disorder, significant difficulty cooperating (such as insufficient Finnish language skill)	
		• Women who did not become pregnant within 1 year from their first visit	
		Number of participants: Intervention: *n* = 65	
		Control: *n* = 63	
		Type of intervention: Mixed	

continued

TABLE 32 Individual participant data trials (*continued*)

Ruiz, 2013;[76] English (Spain)	**Method of randomisation:** Computer generated	**Inclusion criteria:**	The programme consisted of supervised 50–55-minute physical activity sessions thrice weekly from week 9 to weeks 38–39, with an estimated average of 85 sessions per participant. Each group consisted of 10–12 women. The exercise activity was of light to moderate intensity with a target HR of ≤ 60% of maximum predicted HR for age [208 – (0.7 × age in years)]. All participants were provided with HR monitors. Intensity was also guided by Borg's conventional (6–20 point) scale, with the rate of perceived exertion ranging from 10 to 12 ('fairly light' to 'somewhat hard') Each session included a warm-up period (10 minutes), a core session (25–30 minutes) and a cool-down period (10 minutes). Warm-up and cool-down components involved walking and light stretching exercises for limbs, neck and trunk. In addition, the cool-down period included relaxation and pelvic floor exercises. The core portion involved moderate-intensity aerobic exercises once weekly and resistance exercises twice a week. Aerobic dance took place for periods of 3–4 minutes with 1-minute breaks and included stretching and relaxation. Resistance exercises for pectoral muscles, back, shoulder, upper and lower limb muscles aimed to improve posture, strengthen muscles of labour and pelvic floor and prevent lower back pain. They involved exercises using barbells (3 kg/exercise) or low to medium resistance elastic and included biceps curls, arm side lifts and extensions, shoulder elevations, bench press, seated lateral row, leg circles and lateral leg	Usual care with regular scheduled visits to obstetricians and midwives. Information healthcare professionals provided nutrition and physical activity counselling and they were not discouraged from exercising.	**Primary outcome:**

TABLE 32 Individual participant data trials (*continued*)

			elevations, knee (hamstring) curls and extensions and ankle flexions and extensions. Exercises such as jumping, ballistics, extreme stretching and joint overextension were avoided. Supine exercises were limited to a maximum of 2 minutes.		
	Allocation concealment: Not reported **Blinding:** Not reported	• Sedentary (not exercising > 20 minutes on > 3 days a week) • Singleton pregnancy • Uncomplicated pregnancy • Not at high risk of preterm delivery (≤ 1 previous preterm delivery) • No participation in any other trial **Exclusion criteria:** • Contraindication to exercise **Number of participants:** Intervention, *n* = 481 Control, *n* = 481 **Type of intervention:** Physical activity			• GWG **Secondary outcomes:** • GDM • Hypertension • Gestational age at delivery • Type of delivery (natural, instrumental or caesarean) • Time of dilatation • Expulsion childbirth • Low birthweight • Macrosomia
Sagedal, 2016;[77] English (Norway)	**Method of randomisation:** Computer-generated randomisation list with groups of 20 women. Consecutive randomisation based on the time of completion of consent form, questionnaires and blood tests required prior to enrolment	**Inclusion criteria:**	Diet: an initial telephone consultation with a physician, nutritionist or graduate student of public health, followed by another follow-up session 4–6 weeks later. Recommendations based on Norwegian directorate of health guidance. Focus on 10 key recommendations including intake of fruits and vegetables, drinking water instead of energy drinks, having regular meals and reducing intake of drinks and	Standard prenatal care	**Outcomes:**

continued

TABLE 32 Individual participant data trials (*continued*)

			snacks containing added sugar. Pamphlets containing the key recommendations provided to the IG along with password-protected access to an interactive website containing information on healthy eating and exercise in pregnancy. They were also invited to two evening meetings where further information on the trial was provided along with a hands-on cooking class to reinforce their dietary recommendations.	
Allocation concealment: Staff providing intervention and checking outcomes were not involved in randomisation	• Aged ≥ 18 years		Physical activity: two exercise sessions each week lasting 1 hour at local fitness centres where attendance was registered. The sessions were supervised by physiotherapists or graduates of sports science. Uniform exercise plan for all the women in IG, consisting of 40 minutes of strength training and moderate cardiovascular exercises, and 20 minutes warm-up and stretching. Pelvic floor exercises were included in each session. The women were also encouraged to have at least one additional unsupervised exercise session weekly with the eventual goal of achieving a total of 30 minutes of moderate activity 5 days a week. Information on safe physical activity in pregnancy provided in pamphlets and on the website.	• GDM
Blinding: Not reported.	• BMI of ≥ 19 kg/m^2			• GWG
	• Singleton pregnancy			• Infant birthweight and the per cent of LGA (> 90th percentile) infants
	• Gestational age of < 20 weeks			• Maternal glucose values hormones related to glucose metabolism

TABLE 32 Individual participant data trials (*continued*)

		• Fluency in Norwegian or English **Exclusion criteria:** • Pre-existing diabetes • Physical disabilities preventing participation in a physical activity programme (as per recommendations of the ACOG) • Current substance abuse • No plans to deliver in the study centres (planned relocation) **Number of participants:** Intervention, *n* = 303 Control, *n* = 303 **Type of intervention:** Mixed			• Incidence of operative deliveries • Delivery complications
Stafne, 2012;[78] English (Norway)	**Method of randomisation:** Concealed randomisation in blocks of 30 by web-based computerised procedure **Allocation concealment:** Staff involved with training/assessment not involved in randomisation	**Inclusion criteria:** • White women	Standardised exercise programme including aerobic activity, strength training and balance exercises supervised by a physiotherapist. Training sessions in groups of 8–15 women offered once weekly for 12 weeks (between 20 and 36 weeks of gestation). Each session lasted 60 minutes. A written 45-minute home exercise programme (30 minutes of endurance training and 15 minutes of strength/balance exercises) was recommended twice weekly and women were asked to record the exercise activities in personal training diaries. Physical activity was also assessed by questionnaires.	Usual care, not discouraged from exercising. Written recommendations on diet, pelvic floor exercises and pregnancy-related lumbopelvic pain.	**Primary outcome:** • GDM

continued

TABLE 32 Individual participant data trials (*continued*)

	Blinding: Unblinded except glucose and insulin measurements blinded to group allocation	• Aged ≥ 18 years • Singleton live fetus **Exclusion criteria:** • High-risk pregnancies diseases that could interfere with participation • Women who lived too far (more than 30-minute drive) from the hospitals **Number of participants:** Intervention, *n* = 375 Control, *n* = 327 **Type of intervention:** Physical activity			**Secondary outcomes:** • GWG • BMI at follow-up • PE • Gestational hypertension • Caesarean delivery • Operative vaginal delivery • Gestational age at delivery • Birthweight ≥ 4000 g • Apgar score • Admission to the NICU
Vinter, 2011;[41] English (Denmark)	**Method of randomisation:** Computerised 1 : 1 randomisation with stratification by smoking status **Allocation concealment:** Closed envelopes were used **Blinding:** Not reported	**Inclusion criteria:** • Aged 18–40 years • Gestational age of 10–14 weeks	Intervention type: dietary counselling and exercise Diet: trained dietitians provided counselling based on official Danish recommendations at 15, 20, 28 and 35 weeks' gestation. The goal was to limit GWG in pregnancy to 5 kg. Individualised calorie goals based on weight and activity level were provided	Information on purpose and content of the study. Access to a website with advice on diet and physical activity in pregnancy.	**Outcomes:** • GDM • GWG (weight at 35 weeks minus weight at inclusion)

TABLE 32 Individual participant data trials (*continued*)

		• BMI of 30–45 kg/m^2 (pre-gestational or first measured weight in pregnancy) **Exclusion criteria:** • Prior major obstetric complications • Chronic diseases (e.g. diabetes and hypertension) • Positive OGTT in pregnancy • Alcohol/drug abuse • Unable to speak Danish Multiple pregnancy **Number of participants:** Intervention, *n* = 180 Control, *n* = 180 **Type of intervention:** Mixed	Physical activity: moderate physical activity lasting 30–60 minutes was encouraged and a pedometer was provided to motivate and improve physical activity. A free full-time membership to local fitness centre was provided for 6 months. This included a 1-hour weekly closed training session with a physiotherapist. The exercises included aerobic activities with elastic bands and light weights, and balance exercises. The women were grouped 4–6 times with the physiotherapist after physical training.		• PE • PIH • CS • Macrosomia/LGA • Admission to the NICU
Vitolo, 2011;[79] English (Brazil)	**Method of randomisation:** Not reported	**Inclusion criteria:**	Dietary counselling according to nutritional status. For pregnant women with low birthweight, this was adopted as a priority to increase the energy density of the diet with the addition of a tablespoon of oil in the main meals, eat two snacks per day of high energy (with sample portions)	The CG did not receive the dietary guidelines but were informed about their nutritional status and were asked to carry on with their prenatal care.	**Outcomes:**

continued

TABLE 32 Individual participant data trials (*continued*)

			100 g once a week and fruit daily. Well-nourished pregnant women received vegetables, legumes, fruits and water six times per day and restricted the consumption of foods rich in fat and cooking oils. For pregnant women with excess weight, between meals (3–4 hours) were prioritised; not repeat the food portions of meals and snacks; restrict daily consumption of soft drinks and sweets, processed foods high in fat and also oil preparations. They were determined daily servings of vegetables, vegetables and fruit. All guidance provided values and portion sizes.		
	Allocation concealment: Not reported **Blinding:** Not reported	• Pregnant women between 10 and 29 weeks' gestation **Exclusion criteria**: • Positive human immunodeficiency virus test • Previous diagnosis of GDM • Hypertension • Anaemia • Any conditions preventing women from undertaking exercise in pregnancy • Aged > 35 years **Number of participants:** Intervention, *n* = 159 Control, *n* = 162 **Type of intervention:** Diet			• GDM • GWG • PE • Infant birthweight • Prematurity
Walsh, 2012;[80] English (Ireland)	**Method of randomisation:** Not reported	**Inclusion criteria:**	One 2-hour dietary education session with the research dietitian in groups of two to six women. The diet was in line with current	Routine antenatal care with no specific dietary recommendation or advice about GWG.	**Outcomes:**

TABLE 32 Individual participant data trials (*continued*)

		recommendations for pregnant women. General advice on healthy eating in pregnancy and following the food pyramid was provided. Women were taught about the rationale for having low glycaemic index food and encouraged to replace high glycaemic index carbohydrates with low glycaemic index alternatives. Written resources were provided after the education session. Women were not advised to reduce their total caloric intake. The research dietitian met women again at 28 and 34 weeks of gestation to reinforce the advice and clarify any doubts. All women completed three food diaries of 3 days each: before dietary intervention and in the second and third trimesters of pregnancy.	
Allocation concealment: Not reported **Blinding:** Not reported	• Secundigravid women with previous macrosomic infant (birthweight > 4 kg) **Exclusion criteria:** • Women with medical disorders including history of GDM, those on any drugs • Unable to give full informed consent • Aged < 18 years • Gestational age > 18 weeks • Multiple pregnancy **Number of participants:** Intervention, *n* = 394 Control, *n* = 406 **Type of intervention:** Diet		• GDM • GWG Birthweight • Maternal glucose intolerance

continued

TABLE 32 Individual participant data trials (*continued*)

Willcox, 2017;[53] English (Denmark)	**Method of randomisation:** Computer-generated random numbers.	**Inclusion criteria:**	At baseline the trained researcher conducted the initial interview where they outlined the intervention and provided a booklet outlining the txt4two program, weight tracking and goal setting. In addition, the researcher discussed appropriate GWG targets, individual GWG monitoring and recording, and asked the woman to set a nutrition or physical activity goal to work towards the above-mentioned evidence-based recommendations.	As part of usual care, participants in both intervention and standard care groups were mailed brief information brochures containing advice regarding diet and physical activity prior to the first hospital visit and were also encouraged to weigh at first visit.	**Outcomes:**
	Allocation concealment: Numbered cards allocating women to either the intervention or CGs were placed in opaque, sequentially numbered envelopes.	• Women with a singleton	Following the initial interview, intervention participants received four to five individually tailored, interactive text messages per week, a frequency found acceptable in other mHealth interventions. The texts delivered information specific to the individual's gestational week, encouragement of positive health behaviours, monitoring of individual goals and encouragement of self-monitoring of GWG. Texts were developed and mapped according to the behaviour change techniques by the authors JW and BF. Women chose the frequency of texts that aimed to: prompt review of their weight (weekly or fortnightly); and check their behavioural goals (weekly or fortnightly). A study-specific website outlined intervention content information. Short videos featuring an obstetrician, dietitian or physiotherapist were embedded on the website and outlined the benefits of the intervention and explained the components. The private Facebook chat page, only accessible to participants, encouraged interaction with other participants and posing of questions to health professionals. The website and Facebook group were promoted and linked in the text message content.		• GDM

TABLE 32 Individual participant data trials (*continued*)

	Blinding: Given the nature of the intervention, participants could not be blinded to group assignment.	• Live gestation between 10 + −0 and 17 + −6 weeks • Self-reported pre-pregnancy BMI > 25 kg/m^2 • Able to speak, read and write English • Owning a mobile phone **Exclusion criteria:** • < 18 years of age • Multiple pregnancy • Comorbidities requiring significant medical and/or dietary management • Discontinuation of hospital care **Number of participants:** Intervention, *n* = 50 Control, *n* = 50 **Type of intervention:** Mixed			• GWG • Diet and physical activity were assessed at baseline and the 36-week visit.
Wolff, 2008;[42] English (Denmark)	**Method of randomisation:** Computerised randomisation	**Inclusion criteria:**	Ten 1-hour dietary consultations (healthy diet, restriction of energy intake): the IG received 10 consultations of 1 hour each with a trained dietitian during the pregnancy. Women were asked to eat a healthy diet according to the official Danish dietary recommendations (fat intake, maximum 30 energy per cent; protein intake, 15–20 energy per cent; carbohydrate intake, 50–55 energy per cent). Energy intake was restricted on the basis of	No intervention	**Outcomes:**

continued

TABLE 32 Individual participant data trials (*continued*)

		individually estimated energy requirements and estimated energy requirements of fetal growth [energy requirement = basal metabolic rate × 1.4 (physical activity level factor of 1.2 + 0.2 added to cover energetic cost of fetal growth)].	
Allocation concealment: Not reported	• White women		• GDM
Blinding: Investigators/ clinicians	• BMI of ≥ 30 kg/m^2 early pregnancy (15 ± 3 weeks of gestation)		• GWG
	• Non-diabetic at inclusion		• Gestational age at delivery
	Exclusion criteria:		• PIH
	• Smoking		• PE
	• Aged < 18 or > 45 years		• Prolonged pregnancy
	• Multiple pregnancy		• Caesarean delivery
	• Medical complications known to affect fetal growth		• Birthweight
	• Adverse contraindication for limiting weight gain		• Placental weight
	Number of participants: Intervention, *n* = 28		• Infant length
	Control, *n* = 38		• Head circumference
	Type of intervention: Diet		• Abdominal circumference

TABLE 33 Non-individual participant data trials

Abdel-Aziz *et al.*, 2018;[101] English (Egypt)	**Method of randomisation:**	**Inclusion criteria:**	Women in the IG received standard care delivered at the centre group and attended six extra counselling sessions with the nutrition counsellor, with face-to-face appointments every 2 weeks during the implementation phase. The nutrition counsellor assessed participants' compliance with the intervention sessions by registering the number of counselling sessions attended by the participants and illustrated the response rate of attendance. All women in the IG received three brief (i.e. 10–15 minutes) supportive phone calls from the nutrition counsellor during the intervention.	Participants of the CG received standard maternity care.	**Maternal outcomes:**
	A computer-generated randomisation using an allocation table.	• Women between 20 and 30 years in the first trimester (< 12 weeks of gestation) of pregnancy	Nutrition counselling message	Women in standard care attended their regularly scheduled visits with their prenatal care providers, which typically occurred monthly until 28 weeks of gestation, biweekly for 28–36 weeks of gestation, and weekly until delivery.	• Gestational weight gain (GWG)
	Allocation concealment: Not reported	• Women attending the antenatal care clinic.	The nutrition counsellor who was a member of the research team discussed with the participants how to control weight gain during pregnancy and how to maintain or optimise a healthy lifestyle in a period of physical and mental changes. Each counselling session took about 20 minutes, except for the first session, which took approximately half an hour; the counsellor explained the aim of the study and the intervention again.	Women received standard nutrition counselling provided by the physicians and nurses based on the Maternal and child Health Program components.	• Anaemia
	Blinding: Not reported	• Without a history of any chronic medical problems	The counsellor provided nutritional guidance to pregnant women based on dietary guidelines. They aimed to improve		• GDM

continued

TABLE 33 Non-individual participant data trials (*continued*)

			eating habits, educate participants on healthier food choices, and prevent excess gestational weight gain. Participants were taught to choose whole grains, fruits and vegetables, healthy fats and protein sources, limit intake of unhealthy foods and drinks, and avoid unhealthy habits. Walking for 30 minutes three times per week was encouraged.		
		Exclusion criteria: • Women under 18 years of age. • With a previous history of abortion, stillbirth and any chronic disease. • Women on any medications that might interfere with their body weight (steroids, diuretics, and thyroid hormones). **Number of participants:** Intervention, *n* = 75 CG, *n* = 72 **Type of intervention:** Diet			• Pregnancy-induced hypertension (PIH) • CS **Fetal outcomes:** • Macrosomia • Preterm
Barakat *et al.*,2012;[84] English (Spain)	**Method of randomisation**: Not reported	**Inclusion criteria:**	**Exercise:**	Standard care	**Maternal outcomes:**

TABLE 33 Non-individual participant data trials (*continued*)

	Allocation concealment: Not reported	• Women with singleton pregnancies	Participants followed a physical conditioning programme consisting of three 35–45-minute sessions per week (on Mondays, Wednesdays and Fridays). Two of these sessions were land-based aerobic exercises, while the third session involved aquatic activities. The programme started at weeks 6–9 of the pregnancy and continued until the end of the third trimester (weeks 38–39). The original plan was for each participant to complete an average of 85 training sessions, with exercise intensity monitored using a heart rate (HR) monitor (Accurex Plus; Polar Electro OY, Kempele, Finland). Participants were instructed to maintain light to moderate exercise intensity, keeping their HR consistently under 70% of their age-predicted maximum HR value (220−age).	• 50 g maternal glucose screen (MGS)
	Blinding: Not reported	• Women with uncomplicated pregnancies and healthy.	**Land exercise**	• GWG
		Exclusion criteria:	Each workout session consisted of a 7–8-minute warm-up and cool-down period, including walking and light stretching exercises targeting most muscle groups. The 25-minute core session featured toning and light resistance exercises, targeting major muscle groups like the pectoral, dorsal and shoulder muscles. Participants completed one set of 10–12 repetitions of abdominal curls and exercises using either barbells (3 kg/exercise) or low-to-medium resistance bands (Therabands). Exercises that involved extreme stretching, joint overextension, ballistic movements, or jumps were avoided. Lying on their back was limited to a maximum of 2 minutes.	• GDM

continued

TABLE 33 Non-individual participant data trials (*continued*)

	Women with the following obstetric contraindications:		**Pregnancy outcomes:**
	• Active illness of the myocardium.	The exercise programme included workouts that target major muscle groups such as the arms and abdomen. These exercises help improve your posture, prevent low back pain, and strengthen the muscles that are important for labour and the pelvic floor during the third trimester. Additionally, the programme includes an aerobic dance routine every 2 weeks.	Type of delivery:
	• Heart insufficiency.	**Aquatic activities**	• Instrumental delivery
	• Rheumatic heart illness (type II or above).	Exercising in water minimises joint impact. Aquatic sessions include swimming, jogging, walking, stretching, lunges, step climbs, skiing and strength exercises. Tools like noodles, floats and gloves are used for muscle conditioning. Water was kept at 28–29 °C and precautions were taken to prevent infections.	
	• Thrombophlebitis.		• CS
	• Recent pulmonary embolism (last 5 years).		• Systolic blood pressure (mmHg)
	• Acquired infectious disease.		• Diastolic blood pressure (mmHg)
	• Cervical incompetence.		**Fetal outcomes:**
	• Multiple pregnancy.		• Birthweight
	• Genital haemorrhage.		• Apgar score 1 minute
	• Premature breakage of the ovular membranes.		• Apgar score 5 minutes
	• Retarded intrauterine. development.		• Size of newborn
	• Fetal macrosomia.		
	• Serious blood disease.		

TABLE 33 Non-individual participant data trials (*continued*)

		• Serious hypertension. • Absence of prenatal control. • Suspects of fetal suffering. • Risk of premature labour. • Prepregnant type 1 or 2 diabetes. **Number of participants:** Intervention, *n* = 40 Control, *n* = 43 **Type of intervention:** Physical activity			
Barakat *et al.*, 2013;[85] English (Spain)	**Method of randomisation:** Women were randomly selected and assigned to the control and IG	**Inclusion criteria:**	**Exercise:** The exercise IG trained for 50–55 minutes, 3 days a week (Monday, Wednesday, Friday) from week 10 to 12 of pregnancy until the end of the third trimester (weeks 38–39). The intervention included aerobic, strength and flexibility exercises, met the standards of the American College of Obstetricians and Gynaecologists, and used a HR monitor to maintain moderate exercise intensity. The participants' HR was consistently below 70% of their age-predicted maximum, and the rate of perceived exertion was between 10 and 12, corresponding to 'fairly light' and 'somewhat hard' exertion.	The CG received general advice on physical activity from their midwife and had the same prenatal care and visits with healthcare providers (midwives, obstetricians and family doctors) as the exercise group. They were not discouraged from exercising on their own.	**Primary outcomes:**
	Allocation concealment: The researcher in charge of randomly assigning participants did not know in advance which treatment the next person would receive and did not participate in the assessments	• Being sedentary (not exercising > 20 minute on > 3 days/week)	The participants began with a 10–12-minute gradual warm-up and followed it with a similar cool-down period. They engaged in walking and stretched almost all the muscle groups of their body. The session lasted 25–30 minutes and included moderate-intensity resistance exercises that toned the muscles and mobilised the joints.		• GWG

continued

TABLE 33 Non-individual participant data trials (*continued*)

			They avoided extreme stretching, joint overextension, ballistic movements and jumps. They also included one session per week of aerobic dance, involving the upper and lower body limbs of very low impact, designed in sections of 3–4 minutes with 1-minute breaks, which included stretching and relaxation activities.		
	Blinding: The assessment staff was blinded to the participant randomisation assignment	• Singleton, uncomplicated gestation • Not at high risk for preterm delivery (i.e. ≤ 1 previous preterm delivery). **Exclusion criteria:** • Women not planning to give birth in the same obstetrics hospital department (Hospital Severo Ochoa, Madrid, Spain) and not under medical follow-up throughout the entire pregnancy period. • Women with medical conditions preventing them from exercising. **Number of participants:** Intervention, *n* = 210 Control, *n* = 218 **Type of intervention:** Physical activity			• GDM-World Health Organization (WHO) criteria • GDM IADPSG criteria **Secondary outcomes:** • Birthweight gestational age • Caesarean delivery • Apgar score 1 minute • Apgar score 5 minutes
Barakat *et al.*, 2014;[86] English (Spain)	**Method of randomisation:** A computer-generated list of random numbers was used.	**Inclusion criteria:**	**Exercise:** The programme had three 55–60-minute sessions per week, starting between 9 and 13 weeks of pregnancy till the end of the third trimester (weeks 39–40).	During this period, women in the CG did not engage in physical activity and solely relied on information from their midwives or healthcare providers.	**Maternal outcomes:**

TABLE 33 Non-individual participant data trials (*continued*)

	Allocation concealment: Not reported	• Pregnant women who underwent their first ultrasound examination in Hospital Universitario de Fuenlabrada at 10–12 weeks of pregnancy	The exercise routine included a 5-minute walk and static stretching, toning and joint mobilisation exercises, aerobic dance, and specific exercises targeting major muscle groups in the legs, buttocks and abdomen to stabilise the lower back. Balancing exercises were included for 10 minutes, followed by pelvic floor muscle training exercises for 10 minutes, and a 5-minute cool-down period. Exercises involving Valsalva manoeuvre, extreme stretching, joint overextension, ballistic movements and jumping were avoided. The workout prescribed light- to moderate-intensity aerobic activity to achieve a 55–60% maximal HR. Participants were shown their HR on a poster to determine the appropriate intensity for their aerobic exercise. HR was calculated using the Karvonen formula based on trimester, physical condition, and age.	• GDM
	Blinding: Not reported	• Women with singleton pregnancies	Exercise intensity was adjusted based on Borg Scale ratings, with the aim of a level of 12–13. All subjects wore HR monitors during training to maintain light to moderate intensity.	• GDM
		Exclusion criteria:	To ensure patient safety and adherence, a qualified fitness specialist supervised group sessions of 10–12 subjects with the assistance of an obstetrician. Sessions were held in a spacious, well-lit room at the University Hospital of Fuenlabrada with favourable environmental conditions and accompanied by music.	**Fetal outcomes**:
		Pregnant women with the following contraindications for exercise:	Participants were provided with adequate nutrition before each session.	• Gestational age

continued

TABLE 33 Non-individual participant data trials (*continued*)

		• Haemodynamically significant heart disease • Restrictive lung disease Incompetent cervix • Multiple gestation • Ruptured membranes PE/PIH **Number of participants**: Intervention, *n* = 107 Control, *n* = 93 **Type of intervention:** Physical activity			• Preterm delivery • Apgar score • Head circumference • Birth size and weight • Gender • pH of umbilical cord
Barakat *et al.*, 2019;[61] English (Spain)	**Method of randomisation:** Computer-generated list of random numbers	**Inclusion criteria:**	**Exercise:** Pregnant women in the IG received standard care and a supervised moderate exercise programme, 3 days a week (55–60 minutes per session) from the 8th to 10th week of pregnancy until the end of the third trimester. The exercise protocol was supervised by a qualified of physical activity and sport science professional (10 years of experience). The programme included 83–85 group training sessions adhering to ACOG guidelines. It consisted of gradual warm-up, aerobic exercises, muscle strengthening, coordination, stretching, pelvic floor strengthening, relaxation, and a final talk.	Pregnant women in the standard care group attended regular visits with obstetricians and midwives, (according to Hospital protocol), usually every 4–5 weeks until the 36th–38th week of gestation and then weekly until delivery. They received counselling on nutrition and physical activity and were asked about their exercise habits once each trimester using a 'Decision Algorithm' by telephone.	**Primary outcomes:**
	Allocation concealment: Not reported.	• Women with singleton and uncomplicated pregnancies (no type 1, 2 or gestational diabetes at baseline)	Women wore a HR monitor (Accurex Plus) during training to keep HR under 70% of the age-predicted maximum. Perceived exertion was rated 12–14 (Somewhat Hard).		• GDM

TABLE 33 Non-individual participant data trials (*continued*)

