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Optimising gestational weight gain and improving maternal and infant health outcomes through antenatal dietary, lifestyle and physical activity advice: the OPTIMISE randomised controlled trial protocol

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TITLE: Optimising gestational weight gain and improving maternal and infant health outcomes through antenatal dietary, lifestyle and physical activity advice: the OPTIMISE randomised controlled trial protocol.

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ABSTRACT

INTRODUCTION

Obesity represents a significant health burden and the World Health Organisation recognises the importance of preventing weight gain and subsequent development of obesity among adults who are within the healthy weight range. Women of reproductive age have demonstrated high rates of weight gain during pregnancy placing them at risk of becoming overweight or obese. We will evaluate the effects of dietary and physical activity advice on maternal, fetal and infant health outcomes, among pregnant women of normal body mass index (BMI).

METHODS AND ANALYSIS

We will conduct a randomised controlled trial, consenting and randomising women with a live singleton pregnancy between 10⁺⁰-20⁺⁰ weeks, and BMI 18.5-24.9kg/m² at first antenatal visit, from a tertiary maternity hospital. Women randomised to the *Lifestyle Advice Group* will receive 3 face-to-face sessions (2 with a research dietitian and 1 with a trained research assistant), and 3 telephone calls over pregnancy, in which they will be provided with dietary and lifestyle advice, and encouraged to make change utilising a SMART goals approach. Women randomised to the *Standard Care Group* will receive routine antenatal care. The primary outcome is infant birth weight >4kg. Secondary outcomes will include adverse infant and maternal outcomes, maternal weight change, maternal diet and physical activity changes, maternal quality of life and emotional wellbeing, fetal growth and costs of healthcare. We will recruit 624 women to detect a reduction from 8.72% to 3.87% (alpha 0.05 (two-tailed); power 70%) in infants with birth weight >4kg. Analyses will be intention to treat with estimates reported as relative risks and 95% confidence intervals.

ETHICS AND DISSEMINATION

Ethical approval has been obtained from the Women's and Children's Hospital ethics committee. Findings will be disseminated widely via journal publication and conference presentation(s) and participants informed of results.

TRIAL REGISTRATION NUMBER ACTRN 12614000583640

STRENGTHS & LIMITATIONS

- Robust evaluation of the effects of a dietary and lifestyle intervention during pregnancy for women of normal BMI.
- Prospectively measured and calculated height, weight and BMI at the time of the first antenatal booking visit.
- A wide range of clinically relevant maternal and infant health outcomes will be reported.

INTRODUCTION:

World-wide, more than 1.9 billion adults, and 41 million children under the age of 5 years are overweight or obese.¹ Obesity represents a significant healthcare burden, with the World Health Organisation recognising the importance of preventing weight gain among adults who are within the healthy weight range.² Women of reproductive age have demonstrated high rates of gestational weight gain (GWG) during pregnancy, and post-partum weight retention (PPWR),³ and therefore represent an “at-risk” population.

The Institute of Medicine (IoM) has reviewed the considerable observational literature which is available, recommending GWG between 11.5 and 16.0kg for pregnant women of normal body mass index (BMI), defined as BMI between 18.5 and 24.9kg/m².⁴ Weight gain in excess of these recommendations is well recognised as a significant risk factor for adverse maternal and infant outcomes during pregnancy and childbirth, even among women of normal BMI,⁵⁻⁸ and more than doubles a woman’s risk of postpartum weight retention.⁹ Indeed, more than 70% of women with a BMI retain more than 5kg weight up to 1 year after birth,^{10 11} contributing to an increase in inter-pregnancy BMI, an increased risk of adverse outcomes in a subsequent pregnancy, and longer-term risk of obesity.¹²⁻¹⁴ There is also increasing evidence that excessive GWG increases the chance of high infant birth weight, with both factors independently associated with an increased risk of child obesity.¹⁵⁻¹⁷ Specifically, the risk of early childhood obesity increases by a factor of 1.08 (95% CI 1.03-1.14) per kilogram of maternal weight gained above the recommendations.¹⁸ All of these factors combine to create a vicious cycle in which the intergenerational effects of obesity are perpetuated.¹⁹

