A Mixed Methods Study of Interventions and Experiences to Prevent Type 2 Diabetes Mellitus Following Gestational Diabetes Mellitus

Ann Peacock
RN RM BMid (Hons Class 1)

A thesis submitted for the degree of Doctor of Philosophy at
The University of Queensland
School of Nursing and Midwifery
Abstract

Background: The prevalence of Gestational Diabetes Mellitus (GDM) is increasing globally and the link between GDM, obesity and the development of Type 2 Diabetes Mellitus (T2DM) in later life is increasingly recognised by international health authorities. Previous research suggests that strategies aimed at postpartum women and designed to promote weight loss through increased physical activity and dietary modifications may be feasible. However, recruitment and engagement of this cohort has met with differing success. Development of an evidence-based program that encourages behaviour modification resulting in weight loss may delay or prevent T2DM in this cohort.

Aim: To develop, implement and evaluate a behaviour modification program to support lifestyle changes for women with a Body Mass Index (BMI) >25kg/m², and who have experienced GDM, to delay or prevent development of T2DM.

Method: Following a review of the literature, a mixed method approach was employed. A randomised controlled trial (RCT) of a behaviour modification intervention (which combined a pedometer web-based program with nutrition coaching) was conducted over a three month period. The primary outcome for the RCT was weight loss, and secondary outcomes included; improved insulin sensitivity, increased physical activity, improved diet quality and self-efficacy, decreased waist and hip measurements, and a decreased Free Fat Mass (FFM). Qualitative data collected through semi structured interviews conducted after the intervention, were thematically analysed to examine the women’s experiences of the intervention, barriers and enablers to participation, and to identify T2DM risk perceptions.

Sample: Women with a BMI >25kg/m², previously diagnosed with GDM were invited to participate six months (up to two years) postpartum.
**Results:** Thirty-one women were randomised, with recruitment lower than originally projected. The intervention group had a median weight loss of 2.5 kg (IQR 1.4) ($p=0.002$), increased activity by 135 minutes/week, improved self-efficacy eating behaviour ($p=0.036$), decreased median waist measurement of 3 cm (IQR 4.0) ($p=0.037$), and decreased median hip measurement of 3 cm (IQR 5.0) ($p=0.006$). There was no difference in insulin sensitivity or FFM. Qualitative results revealed the pedometer and nutrition coaching were well received, and educating women in the immediate postpartum period outlining the risks of T2DM and an evidence-based behaviour modification program with follow up within the first year was considered optimum.

**Implications:** These findings have important clinical implications for future programs designed to engage women previously diagnosed with GDM, with the aim of an eventual reduction in the risk of T2DM. A web-based pedometer intervention program combined with nutrition coaching has the potential to be translated into other settings. Education of women with GDM regarding self care in the immediate postpartum period could be incorporated into routine care, with health care professionals contacting women following discharge from hospital to support behaviour modifications designed to decrease the risk of T2DM.
Declaration by author

This thesis is composed of my original work, and contains no material previously published or written by another person except where due reference has been made in the text. I have clearly stated the contribution by others to jointly-authored works that I have included in my thesis.

I have clearly stated the contribution of others to my thesis as a whole, including statistical assistance, survey design, data analysis, significant technical procedures, professional editorial advice, and any other original research work used or reported in my thesis. The content of my thesis is the result of work I have carried out since the commencement of my research higher degree candidature and does not include a substantial part of work that has been submitted to qualify for the award of any other degree or diploma in any university or other tertiary institution. I have clearly stated which parts of my thesis, if any, have been submitted to qualify for another award.

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Publications during candidature

Publications


Conference abstracts and presentations during candidature


2. Peacock AS. Walking for Exercise to prevent Diabetes for You. Paper presented at: The Thai Nursing Delegation Research Seminar, 2013 March; Royal Brisbane and Women’s Hospital, Brisbane, Australia.


5. Peacock AS, Bogossian FE, Wilkinson SA, McIntyre HD. Walking for Exercise and Nutrition to prevent Diabetes for You; The WENDY Study; Paper presented at: The Triennial Congress of The International Confederation of Midwives; 2014 June; Prague, Czech Republic.

Publications included in this thesis


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<td>Prepared drafts, edited the paper (50%)</td>
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<tr>
<td>A/Prof Fiona Bogossian</td>
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Contributions by others to the thesis

A/Prof Fiona Bogossian, Prof H. David McIntyre (Principal Advisors), and Dr Shelley Wilkinson (Associate Advisor) provided extensive guidance and input into the conception and content of this thesis and throughout the PhD candidature. All supervisors both critically reviewed and provided extensive feedback on the content of this thesis on multiple occasions.


Statement of parts of the thesis submitted to qualify for the award of another degree

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gestational diabetes, type 2 diabetes mellitus, prevention, intervention, exercise, diet, barriers, enablers.