	Blinding: The randomisation blinding process was performed by three different researchers	• Without history or risk of preterm delivery (i.e. ≥ 1 previous preterm delivery) • Not participating in any other trial **Exclusion criteria:** • Women not planning to give birth in the same obstetric hospital, or with no medical follow-up throughout pregnancy. • Women having any serious medical conditions (contraindications) that prevented them from exercising safely. **Number of participants:** Intervention, *n* = 234 Control, *n* = 222 **Type of intervention:** Physical activity	The exercise session began with a 10-minute light warm-up consisting of walking and static stretching to avoid muscle pain. Similarly, the session ended with a 10-minute cool-down, including relaxation and pelvic floor muscle training. The main section was 30–35 minutes long and included moderate-intensity aerobic and resistance exercises. All sessions were supervised by a qualified fitness specialist and an obstetrician and performed in a well-lit spacious room with music and favourable environmental conditions. The programme involved group sessions with 12–15 participants, and adherence was measured using a checklist.	• GWG **Secondary outcomes:** • Maternal gestational age at delivery • Type of delivery • Birthweight

continued

TABLE 33 Non-individual participant data trials (*continued*)

Brownfoot *et al.*, 2016;[102] English (Australia)	**Method of randomisation:** The randomisation sequence was generated by an independent organisation (Australian Research Centre for Health of Women and Babies, University of Adelaide) **Allocation concealment:** The randomisation sequence was properly concealed in consecutively numbered opaque, sealed envelopes	**Inclusion criteria:**	As part of the intervention, women were weighed at each antenatal clinic appointment, followed by counselling from their treating clinician according to the Institute of Medicine (IoM) GWG guidelines.	The CG had standard antenatal care comprising recording weight at booking and then at 36 weeks.	**Primary outcome:**
	Blinding: Not reported	• Women with a singleton pregnancy who attended their first antenatal booking visit prior to 21 weeks and were planning to have their pregnancy care through hospital clinics.	In the IG, the weight of the women was recorded in the antenatal clinic notes at every visit. All antenatal clinic rooms had a prominently displayed sign with suggested weight gains according to the IoM guidelines. According to these guidelines, the clinicians were encouraged to discuss appropriate weight gain with the women, but their responses were not scripted. The recorded weight was intended to trigger a discussion about weight gain guided by the IoM information, as would be the situation in normal clinical practice. Furthermore, the scales were removed from the general antenatal clinic waiting area to prevent the control women from weighing themselves during their antenatal visit.		• GWG
		• Women between 18 and 45 years of age			**Secondary outcomes**
		Exclusion criteria:			**Maternal outcomes:**
		• Women younger than 18 or older than 45 years of age			• GDM

TABLE 33 Non-individual participant data trials (*continued*)

	• Women who had medical comorbidities • Women with substance abuse • Women unable to understand English. **Number of participants**: Intervention, *n* = 386 Control, *n* = 396 **Type of intervention:** Mixed	• PIH • PE • Macrosomia • Intrauterine growth restriction • Delivery gestation • Induction • 3rd- or 4th-degree tear shoulder dystocia • Mode of delivery • Neovascularisation of the disc • Instrumental delivery Caesarean delivery • Elective • Caesarean delivery, Emergency • Post partum haemorrhage (PPH) • Wound infection **Perinatal outcome**: • Mean birthweight (g) • Hypoglycaemia • Respiratory distress syndrome • Jaundice • Infection • Birth trauma • Perinatal death	

continued

TABLE 33 Non-individual participant data trials (*continued*)

					• Low Apgar (< 7 at 5 minutes) • Admission to Special Care Nursery (SCN) • NICU
Buckingham *et al.*, 2019;[103] English (USA)	**Method of randomisation:** Women were randomly assigned to the IG and the CG **Allocation concealment**: Not reported	**Inclusion criteria**: • Exercising < 3/weeks for 30 minutes/session for the 6 months before conception	Participants in the intervention received a behavioural lifestyle intervention that included counselling and a wearable fitness tracker including dietary software (Fitbit Flex Activity Monitor; Fitbit Inc.). The intervention was targeted towards increasing physical activity and modifying carbohydrate intake, with the primary goal of increasing the proportion of women who met the 2009 IoM GWG weight-gain guidelines. Participants in this group took part in a minimum of six 15- to 30-minute one-on-one visits with a Registered Dietitian Nutritionist (RDN)/Licensed Dietitian from no later than gestation week 14 to childbirth. Participants were weighed by the RDN at each face-to-face session. Weight gain was plotted on an IoM weight-gain chart and feedback on weight gain was provided. The counselling sessions focused on appropriate weight gain during pregnancy using an individualised meal plan, physical activity goals, and behavioural modification using motivational interviewing. Participants were able to view steps taken per day and log food intake on the wearable fitness tracker website. Additionally, participants had weekly e-mail contact with the RDN to discuss nutrition and physical activity goals and weight gain and to address any questions or concerns.	Participants in the usual care group attended routine prenatal visits with their healthcare providers. Nurses recorded their weight, which was plotted on an IoM weight-gain chart specific to each participant's pre-pregnancy BMI. The chart was e-mailed to the participant within a week of the appointment. Appropriate weight gain was determined based on pre-pregnancy BMI calculated from self-reported weight and height measured at enrolment. Weight gain was calculated as weight measured at each prenatal appointment minus self-reported pre-pregnancy weight. No additional lifestyle counselling was provided to this group.	**Primary outcomes:** • GDM

TABLE 33 Non-individual participant data trials (*continued*)

	Blinding: Not reported	• BMI between 18.5 and 45.5 kg/m^2 • Receiving regular prenatal care • Willing, if asked, to walk 10,000 steps/day • Meet with a Registered Dietitian Nutritionist (RDN) every month and follow nutrition recommendations provided by the RDN. **Exclusion criteria:** • A history of chronic disease (e.g. type 1 diabetes, cardiovascular disease, thyroid disease) • Previous diagnosis of gestational diabetes or PE. **Number of participants:** Intervention, *n* = 23 Control, *n* = 24 **Type of intervention:** Mixed			• GWG • Physical activity • Dietary intake **Secondary outcomes:** • Birthweight • Birth length • Gestational age at delivery • Apgar score 1 and 5 minutes, preterm delivery • Low birthweight • Macrosomia • Caesarean delivery (planned and unplanned) • PE • PIH
Cahill *et al.*, 2018;[104] English (USA)	**Method of randomisation:** The randomisation sequence was determined by using a random number generator and a fixed allocation block strategy	**Inclusion criteria:**	Parents as Teachers (PAT) participants received the standard curriculum plus a cognitive–behavioural lifestyle programme. This included goal-setting for appropriate GWG, regular self-assessment, education, observational learning through role-play, and home environment changes. The lifestyle programme addressed barriers and facilitators for healthy GWG identified by African American women.	Participants assigned to the standard PAT curriculum had home visits focused on development-centred parenting support and education and parent–child interaction using a family strength-based approach.	**Maternal outcomes**

continued

TABLE 33 Non-individual participant data trials (*continued*)

			Parent educators audiotaped visits and completed checklists, reviewed by study staff. Study staff also randomly observed two home visits per year per educator, as per PAT standards.	
Allocation concealment: Not reported	• African American ancestry	During the study, participants visited the Washington University Clinical Research Unit twice; once at 15 weeks and again at 35 weeks of gestation. During these visits, various measurements were taken, including body weight, body composition, plasma glucose, insulin and lipid concentrations, and the plasma glucose and insulin response to an oral glucose load. Blood samples were collected before and at 30, 60, 90 and 120 minutes after ingesting a 75-g glucose drink. Additionally, infant plasma glucose and insulin concentrations were assessed from cord blood obtained at the time of delivery. After delivery, infant length, weight and body composition were determined before hospital discharge. All research and clinical visits were conducted by staff who were blinded to the participant's treatment assignment.	• GWG
Blinding: Investigators and study staff were blind to group assignment	• Age 18–45 years		• Body fat and fat-free masses
	• BMI of 25.0–45.0 kg/m^2 measured at the initial visit during the first trimester		• Indices of glycaemic control
	• Singleton viable gestation at or before 15 0/7 weeks (established by date of last menstrual period if it was within 5 days of the first trimester ultrasound dating or by ultrasound itself)		• Plasma lipid profile

TABLE 33 Non-individual participant data trials (*continued*)

	• Disadvantaged socioeconomic status (Medicaid recipient or home zip code associated with a median household income below the poverty level). **Exclusion criteria:** • Diabetes • History of GDM or macrosomia • Glycosylated haemoglobin ≥ 6.5% • Any contraindication to exercise during pregnancy • Substance abuse • Non-English speaker **Number of participants:** Intervention, *n* = 119 Control, *n* = 121 **Type of intervention:** Mixed	• Systolic and diastolic blood pressures. **Obstetric outcomes:** • GDM • Hypertensive disease of pregnancy • Preterm birth (delivery before 37 0/7 weeks) • Caesarean delivery • Fetal death (after 20 0/7 weeks **Neonatal secondary outcomes:** • Birthweight and length • Body composition (fat-free mass and per cent body fat) • Per cent who were LGA • Per cent who were SGA • Umbilical cord plasma glucose • Insulin concentrations **Medical complications:** • NICU admission within 24 hours of life • Respiratory distress syndrome	

continued

TABLE 33 Non-individual participant data trials (*continued*)

					• Hypoglycaemia (plasma glucose < 30 mg/dL at any time) • Neonatal death within the first 28 days of life).
Chan *et al.*, 2018;[105] English (Hong Kong)	**Method of randomisation**: A computer-generated list of random numbers in blocks of 6 was used by a study co-ordinator	**Inclusion criteria:**	In addition to regular antenatal care, the IG received a dietitian-led lifestyle programme based on a clinically proven LMP from the first antenatal booking (up to 12 weeks of gestation) until 24 weeks of gestation. They had bi-weekly face-to-face/phone consultations in the first 2 months and monthly face-to-face sessions until the end of the programme. During the first face-to-face session, the dietitian reviewed the participant's lifestyle habits, medical and pregnancy history, fetal growth status and weight-gain progress and discussed specific dietary and lifestyle advice to achieve a desirable weight status. In follow-up consultations, the dietitian reviewed the participant's dietary and lifestyle practices and provided recommendations. Each participant was given an individualised menu plan and healthy lifestyle booklets to achieve a varied, balanced diet emphasising fruit and vegetable consumption, moderate-carbohydrate, low-fat, low-glycaemic index (GI), and low-caloric products in appropriate portions. The diet plan was designed to achieve desirable fetal growth and maternal weight throughout pregnancy. The dietitian also offered advice on using dietary supplements and managing pregnancy discomforts.	The CG received routine antenatal care. During each antenatal visit, nurses monitored the body weight of pregnant women. They were also given an educational booklet with dietary and exercise recommendations for pregnancy. Optional antenatal classes were offered, subject to availability.	**Outcomes:**

TABLE 33 Non-individual participant data trials (*continued*)

	Allocation concealment: Treatment assignments were concealed in consecutively numbered sealed envelopes, which were opened sequentially upon subject enrolment	• Maternal age > 35 years old at the expected date of confinement	Participants met the exercise instructor once during the LMP. The instructor reviewed their medical history, fitness level and musculoskeletal problems. Based on international guidelines, the instructor designed a suitable exercise regime – 30 minutes of low-impact aerobic exercise three times a week.	• GDM
	Blinding: All investigators, outcome assessors, clinicians and nurses of routine antenatal and postnatal care were blinded to the treatment assignment	• Prior history of GDM or birth of child ≥ 4 kg		• GWG
		• Pre-pregnant BMI or BMI at the 1st trimester > 25 kg/m^2		• SGA (< 10th percentile)
		• Family history of diabetes at the first-degree relatives		• LGA (> 90th percentile)
		Exclusion criteria:		• Macrosomia (birthweight ≥ 4 kg)
		• Those who were participating in any clinical trial		• PE
		• Women with pre-existing diabetes		• Gestational hypertension
		• Multiple pregnancies		• CS
		• Substance abuse		• Preterm delivery
		• Renal, liver and thyroid dysfunction		• Gestation age at birth (week)
		• Cognitive impairment		• Birthweight (g)
		• Any other indication of major medical or psychological illnesses		• Birthweight < 2500 g
		• Physical restriction that led to exercise avoidance		• Apgar score at 5 minutes < 7

continued

TABLE 33 Non-individual participant data trials (*continued*)

		Number of participants: Intervention, *n* = 110 Control, *n* = 110 **Type of intervention:** Mixed			• Shoulder dystocia
Da Silva *et al.*, 2017;[87] English (Brazil)	**Method of randomisation:** A computerised random-number generator was used. The randomisation process occurred in blocks of nine pregnant women. Each block resulted in the allocation of three women for the intervention and six women for the CG, ensuring a recruitment balance of 1 : 2 throughout the study.	**Inclusion criteria:**	A structured exercise training programme was initiated between 16 and 20 weeks of gestation and continued for at least 16 weeks. Women in the IG were provided with moderate-intensity exercise sessions three times a week for an hour, planned according to the ACOG recommendations and supervised individually. Each session consisted of warm-up exercises, aerobic activities (treadmill or stationary bike), strength training (dumbbells, machines, or elastic bands) and stretching exercises. The intensity of the exercises was measured based on individual perceived effort, which was kept between 12 and 14 on the Borg Scale. A total of 48 training sessions were planned for each participant and were divided into three stages.	Women in the CG received standard antenatal care and were encouraged to continue their normal daily activities.	**Primary outcomes:**
	Allocation concealment: Not specified	• Women whose pregnancy exercise levels did not include self-reported participation in an exercise programme (LTPA > 150 minutes/week)	The first stage (week 1–4) began with a 5-minute warm-up period, followed by 15 minutes of aerobic exercise, 35 minutes of strength training/floor exercises (3 sets of 12 repetitions each) and a 5-minute stretching session. The second stage (week 5–10) started with a 5-minute warm-up period, followed by 20 minutes of aerobic exercise, 30 minutes of strength training/floor exercises (3 sets of 10 repetitions each) and a 5-minute stretching session. Lastly, the third stage (11–16) began with a 5-minute warm-up period, followed by 25 minutes of aerobic exercise, 25 minutes of strength training/floor exercises (3 sets of 8 repetitions each) and a 5-minute stretching session.		• Preterm birth

TABLE 33 Non-individual participant data trials (*continued*)

	Blinding: The principal researcher was not involved in the exercise training and analyses were performed blinded for group allocation. The staff involved with exercise intervention or outcome assessments had no influence.	• 18 years or older • Living in the urban area of the city of Pelotas, Rio Grande do Sul State, Brazil **Exclusion criteria:** • Self-reported hypertension • Cardiovascular disease • Diabetes diagnosed before pregnancy • History of miscarriage or preterm birth • In vitro fertilisation in the current pregnancy • Twin pregnancy • Persistent bleeding in the current pregnancy • BMI > 35 kg/m^2 • Heavy smoker (> 20 cigarettes a day) **Number of participants:** Intervention, *n* = 213 Control, *n* = 426 **Type of intervention:** Physical activity	Each session was led by a team of five trained physical education professionals, and two physical education professionals were present during each shift, supervising a maximum of six pregnant women per hour to provide personalised attention. The intervention programme was conducted at the gym of the Physical Education School in the Federal University of Pelotas.	• PE • Gestational age • Birthweight • Length and head circumference **Secondary outcomes:** • GWG • GDM • SGA • LGA

continued

TABLE 33 Non-individual participant data trials (*continued*)

Deng *et al.*, 2022;[106] English (China)	**Method of randomisation:** The random allocation sequence was generated electronically using a simple randomisation based on a random number table, with an equal allocation ratio	**Inclusion criteria:**	Diet and exercise: Diet and exercise interventions were provided for the IG from 14 weeks of gestation, until the 75-g OGTT was measured at 24–28 weeks of gestation, with a total of seven interventions. Researchers included nurses, nutritionist and exercise experts. The diet and exercise programme was tailored for every pregnant woman. The nurses managed the programme during the whole intervention, including follow-up, recording and WeChat group contact.	The CG only received routine health management until the birth of the baby. Body weight measurement and the pregnancy outcomes of all women were recorded.	**Primary outcome:**
	Allocation concealment: Not reported	• < 13 weeks of gestation; resident in Beijing	The study involved pregnant women receiving guidance from nutritionists and exercise experts. The intervention included a 1-hour clinic visit with two steps: filling out a questionnaire to determine their prior diet and exercise habits and receiving a personalised diet and exercise programme. The programme included educational manuals and recording of a diet and exercise diary. Nurses established WeChat contact to remind participants to adhere to the programme. The IG uploaded their diary, measured their body weight, and controlled their weight gain every 2 weeks at the clinic. WeChat intervention was offered to those who could not attend the clinic due to work. Researchers adjusted the programme according to the diaries and biochemical indicators. The women attended routine antenatal visits from 29 weeks of gestation until delivery.		• GDM
	Blinding: Due to the nature of the intervention, blinding of participants after	• Single pregnancy			**Secondary outcomes:**

TABLE 33 Non-individual participant data trials (*continued*)

	assignment was not feasible and the researchers who performed outcome assessment and data analysis were not blinded	At least one risk factor for GDM • Age ≥ 35 years • Pre-pregnancy overweight or obesity • Fasting blood glucose ≥ 5.1 mmol/l in early pregnancy • Family history of first-degree relatives with diabetes • History of or current abnormal lipid metabolism • History of macrosomia • History of GDM; or polycystic ovary syndrome **Exclusion criteria:** • Diagnosis of diabetes vaginal bleeding • Severe medical conditions preventing physical exercise • Psychiatric illness **Number of participants:** Intervention, *n* = 41 Control *n* = 43 **Type of intervention:** Mixed			• GWG • Delivery mode (CS, natural delivery) • Gestational hypertension • Premature infants • Macrosomia
Ding *et al.*, 2021;[107] English (China)	**Method of randomisation:** A computer-generated algorithm was used.	**Inclusion criteria:**	Dietitians send weekly dietary guideline messages to pregnant women in a WeChat group. The IG receives monthly personalised nutrition care until receiving an OGTT. Personalised guidelines are based on 'the guide of diagnosis	There were no requirements for the CG.	**Primary outcome:**

continued

TABLE 33 Non-individual participant data trials (*continued*)

			and treatment of gestational diabetes mellitus (2014)'. The group follows Beijing Friendship Hospital Pregnancy Education's WeChat account for detailed guidance. Participants walk at least 6000 steps a day, with walking data obtained from smartphones.		
	Allocation concealment: Not reported **Blinding:** Not reported	• BMI ≥ 24 kg/m^2 at the onset of pregnancy • Age below 35 years • < 12 weeks of gestation, Active on WeChat every day **Exclusion criteria:** • Women with a history of GDM and macrosomia in previous pregnancies • Women who had a history of diagnosis with diabetes • Polycystic ovary syndrome Hyperthyroidism • Hypothyroidism • Previous abortion **Number of participants:** Intervention, *n* = 104 CG, *n* = 111 **Type of intervention:** Mixed			• GDM **Secondary outcomes:** • GWG • Preterm delivery • Gestational hypertension • PE • PPH, caesarean delivery • Macrosomia • Low birthweight (LBW) • Fetal distress • Amniotic fluid contamination
Eslami *et al.*, 2018;[108] English (Iran)	**Method of randomisation:** Randomisation was conducted using randomised blocks with block sizes of 4 and 6, an allocation ratio of 1 : 1, and stratification by health centres	**Inclusion criteria:**	The IG received relevant education on various topics related to their health, including nutrition and physical activity. The education was delivered in the form of a 60- to 90-minute group session followed by a half-hour question-and-answer session. The participants were provided with two phone numbers to contact	The CG did not receive any educational booklet (standard care)	**Outcomes:**

TABLE 33 Non-individual participant data trials (*continued*)

			in case they had any questions and given an educational booklet which was developed based on the WHO recommendations and the Ministry of Health advice. The content of the booklet was based on a review of the literature on nutrition and physical activity in overweight and obese females.	
Allocation concealment: The type of intervention given was written on pieces of paper, placed in opaque envelopes, and numbered consecutively	• Age of 18 and older		After the training session, the mothers in the IG received educational text messages every other day for 4 weeks. Eight weeks after the start of the intervention, all participants were contacted by phone and their weight was measured again. Finally, their diabetes status was determined by interpreting the results of fasting blood sugar (FBS) and glucose tolerance test (GTT), which were conducted in all participants at 24–28 weeks of gestation.	• GDM
Blinding: Since the intervention was training-based, blinding the researcher and participants was not possible, and only the data analyser was blinded	• Gestational age of 16–20 weeks		The educational booklet was later also given to the CG after the intervention was over and the results had been assessed.	• GWG
	• Minimum secondary school education			
	• Singleton pregnancy without complications			
	• The pregnancy being the female's first, second or third			
	• BMI over 25 based on the prenatal care records or according to the first trimester's weighing			

continued

TABLE 33 Non-individual participant data trials (*continued*)

		• Willingness to participate in the study • Owning a cell phone **Exclusion criteria:** • A diagnosis of physical or mental illness in the mother maternal diabetes • Following a specific dietary regiment • History of hospitalisation in the current pregnancy • Change of residence over the course of the study • Separation from the spouse Being at risk of preterm childbirth • Addiction or habitual use of drugs and alcohol • History of infertility • The use of assisted reproduction techniques • The death of close relatives • Divorce • Other acute emotional problems over the past month **Number of participants:** Intervention, *n* = 70 Control, *n* = 70 **Type of intervention:** Mixed			
Ferrara *et al.*, 2020;[109] English (USA)	**Method of randomisation:** Women were randomly assigned to the IG and the CG.	**Inclusion criteria:**	In addition to regular prenatal care, a group of women were randomly selected to receive a lifestyle intervention programme that was adapted from the DPP	Women in the CG received standard Kaiser Permanente Northern California (KPNC) antenatal medical care, which included an antenatal visit at	**Outcomes:**

TABLE 33 Non-individual participant data trials (*continued*)

			and mainly delivered through telehealth. The programme was designed to be practical for pregnant women and easy to implement by healthcare facilities. The core of the lifestyle intervention programme included two in-person sessions and 11 telephone sessions aimed at teaching behavioural strategies to improve weight, diet, physical activity and stress management. The goal of the programme was for women to gain weight within the IoM guidelines range, with a target of 7 kg for women with overweight and 5 kg for women with obesity.	7–10 weeks' gestation, an additional seven antenatal visits on average, and periodic health education newsletters, including the IoM GWG guidelines and information on healthy eating and physical activity in pregnancy.	
Allocation concealment: Not reported **Blinding:** Not reported	• Pre-pregnancy BMI between 25 and 40 kg/m^2 • Aged 18 years or older • Singleton pregnancy **Exclusion criteria**: • Fertility-assisted pregnancy on bed rest • Diabetes diagnosis • Current uncontrolled hypertension • Thyroid disease diagnosed in last 30 days • History of cardiovascular, cancer • Lung or serious gastrointestinal disease • History of eating disorder or bariatric surgery • Serious mental illness				• GDM • Gestational hypertension • PE • Primary CS • Preterm delivery at 25–37 weeks • SGA • LGA

continued

TABLE 33 Non-individual participant data trials (*continued*)

		• Recent history of mood or anxiety disorder • Drug or alcohol use disorder • More than 13 weeks' gestation • GDM **Number of participants:** Intervention, *n* = 199 Control, *n* = 195 **Type of intervention:** Mixed			
Gonzalez-Plaza *et al.*, 2022; English (Spain)	**Method of randomisation:** Randomisation was computer-based in which two random number lists	**Inclusion criteria:**	A digital intervention was used to improve self-control, self-efficacy and outcome expectations. The intervention aimed to overcome barriers to using a smart band and a supportive app for receiving information and assistance from a midwife. The smart band used was the Mi Band 2, and the accompanying app was the Mi Fit app. Pregnant women were advised to take 10,000 steps a day equivalent to 30 minutes per day of moderate physical activity, over the week (≥ 5 days) as recommended by the American College of Obstetricians and Gynaecologists. Participants were trained to set step and weight goals, and the Mi Fit app sent notifications and alerts to help them achieve these goals. The Hangouts app was used to receive personalised information through SMS text messages or videos sent by the research team twice a week. The messages contained information regarding physiological changes in the mother and fetus, and healthy habits related to pregnancy, labour, and post partum. The information sent was extracted from a specialised web page, and	Pregnant women in the CG received oral and written support material. They were advised to perform moderate physical activity for 30 minutes a day, at least 5 days a week, and aim for a GWG between 5 and 9 kg, according to the IoM. Midwives provided instructions to achieve the physical activity goal gradually and recommended a balanced (Mediterranean) diet of 1800 kcal.	**Outcomes:**

TABLE 33 Non-individual participant data trials (*continued*)

		the videos were from the Health Department of Catalonia and the Catalan Midwives Association. Pregnant women were encouraged to use the Hangouts app at least once a week to ask questions to the midwife, and queries were resolved with an immediate response.	
Allocation concealment: Opaque numbered envelopes were prepared to mask the group assignment	• Women with pre-pregnancy obesity (BMI ≥ 30 kg/m^2 based on WHO classification)		• GWG
Blinding: Not reported	• At 12–18 weeks who attended hospital obstetric clinics during prenatal care		• GDM
	• Singleton pregnancy		• PE
	• Aged ≥ 18 years		• Pregnancy-induced hypertensive disorder
	• Users of an android smartphone or iPhone (iOS) with an internet connection		• Prematurity
	Exclusion criteria:		• Type of delivery (unplanned CS)
	• Pregnant women who already used an app for monitoring physical activity and weight.		• Macrosomia
	• Women with a previous diagnosis of psychiatric disorders, endocrine–metabolic disorders, or chronic hypertension		• Admissions to the NICU
	• Pregnant women with a contraindication for performing exercise or mobility problems that do not allow moderate walking; women with language difficulties in understanding Spanish		

continued

TABLE 33 Non-individual participant data trials (*continued*)

		Number of participants: Intervention, *n* = 72 Control, *n* = 78			
Hajian *et al.*, 2020;[110] English (Iran)	**Method of randomisation:** Randomisation was conducted by using a randomiser software.	**Inclusion criteria:**	The IG received personalised nutritional counselling and physical activity training. The researcher provided training on physical activity and nutrition during pregnancy for 30–45 minutes, depending on the mother's awareness and needs. A nutritionist provided a dietary consultation. The group also received educational material and was advised to attend follow-up and weight control sessions. The researcher provided their contact number for self-care questions during the 6-month intervention period. Attempts were made to co-ordinate primary interventions with prenatal care visits to avoid additional costs. During the first visit (16–20 weeks pregnant), the researcher measured the weight, height and BMI of both groups. A food frequency questionnaire and a physical activity questionnaire were used to evaluate energy intake and macronutrients. After completing the questionnaire, the IG received guidance on healthy eating and exercise during pregnancy, and the nutritionist provided individual counselling on their daily diet. At the second visit (26–28 weeks pregnant), the participant's compliance with recommended diets, weight gain and physical activity levels were tracked. Participants completed the International Physical Activity Questionnaire (IPAQ) questionnaire for the second time and were advised to engage in proper physical activities such as aerobic exercise and walking for at least	The CG was evaluated solely for energy intake and level of physical activity and did not receive any further advice or intervention from the researcher.	**Outcomes:**