While there is extensive observational literature defining the pregnancy and childbirth complications associated with excessive GWG and postpartum weight retention for

women of normal BMI, there is limited information describing effective interventions. Our systematic review of the literature identified 12 RCTs of 2,713 pregnant women, who were recruited across all BMI categories.²⁰ Of these trials, 8 specifically identified 1,048 women to be of normal BMI, of which only 5 reported clinical outcomes for women of normal BMI (714 women).²⁰ Women of normal BMI who received an antenatal intervention gained less weight (1.25kg; 95% CI -2.39 to -0.11) than those women receiving standard antenatal care, and were less likely to have weight gain above the IoM recommendations (RR 0.72; 95% CI 0.60 to 0.86; 5 studies, 714 women).²⁰ However, the effect on clinical pregnancy outcomes was less clear (2 studies, 243 women), and only two studies reported post-partum weight retention at 8 weeks and 6 months after birth.²⁰ While there was a modest overall effect on GWG, effects on clinical pregnancy and birth outcomes have been poorly reported to date, and there is no information relating to longer-term effects on both maternal and child health.

The aims of the OPTIMISE randomised trial are to evaluate the effects of dietary and physical activity advice on maternal, fetal and infant health outcomes, among pregnant women of normal BMI.

METHODS AND ANALYSIS:

Study Design: Randomised controlled trial.

Inclusion Criteria: Women with a singleton, live gestation between 10⁺⁰-20⁺⁰ weeks who are of normal BMI (BMI 18.5 to 24.9kg/m²) at their first antenatal visit will be eligible to participate.

Exclusion Criteria: Women with a multiple pregnancy, or who have type 1 or 2 diabetes which was diagnosed prior to pregnancy will be excluded from participation.

Trial Entry: Eligible women will be identified in the antenatal clinic of the Women's and Children's Hospital, given the trial information sheet and counselled by a researcher, before obtaining informed written consent. Randomisation will occur using the computer based randomisation service in the Discipline of Obstetrics and Gynaecology, The University of Adelaide. Recruitment commenced June 2014, and the study is ongoing.

The randomisation schedule will use balanced variable blocks, and will be prepared by an investigator not involved with recruitment or clinical care. There will be stratification of women according to parity (0 versus 1 or more). Eligible women will be randomised to either the 'Lifestyle Advice Group' or the 'Standard Care Group'. Blinding of participants is not possible given the nature of the intervention. Where possible, antenatal care-providers, outcome assessors and data analysts will be blinded to treatment allocation.

Treatment Schedules: Women who are randomised to the *Lifestyle Advice Group* will receive 3 individual face-to-face sessions during pregnancy, with 2 provided by the dietitian shortly after trial entry and again at 28 weeks gestation, and one provided by a research assistant at 36 weeks gestation. Women will also receive 3 telephone calls from the research assistant at 20, 24, and 32 weeks gestation. The dietary advice provided will be individually tailored, consistent with current Australian dietary standards,²¹ and based on our experience with the LIMIT randomised trial.^{22 23}

Recommendations and dietary targets will be individualised, taking into account each woman's basal metabolic rate and activity levels.²⁴ The dietary intervention will maintain a balance of carbohydrates, fat and protein, while specifically encouraging women to reduce their intake of energy dense and non-core foods high in refined carbohydrates and saturated fats, while increasing their intake of fibre, and to consume of two serves of fruit, five serves of vegetables, and three serves of dairy each day.²¹⁻²³

Tailoring of the intervention will be informed by stage theories of health decision making that propose that individuals progress through a series of cognitive phases when undertaking behavioural change.²⁵ Initially, there will be a planning session with a research dietitian, in which women will be provided with written dietary and activity information, an individual diet and physical activity plan, recipe book and example menu plans. Women will be encouraged to set achievable goals for dietary and physical activity change, supported to make these lifestyle changes and to self-monitor their progress, using a SMART goals approach. Women will be encouraged to involve their partner or significant support person in these sessions. These principles will be reinforced at subsequent face-to-face visits with the dietitian and research assistant, and during the telephone contacts.^{22 23}

Women who are randomised to the *Standard Care Group* will receive their antenatal care according to their local hospital practice, which does not currently include information relating to dietary intake and physical activity during pregnancy.