TABLE 33 Non-individual participant data trials (*continued*)

			20–30 minutes daily, preferably in the afternoon. Stretch training was taught to the participants, and nutrition counselling was provided if needed. fasting blood sugar (FBS) and 2-hour OGTT were recorded based on mother's files in reference centres in each health complex in accordance with the screening instructions and diagnosis of gestational diabetes.	
Allocation concealment: Not reported	• Singleton pregnancy with 16–20 weeks of gestational age	At the third visit (35–37 weeks pregnant), compliance with recommended diets regarding weight gain and physical activity levels based on IPAQ were tracked again.		• GWG
Blinding: Not reported	• BMI 25–29.9 kg/m^2 • Age range 18–40 years • No underlying chronic diseases **Exclusion criteria:** • Pregnant women taking any type of chemical or herbal drug (other than dietary supplements recommended during pregnancy) • Unwillingness of the mother to continue the study or to participate simultaneously **Number of participants:** Intervention, *n* = 33 Control *n* = 33 **Type of intervention:** Mixed			• GDM • Neonatal weight • Neonatal height • Head circumference • Variable caesarean (cause of caesarean – elective, bradycardia and progress failure) • Jaundice

continued

TABLE 33 Non-individual participant data trials (*continued*)

Herring *et al.*, 2016;[111] English (USA)	**Method of randomisation:** Randomisation was computer-based	**Inclusion criteria:**	The intervention aimed to help low-income African American mothers build motivation, support and self-efficacy for weight-related behaviour change while being responsive to their social context. To achieve this, we used Social Cognitive Theory and the Social Ecological Model. The intervention provided skills training and support via three mechanisms. Firstly, participants received personalised daily texts to build self-efficacy and skills. For instance, they may receive a message like 'Snacking at night will just give me heartburn. But if it's yoghurt, then I'll be good. I don't eat any junk late at night'. Secondly, they received self-monitoring texts three to four times weekly and automatic feedback. Lastly, incentives like raffle entries were provided for responding to self-monitoring texts.	Women receiving usual care at Temple University received standard obstetrical care, including an initial visit during the first trimester, monthly follow-ups until week 24, and every 2–3 weeks until week 36. Weekly visits were conducted from week 36 until delivery. Providers assessed patient weight, blood pressure, urine protein, and fetal HR, and the ACOG provided information about optimal weight gain during pregnancy.	**Outcomes:**
	Allocation concealment: The randomisation status was concealed in opaque envelopes prepared by the statistician	• Age ≥ 18 years	We identified three evidence-based weight control targets – energy intake, physical activity and self-weighing – and created behaviour change goals around them. We recommended limiting sugar-sweetened beverages and high-fat/junk food, sticking to one plate of food at each meal, walking 5000 steps daily, gradually increasing walking by 500 steps weekly, and weighing themselves weekly at home. We also provided pedometers and a walking DVD to promote activity. Participants were invited to a private Facebook group ('Pregnant Moms Temple') for additional support and training via links to websites and videos. Only invited members were allowed access to maintain confidentiality.		• GDM

TABLE 33 Non-individual participant data trials (*continued*)

	Blinding: Providers and clinic staff were blinded to subject randomisation to prevent contamination	• Self-identification as African American	A health coach with a bachelor's degree provided behavioural weight control counselling to participants. Weekly calls in the first 2 weeks were followed by twice-monthly calls (15–20 minutes calls). The scripted calls were recorded for quality control purposes, and a web application was used for notetaking and storing process data.	• GWG
		• Gestational age < 20 weeks; first trimester	The intervention was created to support clinical care but was not fully integrated into it. Healthcare providers often prioritise other clinical needs overweight control. To make the intervention more widely available, it was designed to use technology for content delivery.	• Birthweight
		• BMI 25–45 kg/m^2		• SGA
		• Medicaid recipient (income proxy)		• LGA
		• Cell phone ownership with unlimited text messaging		• Mode of delivery
		• Facebook (Facebook, Inc., Menlo Park, CA, USA) member		
		Exclusion criteria:		
		• Pregnant women with conditions requiring specialised nutritional care (e.g. history of bariatric surgery)		
		• Current tobacco use		
		• Multiple pregnancies		
		Number of participants: Intervention, *n* = 27		
		Control, *n* = 29		
		Type of intervention: Mixed		

continued

TABLE 33 Non-individual participant data trials (*continued*)

Horn *et al.*, 2018;[112] English (USA)	**Method of randomisation:** Women were randomised at a 1 : 1 allocation in random blocks of 4 and 6	**Inclusion criteria:**	An RDN greeted participants in the intervention and provided coaching throughout the study. The coaching focused on healthier diets, increased activity and better sleep. Participants received weekly e-mail resources that reinforced the MAMA-DASH goals. The Dietary Approaches to Stop Hypertension (DASH) diet, modified for pregnant women, was encouraged; the DASH diet is particularly beneficial during pregnancy due to its high nutrient density, which includes low-fat dairy and milk products, fish, skinless poultry, lean meat and vegetable protein, unsaturated fats, fibre-rich whole grains, fruits, vegetables and legumes, while consumption of sugar-sweetened beverages and non-nutrient-dense snack foods was discouraged. The RDN monitored dietary adherence and used the LOSE IT! application to provide feedback during weekly coaching calls. The coach generated weekly nutrition, activity and weight progress reports comparing the individual LOSE IT! account entries from the preceding 7-day period with the MAMA-DASH goals. These reports were e-mailed and discussed during coaching calls.	Usual-care participants received access to the MOMFIT website, which included dietary guidelines and pregnancy recommendations the American College of Obstetrics and Gynecology. They also received biweekly newsletters on pregnancy and infant care.	**Outcomes:**
	Allocation concealment: Not reported	• Women aged between 18 and 45 years	Participants were encouraged to engage in more than 30 minutes of activity or walk more than 10,000 steps per day and sleep for 7–9 hours daily. Both groups were given access to password-protected websites with publicly available guidelines. The IG received additional training, LOSE IT!, individualised e-mails, text messages, electronic handouts and phone calls from the RDN coaches. Group intervention		• GWG

TABLE 33 Non-individual participant data trials (*continued*)

			sessions were recorded for participants who were unable to attend. Coaching calls were recorded, and Motivational Interviewing techniques were used. Participants' weekly nutrition reports were discussed, and new/revised goals were set. Adherence to self-monitoring behaviour was assessed. Six 30-minute group sessions were provided throughout the study. Lastly, the prenatal lactation session was in-person for intervention participants and their significant others.	
	Blinding: Randomisation was sequentially blinded, with statistician-provided allocation stored in a Microsoft Access (Microsoft Corporation, Redmond, WA, USA) database	• Singleton pregnancy Fluency in English • Access to the Iinternet and smartphone • BMI between 25 and 40 gestational age < 16 weeks (verified by ultrasonography) • Willingness to participate in the study **Exclusion criteria:** • Diagnosis of diabetes or glycated haemoglobin (HbA1c) > 6.5% measured before enrolment • In vitro fertilisation • Weight difference > 15 lb relative to self-reported pre-pregnancy weight		• GDM • Activity/sleep (35 weeks) • Diet (35 weeks) • CS • SGA • LGA

continued

TABLE 33 Non-individual participant data trials (*continued*)

		• Substance abuse • Smoking • Plans to terminate pregnancy • Plans to move out of the area **Number of participants:** Intervention, *n* = 140 Control, *n* = 141 **Type of intervention:** Mixed			
Ko *et al.*, 2014;[88] English (USA)	**Method of randomisation:** Randomisation was computer-based in a list of random numbers **Allocation concealment:** Not reported	**Inclusion criteria:**	The intervention comprised of a moderate to vigorous exercise programme. It began with 30-minute sessions thrice a week and aimed to increase the frequency to 4–5 times per week, with each session lasting for 45–60 minutes.	The women in the CG did not participate in any instructional sessions with the exercise interventionist and did not receive any motivational mailings. They were advised to maintain their usual levels of physical activity, but were not instructed to stop or avoid exercising.	**Primary outcome:**
	Blinding: Instigators and the subjects' obstetricians were blinded to the intervention assignment, but participants were not	• Women aged 18–45 years attending prenatal clinics at Madigan Army Medical Center	Participants were provided with supervised sessions to learn the exercise techniques and were encouraged to meet with the exercise interventionist monthly to learn techniques for self-motivation and adherence to behaviour change. The participants gradually increased their sessions to three times per week at the gym and one to two sessions at home, each lasting for 30 minutes. From the second to the sixth month, the participants performed aerobic training at the gym three times a week, with one or two sessions at home.		• The presence of gallbladder sludge or stone
		Exclusion criteria:	Women participated in the intervention programme from enrolment until 36 weeks of gestation and received regular mailings at home with information about setting goals for physical activity, reflecting on the reasons for exercising, and additional behavioural tip sheets developed for the APPEAL study.		**Secondary outcomes:**

TABLE 33 Non-individual participant data trials (*continued*)

		• Women who did not have a gallbladder • Over 20 weeks pregnant when first presenting for prenatal care • Not expecting to deliver at Madigan • Women who were medically unable to participate in an exercise programme according to the criteria of the ACOG **Number of participants:** Intervention, *n* = 591 Control, *n* = 605 **Type of intervention:** Physical activity			• GDM • Cholesterol • Insulin • Leptin • Adiponectin
Kong *et al.*, 2014;[89] English (USA)	**Method of randomisation:** Women were randomly assigned to the intervention or CG using a computer-based random number generator (Microsoft Excel 2010, WA)	**Inclusion criteria:**	The study involved an unsupervised walking programme for pregnant women. The IG attended a training session where they were given instructions on using a treadmill safely and advised to follow the 2008 US physical activity guidelines. Treadmills were provided to eliminate barriers pregnant women faced when engaging in physical activity. Participants were given logs to report the location and duration of their walks, but the intensity of the walks was not reported. The unsupervised walking programme started between week 12 and week 15 of gestation and continued until at least week 35. Depending on the duration of each participant's pregnancy, all intervention participants could complete a minimum of 20 weeks. The first 2 weeks of the programme	Both groups were given physical activity logs, but the CG's self-reported leisure-time physical activity was not analysed due to inconsistencies. The unsupervised walking programme began between weeks 12 and 15 and lasted until week 35. Participants had at least 20 weeks to complete the programme, reaching 150 minutes of MPA per week. The first 2 weeks of the intervention programme served as an acclimation period whereby participants were asked to walk for 50 minutes in week 1, followed by 100 minutes in week 2. By the third week, all participants were encouraged to be at their walking goal of 30 minutes most days of the week for an overall total of at least 150 minutes of weekly. Women in the CG	**Outcomes:**

continued

TABLE 33 Non-individual participant data trials (*continued*)

		were an acclimation period where participants were required to walk for 50 minutes in week 1, followed by 100 minutes in week 2. By the third week, all participants were encouraged to walk for at least 30 minutes most days of the week, for a total of at least 150 minutes of moderate physical activity per week.	were not given physical activity recommendations but were not restricted from participating in physical activity during pregnancy.	
Allocation concealment: Not reported **Blinding:** Not reported	• Maternal age between 18 and 45 years • Singleton pregnancy • Non-smoker • Self-reported overweight (BMI 25 kg/m^2) or obese (BMI 30.0 kg/m^2) before pregnancy • No prior history of chronic diseases (including type 1 diabetes, cardiovascular disease, thyroid, or lung disorder) • No prior history of GDM Women who engaged in less than three 30-minute bouts of leisure physical activity for 6 months preceding enrolment **Exclusion criteria:** • Not listed **Number of participants:** Intervention, *n* = 18 CG, *n* = 19 **Type of intervention:** Physical activity			• GDM • GWG • Gestational length at delivery • Birthweight *z*-score • Low birthweight • Macrosomia • Apgar score 1 minute and 5 minutes. Preterm delivery • Caesarean delivery • PE • Maternal hypertension

TABLE 33 Non-individual participant data trials (*continued*)

Korpi-Hyovalti *et al.*, 2012;[98] English (Finland)	**Method of randomisation:** Randomisation was computer-based. **Allocation concealment:** Not reported	**Inclusion criteria:** • Pregnant women (weeks 8–12)	The study involved a clinical nutritionist providing personalised dietary advice to the lifestyle IG. The dietary goals were carbohydrates at 50–55% of energy, fat at 30%, saturated fat < 10%, and protein at 15–20%, with at least 15 g of dietary fibre per 4184 kJ. The women were advised to consume a diet rich in vegetables, fruits and berries, and to use low-fat dairy products, meats and vegetable oils. The recommended energy intake was 126 kJ/kg per day for normal-weight women and 105 kJ/kg per day for overweight women. The nutritionist provided information about the goals of eating, demands of pregnancy, meals and snacks, fibre intake and quality of fats. The Three Factor Eating Questionnaire was used in the beginning of pregnancy and at weeks 36–40, and the women completed a baseline 4-day food record before the first appointment and repeated it before the fifth at weeks 26–28 and sixth appointments weeks 36–40.	Diet counselling in the follow-up group The women were given general information by a nurse on diet and physical activity in a single session to decrease the risk of GDM during pregnancy. The advice was provided both verbally and in writing. The women returned to the Three-Factor Eating Questionnaire at the beginning of pregnancy and at weeks 36–40. The 4-day food record was completed at the beginning of pregnancy and at weeks 26–28 and 36–40. Otherwise, the women were followed up in the prenatal clinic of the municipal health centre at 1-month intervals according to standard care in Finland.	**Outcomes:** • GDM

continued

TABLE 33 Non-individual participant data trials (*continued*)

	Blinding: Not reported	• With one or more risk factors: • BMI > 25 kg/m^2 • Previous history of GDM or birth of child > 4.5 kg • Age > 40 years • Family history of diabetes **Exclusion criteria:** • Women who were diagnosed as having GDM already during gestational weeks 8–12 **Number of participants:** Intervention, *n* = 27 Control, *n* = 27 **Type of intervention:** Diet	Dietary assessment The dietary assessment was conducted using the Nutricaw nutrient calculation software (Version 2.5; Social Insurance Institute, Turku, Finland), which is based on Finnish nutrient composition analyses and international food composition tables. 1n total, the women provided 26 food records in the beginning, 22 at weeks 26–28, and 17 at the end of pregnancy in the lifestyle IG. In the close follow-up group, there were 25 food records at the beginning, at weeks 26–28, and 18 at the end of pregnancy. The analysis was carried out on the data of only those 17 women in the IG and 18 women in the close follow-up group who returned all three food records.	• GWG • Birthweight

TABLE 33 Non-individual participant data trials (*continued*)

Liu *et al.*, 2022;[113] English (USA)	**Method of randomisation:** A randomisation list was generated by the statistician **Allocation concealment:** Not reported **Blinding:** Not reported	**Inclusion criteria:** • 18–44 years of age • Gestational age ≤ 16 weeks	Intervention participants were advised to attend clinic visits with their prenatal care providers and follow guidelines for healthy GWG, physical activity and dietary intake for pregnant women. They were encouraged to accumulate 150 minutes per week of moderate-intensity physical activity and follow a diet high in fruits, vegetables and whole grains while low in saturated and *trans* fats. The 'MyPlate Daily Checklist for Moms' was used to help participants select a balanced diet, and customised calorie goals were provided. Social Cognitive Theory guided the intervention components. The intervention began with a detailed counselling session before the 18th week of pregnancy. The participant's dietary intake and physical activity report were shared, and a weight-gain-tracking graph was provided. Participants set a goal for physical activity and diet. They received a binder of study handouts, a pedometer and a bathroom scale. The initial 10 weekly group sessions were replaced with 10 individual phone counselling calls due to recruitment challenges and low attendance. Only one IG was conducted before the protocol change, with six participants. Participants were analysed after an in-depth counselling session. They received 10 weekly phone calls and 10 podcasts, discussing diet, physical activity and behavioural strategies. They plotted their weight and discussed progress towards goals	The participants of this group were advised to attend their prenatal care provider's clinic visits. To ensure their engagement and retention throughout the programme, the group was provided with 6 monthly mailings and 10 weekly podcasts, which were publicly available online. These podcasts mainly focused on healthy pregnancy and fetal development, and were similar in duration and frequency to the ones provided to the IG. It's worth noting that the mailings and podcasts did not discuss any topics related to weight, physical activity, or diet.	**Outcomes:** • GWG • GDM

continued

TABLE 33 Non-individual participant data trials (*continued*)

		during each call. After 10 calls, they received shorter weekly or biweekly counselling calls throughout pregnancy. A private Facebook group was created for participants to support each other.	
	• Self-identification as White or Black/African American • English-speaking • Pre-pregnancy BMI ≥ 25 kg/m^2 and weight ≤ 370 lb (maximum weight assessed by scale) **Exclusion criteria:** • Multiple gestations • Contraindications to aerobic exercise during pregnancy hospitalisation for a mental health • Substance abuse disorder in the past 6 months • A physical disability that prevents exercise • Doctor's advice not to exercise during pregnancy • Current or previous eating disorder • Participants were withdrawn from the study if they had a miscarriage, stillbirth, or discovery of multiple gestation after randomisation **Number of participants:** Intervention, *n* = 112 Control, *n* = 105		• Gestational hypertension • PE • CS • Long hospital stay (> 4 days for caesarean deliveries and > 2 days for vaginal deliveries) • Preterm delivery • Low birthweight • Macrosomia • Low 1-minute Apgar score (< 7) • Gestational hypertension • PE • Preterm birth • SGA

TABLE 33 Non-individual participant data trials (*continued*)

		Type of intervention: Mixed			
McDonald *et al.*, 2021;[90] English (USA)	**Method of randomisation:** Randomisation was done via computerised sequencing (GraphPad software) **Allocation concealment:** Not reported **Blinding:** Not reported	**Inclusion criteria:** • Singleton pregnancy (< 16 weeks of gestation) • Between 18 and 40 years of age • Pre-pregnancy BMI between 18.5 and 34.99 kg/m^2 • Physician clearance to participate in an exercise programme • Able to communicate fluently in English and be contacted via phone or e-mail **Exclusion criteria**: • Pre-existing medical conditions (e.g. diabetes,) • Comorbidities known to affect fetal development (e.g. lupus)	The exercise sessions included a 5-minute warm-up at the start, and a 5-minute cool-down at the end, during which the treadmill speed was reduced to 3.0 mph or lower. The aerobic exercise group underwent individual supervised sessions of moderate-intensity exercise (40–59% VO_2peak) for 50 minutes, three times a week. The intensity of the exercise was monitored using a previously validated Target HR (THR) for pregnant women. Aerobic exercises such as treadmill running, elliptical training, stationary cycling, rowing and stair stepping were performed during the sessions.	Participants in the CG were given the option to participate in low-intensity stretching sessions with a focus on major muscle groups. These sessions involved standing or sitting stretches and included breathing techniques. Both exercise and stretching/breathing sessions were supervised and held at one of two university-affiliated gyms.	**Outcomes:** • GWG • GDM • Neonatal weight (kg) • Length (cm) • Pre-pregnancy weight

continued

TABLE 33 Non-individual participant data trials (*continued*)

		• Taking medications known to affect fetal development or pregnancy outcome Using tobacco, alcohol, or other recreational drugs **Number of participants:** Intervention, *n* = 42 Control, *n* = 32 **Type of intervention:** Physical activity			
Okesene-Gafa *et al.*, 2019[114]; English (New Zealand)	**Method of randomisation:** Eligible women were allocated randomly by the research midwife using a web-based randomisation programme using random permuted blocks of 4–8 participants	**Inclusion criteria:**	As part of the HUMBA study, women in the dietary IG received a handbook with information on healthy foods, recipes, managing cravings and staying active. They also received home-based education sessions from a community health worker trained in SMARTER goal setting and behaviour change techniques. During subsequent visits, the community health worker plotted the woman's weight on a pregnancy weight-gain chart and provided feedback. Women in this group also received motivational text messages three times a week. The messages were created to supplement dietary education and were written in a way that mimicked communication from a baby to their mother. For instance, one message said, 'Mum, remember to read food labels'. The service was completely voluntary, allowing women to opt out of the messaging programme at any time. Women who were placed in the routine dietary advice group received Ministry of Health pamphlets titled 'Eating for Healthy Pregnant Women' and 'Healthy Weight-Gain in Pregnancy', without any dietary guidance from community health workers or	As part of their routine dietary advice, women were given daily capsules containing either Lactobacillus rhamnosus GG or Bifidobacterium lactis BB12 (at a minimum dose of 6.5×10^{-9} colony forming units; www.chr-hansen.com) or identical capsules containing microcrystalline cellulose and dextrose anhydrate as a placebo. The former group, which received probiotics, was instructed to take one capsule daily until birth alongside their routine antenatal care, while the latter group was given the same instructions for the placebo capsules.	**Outcomes:**

TABLE 33 Non-individual participant data trials (*continued*)

		text messages. Women in this group also had intervention visits before the 26–28 weeks HUMBA study glucose test (75-g OGTT). Women in the routine dietary advice group received NZ Health Ministry pamphlets with no additional support.	
Allocation concealment: Not reported **Blinding:** Participants, researchers and data analysts were blinded to probiotic and placebo allocation.	• Women with a singleton pregnancy at 12–17 weeks of gestation • BMI > 30 kg/m^2 **Exclusion criteria:** • Pregnant women (12–17 weeks) with pre-existing diabetes or haemoglobin A1c > 50 mmol/mol • Known congenital abnormality • Taking capsules or supplements containing probiotics • Previous bariatric surgery Severe hyperemesis • Medications or medical conditions that alter glucose metabolism **Number of participants:** Dietary intervention, *n* = 116 [maternal primary outcome: evaluated for ITT analysis (*n* = 107) and neonatal primary outcome: evaluated for ITT analysis (*n* = 111)] vs. routine dietary advice *N* = 114 (maternal primary outcome: evaluated for ITT analysis (*n* = 110), neonatal	• GWG • GDM • SGA • Admission to NICU	

continued

TABLE 33 Non-individual participant data trials (*continued*)

		Number of participants: Dietary intervention, *n* = 116 [maternal primary outcome: evaluated for ITT analysis (*n* = 107) and neonatal primary outcome: evaluated for ITT analysis (*n* = 111)] vs. routine dietary advice *N* = 114 (maternal primary outcome: evaluated for ITT analysis (*n* = 110), neonatal primary outcome: evaluated for ITT analysis (*n* = 111)]; probiotics *N* = 115 [maternal primary outcome: evaluated for ITT analysis (*n* = 108) and neonatal primary outcome: evaluated for ITT analysis (*n* = 110)] vs. placebo *N* = 115 [maternal primary outcome: evaluated for ITT analysis (*n* = 109) and neonatal primary outcome: evaluated for ITT analysis (*n* = 112)]. **Type of intervention:** Mixed			
Parat *et al.*, 2019;[115] English (France)	**Method of randomisation:** Randomisation was performed using a computer-generated sequence	**Inclusion criteria:**	As part of the intervention, an individualised plan was created for each participant based on their educational diagnosis and in consultation with them. This plan included strategies to achieve realistic goals for lifestyle changes. Each participant was scheduled for at least two face-to-face visits with a dietitian (at 26 and 30 GW) and four group education sessions (at 21, 28, 35 GW, and 2 months post partum). During these sessions, participants discussed their behaviours, successes and difficulties in achieving their goals. The individualised plan was then adapted based on these discussions.	The women in the CG received general information about diet and exercise during a face-to-face meeting with a dietitian at 26 weeks' gestation. They were provided with the national booklet on nutrition during pregnancy www.mangerbouger.fr/PNNS/Guides-et-documents/Guides-nutrition. If the participant requested it, or if GDM was diagnosed, an additional dietitian visit was arranged.	**Outcomes:**

TABLE 33 Non-individual participant data trials (*continued*)

	Allocation concealment: Sealed opaque envelopes containing the random allocation were numbered consecutively and delivered to each study centre	• Pregnant women with a maximum of 21 gestational weeks (GWs)	The first group education session at 21 GW focused on improving participants' knowledge of healthy diets and the benefits of physical activity during pregnancy. The second session at 28 GW focused on the psychosocial aspects of pregnancy, weight gain, balanced diet and physical activity. The third session at 35 GW was dedicated to the baby's needs and how to feed the baby. The last session, held 2 months after birth, focused on baby's health, weaning and nutrition. Each session ended with physical activity and relaxation.	• GDM
	Blinding: Not reported	• Aged ≥ 18 years	Between sessions, participants could have face-to-face visits with dietitians and/or a diabetologist at 26 and 30 GW to discuss maintaining a healthy diet and motivation. The intervention aimed to promote healthy lifestyle changes without focusing specifically on weight objectives. More details about the intervention can be found in the supplementary information.	• GWG
		• Pre-pregnancy BMI > 25 kg/m^2		• Hypertension during pregnancy requiring anti-hypertensive treatment,
		• Women who agreed to participate		• PE
		• Women covered by the French medical insurance system		• Delivery mode including CS and need for instrumental delivery
		• Singleton pregnancy		
		• Able to understand (written and spoken) French		

continued

TABLE 33 Non-individual participant data trials (*continued*)

		Exclusion criteria: • Any maternal condition that could possibly impact the fetus or fetal conditions in early pregnancy • Psychological disorders (including eating disorders) • Pre-existing diabetes • Newly diagnosed gestational dysglycaemia • History of bariatric surgery **Number of participants:** Intervention, *n* = 102 Control, *n* = 104 **Type of intervention:** Mixed			
Perales *et al.*, 2016a;[91] English (Spain)	**Method of randomisation:** Randomisation was computer-based	**Inclusion criteria:**	The exercise programme for pregnant women followed ACOG guidelines and involved three 60-minute supervised sessions per week. Women wore HR monitors to maintain a target HR intensity zone during aerobic activities which included different exercises and music choreographies. The sessions included a 5–7-minute warm-up, aerobic activities for 25–30 minutes, strength training, and 5–10 minutes cool-down periods. Exercises were performed using light weights (0.5–1 kg) or body weight to improve muscle strength and prevent muscle imbalances. The strength part of the session engaged major muscle groups, such as upper/lower limb muscles, back, shoulders and abdominal muscles, with the aim of improving general muscle strength and preventing common muscle imbalances	Standard care	**Outcomes:**

TABLE 33 Non-individual participant data trials (*continued*)

			during pregnancy. The participants used 3-kg dumbbells or their own weight to perform strength exercises. The programme also involved exercises aimed at improving balance, pelvis mobility and body awareness, as well as pelvic floor muscle exercises for the prevention of urinary incontinence. The programme avoided exercises involving extreme stretching, joint overextension, ballistic movements, or jumps. The aerobic and strength training components lasted the same duration throughout the programme. The exercises were modified based on the trimester to improve body awareness, balance, and pelvis mobility to ease delivery.	
Allocation concealment: Not reported **Blinding:** Not reported	• Healthy pregnant women having no obstetric complications • No serious medical condition preventing them from exercising safely • Time of pregnancy 16 weeks • Not exercising regularly for more than 30 minutes on 3 days a week • Able to communicate in Spanish • Giving birth and being followed throughout pregnancy at the Hospital Universitario de Fuenlabrada **Exclusion criteria:** • Not listed **Number of participants:** Intervention, *n* = 120 Control, *n* = 121			• GWG • GDM • Hypertension • Type of delivery • Duration of labour • Gestational age • Birthweight • Height • Apgar (1 and 5 minutes) • pH of umbilical cord

continued

TABLE 33 Non-individual participant data trials (*continued*)

		Type of intervention: Physical activity			
Polley *et al.*, 2002;[116] English (USA)	**Method of randomisation:** Women were randomly assigned to the control group or to the IG	**Inclusion criteria:** Pregnant women before 20 weeks gestation (mean ± = 14.5 ± 3.1 weeks) from an obstetric clinic for low-income women at a hospital in Pittsburgh, PA, USA.	Professionals with a master's or doctoral degree in nutrition or clinical psychology provided intervention during regularly scheduled clinic visits for pregnant women. Women were given information on healthy weight gain, exercise during pregnancy and healthy eating during pregnancy. Newsletters were sent biweekly to promote healthy habits. Personalised graphs of weight gain were sent after each visit. Women exceeding recommended weight gain received individualised nutrition and behavioural counselling. A stepped-care approach was used, with increasingly structured behavioural goals set for women exceeding recommended weight gain. The main objective of the dietary intervention was to reduce the consumption of high-fat foods, particularly fast-food items, and replace them with healthier options such as fruits and vegetables. If these changes were insufficient to help the woman attain the IoM-recommended weight, a more structured meal plan with customised calorie goals was devised. The exercise intervention focused on encouraging more physical activity, such as walking, and making lifestyle changes, like walking instead of driving short distances. Women were also contacted by phone in between clinic visits to monitor their progress towards achieving the goals set at their previous appointments.	Participants in the standard prenatal care group only received the nutrition counselling provided by the doctors, nurses, nutritionists and Women, Infants, and Children's Special Supplemental Nutrition Program (WIC) counsellors at Magee-Womens Hospital. The focus of this counselling was to promote a well-balanced diet and encourage the use of multivitamin/iron supplements. The research staff did not provide any additional information or counselling to this group.	**Outcomes:**

TABLE 33 Non-individual participant data trials (*continued*)

	Allocation concealment: Not reported	**Exclusion criteria:** Pregnant women younger than 18 years, those whose first prenatal visit was > 12 weeks gestation, and those with a high-risk pregnancy (i.e. drug abuse, chronic health problems, previous complications during pregnancy, or current multiple gestation). Underweight women (BMI< 19.8 based on self-reported weight at height at the last menstrual period).	• GDM
	Blinding: Not reported	**Number of participants:** Intervention, *n* = 57 (30 normal weight, 27 overweight) Control, *n* = 53 (31 normal weight, 22 overweight) **Type of intervention:** Mixed	• Pre-pregnancy BMI (kg/m^2) • Pre-pregnancy weight (kg) • Infant birthweight • Low birthweight (4000 g) • Gestation at delivery, preterm delivery (< 36 weeks) • Caesarean delivery • PE • Maternal hypertension

continued

TABLE 33 Non-individual participant data trials (*continued*)

Price *et al.*, 2012;[93] English (USA)	**Method of randomisation:** Women were randomly assigned to the CG or to the intervention.	**Inclusion criteria:**	The intervention involved a supervised aerobic training programme lasting 45–60 minutes, four times per week at a moderate-intensity level (12–14 on the Borg Scale of perceived exertion) in line with the exercise guidelines of the ACOG. The programme consisted of step aerobics on the first day, group walks over hilly terrain on the second day, and circuit training on the third day. The circuit training included 1–10 minutes of aerobic exercise on treadmills, elliptical trainers or stationary bicycles, alternating with an equal time interval of weight training, mostly using weight machines with a weight that allowed for one set of 20 repetitions. Upper extremity exercises involved overhead press, seated bench press, seated rowing, pectoral flexion, triceps extension and bicep curls. Lower extremity exercises included leg extension and hip adduction/abduction. Core muscle exercises included back extension and loaded torso rotation on weight machines, followed by crunches as well as prone and supine bridges on 55-cm exercise balls. The circuit session ended with 5 minutes of hamstring, quadriceps, and calf stretching. To ensure four exercise sessions per week, each woman completed a brisk 30–60-minute walk once a week. The author recorded exercise activities and attendance. Active subjects continued to exercise with the group until 36 weeks gestation or until delivery if they wished to do so.	CG did not exercise, only exerted as needed for work/household chores. Told not to exercise to keep group distinction. Tested every 6 weeks after randomisation. Dietary advice followed, no calorie estimation.	**Outcomes:**
	Allocation concealment: Opaque envelopes containing an equal number of group assignments were prepared by the study statistician	• No aerobic exercise more than once per week for at least the past 6 months; Viable singleton pregnancy at 12–14 weeks BMI < 39 kg/m^2			• GDM

TABLE 33 Non-individual participant data trials (*continued*)

	Blinding: Not reported	• No chronic heart or lung disease • No poorly controlled diabetes, hypertension, epilepsy, or hyperthyroidism • No severe anaemia • No orthopaedic limitations • No history of premature delivery, infant delivered for SGA, or unexplained fetal death **Exclusion criteria:** • Not listed **Number of participants:** Intervention *n* = 31 Control *n* = 31 **Type of intervention:** Physical activity			• Length of pregnancy • Newborn birthweight • Gestational hypertension length of first • Second stages of labour • Frequency of CS • Frequency of assisted delivery • Newborn Apgar scores placenta weight
Quinlivan *et al.*, 2011;[99] English (Australia)	**Method of randomisation:** Randomisation was conducted using computer-generated numbers	**Inclusion criteria:**	Women who were part of the IG during the study attended a specialised antenatal clinic that differed from routine care only in four ways: (1) they received continuous care from the same provider, (2) they were weighed upon arrival, (3) they were given brief dietary interventions by a food technologist at each antenatal visit and (4) they received psychological assessments and interventions if required. If any of these women were diagnosed with GDM, they continued to receive care at the obesity clinic but were treated using the same clinical care guidelines as the women in the general obstetric diabetes clinic.	Women in the CG were allocated to routine public antenatal care. This consisted of midwifery, obstetrician and general practitioner antenatal clinics, with access to high-risk antenatal clinics if indicated on medical grounds. Women in the CG who were subsequently diagnosed with GDM were referred to a public obstetric diabetes clinic for ongoing care.	**Outcomes:**

continued

TABLE 33 Non-individual participant data trials (*continued*)

	Allocation concealment: Sealed opaque envelopes were used **Blinding:** Not reported	• Pregnant with a fetus with no known anomalies • Spoke English • Did not intend to relinquish their infant • Did not have a multiple gestation • Able to attend hospital for antenatal care overweight (BMI 25–29.9 kg/m^2) • Obese (BMI > 29.9 kg/m^2) **Exclusion criteria:** • Not listed **Number of participants:** Intervention, *n* = 63 Control, *n* = 61 **Type of intervention:** Diet			• GDM • GWG • Birthweight
Rakhshani *et al.*, 2012;[94] English (India)	**Method of randomisation:** Randomisation was conducted on an online random number generator	**Inclusion criteria:**	During the study, the yoga group underwent a 1-hour yoga session three times a week from the 13th week to the 28th week of gestation. This amounted to a total of 28 sessions. The gestational periods for the interventions were chosen since most women detect pregnancy by the 12th week of gestation, and those at high risk are likely to deliver preterm. Moreover, organ developments are usually complete by the 28th week of gestation. Certified yoga therapists conducted the yoga classes using an instruction manual in a designated room.	The CG, on the other hand, was offered standard care alongside walking for half an hour in the morning and evening, which was the usual antenatal exercise provided by the hospital during the same period.	**Outcomes:**

TABLE 33 Non-individual participant data trials (*continued*)

	Allocation concealment: The selections (yoga or control) were then written on paper and placed in sealed, opaque envelopes, which were kept in a locked cabinet.	• Pregnant women within 12 weeks of gestation	The interventions offered to the study group were classified into three categories, including (1) breathing exercises, (2) yogic postures and (3) meditative exercises. The meditative exercises consisted of visualisation, guided imagery, and sound resonance techniques. The participants were asked to visualise the fetus in the uterus, the umbilical cord, and the placenta. They were guided to imagine the blood flowing from their bodies, into the placenta, through the umbilical cord, and nourishing their fetuses.	• GDM
	Blinding: This was a single blind study; the physicians, laboratory technicians and hospital staff were blinded on the group selection	• Women with any of the following risk factors: History of poor obstetrical outcome	Both the study and CGs received standard care, including pamphlets about diet and nutrition during pregnancy, regular check-ups by the obstetrician, and bi-weekly follow-ups by the research staff. The purpose of the bi-weekly follow-ups was to ensure that the study participants were adhering to their intervention practices and routine hospital check-ups.	• Pregnancy induced- hypertension
		• Women who had experienced any of the complications in previous pregnancies		• PE
		• Twin pregnancies – pregnancy with two fetuses		• Eclampsia
		• Extremes of age – maternal age below 20 or above 35 years		• Preterm deliveries, Emergency CS
		• Obesity – BMI above 30 at the time of recruitment		• SGA
		• Women with a history of poor obstetrical outcomes among blood relatives, that is sister, mother or grandmother (pregnancies with family)		• LGA

continued

TABLE 33 Non-individual participant data trials (*continued*)

		Exclusion criteria: • Severe renal, hepatic or gallbladder, or heart disease • Structural abnormalities in the reproductive system • Hereditary anaemia • Seizure disorders • Sexually transmitted diseases • Any medical conditions that prevented the subject from safely and effectively practising the interventions **Number of participants:** Intervention, *n* = 30 Control, *n* = 38 **Type of intervention:** Mixed			• Low 1 minute Apgar score • Low 5 minute Apgar score
Seneviratne *et al.*, 2016;[95] English (New Zealand)	**Method of randomisation:** Women were randomly assigned to the intervention and the CG	**Inclusion criteria:**	The IG participated in a home-based antenatal exercise programme using magnetic stationary bicycles (Sportop NB600/NB800) from 20 to 35 weeks of gestation. Participants were provided with a written programme prescribing frequency and duration of weekly exercises. They were given HR monitors (Polar S625/Polar RS800; Polar Electro Oy, Kempele, Finland) to wear during all cycling sessions. Each exercise session comprised of a 5-minute warm-up and cool-down period at low intensity. A total of 67 sessions were prescribed, with the frequency varying from 3 to 5 sessions per week and duration of moderate-intensity exercise between 15 and 30 minutes per session. Each participant was visited at home by an exercise	The CG was not prescribed an exercise intervention or provided with HR monitors.	**Outcomes:**

TABLE 33 Non-individual participant data trials (*continued*)

			physiologist for assistance. The data were obtained by downloading HR monitor data (using POLAR PROTRAINER 5 software; Polar Electro Oy).		
	Allocation concealment: Not reported **Blinding:** Not reported	• Women aged 18–40 years • BMI ≥ 25 kg/m^2 • Singleton pregnancy < 20 weeks of gestation. **Exclusion criteria:** • Ongoing smoking Multiple pregnancy • Pre-existing Contraindications to antenatal exercise • Living outside the Auckland Region **Number of participants:** Intervention, *n* = 37 Control, *n* = 37 **Type of intervention:** Physical activity			• GDM • GWG • Length of hospital stay (hours) • Gestational hypertension • PE • Preterm birth • Induction of labour • Augmentation of labour • CS
Simmons *et al.*, 2016;[117] English, European countries [United Kingdom, Ireland, the Netherlands, Austria, Poland, Italy (Padua and Pisa), Spain, Denmark (Odense and Copenhagen), and Belgium]	**Method of randomisation:** Randomisation was conducted using a computerised electronic random number generator	**Inclusion criteria:**	Women were assigned a lifestyle coach who discussed seven Health Eating (HE) and/or five physical activity 'messages' according to previous work. The HE intervention promoted a food-based, lower simple and complex carbohydrate, lower fat, higher fibre, higher protein diet, including a focus on portion size and, therefore, a more limited intake of total calories. The physical activity intervention promoted both aerobic and resistance physical activity. All interventions recommended a limitation in	Not specified	**Primary outcomes:**

continued

TABLE 33 Non-individual participant data trials (*continued*)

		GWG to 5 kg. The messages were supported by a 'toolkit' for each participant, including educational materials, pedometers and flexible elastic Dyna-Bands. The coaching included five face-to-face sessions of approximately 30–45-minute duration, and 4 telephone calls of </=20 minutes or contacts using electronic mail. At least four face-to-face coaching sessions were expected to occur before the second measurement session (24–28 weeks), and the intervention was completed by 35 weeks of gestation. Standardisation of the lifestyle intervention was achieved through a coach training programme, which included an observed session with an actor, provision of a desk-file with all materials and methods, and the use of a personal digital assistant (PDA) with made-to-order software to provide a framework for the session. A key component was for women to strive to achieve a maximum GWG of 5 kg. The coaches had scales available to help women with their weight management if weight scales were not available in the home.	
Allocation concealment: Not reported **Blinding:** The staff involved with measurements, but not the participants, were kept unaware of the intervention. Statistical analyses were performed blinded for allocation	• Pregnant women with a pre-pregnancy • BMI of > 29 kg/m^2 • < 19 ± 6 days of gestation • A singleton pregnancy • Aged over 18 years		• GDM • GWG **Secondary outcomes:** • Physical activity • Nutrition

TABLE 33 Non-individual participant data trials (*continued*)

		Exclusion criteria: • A diagnosis of GDM (using the OGTT by the IADPSG) • Pre-existing diabetes • Chronic medical conditions (local investigator defined; e.g. valvular heart disease) • A psychiatric disorder, Inability to walk > 100 m safely • Requirement for a complex diet • Not fluent in the major language of the country of recruitment or unable to have a conversation with the lifestyle coach in another language for which the intervention materials were available. **Number of participants:** *n* = 94 usual care; *n* = 93 HE&PA; *n* = 103 HE and *n* = 98 PA. **Type of intervention:** Mixed			• Birthweight • Gestational age • SGA • LGA
Thornton *et al.*, 2009;[100] English (USA)	**Method of randomisation:** A randomisation system was used to determine the group assignment	**Inclusion criteria:**	Both groups of participants received counselling on conventional prenatal nutrition guidelines from a registered dietitian. However, the study group received a more detailed dietary intake protocol, following guidelines similar to those used for gestational diabetes. The monitored patients were placed on an 18–24 kcal/kg balanced nutritional regimen. Six weeks after delivery, all women in the study group were asked to record all foods and beverages consumed daily, which were reviewed at each prenatal visit by a physician.	Standard care	**Outcomes:**

continued

TABLE 33 Non-individual participant data trials (*continued*)

		Patients were weighed at every prenatal visit and encouraged to walk for 30 minutes per day. Blood pressure readings and urine samples for glucose, protein and ketones were taken from both groups. The weight of all participants was recorded at the time of entry into the study, before delivery, and at 6 weeks post partum, and the newborn was weighed by the delivery room nurse immediately after delivery. Neonatal outcome was assessed using Apgar scoring, which is routine for all deliveries. Antepartum and intrapartum complications including GDM, PE and shoulder dystocia were identified from medical records. The type of delivery, macrosomia, anaesthesia and complications such as wound dehiscence/infection and post partum haemorrhage were recorded.	
Allocation concealment: Envelopes were prepared and sequentially numbered. A card indicating the assigned group was placed in the envelope, and the envelope was sealed	• Pregnant with a single fetus between 12 and 28 weeks of gestation		• GDM
Blinding: Not reported	• BMI ≥ 30 kg/m^2		• GWG
	Exclusion criteria:		• PE
	• Patients with pre-existing diabetes, hypertension, or chronic renal disease		• Gestational hypertension
	Number of participants: Intervention, *n* = 116		• Preterm delivery (< 37 weeks)
	Control, *n* = 116		• Post-term delivery (> 41 weeks)

TABLE 33 Non-individual participant data trials (*continued*)

		Type of intervention: Mixed			• Labor induction, caesarean delivery • Adherence with prescribed nutritional regimen • Gestational age at birth • Infant birthweight • Macrosomia • Apgar score (< 7 at 5 minutes)
Tomic *et al.*, 2013;[96] English (Croatia)	**Method of randomisation:** Not reported	**Inclusion criteria:**	Pregnant women in the study group performed regular aerobic exercise three times per week during pregnancy under expert supervision. The exercise routine consisted of a warm-up period of 5 minutes, 30 minutes of aerobic activity, 10 minutes of stretching, and a cool-down period of 5 minutes. The intensity of aerobic activities was in accordance with ACOG and American College of Sports Medicine guidelines and was measured using the Rated Perceived Exertion Scale and a HR monitor.	The women in the CG were instructed not to engage in any kind of exercise except daily routine activities and received standard antenatal care.	**Outcomes:**
	Allocation concealment: Not reported	• Good general health	The CG consisted of healthy pregnant women who did not perform any organised regular physical exercise during pregnancy. All control participants were engaged in everyday physical activities, which included all activities performed in everyday life, household and/or at the workplace, which were also performed by participants from the experimental group.		• GDM
	Blinding: Not reported	• Age 18–35 years	All participants visited an obstetrician four times, where their health, pregnancy details, and fetal vital signs were assessed. The obstetrician also noted complications and recorded the obstetric outcome, including pregnancy length, mode of delivery and neonatal birthweight.		• PE

continued

TABLE 33 Non-individual participant data trials (*continued*)

		• Viable fetus at the regular ultrasound scan, and normal pregnancy confirmed by a clinical obstetrician or primary care obstetrician **Exclusion criteria:** • Chronic or acute medical conditions (cancer; renal, endocrinological, psychiatric, neurological, infectious and cardiovascular diseases) • Multiple gestations • Persistent second or third trimester bleeding, placenta previa after the 26th week of gestation • Poorly controlled hypertension, DM or thyroid gland disease • Incompetent cervix, history of recurrent miscarriages • Heavy smoking habit Conditions that could interfere with ACOG guidelines **Number of participants:** Intervention, *n* = 166 Control, *n* = 168 **Type of intervention:** Physical activity			• PIH • Mode of delivery
Trak-Fellermeier, 2020;[118] English (Puerto Rico)	**Method of randomisation:** Women were randomly assigned to the intervention and the CG	**Inclusion criteria:**	PEARLS was a study that involved a lifestyle intervention delivered by Registered Dietitians. The intervention aimed to improve diet and physical activity by reducing sedentary behaviours and encouraging frequent movement. Participants were encouraged to meet appropriate GWG recommendations by monitoring their diet, physical activity, and	Women assigned to the CG participated in informative group sessions imparted by study staff, receiving health advice about dental care and child safety.	**Outcomes:**

TABLE 33 Non-individual participant data trials (*continued*)

		weight trajectory. The dietary intervention focused primarily on total calorie intake, improving carbohydrate and fat quality, reducing salt intake, and replacing red meat with low-mercury fish, nuts and beans. Participants were also encouraged to take prenatal multivitamin supplements as prescribed by their obstetrician. The physical activity component of the intervention aimed to increase movement and reduce sedentary time. Participants were encouraged to set goals for a daily physical activity/exercise routine that was considered safe during pregnancy, according to the American Congress of Obstetrics and Gynecology. The intervention also motivated participants to increase non-exercise activity thermogenesis by promoting regular movement and encouraging specific behaviours such as standing, walking and taking the stairs. To reduce sedentary periods, we recommended interrupting periods of sitting time with short 2–5-minute activities such as standing or walking. More details about the intervention can be found in published literature. Additional details regarding the intervention have been published elsewhere.	
Allocation concealment: Not reported **Blinding:** Study staff other than a designated statistician and intervention staff remained blinded until the trial concluded	• Women 18 years of age BMI > 25 kg/m^2 • Between 8 and 16 weeks of gestation		• GDM • PE	

continued

TABLE 33 Non-individual participant data trials (*continued*)

		• Willing to deliver at University Hospital **Exclusion criteria:** • History of health conditions that would affect the woman's capacity to comply with the intervention (i.e. contraindication to aerobic exercise) or have a direct impact on fetal growth (i.e. diabetes or multiple pregnancy) **Number of participants:** Intervention, *n* = 15 Control, *n* = 16 **Type of intervention:** Mixed			• Eclampsia • Primary CS • NICU admission • Prematurity neonatal
Vesco *et al.*, 2014;[119] English (USA)	**Method of randomisation:** Women were randomly assigned to the intervention and the CG **Allocation concealment:** Not reported	**Inclusion criteria:** • Pregnant women up to 21 weeks gestational age	The intervention programme aimed to help participants maintain their weight during pregnancy and improve their pregnancy outcomes. It combined dietary and exercise recommendations with behavioural self-management techniques. The intervention diet recommended an energy-reduced eating plan based on the DASH dietary pattern without sodium restriction. Participants were encouraged to accumulate at least 30 minutes of moderate physical activity per day. Intervention participants attended two individual counselling sessions and started attending weekly group sessions. The group sessions were designed to help participants set reasonable short-term goals, formulate action	Control participants in our study received a one-time advice session from the study dietitian. They were given general information about healthy eating during pregnancy, without specific focus on the DASH dietary pattern or weight management. The dietitian provided feedback on their food diaries and advised them to follow their obstetrical care providers' recommendations. It is important to note that our study did not provide routine prenatal care to either group of participants. The information provided through the study was given in addition to their regular medical care.	**Maternal Outcomes:** • GDM

TABLE 33 Non-individual participant data trials (*continued*)

			plans and develop sources of reinforcement and social support to support behaviour change. Each 90-minute group session included a nutrition and/or exercise topic, a behaviour change topic, and a goal-setting activity for the next week.		
	Blinding: Not reported	**Exclusion criteria:** • DM or other medical conditions requiring specialised nutritional care (e.g. a history of bariatric surgery) • Has plans to leave the area during the expected follow-up period (through 1 year post partum) **Number of participants:** Intervention, *n* = 56 Control, *n* = 58 **Type of intervention:** Mixed			• Gestational hypertension • PE • Caesarean delivery **Neonatal outcomes:** • LGA • Macrosomia • SGA • Preterm birth (< 37 weeks) • Preterm birth (< 34 weeks) • NICU admission
Wang *et al.*, 2016;[97] English (China)	**Method of randomisation:** Women were randomly allocated to either the IG or the CG in a 1 : 1 ratio **Allocation concealment:** Not reported **Blinding:** Not reported	**Inclusion criteria:** • Pregnant women with a mean pre-pregnancy BMI of 26 kg/m^2 and above • Before 12–16 gestational week	Participants randomised to the IG engaged in a supervised cycling programme (3 times/week).	Participants allocated to the CG continued with their usual daily activities (not detailed).	**Outcomes:** • GDM • 75-g OGTT blood glucose levels

continued

TABLE 33 Non-individual participant data trials (*continued*)

		Exclusion criteria: • Not listed **Number of participants:** Intervention, *n* = 132 Control, *n* = 133 **Type of intervention:**Physical activity			
Xu *et al.*, 2021;[120] English (China)	**Method of randomisation:** Each participant was randomly placed into the IG or the CG according to the group result produced by a statistician using a computer in the clinic room	**Inclusion criteria:**	Firstly, the participants were educated on the importance of weight management during pregnancy and the adverse outcomes of excessive GWG. The education was provided by obstetricians.	Standard obstetrical care	**Outcomes:**
	Allocation concealment: Not reported	• Pregnant women with excessive GWG according to the IoM guidelines, singleton pregnancy, no complications before pregnancy (i.e. type 2 DM, pre-pregnancy hypertension, and renal, immunologic, or hepatic diseases)	Secondly, the nutritionists assessed the participants' dietary habits. All participants in the IG were given a dietary habit questionnaire and a 3-day 24-hour dietary survey. Based on their answers, the pregnant women were instructed to adjust their dietary structure and guide their lifestyle adjustment on eating speed, drinking frequency, and work and rest time.		• GDM
	Blinding: No blinding method used	**Exclusion criteria:**	Thirdly, individual meal plans were given by nutritionists. The pregnant women's basal metabolic rate was analysed to determine their initial target energy, which is basal metabolism plus 300–500 kcal. Then, the daily target energy and food amount were fine-tuned according to the patient's body fat rate, weight, exercise, dietary habits, and so on, based on the 2016 Dietary Guidelines for Pregnant Women in China.		• GWG

TABLE 33 Non-individual participant data trials (*continued*)

	• Pregnancy outcome data were not available	Fourthly, the participants were prescribed physical activity according to the ACOG recommendations for at least 150 minutes per week of moderate-intensity aerobic activity or at least walking 5000 steps daily until delivery. The participants were asked to record the number of daily exercise steps for 5–7 days every month to evaluate their daily exercise status.	• Premature rupture of membrane
		The participants were asked to weigh themselves weekly with the goal of meeting target IoM weight in the second and third trimesters. During their check-ups, all dietary and exercise plans were assessed and readjusted based on the participants' progress. The nutritionist was also available for counselling during the entire study.	• Post partum haemorrhage
	Number of participants: Intervention, *n* = 203	The participants accepted the intervention from the time of inclusion. The IG and the CG received standard dietary advice and precautions from the doctors in the Department of Obstetrics and Gynecology.	• PE
	Control, *n* = 145		• Gestational hypertension
	Type of intervention: Diet		• Thyroid diseases • Anaemia • Uterine inertia • Abnormal amniotic fluid

Appendix 2 TIDieR intervention core components of individual participant data studies