Ongoing Follow-up of All Women in Both Treatment Groups:

All women will be asked to complete a food frequency questionnaire, physical activity diary, and quality of life assessments at trial entry, 28 and 36 weeks gestation, and six months postpartum. Their weight will be recorded at trial entry, at 28 weeks gestation, and at 36 weeks gestation or nearest to birth. All women will be encouraged to attend for a research ultrasound at 28 and 36 weeks gestation that does not constitute routine clinical care to monitor fetal growth and wellbeing.

After birth, information will be obtained relating to birth and infant outcomes from the case notes by the research assistant, who will remain blinded to the woman's allocated treatment group.

Study Endpoints:

The primary trial outcome is the incidence of infants with birth weight >4 kg.

The secondary study outcomes are

1) Adverse outcomes for the infant including preterm birth (birth before 37 weeks gestation); mortality (either stillbirth (intrauterine fetal death after trial entry and prior to birth), or infant death (death of a live born infant prior to hospital discharge, and excluding lethal congenital anomalies)); infant birth weight; infant birth weight <2500 grams; infant birth weight >4500 grams; large for gestational age defined as infant birth weight $>90^{\text{th}}$ percentile for gestational age and infant sex; small for gestational age defined as infant birth weight $<10^{\text{th}}$ percentile for gestational age and infant sex; hypoglycaemia requiring intravenous treatment; admission to neonatal intensive care unit, or special care baby unit; hyperbilirubinaemia requiring phototherapy; nerve

palsy; fracture; birth trauma; shoulder dystocia; corticosteroid use; respiratory distress syndrome (with moderate or severe respiratory disease defined as mean airway pressure >10cm H₂O and/or inspired oxygen fraction (FiO₂) >0.80 with ventilation);²⁶ discharge home on oxygen; patent ductus arteriosus; proven systemic infection requiring treatment; retinopathy of prematurity; necrotising enterocolitis; neonatal encephalopathy;²⁷ seizures; length of stay; and infant exclusively breast fed at hospital discharge.

2) Adverse outcomes for the woman including maternal hypertension and pre-eclampsia (in accordance with recognised Australasian Society for the Study of Hypertension in Pregnancy criteria)²⁸; maternal gestational diabetes; need for and length of antenatal hospital stay; antepartum haemorrhage requiring hospitalisation; preterm prelabour ruptured membranes; chorioamnionitis; need and reason for induction of labour; any antibiotic use during labour; caesarean section; postpartum haemorrhage (blood loss \geq 600mL); perineal trauma; wound infection; endometritis; length of postnatal hospital stay; thromboembolic disease; maternal death.

3) Maternal weight changes including total gestational weight gain; average weekly gestational gain; gestational weight gain below / within / above IoM recommendations;⁴ maternal weight at 6, 12, and 18-24 months after birth to calculate postpartum weight retention; return to early pregnancy weight; and anthropometric assessment (skin-fold thickness, body circumferences, and bio-impedance to assess adiposity).

4) Maternal changes in diet and physical activity as measured by questionnaires completed by the woman at trial entry, 28 and 36 weeks gestation, and 6, 12 and 18-24

months after birth (Harvard Semi-quantitative Food Frequency Questionnaire,^{29 30} and the Short Questionnaire to Assess Health-enhancing physical activity (SQUASH)³¹).

5) Maternal quality of life and emotional wellbeing as measured by questionnaires completed by the woman at six months postpartum relating to quality of life (as measured using the SF12 Health Survey Questionnaire);³² preferences for treatment, satisfaction with care; anxiety (as measured by the Short Form Spielberger State Trait Inventory³³) and depression (as measured by the Edinburgh Postnatal Depression Scale³⁴). Women will be asked a series of questions about their satisfaction with the intervention, using items modified from a previous childbirth questionnaire.³⁵

6) Fetal growth and wellbeing at 28 and 36 weeks' gestation assessed by ultrasound (fetal biometry, estimated weight, liquor volume, umbilical artery Doppler waveform, and adiposity).³⁶

7) Costs of health care: The primary measure of outcome for the economic analysis will be the cost per live birth. Resource use will include the provision of the dietary intervention and direct costs of health care (expected average clinic fees, the frequency and duration of GP and antenatal visits, as well as in-patient admissions), determined by hospital out-patient visits, in-patient admissions and published data sets including PBS, MBS and Australian Refined Diagnosis Related Groups (AR-DRG) cost weights. Mean costs and effectiveness between treatment groups will be compared and incremental cost effectiveness ratios (ICERs) and confidence intervals presented. For varying threshold values of cost effectiveness, acceptability curves will be presented as described previously.³⁷ An assessment of the sensitivity of the results to variation in

measured resource use, effectiveness and/or unit costs will be undertaken using appropriate one-way and multi-way sensitivity analysis, as described previously.³⁷

Sample Size Estimation:

The primary clinical endpoint is the incidence of infants born with birth weight >4kg, with an estimated incidence in women eligible for this trial of 8.72%.³⁸ To detect a difference from 8.72% to 3.89% (alpha 0.05; power 70%), we will recruit a total of 624 women. This sample size will be powered (70%) to detect the differences in secondary outcomes as detailed in table 1 below.

Table 1: Estimated differences in secondary outcomes.

Outcome	Assumed Control Group %	Intervention %
GDM	3.4	0.6
Hypertension/Pre-Eclampsia	4.6	1.3
Induction of labour	26.8	18.5
Caesarean Section	24.6	16.6
Birth weight < 2.5kg	6.2	2.2

Analysis and Reporting of Results:

The initial analysis will examine baseline characteristics of all randomised women, as an indication of comparable treatment groups, and include maternal age, parity, race, height, weight, smoking history, past obstetric history, and previous gestational diabetes. Primary and secondary outcomes will be analysed on an “intention to treat” basis, according to treatment allocation at randomisation. Relative risks and 95% confidence intervals will be reported for the major outcomes, and the number needed to treat to benefit or harm calculated. Regression techniques will examine the influence of prognostic factors on the major outcomes.

As the lead investigator, JMD will have access to the data, and acts as guarantor to the final data set. The trial manager (ARD) and statistician (JL) will have access to the data, and the statistician (JL) will be responsible for the development of the statistical analysis plan, prior to the conduct of any statistical analyses.

ETHICS AND DISSEMINATION:

Data Management:

All information obtained from this study will remain strictly confidential. While the results of the study will be published, no data will be presented to allow the identification of individual women. Data will be stored in a locked filing cabinet or on password protected computer file, and accessible only by the study team.

We have previous experience recruiting women for lifestyle intervention trials in this setting ²³ and will consider adding further sites as required. Women who withdraw from ongoing participation after randomisation will be asked for consent to utilise the data already collected prior to withdrawal, including birth outcomes where possible.

Following completion of the relevant statistical analyses, manuscripts will be prepared for publication, with subsequent presentation of results at relevant scientific and clinical meetings. Participants will be notified of the findings of the trial. The findings of this trial will contribute to the currently available literature regarding the effect of antenatal dietary and lifestyle interventions for women of normal BMI, and to the development of evidence based clinical practice guidelines.

Recruitment commenced in June 2014. We expect to have completed data collection and data cleaning by April 2018. The final results of the trial will be published in international peer-reviewed journals.

Ethical Approval:

Approval to conduct this study has been obtained from the research and ethics committee of the Women's and Children's Hospital (Adelaide, South Australia).

A data and safety monitoring board (DSMB) will monitor efficacy (or futility) and adverse effects. Based on these considerations, the DSMB may recommend that the protocol be modified or that the OPTIMISE trial be terminated. The DSMB will consist of experts in relevant obstetrics, neonatology and research methodology. All adverse events involving women and infants enrolled in the trial will be reviewed by a multidisciplinary committee, who will be blinded to treatment allocation, in order to clarify cause. These data will be made available for the Data Safety Monitoring Board.

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AUTHORS' CONTRIBUTIONS:

JD drafted the initial protocol and manuscript. JD, JL and AD contributed to revisions of the protocol and manuscript, and give approval for the final version to be published. JL conducted the sample size calculation and statistical analyses, and will be responsible for completion of the final statistical analysis plan.

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COMPETING INTERESTS STATEMENT:

The authors have no competing interest to declare.