TABLE 34 TIDieR intervention core components of IPD studies

Study name	Intervention type	Theory (yes/no)	Resources	Structure	Method	Facilitators	Prior training	Location	Duration	Number of sessions	On-going supportt	Gestation weeks
Arthur 2020	Mixed	No	Self-monitoring tool	Individual	Face-to-face	N/A	No/NR	Other	Moderate	Low	No	≥ 20
Assaf-Balut 2017	Diet	No	None	Group	Face-to-face	Allied health staff	No/NR	Hospital/antenatal clinic	Low	Low	No	< 20
Baciuk 2008	Exercise	No	Other resource	Group	Face-to-face	Allied health staff	No/NR	Exercise centre	High	High	No	< 20
Barakat 2008	Exercise	No	Other resource	Group	Face-to-face	Allied health staff	Yes	Hospital/antenatal clinic	Moderate	High	Yes	≥ 20
Barakat 2011	Exercise	No	None	Group	Face-to-face	Allied health staff	No/NR	Hospital/antenatal clinic	High	High	No	< 20
Barakat 2012a	Exercise	No	None	Group	Face-to-face	Allied health staff	No/NR	Hospital/antenatal clinic	High	High	No	< 20
Barakat 2016	Exercise	No	None	Group	Face-to-face	Allied health staff	No/NR	Hospital/antenatal clinic	High	High	No	< 20
Barakat 2018	Exercise	No	None	Group	Face-to-face	Allied health staff	No/NR	Hospital/antenatal clinic	High	High	No	< 20
Bisson 2015	Exercise	No	None	Individual	Face-to-face	Allied health staff	No/NR	Exercise centre	Low	High	No	< 20
Bogaerts 2012	Mixed	Yes	Other resource	Group	Face-to-face	Medical staff	Yes	Hospital/antenatal clinic	Moderate	Low	No	< 20
Bruno 2016	Mixed	No	Self-monitoring tool	Individual	Face-to-face	Allied health staff	No/NR	Hospital/antenatal clinic	High	Low	No	< 20
Chao 2017	Mixed	Yes	Self-monitoring tool	Individual	Face-to-face + Remote	Allied health staff	Yes	Hospital/antenatal clinic	Moderate	High	Yes	< 20
Cordero 2014	Exercise	No	None	Group	Face-to-face	Allied health staff	No/NR	Exercise centre	High	High	No	< 20
Dekker 2015	Exercise	No	Other resource	Individual	Face-to-face	Allied health staff	No/NR	Hospital/antenatal clinic	High	Low	Yes	< 20
Dodd 2014	Mixed	Yes	Combination	Individual	Face-to-face	Allied health staff	Yes	Hospital/antenatal clinic	Moderate	Low	Yes	< 20
Dodd 2019	Mixed	Yes	Combination	Individual	Face-to-face	Allied health staff	Yes	Hospital/antenatal clinic	Moderate	Low	Yes	< 20
ESTEEM (Al Wattar 2019)	Diet	Yes	None	Individual	Face-to-face	Allied health staff	Yes	Hospital/antenatal clinic	Moderate	Low	Yes	< 20
El Beltagy 2013	Mixed	No	Combination						Low			< 20
Garmendia 2020	Mixed	No	None	Individual	Face-to-face	Allied health staff	Yes	Hospital/antenatal clinic	High	High	No	< 20
Garnaes 2016	Exercise	Yes	Self-monitoring tool	Group	Face-to-face	Allied health staff	No/NR	Hospital/antenatal clinic	Moderate	High	No	< 20
Guelinckx 2010	Mixed	Yes	Other resource	Group	Face-to-face	Allied health staff	Yes	Hospital/antenatal clinic	Moderate	Low	No	< 20
Harrison 2013	Mixed	Yes	Combination	Individual	Face-to-face	Allied health staff	No/NR	Hospital/antenatal clinic	Low	Low	No	< 20

continued

TABLE 34 TIDieR intervention core components of IPD studies (*continued*)

Study name	Intervention type	Theory (yes/no)	Resources	Structure	Method	Facilitators	Prior training	Location	Duration	Number of sessions	On-going supportt	Gestation weeks
Hawkins 2014	Mixed	Yes	Combination	Individual	Face-to-face + Remote	Other	Yes	Hospital/antenatal clinic	High	Moderate	Yes	< 20
Hui 2011	Mixed	No	Combination	Group	Face-to-face	Allied health staff	No/NR	Exercise centre	Low	Moderate	No	≥ 20
Hui 2014	Mixed	No	Combination	Group	Face-to-face + Remote	Allied health staff	No/NR	Exercise centre	Low	High	No	≥ 20
Jeffries 2009	Mixed	No	Self-monitoring tool	Individual	Face-to-face	Medical staff	No/NR	Hospital/antenatal clinic	High	Low	No	< 20
Kennelly 2018	Mixed	Yes	Other resource	Group	Face-to-face	Allied health staff	No/NR	Hospital/antenatal clinic	High	Low	Yes	< 20
Khaledan 2010	Exercise	No	None	Group	Face-to-face	Other	No/NR	Hospital/antenatal clinic	Low	High	No	≥ 20
Khoury 2005	Diet	No	Other resource	Individual	Face-to-face	Allied health staff	No/NR	Hospital/antenatal clinic	Moderate	Low	No	< 20
Kunath 2019	Mixed	No	Combination	Individual	Face-to-face	Medical staff	Yes	Hospital/antenatal clinic	Moderate	Low	No	< 20
Luoto 2011	Mixed	Yes	Other resource	Individual	Face-to-face	Medical staff	Yes	Hospital/antenatal clinic	High	Moderate	Yes	< 20
McCarthy 2016	Diet	No	Combination	Individual	Face-to-face	Medical staff	No/NR	Hospital/antenatal clinic	Moderate	Low	Yes	≥ 20
Nascimento 2011	Exercise	No	Self-monitoring tool	Group	Face-to-face	Allied health staff	Yes	Hospital/antenatal clinic	Low	Moderate	No	≥ 20
Olson 2018	Mixed	Yes	Combination	Individual	Remote	NA	NA	Other	Moderate	NA	Yes	≥ 20
Ong 2009	Exercise	No	Other resource	Individual	Face-to-face	Other	No/NR	Other	Low	High	No	< 20
Oostdam 2012	Exercise	No	None	Group	Face-to-face	Allied health staff	Yes	Hospital/antenatal clinic	Low	High	No	≥ 20
Peleaz 2019	Exercise	No	None	Group	Face-to-face	Allied health staff	No/NR	Hospital/antenatal clinic	High	High	No	< 20
Perales 2014	Exercise	No	None	Group	Face-to-face	Allied health staff	No/NR	Hospital/antenatal clinic	High	High	No	< 20
Petrella 2013	Mixed	No	Self-monitoring tool	Individual	Face-to-face	Allied health staff	No/NR	Hospital/antenatal clinic	High	Low	No	< 20
Phelan 2011	Mixed	Yes	Combination	Individual	Face-to-face	Allied health staff	No/NR	Other	Moderate	Low	Yes	< 20
Phelan 2018	Mixed	Yes	Combination	Individual	Face-to-face	Allied health staff	No/NR	Other	Moderate	Moderate	No	< 20
Poston 2013	Mixed	Yes	Combination	Individual	Face-to-face + Remote	Allied health staff	Yes	Hospital/antenatal clinic	High	Moderate	Yes	≥ 20
Poston 2015	Mixed	Yes	Combination	Group	Face-to-face + Remote	Other	Yes	Hospital/antenatal clinic	Low	Moderate	Yes	< 20

TABLE 34 TIDieR intervention core components of IPD studies (*continued*)

Study name	Intervention type	Theory (yes/no)	Resources	Structure	Method	Facilitators	Prior training	Location	Duration	Number of sessions	On-going supportt	Gestation weeks
Rauh 2013	Mixed	Yes	Self-monitoring tool	Individual	Face-to-face	Other	Yes	Hospital/antenatal clinic	Low	Low	No	≥ 20
Renault 2013	Diet	No	Self-monitoring tool	Individual	Face-to-face	Allied health staff	No/NR	Hospital/antenatal clinic	High	Moderate	Yes	< 20
Rono 2018	Mixed	No	None	Individual	Face-to-face	Medical staff	No/NR	Hospital/antenatal clinic	High	Low	No	< 20
Ruiz 2013	Exercise	No	None	Group	Face-to-face	Allied health staff	No/NR	Exercise centre	High	High	No	< 20
Sagedal 2017	Mixed	No	Other resource	Group	Face-to-face + Remote	Allied health staff	Yes	Exercise centre	Moderate	High	Yes	≥ 20
Stafne 2012	Exercise	No	None	Group	Face-to-face	Allied health staff	No/NR	Hospital/antenatal clinic	Low	Moderate	No	≥ 20
Vinter 2011	Mixed	Yes	Self-monitoring tool	Group	Face-to-face	Allied health staff	No/NR	Exercise centre	Moderate	High	No	< 20
Vitolo 2011	Diet	No	Other resource	Individual	Face-to-face	Other	No/NR	Hospital/antenatal clinic	Low	Low	No	≥ 20
Walsh 2012	Diet	No	Other resource	Group	Face-to-face	Allied health staff	No/NR	Hospital/antenatal clinic	Moderate	Low	No	< 20
Willcox 2017	Mixed	Yes	Combination	Individual	Face-to-face + Remote	Allied health staff	No/NR	Hospital/antenatal clinic	Low	Moderate	Yes	≥ 20
Wolff 2008	Diet	No	None	Individual	Face-to-face	Allied health staff	Yes	Hospital/antenatal clinic	NAC	Moderate	No	< 20

N/A, not applicable; NR, not reported.

Appendix 3 Risk-of-bias assessment for included studies

TABLE 35 Risk of Bias assessment for included individual patient data studies

Study ID	1: Randomisation	2: Allocation concealment	3: Blinding of participants	4: Blinding of outcome assessment	5: Incomplete outcome data	6: Selective reporting	Overall risk of bias (ignoring item 3 and 6)
Arthur 2020	Low	Low	High	High	Low	Unclear	High
Assaf-Balut 2017	Low	High	High	Low	Low	Unclear	High
Barakat 2012	Low	Unclear	Unclear	Unclear	High	Low	High
Baciuk 2008	Low	Low	High	Low	Low	Low	Low/medium
Barakat 2008	Unclear	Unclear	Unclear	Low	Low	Low	Low/medium
Barakat 2011	Low	Unclear	Unclear	Unclear	Low	Low	Low/medium
Bogaerts 2012	Low	Unclear	High	High	Low	Low	High
Barakat 2015	Low	Low	Unclear	Low	Low	Low	Low/medium
Barakat 2018	Low	Low	Unclear	Unclear	Low	Unclear	Low/medium
Bisson 2015	Low	Low	High	Low	Low	Low	Low/medium
Bruno 2016	Low	Unclear	High	Low	High	Low	High
Chao 2017	Unclear	Unclear	Unclear	Unclear	Low	Unclear	High
Cordero 2014	Unclear	Unclear	High	Unclear	High	Low	High
Dekker 2015	Low	Low	Unclear	Unclear	Low	Low	Low/medium
Dodd 2014	Low	Low	Unclear	Low	Low	Low	Low/medium
Dodd 2019	Low	Low	High	Low	Low	Low	Low/medium
El Beltagy 2013	Low	Low	Unclear	Low	Low	Unclear	Low/medium
Al Wattar 2019	Low	Low	High	Low	Low	Low	Low/medium
Garmendia 2020	Low	Low	High	Unclear	Low	Low	Low/medium
Garnaes 2016	Low	Low	High	Low	Low	Low	Low/medium
Guelinckx 2010	Low	Unclear	Unclear	High	High	High	High
Harrison 2013	Low	Low	Unclear	Low	Low	Low	Low/medium
Hawkins 2015	Unclear	Unclear	Unclear	Low	Low	Low	Low/medium
Hui 2011	Low	Unclear	High	Unclear	Low	Low	Low/medium
Hui 2014	Low	Unclear	High	Low	Low	High	Low/medium
Jeffries 2009	Low	Low	Unclear	Low	Low	Low	Low/medium

continued

TABLE 35 Risk of Bias assessment for included individual patient data studies (*continued*)

Study ID	1: Randomisation	2: Allocation concealment	3: Blinding of participants	4: Blinding of outcome assessment	5: Incomplete outcome data	6: Selective reporting	Overall risk of bias (ignoring item 3 and 6)
Kennelly 2018	Low	Low	High	Unclear	Low	Unclear	Low/medium
Khaledan 2010	Low	Unclear	High	High	Low	Low	High
Khoury 2005	Low	Low	Unclear	Low	Low	Low	Low/medium
Kunath 2019	Unclear	Unclear	Unclear	Unclear	Low	Unclear	High
Luoto 2011	Low	Low	High	High	Low	Low	High
McCarthy 2016	Low	Low	High	Low	Low	Low	low/medium
Nascimento 2011	Low	Low	High	High	Low	Low	High
Olson 2018	Low	Unclear	Low	Unclear	Low	Unclear	Low/medium
Ong 2009	Low	Unclear	High	High	Low	Low	High
Oostdam 2012	Low	Low	High	Low	High	Low	High
Peleaz 2019	Low	Unclear	High	Unclear	Low	Unclear	Low/medium
Perales 2014	Low	Low	High	Low	Low	Low	Low/medium
Petrella 2013	Low	High	High	High	Low	High	High
Phelan 2011	Low	Low	Unclear	Low	Low	Low	Low/medium
Phelan 2018	Low	Unclear	High	Unclear	Low	Unclear	Low/medium
Poston 2013	Low	Low	High	Unclear	Low	Low	Low/medium
Poston 2015	Low	Low	High	High	Low	Low	High
Rauh 2013	Low	Low	High	High	Low	Unclear	High
Renault 2013	Low	Low	High	High	Low	High	High
Rono 2018	Low	Low	High	Unclear	Low	Unclear	Low/medium
Ruiz 2013	Low	Unclear	Unclear	Unclear	Low	Unclear	Low/medium
Sagedal 2016	Low	Low	Unclear	Low	Low	High	Low/medium
Stafne 2012	Low	Low	High	High	Low	Low	High
Vinter 2011	Low	Low	High	High	Low	High	High
Vitolo 2011	Low	High	High	Low	Low	High	Low/medium
Walsh 2013	Low	Low	High	Unclear	Low	High	Low/medium
Willcox 2017	Low	Low	High	Unclear	Low	Low	Low/medium

TABLE 36 Risk of Bias assessment for included Non-individual participant data studies

Study ID	1: Randomisation	2: Allocation concealment	3: Blinding of participants	4: Blinding of outcome assessment	5: Incomplete outcome data	6: Selective reporting	Overall risk of bias (ignoring item 3 and 6)
Abdel-Aziz 2018	Low	Unclear	Unclear	Unclear	Unclear	Unclear	Low/medium
Barakat 2012	Unclear	Unclear	Unclear	Unclear	Low	Low	High
Barakat 2013	Unclear	Unclear	Unclear	Low	Low	Low	Low/medium
Barakat 2014	Low	Low	Unclear	Unclear	Low	Unclear	Low/medium
Barakat 2019	Low	Low	High	Unclear	Low	Unclear	Low/medium
Brownfoot 2016	Low	Low	High	Unclear	Low	Low	Low/medium
Buckingham 2019	Unclear	Unclear	High	Unclear	Low	Unclear	High
Cahill 2018	Low	Unclear	Unclear	Low	Low	Unclear	Low/medium
Chan 2018	Low	Low	High	Low	Low	Unclear	Low/medium
da Silva 2017	Low	Low	High	Low	Low	Low	Low/medium
Deng 2022	Low	Low	High	High	Low	Low	Low/medium
Ding 2021	Low	Low	High	Low	Unclear	Low	Low/medium
Eslami 2018	Unclear	Low	High	Low	Low	Low	Low/medium
Ferrera 2020	Low	Unclear	High	Low	Low	Unclear	Low/medium
Gonzalez-Plaza 2022	Low	Low	Unclear	Unclear	High	Low	High
Hajian 2020	Low	Low	Unclear	Unclear	Low	Unclear	Low/medium
Herring 2016	Low	Low	Unclear	Unclear	Low	Low	Low/medium
Horn 2018	Low	Low	High	Low	Low	Unclear	Low/medium
Ko 2014	Low	Unclear	Unclear	Low	Low	Low	Low/medium
Kong 2014	Low	Low	High	Unclear	Low	Low	Low/medium
Korpi-Hyovalti 2012	Low	Low	High	High	Low	High	High
Liu 2022	Low	Unclear	Unclear	Low	Low	Low	Low/medium
McDonald 2021	Low	Unclear	Unclear	Unclear	Low	Low	Low/medium
Okesene 2019	Low	Low	High	Low	Low	Unclear	Low/medium
Parat 2019	High	Low	High	Unclear	Low	Unclear	High
Perales 2016a	Low	Unclear	High	Low	High	Low	High

continued

TABLE 36 Risk of Bias assessment for included Non-individual participant data studies (*continued*)

Study ID	1: Randomisation	2: Allocation concealment	3: Blinding of participants	4: Blinding of outcome assessment	5: Incomplete outcome data	6: Selective reporting	Overall risk of bias (ignoring item 3 and 6)
Polley 2002	Unclear	Unclear	Unclear	Unclear	Low	Low	High
Price 2012	Low	Low	High	Unclear	High	Unclear	High
Quinlivan 2011	Low	Low	Unclear	Low	Low	Low	Low/medium
Rakhshani 2012	Low	Low	High	Low	High	Low	High
Seneviratne 2015	Low	Low	Unclear	Unclear	Low	Low	Low/medium
Simmons 2016	Low	Low	Unclear	Low	Low	Low	Low/medium
Thornton 2009	Low	Unclear	Unclear	Unclear	Low	Low	Low/medium
Tomic 2013	High	High	Unclear	Unclear	Low	Low	High
Trak-Fellermeier 2020	Low	Low	High	Unclear	Low	Unclear	Low/medium
Vesco 2014	Low	Unclear	Unclear	Unclear	Low	Low	Low/medium
Wang 2017	Unclear	Unclear	High	Unclear	Low	Low	High
Xu 2021	Low	Low	High	Unclear	High	Unclear	High

Appendix 4 Sensitivity analysis excluding individual participant data of studies at high risk of bias

TABLE 37 Effects of lifestyle interventions on GDM (any criteria) in IPD studies at low or medium risk of bias

Intervention	Source	Number of studies	Number of women	OR (95% CI)	95% PI	τ^2
Physical activity	IPD	11	2993	0.59 (0.43 to 0.82)	0.43 to 0.82	0.00 (0.00 to 0.44)
Diet	IPD	5	1930	0.89 (0.69 to 1.16)	0.66 to 1.21	0.00 (0.00 to 0.56)
Mixed	IPD	17	10,624	1.14 (1.01 to 1.29)	1.01 to 1.29	0.00 (0.00 to 0.09)
All	IPD	33	15,547	0.94 (0.82 to 1.08)	0.64 to 1.39	0.03 (0.00 to 0.13)

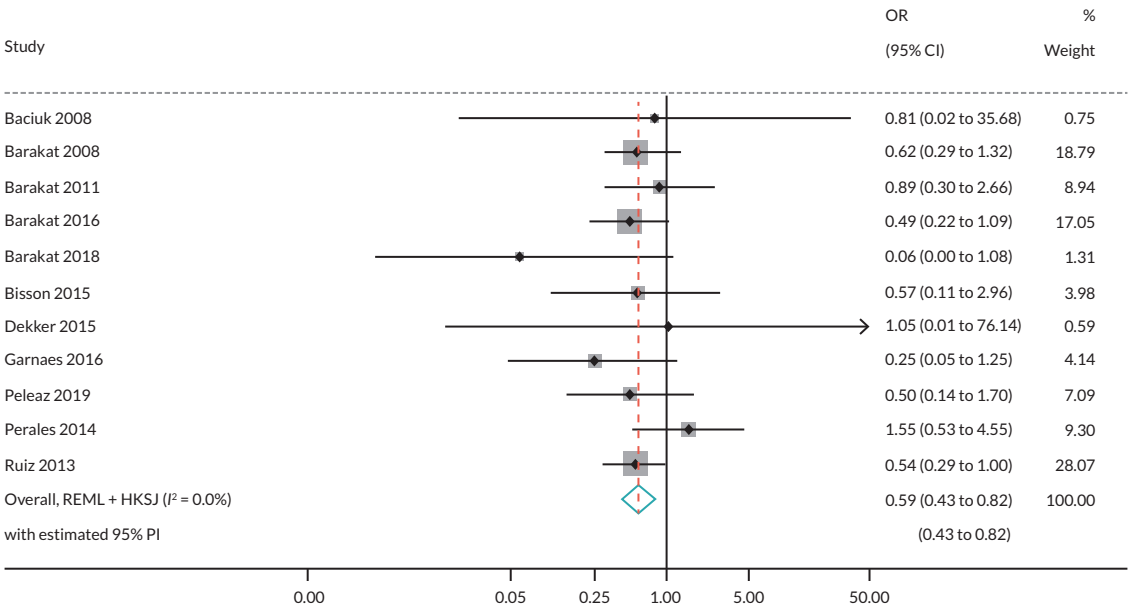

FIGURE 25 Effects of physical activity-based interventions on GDM (any criteria) in IPD studies at low or medium risk of bias.

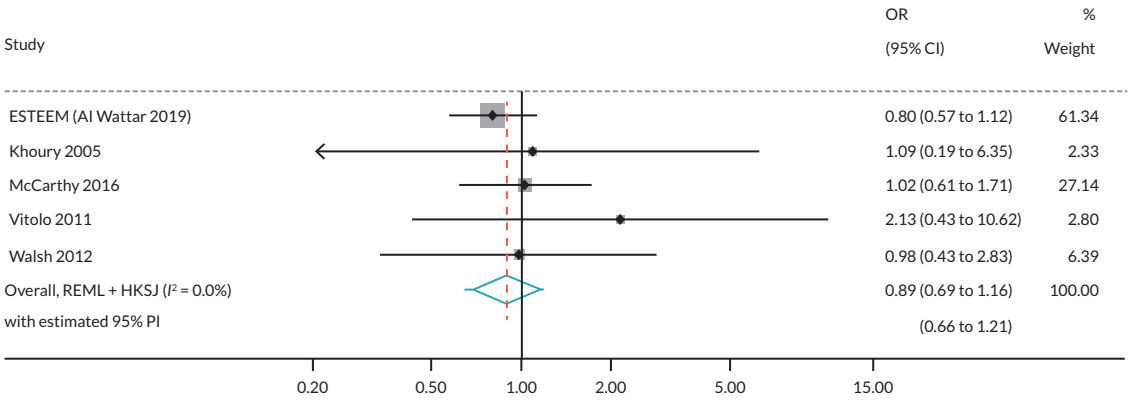

FIGURE 26 Effects of diet-based interventions on GDM (any criteria) in IPD studies at low or medium risk of bias.

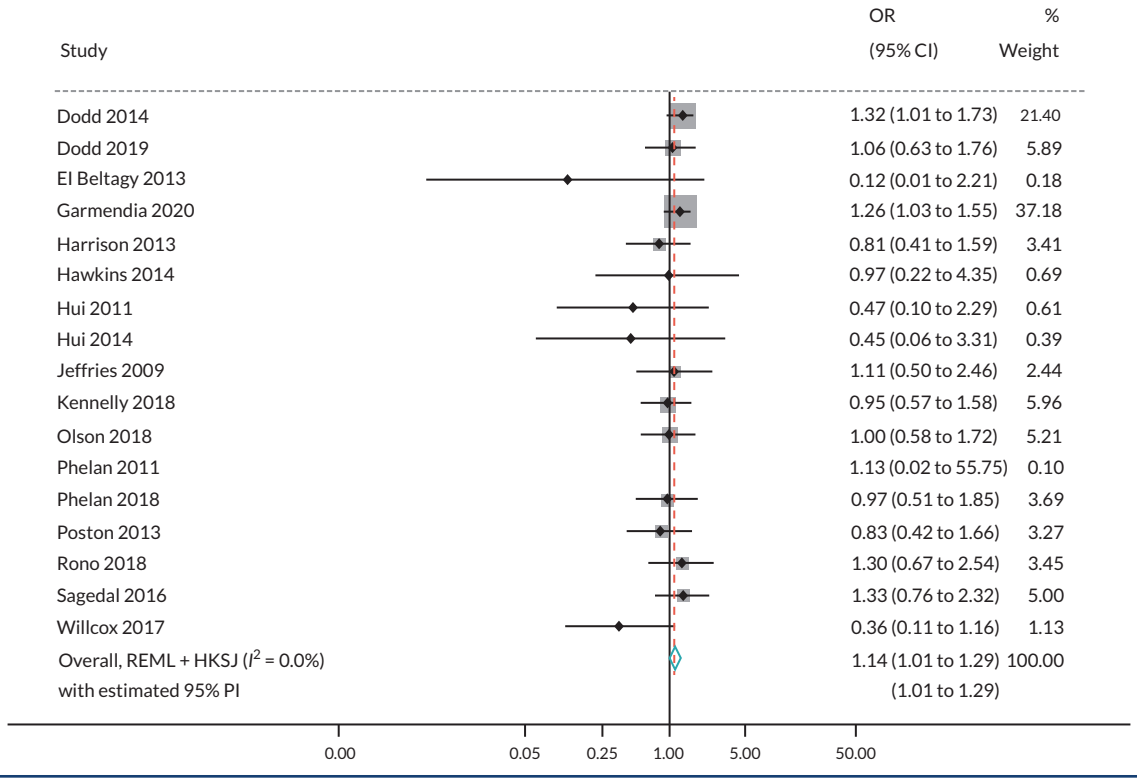

FIGURE 27 Effects of mixed interventions on GDM (any criteria) in IPD studies at low or medium risk of bias.

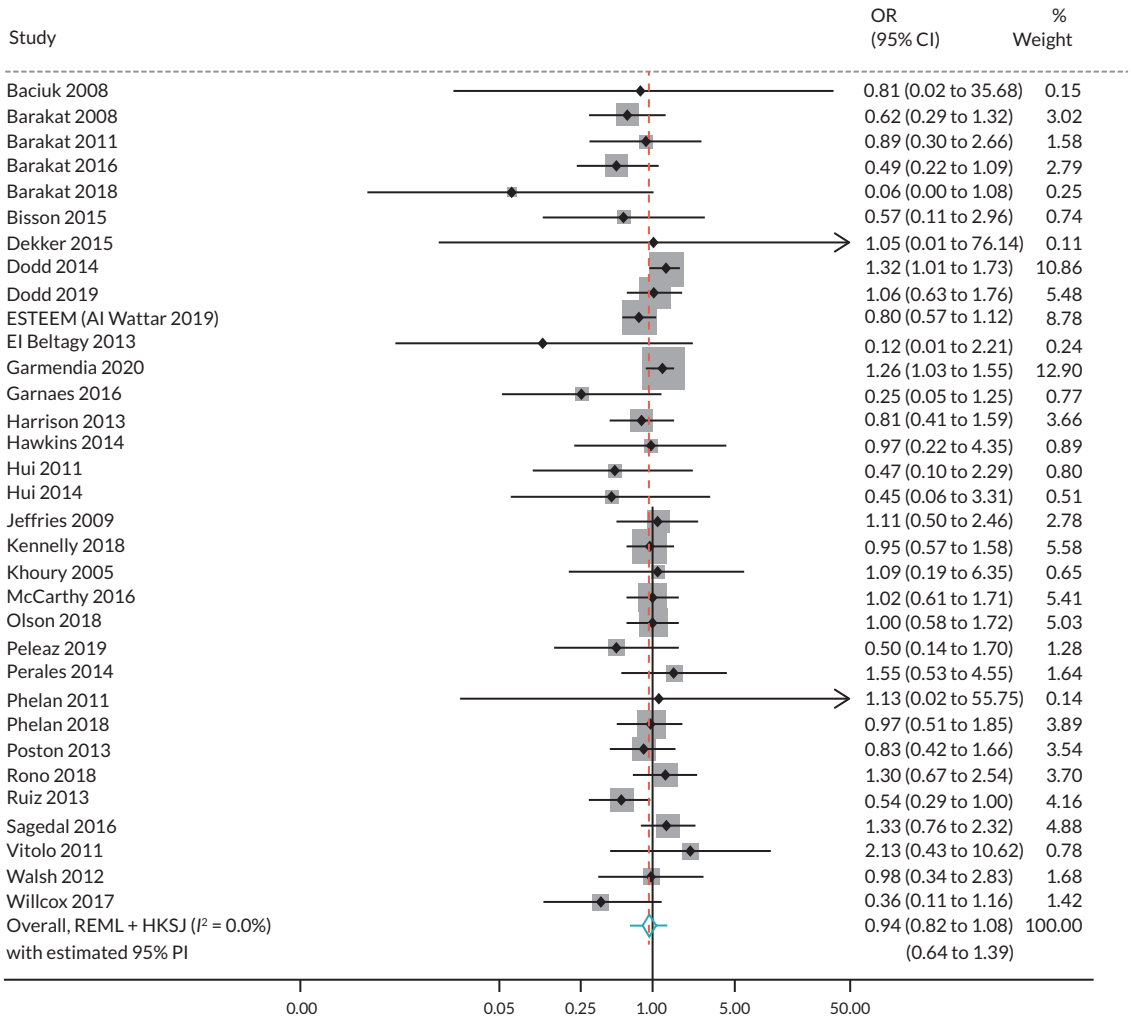

FIGURE 28 Effects of overall lifestyle interventions on GDM (any criteria) in IPD studies at low or medium risk of bias.

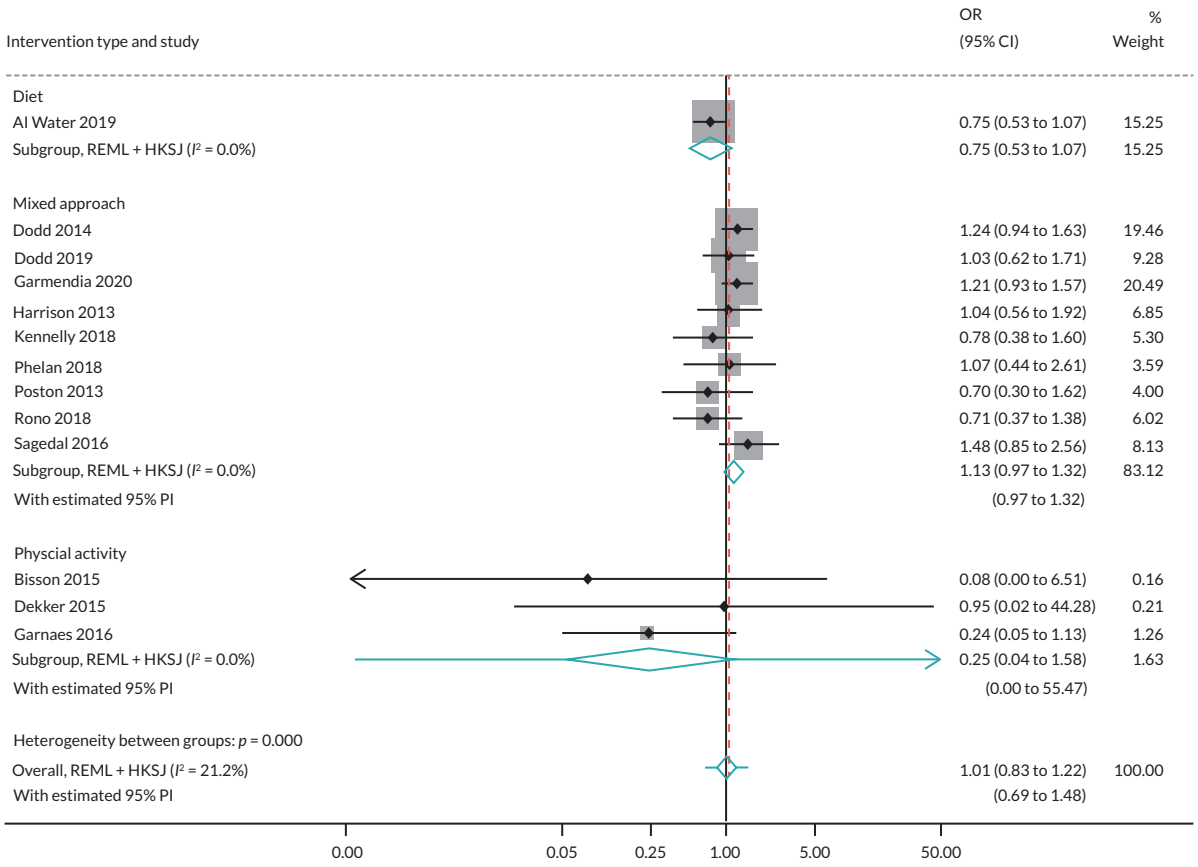

FIGURE 29 Effects of lifestyle interventions on GDM (NICE definition) in IPD studies at low or medium risk of bias. Note: Weights and between-subgroup heterogeneity test are from random-effects model.

TABLE 38 Effects of lifestyle interventions on GDM (NICE definition) in IPD studies at low or medium risk of bias

Intervention	Source	Number of studies	Number of women	OR (95% CI)	95% PI	τ^2
Physical activity	IPD	3	123	0.25 (0.04 to 1.58)	0 to 55.47	0.00 (0.00 to 23.81)
Diet	IPD	1	917	0.75 (0.53 to 1.07)	–	0.00 (0.00 to 0.00)
Mixed	IPD	9	5315	1.13 (0.97 to 1.32)	0.97 to 1.32	0.00 (0.00 to 0.11)
All	IPD	13	6355	1.01 (0.83 to 1.22)	0.69 to 1.48	0.02 (0.00 to 0.18)

Appendix 5 Forest plots for differential effects of lifestyle interventions on gestational diabetes mellitus (any criteria)

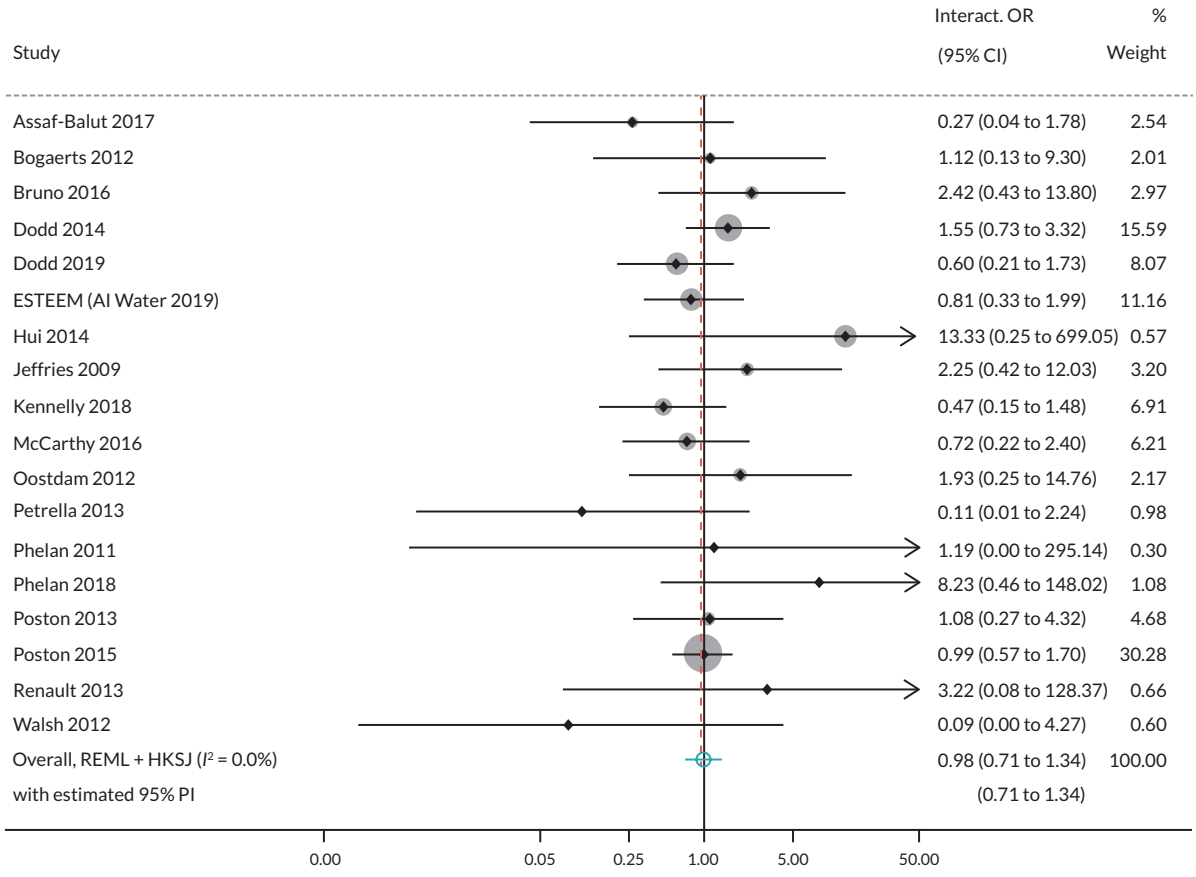

FIGURE 30 Ethnicity subgroup: non-White vs. White.

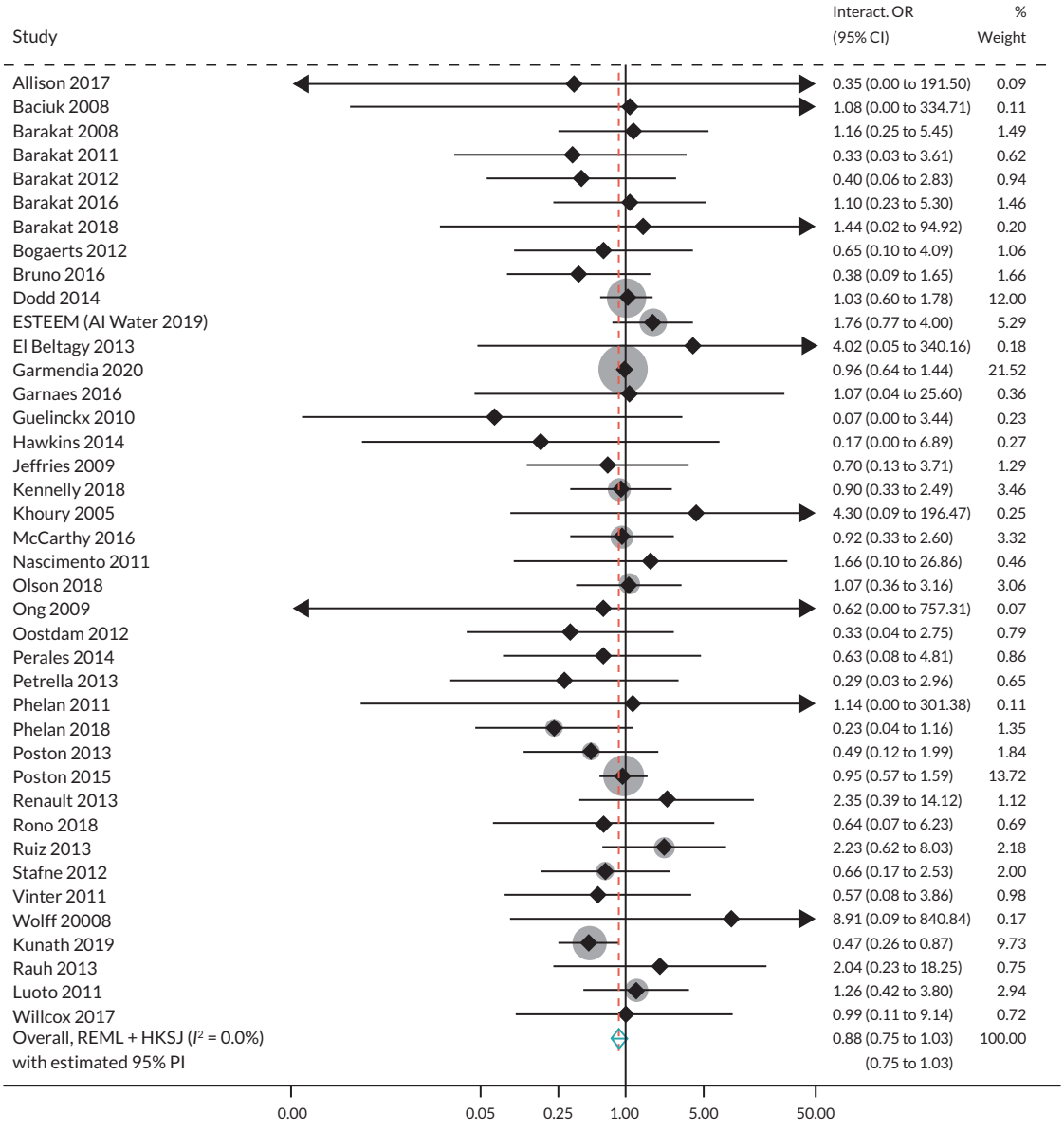

FIGURE 31 Parity subgroup: multiparous vs. nulliparous.

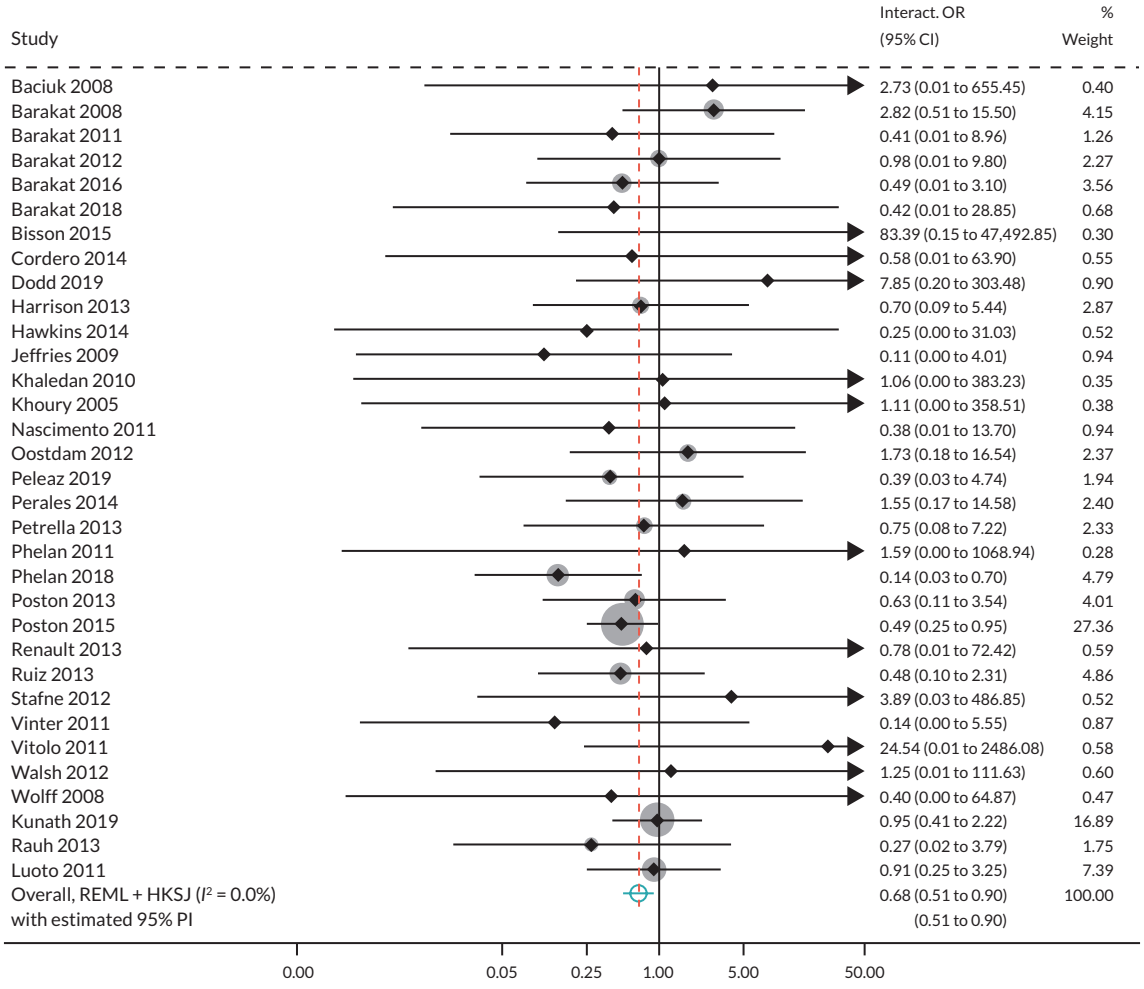

FIGURE 32 Education subgroup: middle education level vs. low education level.

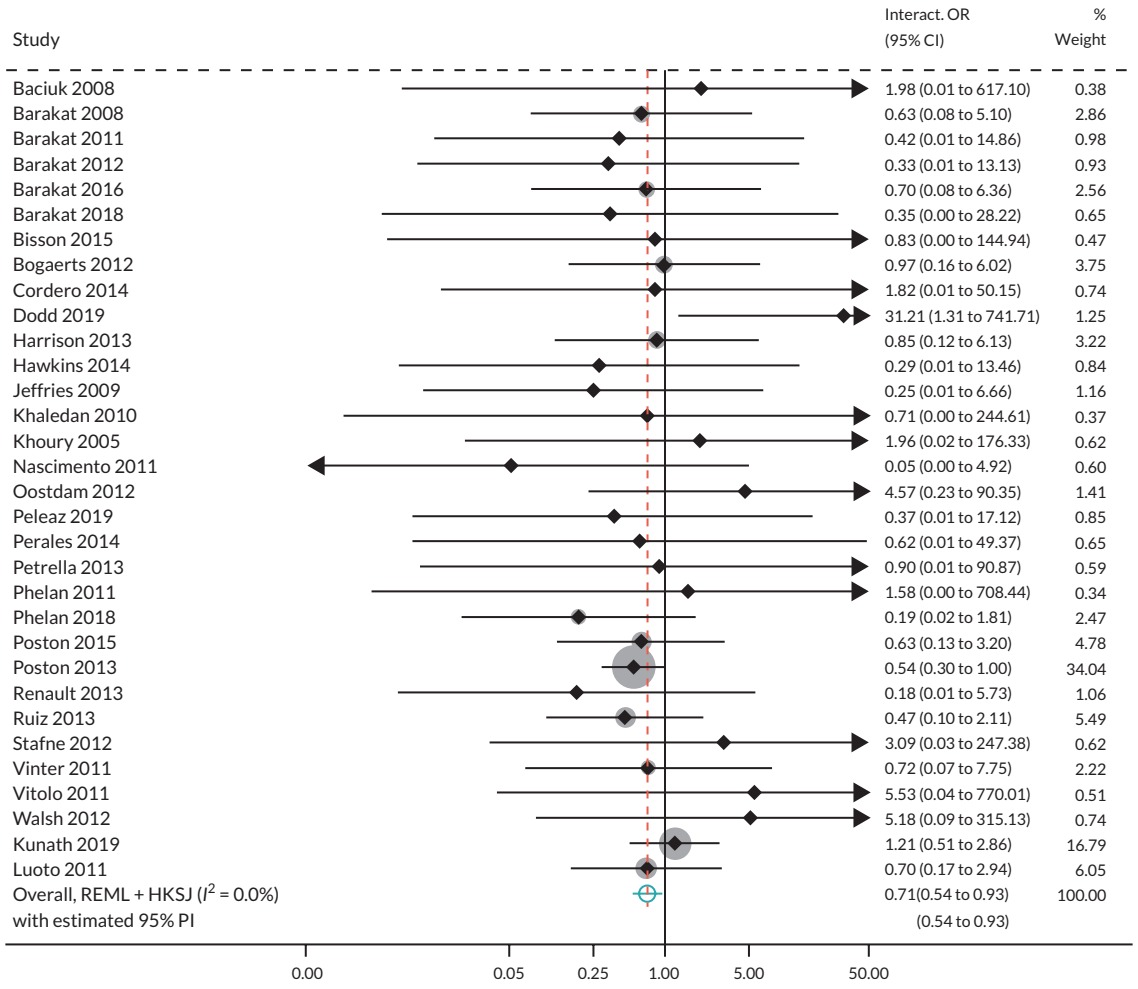

FIGURE 33 Education subgroup: high education level vs. low education level.

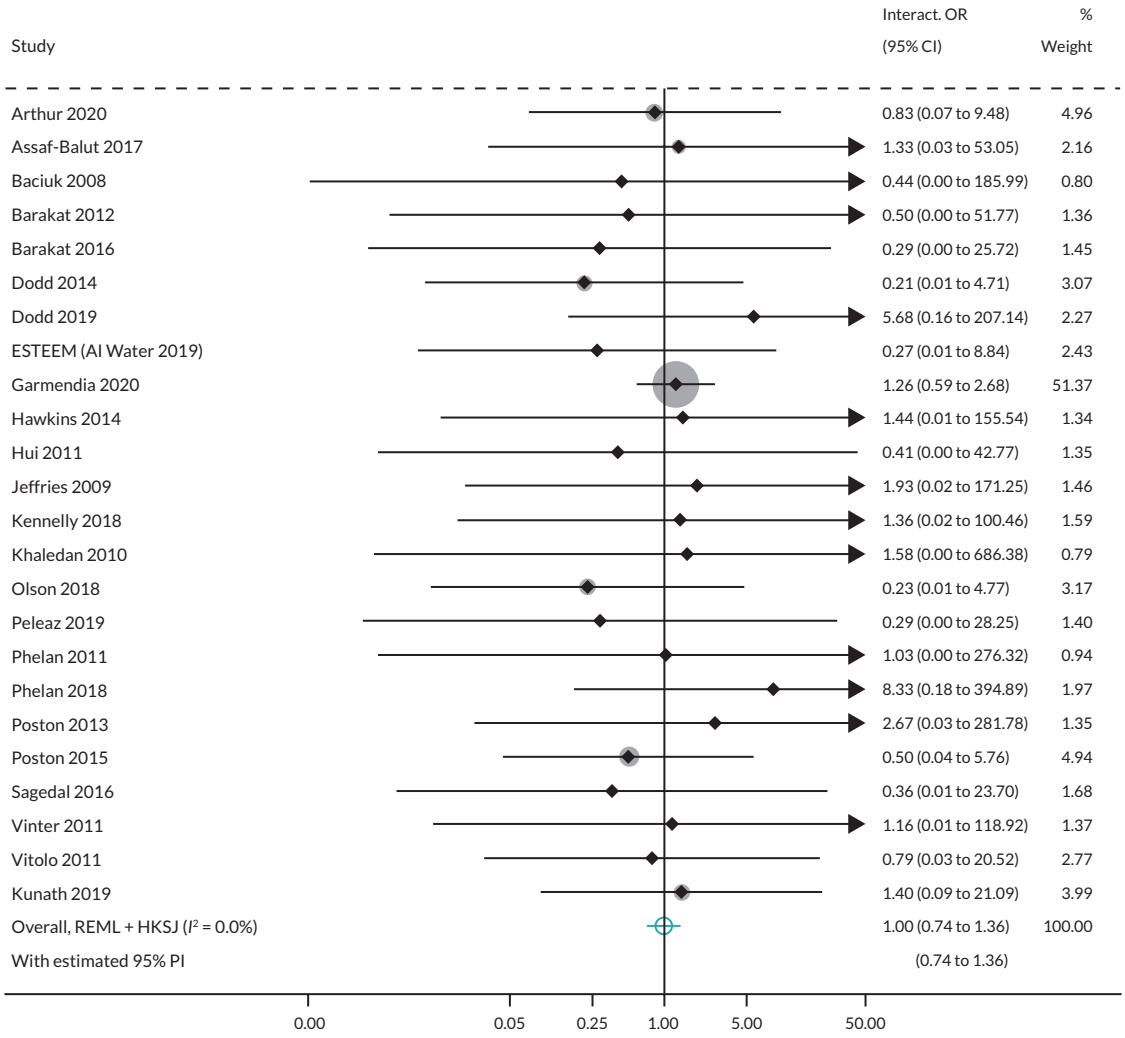

FIGURE 34 Age subgroup: ≥ 20 years old vs. < 20 years old.

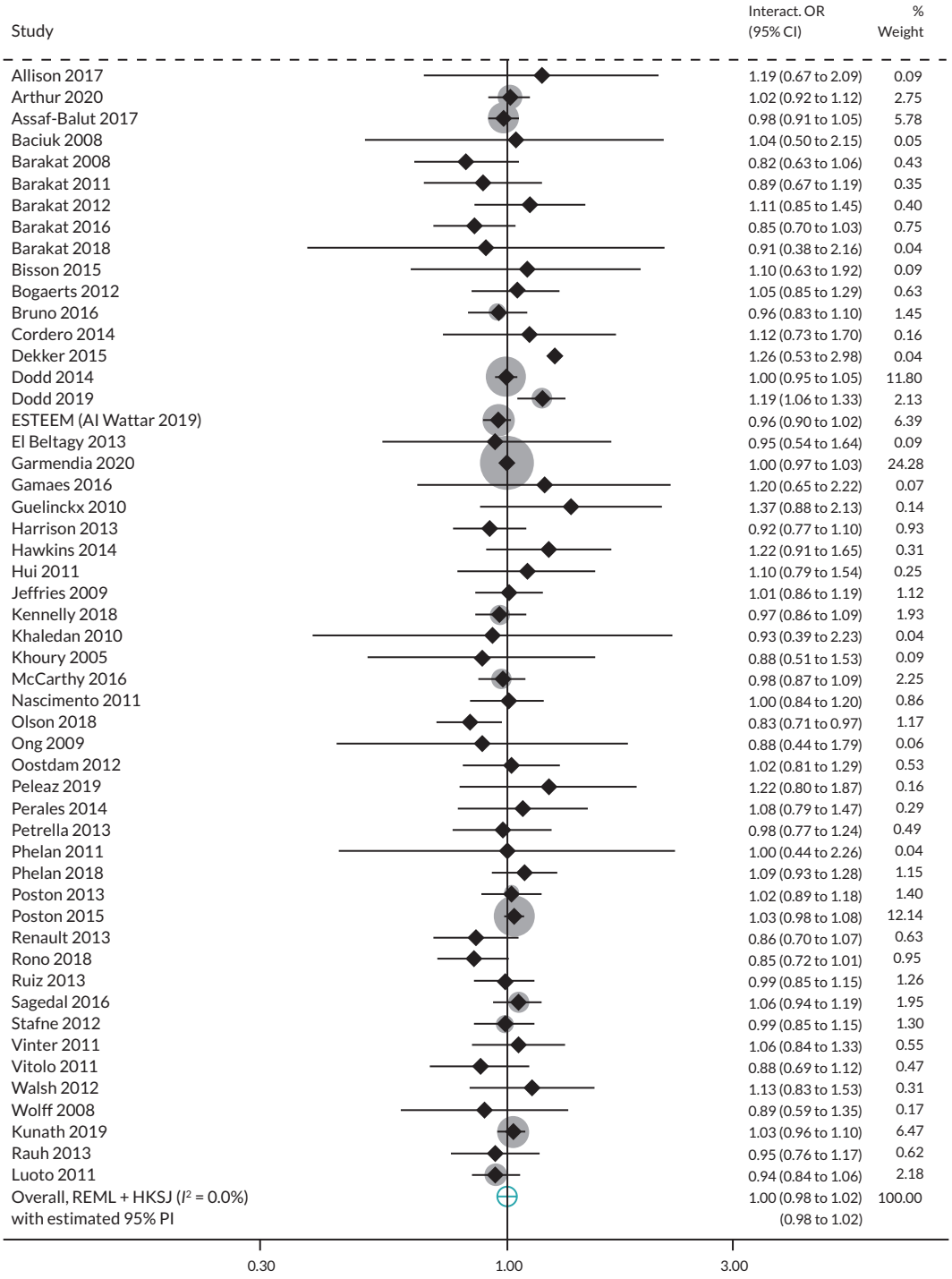

FIGURE 35 Age subgroup: per 1-year increase in age.

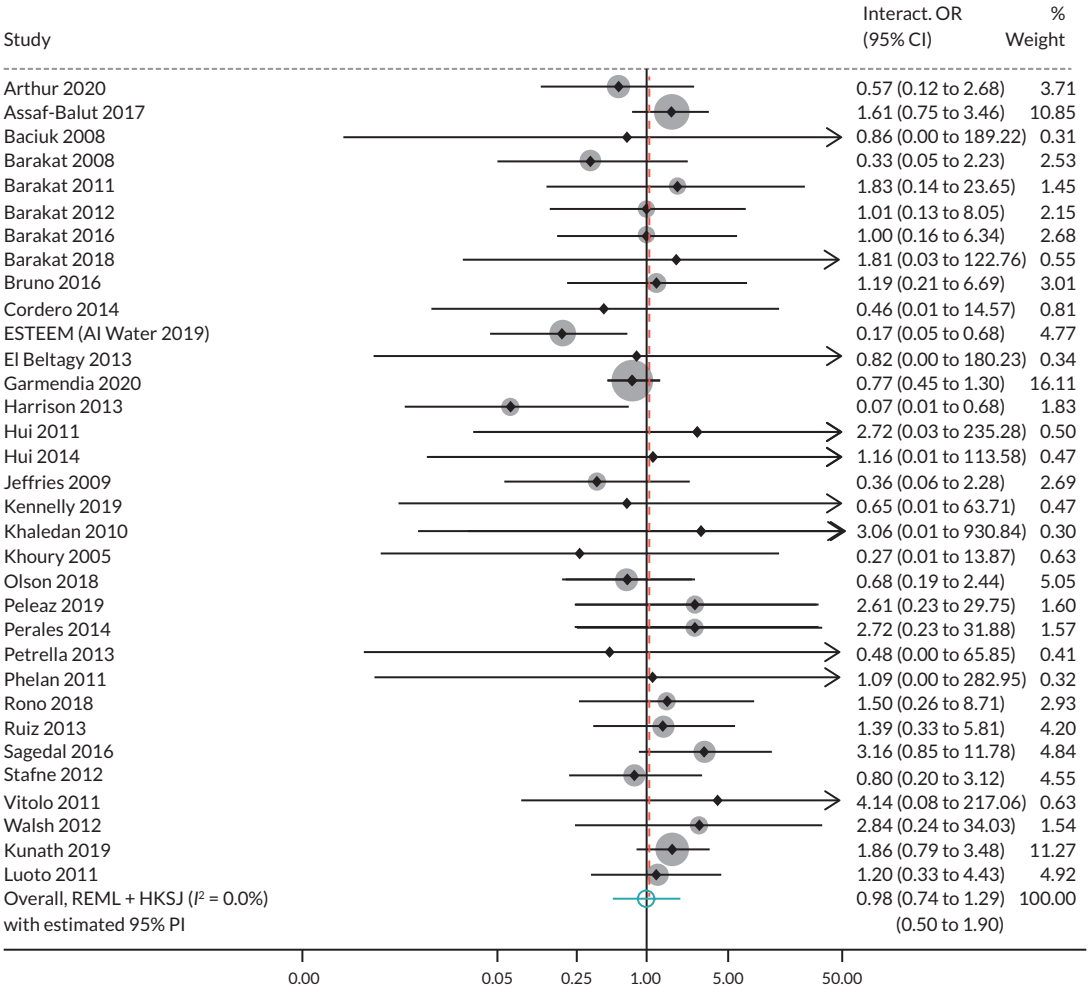

FIGURE 36 Body mass index subgroup: overweight vs. normal.

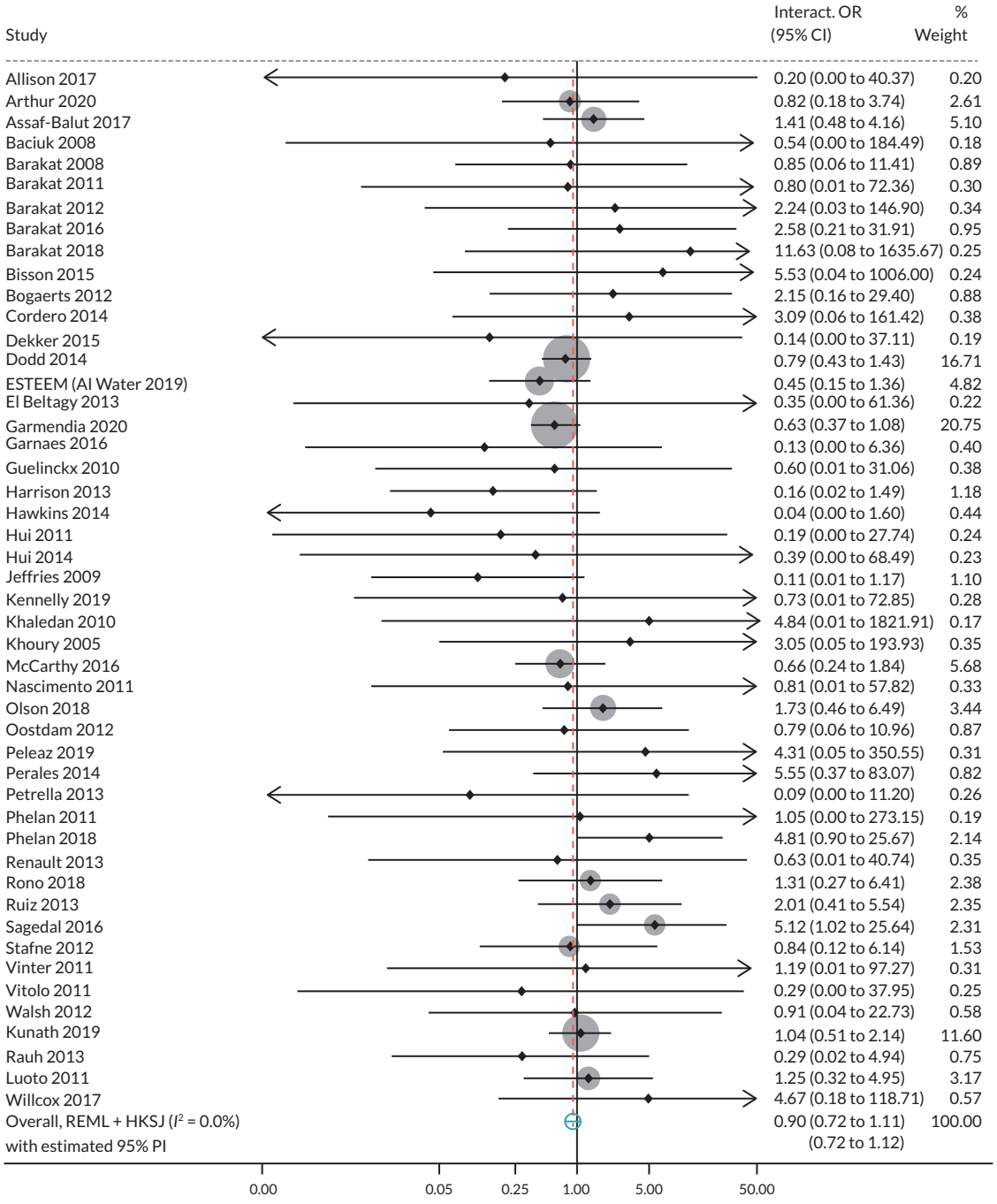

FIGURE 37 Body mass index subgroup: obese vs. normal.

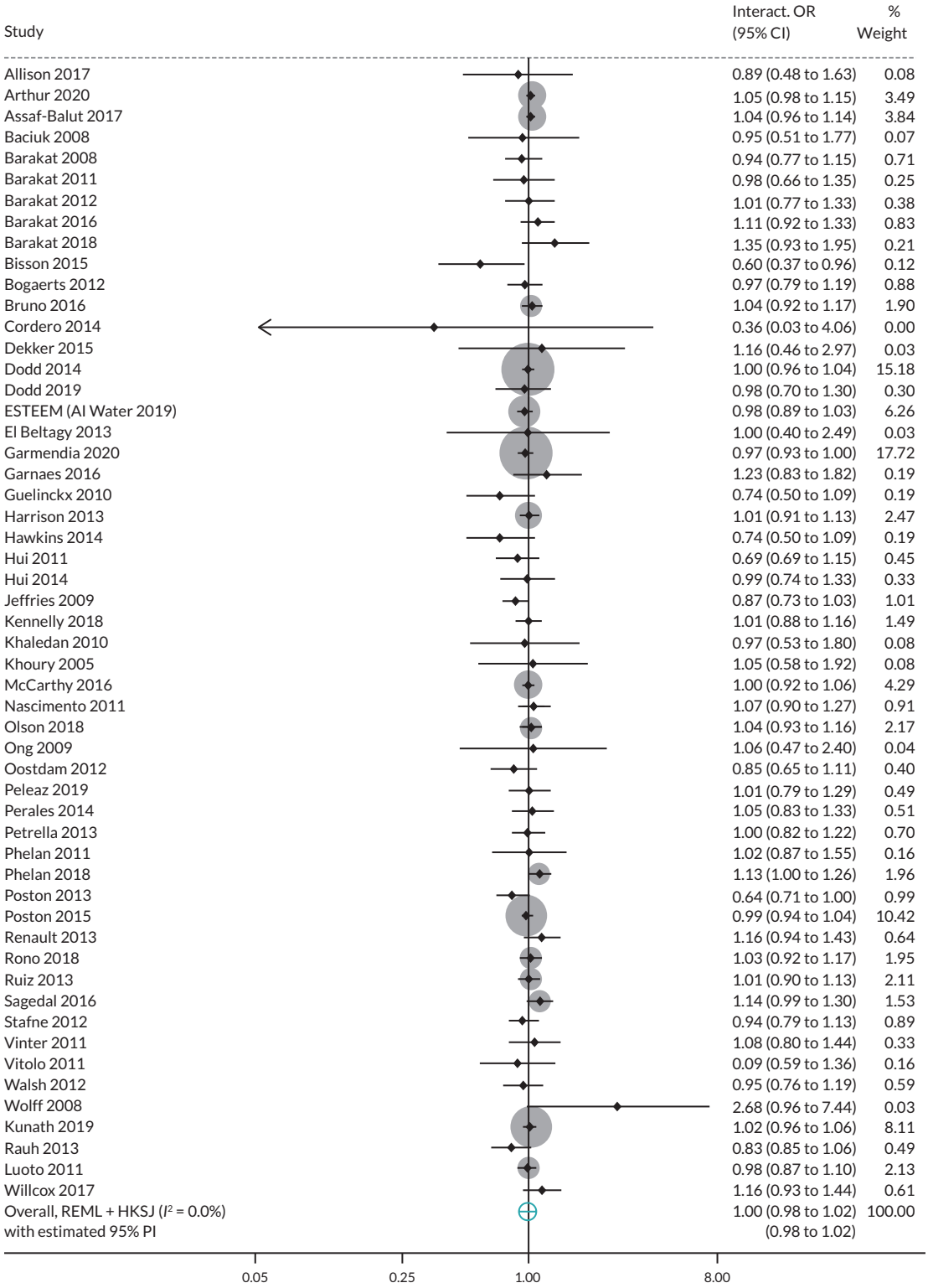

FIGURE 38 Body mass index subgroup: per unit increase in BMI.

Appendix 6 Forest plots for differential effects of lifestyle interventions on gestational diabetes mellitus (National Institute for Health and Care Excellence definition)

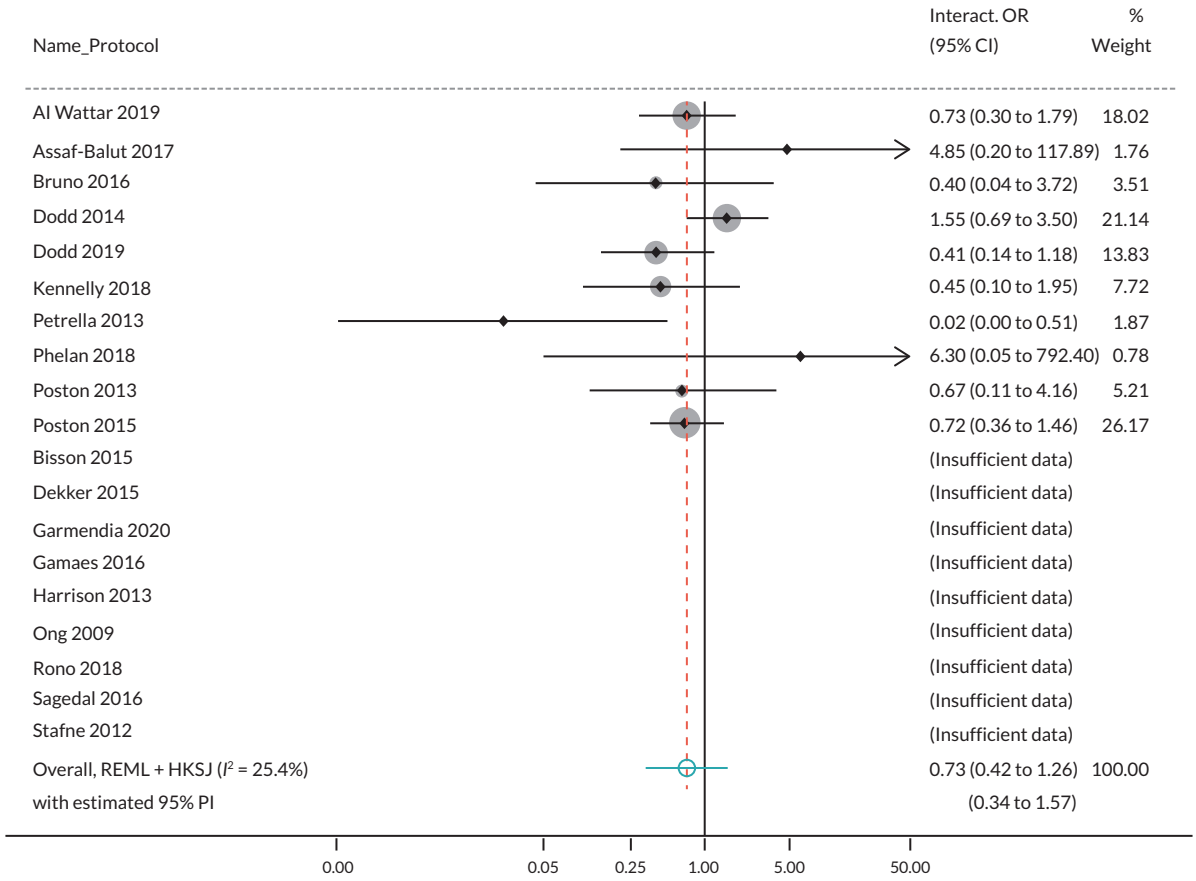

FIGURE 39 Ethnicity subgroup: non-White vs. White. Note: Weights are from random-effects model.

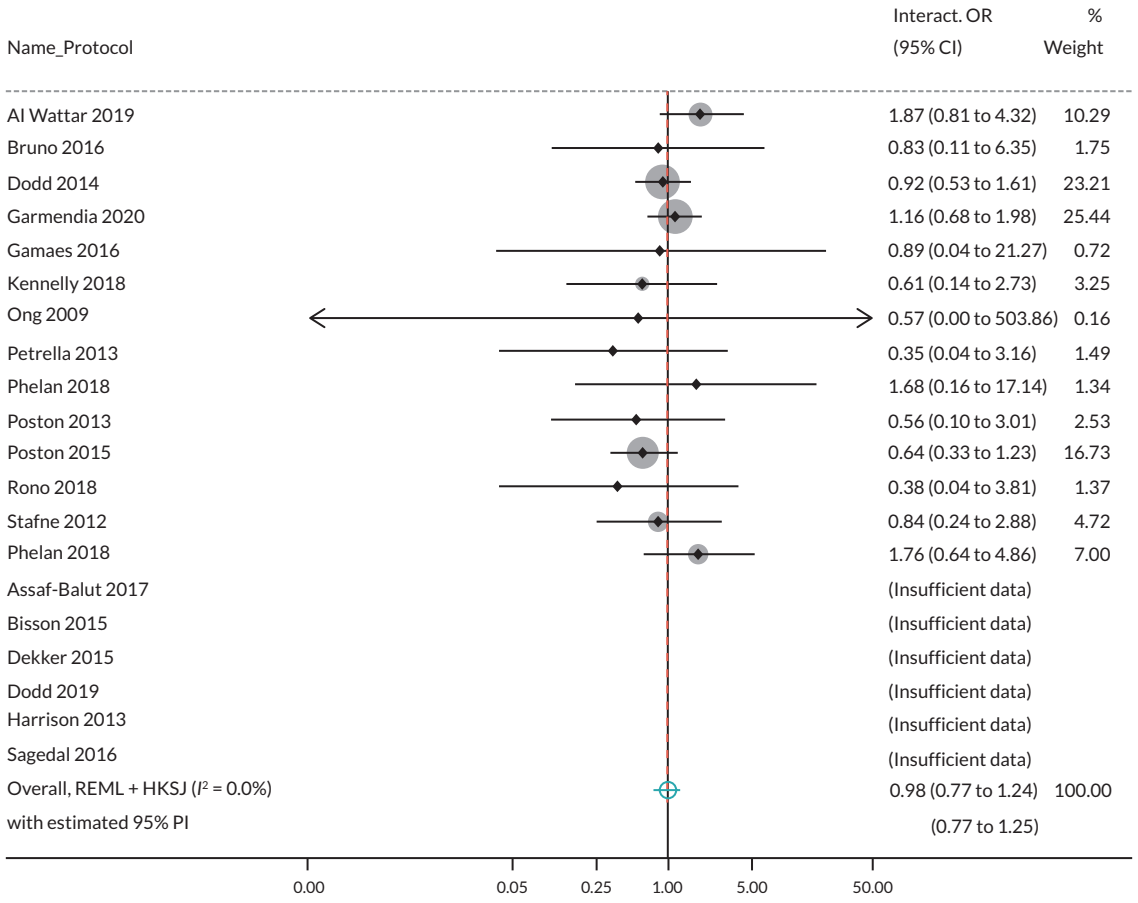

FIGURE 40 Parity subgroup: multiparous vs. nulliparous. Note: Weights are from random-effects model.

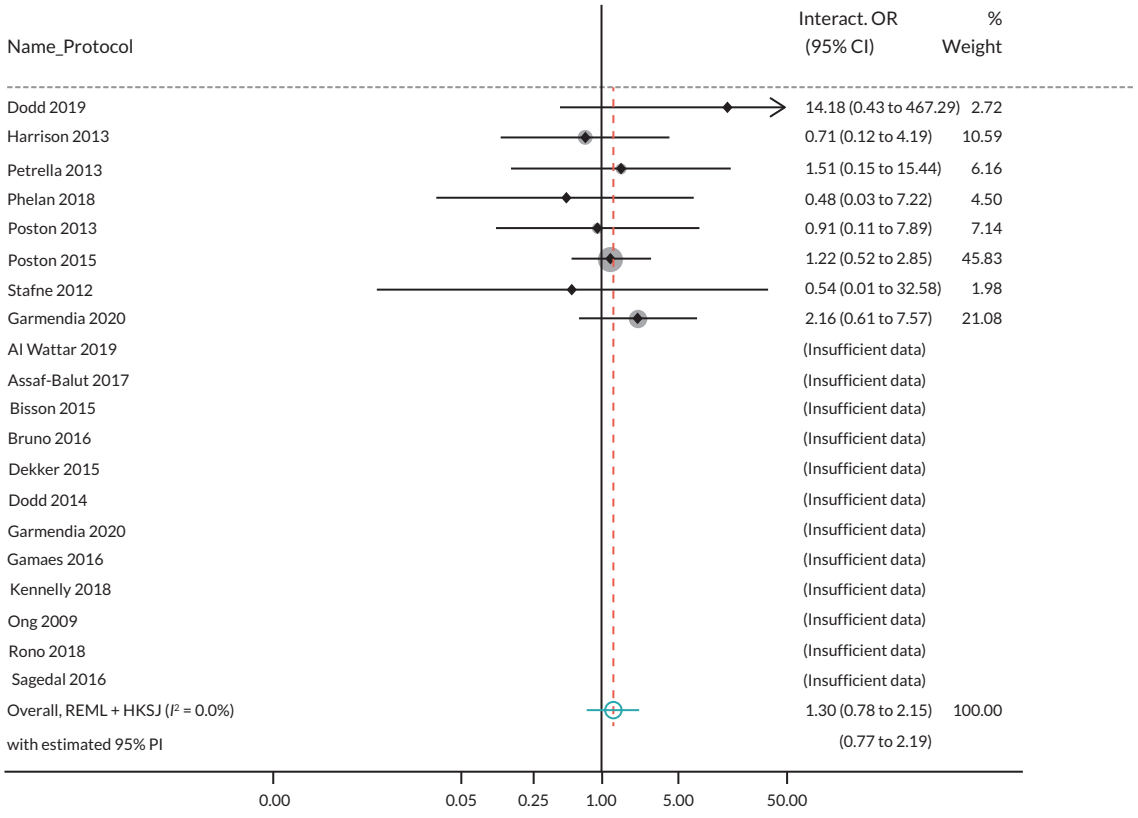

FIGURE 41 Education subgroup: middle education level vs. low education level. Note: Weights are from random-effects model.

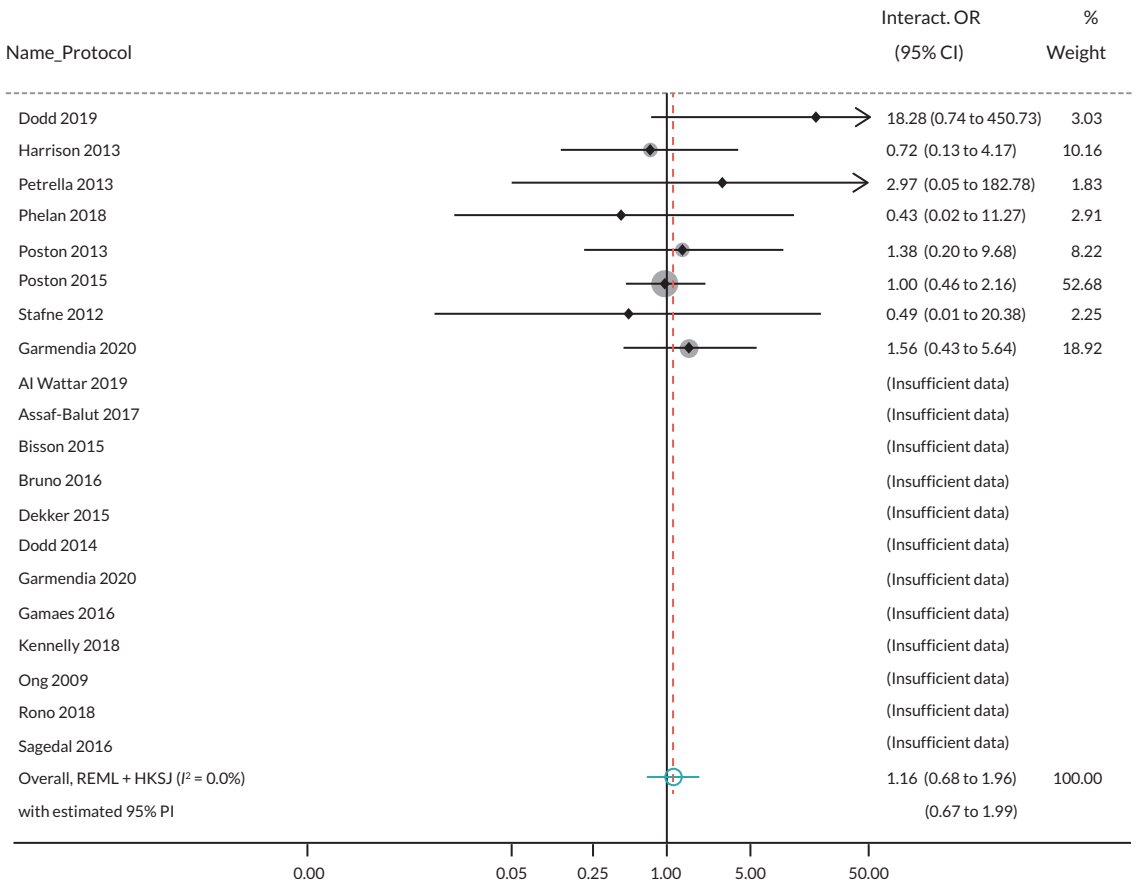

FIGURE 42 Education subgroup: high education level vs. low education level. Note: Weights are from random-effects model.

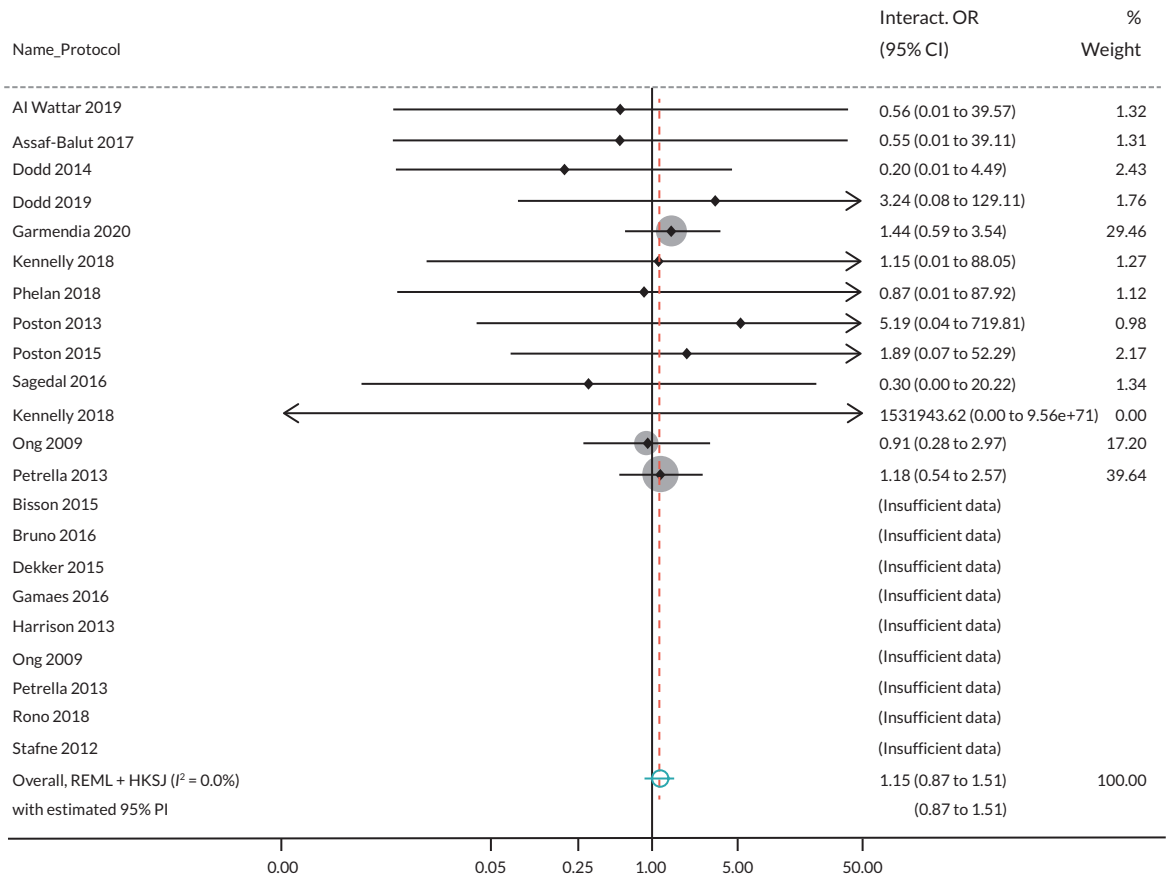

FIGURE 43 Age subgroup: ≥ 20 years old vs. < 20 years old. Note: Weights are from random-effects model.

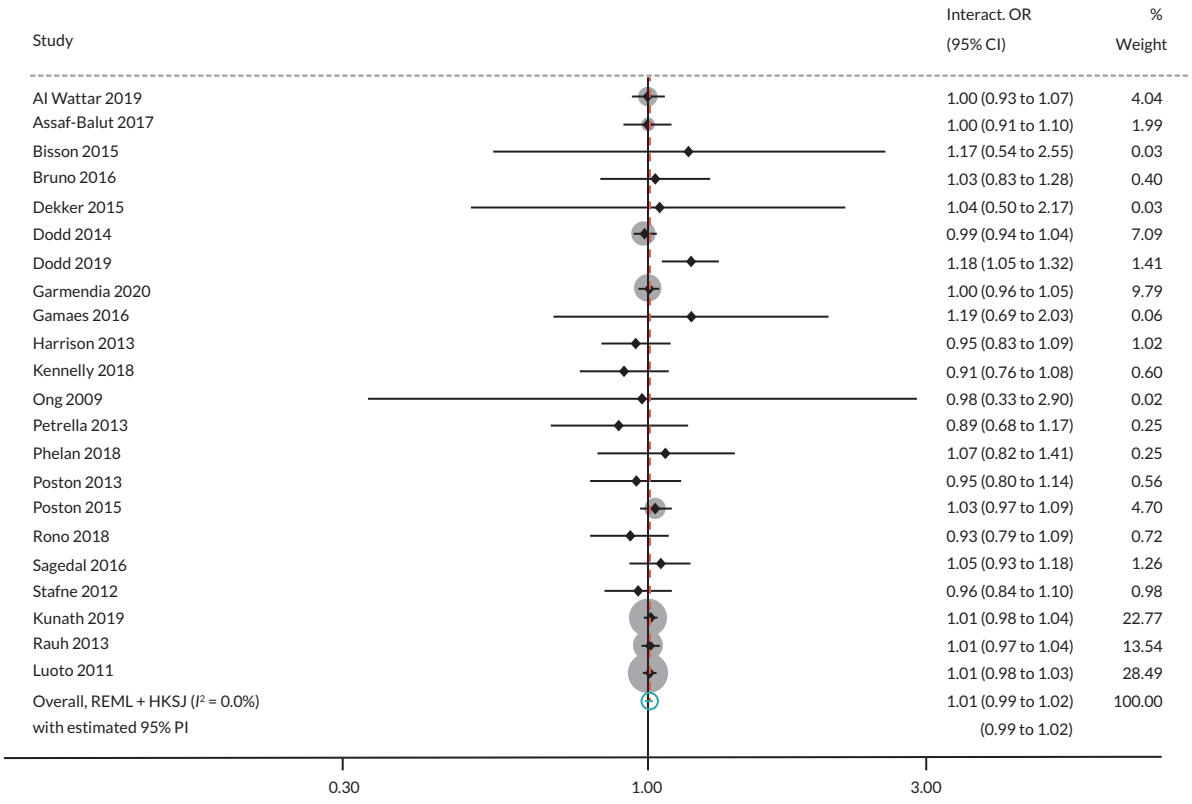

FIGURE 44 Age subgroup: per 1-year increase in age.

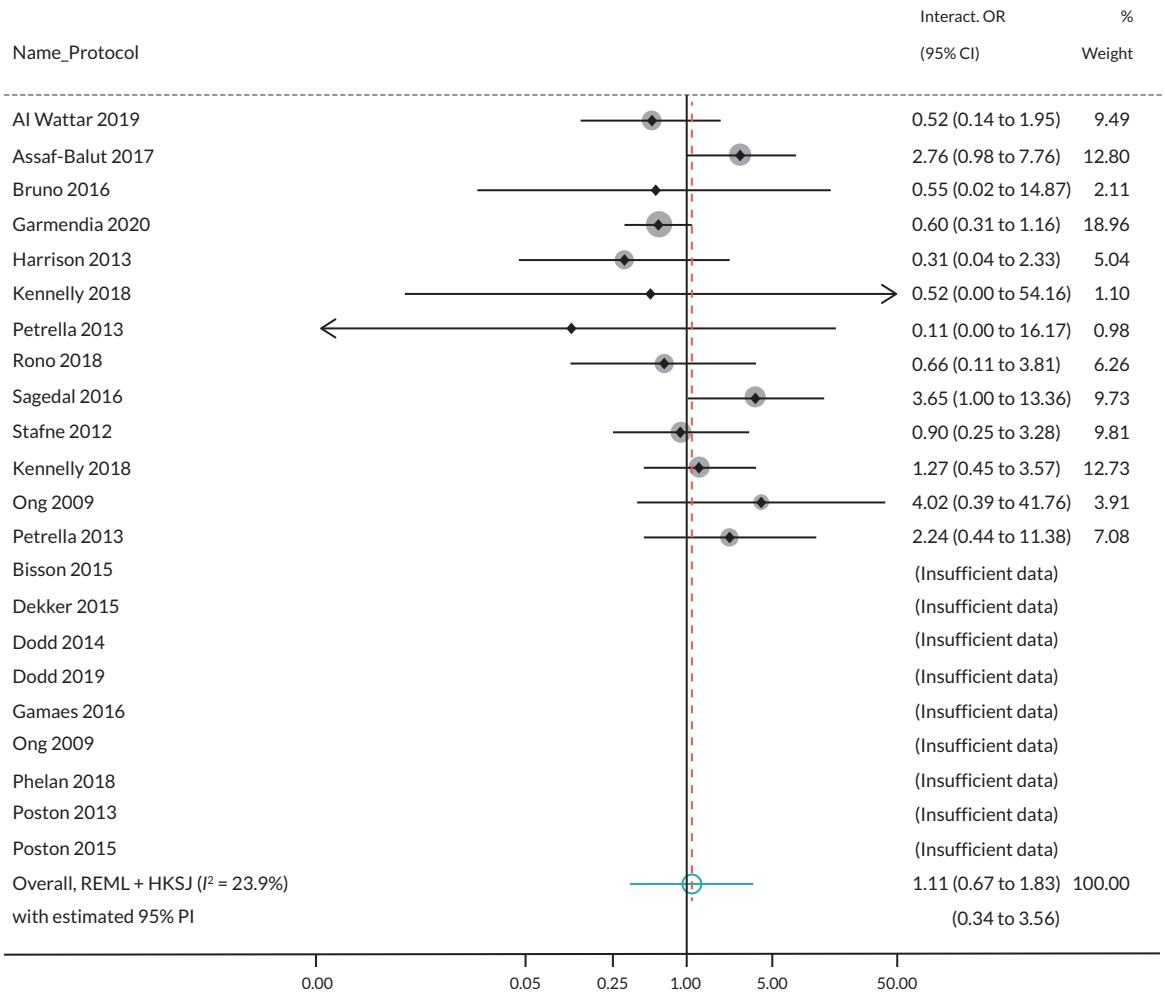

FIGURE 45 Body mass index subgroup: overweight vs. normal. Note: weights are from random-effects model.

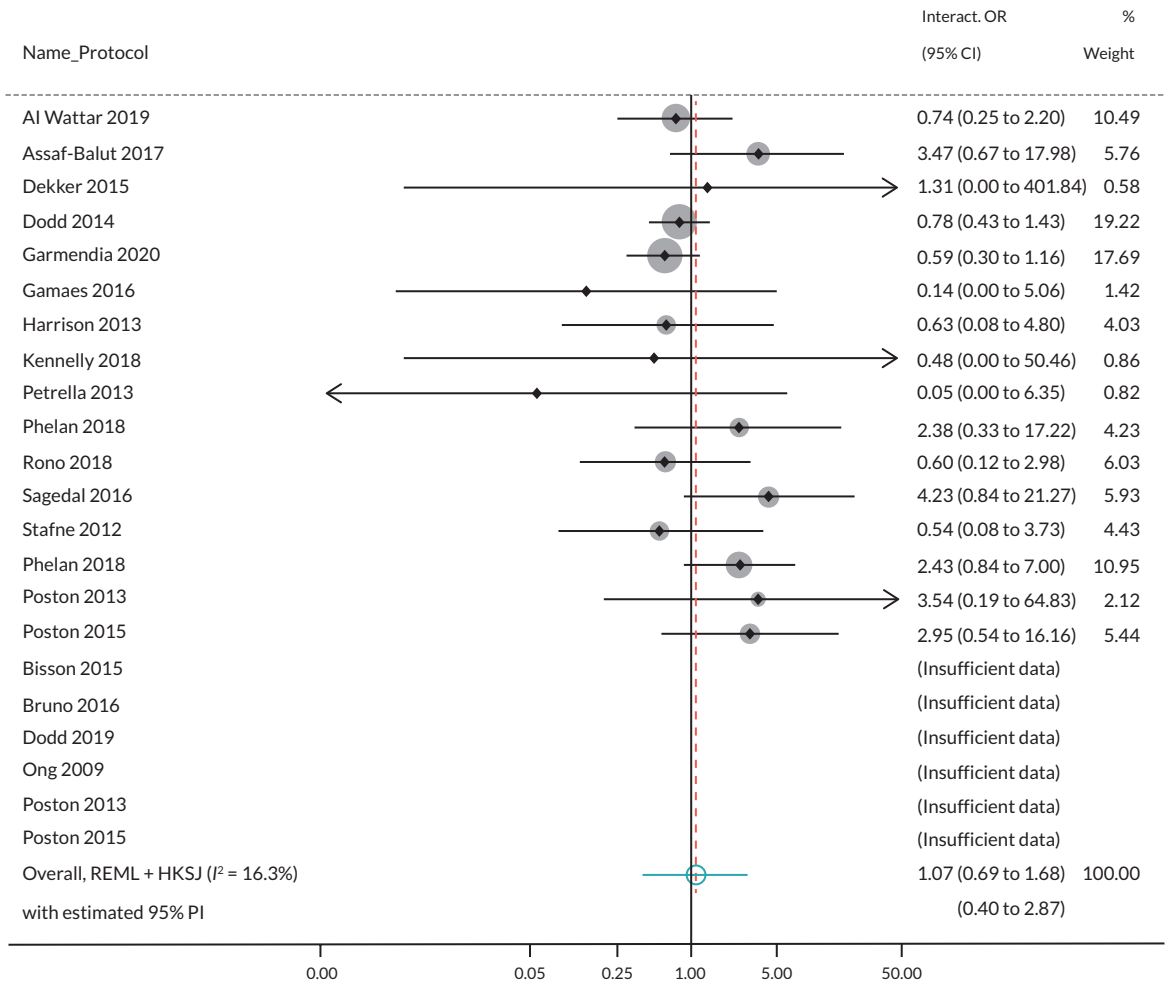

FIGURE 46 Body mass index subgroup: obese vs. normal. Note: Weights are from random-effects model.

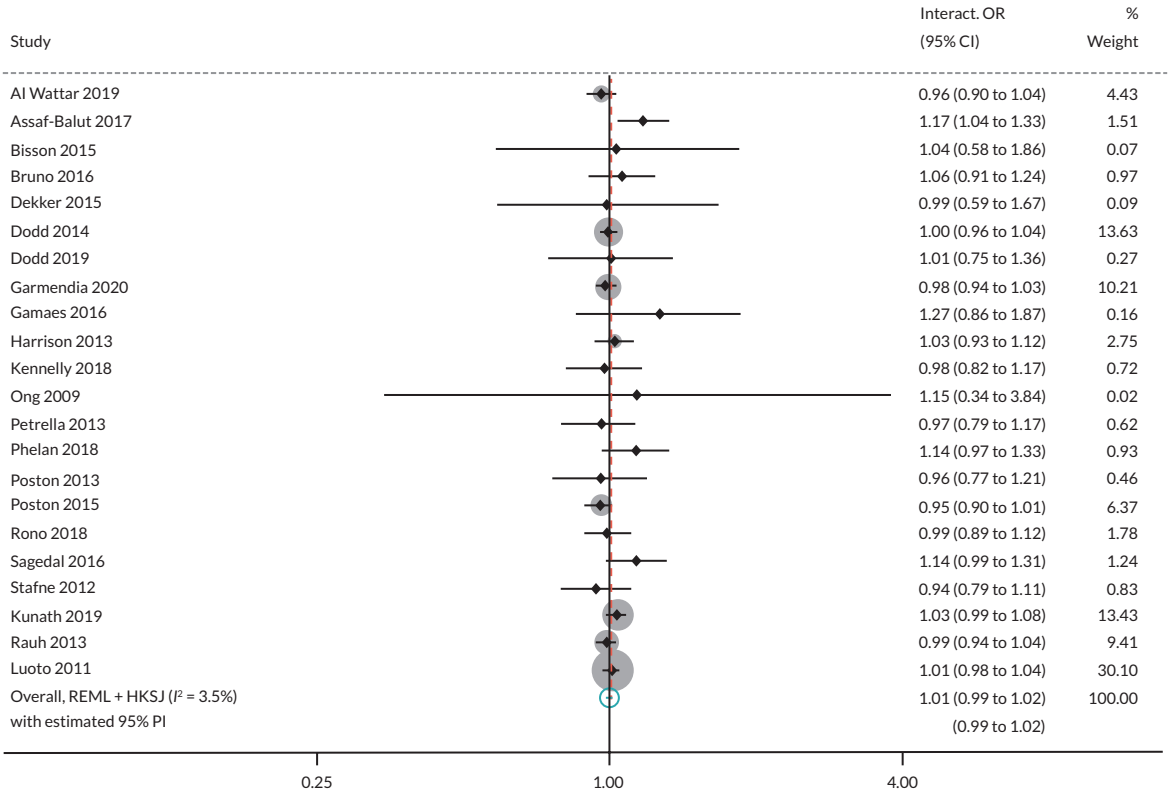

FIGURE 47 Body mass index subgroup: per unit increase in BMI.

Appendix 7 Association of overall lifestyle intervention TIDieR component subgroups with gestational diabetes mellitus

TABLE 39 Association of overall lifestyle intervention TIDieR component subgroups with GDM

Core component	Number of IPD trials, *n* (%)	OR	CI 95%	Comparison *p*-value	Global *p*-value
Structure					
Individual	25 (48.1)	1.02	(0.89 to 1.17)	(reference)	–
Group	27 (51.9)	0.81	(0.68 to 0.97)	0.048	
Number of sessions					
Low + moderate	20 (39.2)	0.95	(0.82 to 1.11)	(ref)	–
High	31 (60.8)	0.80	(0.62 to 1.03)	0.230	
Theory					
No	35 (66.0)	0.86	(0.73 to 1.01)	(ref)	–
Yes	18 (34.0)	1.00	(0.83 to 1.20)	0.230	
Resources					
Combination + other resources	17 (32.1)	1.03	(0.88 to 1.21)	(ref)	0.100
None	26 (49.0)	0.85	(0.69 to 1.04)	0.135	
Self-monitoring tool	10 (18.9)	0.72	(0.52 to 1.00)	0.057	
Method					
Face to face	45 (88.2)	0.90	(0.79 to 1.03)	(ref)	–
Face to face + remote	6 (11.8)	1.00	(0.71 to 1.41)	0.593	
Facilitator					
Allied health staff	39 (76.0)	0.84	(0.72 to 0.98)	(ref)	0.204
Medical staff	6 (12.0)	1.14	(0.85 to 1.53)	0.076	
Other	6 (12.0)	0.91	(0.59 to 1.38)	0.745	
Prior training					
No/NR	33 (64.7)	0.82	(0.69 to 0.96)	(ref)	–
Yes	18 (35.3)	1.04	(0.90 to 1.20)	0.031	
Location					
Hospital/antenatal clinic	39 (75.0)	0.92	(0.81 to 1.05)	(ref)	0.445
Exercise centre	8 (15.4)	0.77	(0.51 to 1.15)	0.385	
Other	5 (9.6)	1.10	(0.74 to 1.66)	0.401	

continued

TABLE 39 Association of overall lifestyle intervention TIDieR component subgroups with GDM (*continued*)

Core component	Number of IPD trials, *n* (%)	OR	CI 95%	Comparison *p*-value	Global *p*-value
Duration					
Moderate	18 (34.6)	1.03	(0.86 to 1.24)	(ref)	0.228
High	20 (38.5)	0.85	(0.69 to 1.05)	0.174	
Low	15 (26.9)	0.81	(0.62 to 1.05)	0.134	
Ongoing support					
No	36 (69.2)	0.86	(0.73 to 1.00)	(ref)	–
Yes	16 (30.8)	1.01	(0.84 to 1.21)	0.172	
Gestational age					
< 20	39 (73.6)	0.90	(0.79 to 1.04)	(ref)	–
≥ 20	14 (26.4)	0.96	(0.75 to 1.23)	0.674	

NR, not reported.

Appendix 8 Association of physical activity-based intervention TIDieR component subgroups with gestational diabetes mellitus

TABLE 40 Association of physical activity-based intervention TIDieR component subgroups with GDM

Core component	Number of IPD trials, *n* (%)	OR	CI 95%	Comparison *p*-value	Global *p*-value
Structure					
Individual	3 (16.7)	0.59	(0.13 to 2.76)	(reference)	–
Group	15 (83.3)	0.64	(0.47 to 0.88)	0.911	
Number of sessions					
Low + moderate	3 (16.7)	1.10	(0.60 to 2.03)	(ref)	–
High	15 (83.3)	0.56	(0.41 to 0.77)	0.056	
Theory					
No	17 (94.4)	0.66	(0.48 to 0.90)	(ref)	–
Yes	1 (5.6)	0.25	(0.04 to 1.48)	0.269	
Resources					
Combination + other resources	12 (66.7)	0.63	(0.25 to 1.55)	(ref)	0.733
None	4 (22.2)	0.66	(0.46 to 0.96)	0.901	
Self-monitoring tool	2 (11.1)	0.43	(0.14 to 1.30)	0.581	
Method					
Face to face	18 (100)	0.64	(0.47 to 0.87)	–	–
Face to face + remote	0 (0)	–	–	–	–
Facilitator					
Allied health staff	16 (88.9)	0.64	(0.47 to 0.87)	(ref)	–
Medical staff	–	–	–	–	–
Other	2 (11.1)	0.88	(0.06 to 12.79)	0.805	
Prior training					
No/NR	15 (83.3)	0.65	(0.45 to 0.94)	(ref)	–
Yes	3 (16.7)	0.58	(0.30 to 1.13)	0.759	
Location					
Hospital/antenatal clinic	13 (72.2)	0.70	(0.49 to 1.00)	(ref)	0.533
Exercise centre	4 (22.2)	0.47	(0.24 to 0.91)	0.275	
Other	1 (5.6)	0.47	(0.01 to 18.21)	0.819	

continued

TABLE 40 Association of physical activity-based intervention TIDieR component subgroups with GDM (*continued*)

Core component	Number of IPD trials, *n* (%)	OR	CI 95%	Comparison *p*-value	Global *p*-value
Duration					
Moderate	2 (11.1)	0.52	(0.25 to 1.10)	(ref)	0.301
High	10 (55.6)	0.58	(0.40 to 0.84)	0.808	
Low	6 (33.3)	0.89	(0.54 to 1.49)	0.226	
Ongoing support					
No	16 (88.9)	0.64	(0.45 to 0.90)	(ref)	–
Yes	2 (11.1)	0.63	(0.24 to 1.63)	0.988	
Gestational age					
< 20	13 (72.2)	0.55	(0.39 to 0.80)	(ref)	–
≥ 20	5 (27.8)	0.83	(0.53 to 1.30)	0.160	

NR, not reported.

Appendix 9 Association of diet-based intervention TIDieR component subgroups with gestational diabetes mellitus

TABLE 41 Association of diet-based intervention TIDieR component subgroups with GDM

Core component	Number of IPD trials, *n* (%)	OR	CI 95%	Comparison *p*-value	Global *p*-value
Structure					
Individual	2 (25.0)	0.84	(0.54 to 1.55)	(reference)	–
Group	6 (75.0)	0.77	(0.51 to 1.16)	0.699	
Number of sessions					
Low + moderate	8 (100)	0.81	(0.64 to 1.04)	–	–
High	0 (0)	–	–	–	–
Theory					
No	7 (87.5)	0.82	(0.60 to 1.12)	(ref)	–
Yes	1 (12.5)	0.80	(0.52 to 1.23)	0.899	
Resources					
Combination + other resources	4 (50.0)	1.07	(0.61 to 1.89)	(ref)	0.366
None	3 (37.5)	0.77	(0.56 to 1.06)	0.252	
Self-monitoring tool	1 (12.5)	0.60	(0.24 to 1.50)	0.223	
Method					
Face to face	8 (100)	0.81	(0.64 to 1.04)	–	–
Face to face + remote	0 (0)	–	–	–	–
Facilitator					
Allied health staff	6 (75.0)	0.77	(0.57 to 1.02)	(ref)	0.375
Medical staff	1 (12.5)	1.02	(0.52 to 2.01)	0.362	
Other	1 (12.5)	2.12	(0.26 to 17.53)	0.272	
Prior training					
No/NR	6 (75.0)	0.82	(0.60 to 1.13)	(ref)	–
Yes	2 (25.0)	0.79	(0.52 to 1.21)	0.876	
Location					
Hospital/antenatal clinic	8 (100)	0.81	(0.64 to 1.04)	–	–
Exercise centre	0 (0)	–	–	–	–
Other	0 (0)	–	–	–	–

continued

TABLE 41 Association of diet-based intervention TIDieR component subgroups with GDM (*continued*)

Core component	Number of IPD trials, *n* (%)	OR	CI 95%	Comparison *p*-value	Global *p*-value
Duration					
Moderate	2 (57.1)	0.87	(0.59 to 1.28)	(ref)	0.633
High	1 (14.3)	0.60	(0.22 to 1.61)	0.381	
Low	4 (28.6)	0.79	(0.49 to 1.27)	0.665	
Ongoing support					
No	6 (75.0)	0.77	(0.54 to 1.10)	(ref)	–
Yes	2 (25.0)	0.86	(0.60 to 1.23)	0.602	
Gestational age					
< 20	6 (75.0)	0.77	(0.58 to 1.01)	(ref)	–
≥ 20	2 (25.0)	1.09	(0.59 to 2.01)	0.243	

NR, not reported.

Appendix 10 Association of mixed intervention component subgroups with gestational diabetes mellitus

TABLE 42 Association of mixed intervention TIDieR component subgroups with GDM

Core component	*N* (%)	OR	CI 95%	Comparison *p*-value	Global *p*-value
Structure					
Individual	18 (69.2)	1.11	(0.97 to 1.27)	(reference)	–
Group	8 (30.8)	1.00	(0.79 to 1.26)	0.413	
Number of sessions					
Low + moderate	20 (80.0)	1.03	(0.90 to 1.18)	(ref)	–
High	5 (20.0)	1.25	(0.99 to 1.58)	0.153	
Theory					
No	11 (40.7)	1.07	(0.88 to 1.30)	(ref)	–
Yes	16 (59.3)	1.06	(0.89 to 1.26)	0.943	
Resources					
Combination + other resources	18 (66.7)	1.06	(0.92 to 1.22)	(ref)	0.168
None	2 (7.4)	1.27	(0.98 to 1.63)	0.215	
Self-monitoring tool	7 (25.9)	0.84	(0.58 to 1.20)	0.226	
Method					
Face to face	19 (76.0)	1.10	(0.96 to 1.27)	(ref)	–
Face to face + remote	6 (24.0)	0.99	(0.75 to 1.29)	0.461	
Facilitator					
Allied health staff	16 (66.7)	1.05	(0.87 to 1.26)	(ref)	0.515
Medical staff	5 (20.8)	1.15	(0.86 to 1.55)	0.568	
Other	3 (12.5)	0.88	(0.61 to 1.28)	0.406	
Prior training					
No/NR	12 (48.0)	0.92	(0.72 to 1.18)	(ref)	–
Yes	13 (52.0)	1.13	(0.98 to 1.30)	0.150	
Location					
Hospital/antenatal clinic	18 (69.2)	1.06	(0.92 to 1.22)	(ref)	0.949
Exercise centre	4 (15.4)	1.11	(0.66 to 1.85)	0.861	
Other	4 (15.4)	1.12	(0.76 to 1.65)	0.778	

continued

TABLE 42 Association of mixed intervention TIDieR component subgroups with GDM (*continued*)

Core component	*N* (%)	OR	CI 95%	Comparison *p*-value	Global *p*-value
Duration					
Moderate	12 (44.5)	1.15	(0.96 to 1.38)	(ref)	0.179
High	9 (33.3)	1.10	(0.89 to 1.34)	0.732	
Low	6 (22.2)	0.84	(0.63 to 1.12)	0.070	
Ongoing support					
No	14 (53.9)	1.04	(0.87 to 1.25)	(ref)	–
Yes	12 (46.1)	1.08	(0.91 to 1.30)	0.462	
Gestational age					
< 20	20 (74.1)	1.08	(0.94 to 1.24)	(ref)	–
≥ 20	7 (25.9)	1.02	(0.74 to 1.39)	0.743	

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