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**Fields of Research (FoR) Classification**

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FoR code: 1110 Nursing 40%

FoR code: 1114 Paediatric and Reproductive Medicine 20%
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<td>WENDY</td>
<td>Walking for Exercise and Nutrition to prevent Diabetes for You</td>
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<tr>
<td>GDM</td>
<td>Gestational Diabetes Mellitus</td>
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<td>T2DM</td>
<td>Type 2 Diabetes Mellitus</td>
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<td>RCT</td>
<td>Randomised Controlled Trial</td>
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<td>OGTT</td>
<td>Oral Glucose Tolerance Test</td>
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<td>BMI</td>
<td>Body Mass Index</td>
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<td>AWAS</td>
<td>Australian Women’s Activity Survey</td>
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<td>HAPO</td>
<td>Hyperglycaemia and Adverse Pregnancy Outcomes study</td>
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<td>BF</td>
<td>Breastfeeding</td>
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<td>ADIPS</td>
<td>Australasian Diabetes in Pregnancy Society</td>
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<td>GP</td>
<td>General Practitioner</td>
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<td>CONSORT</td>
<td>Consolidated Standards of Reporting Trials</td>
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<td>STROBE</td>
<td>STrengthening the Reporting of OBservational studies in Epidemiology</td>
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<td>TRiPOD</td>
<td>Troglitazone in Prevention of Diabetes</td>
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<td>PIPOD</td>
<td>Pioglitazone in Prevention of Diabetes</td>
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<td>DPP</td>
<td>Diabetes Prevention Program</td>
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<td>NHMRC</td>
<td>National Health Medical Research Council</td>
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<td>FFM</td>
<td>Fat Free Mass</td>
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<td>HOMA-IR</td>
<td>Homeostasis Model Assessment</td>
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<td>WEL</td>
<td>Wellbeing Self-Efficacy Survey</td>
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<td>HEPA</td>
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<td>mmol/L</td>
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1. Introduction

“By identifying women early in their course towards diabetes we have the opportunity to change this course. We must not squander this opportunity!” Feig, (2012)

As a midwife for over 30 years, I have cared for an increasing number of women who had been diagnosed with Gestational Diabetes Mellitus (GDM). Although the treatment during pregnancy was thorough and consistent, anecdotally many women requested information regarding the implications of having GDM, both for their babies, and themselves. My interest in GDM expanded through research, as coordinator for the Brisbane cohort of the Hyperglycaemia Adverse Pregnancy Outcomes (HAPO) study, and then other studies around postpartum interventions, in particular the mother’s experiences following the diagnoses of GDM. This thesis is the culmination of developing a program to provide evidence-based options for lifestyle choices for women previously diagnosed with GDM.

The concept of diabetes manifesting in pregnancy, with symptoms dissipating following the birth of the baby has been recognised by the medical profession for more than 50 years (1). It was well recognised that frank or overt diabetes in pregnancy led to complications with the fetus. However, it was not until Pettitt et al. (1980) demonstrated a dramatic increase in the incidence of fetal macrosomia and perinatal mortality in mothers with a blood glucose level >8.9 mmol/L (2), that the effects of milder degrees of hyperglycemia in pregnancy were examined more closely. Other studies also supported these findings (3), and excessive fetal growth (macrosomia) leading to an increased likelihood of an operative delivery and shoulder dystocia also caused concern among researchers, obstetricians and midwives (4).

By the late 1950s, O'Sullivan undertook the first widespread studies of the Oral Glucose Tolerance tests (OGTT) and described changes in carbohydrate metabolism in pregnancy (5).
Recent research confirms that diabetes in pregnancy (either pre-existing or identified during pregnancy) is associated with an increased risk of adverse perinatal outcomes, including macrosomia, neonatal hypoglycemia and respiratory distress syndrome (7). In 1991, screening strategies for GDM in Australia consisted of non-fasting glucose testing at 26–28 weeks gestation, with a fasting OGTT performed if glucose levels were above prescribed thresholds (≥7.8 mmol/L after 50 g carbohydrate load, or ≥8.0 mmol/L after 75 g load) (8). The Australasian Diabetes in Pregnancy Society (ADIPS) developed diagnostic criteria in 1998 to alleviate confusion within maternity health care relating to diagnoses and screening for GDM. They attempted to standardise the approach to glucose testing in pregnancy in Australia and New Zealand, working towards an Australian consensus. ADIPS also supported further research to identify the effect of maternal hyperglycemia on the fetus (9).

To investigate the effect of maternal hyperglycemia on the fetus, the Hyperglycemia and Adverse Pregnancy Outcomes Study (HAPO) recruited over 23,000 women from 16 centers worldwide with the aim of identifying adverse perinatal risks associated with differing degrees of maternal hyperglycemia (10). The results from this study showed a strong link between glucose levels, previously considered as sub-diagnostic, and increased birth weight and increased cord blood C-peptide levels. The study recommended a review of diagnostic criteria for GDM (10, 11).

The relationship between GDM and the onset of Type 2 diabetes (T2DM), while recognised even in the early work of O’Sullivan, has been of increasing interest over the last 15 years to researchers. In general, when excessive adipose tissue is present (especially in the abdominal area), muscles, fat and liver cells require large amounts of insulin to process the glucose within the bloodstream from glucose and carbohydrates ingested by the body. When this process is dysfunctional, it is termed insulin resistance and hyperglycaemia occurs (12). Hyperglycaemia if untreated has been shown to lead to an increased rate of cardio-vascular complications, retinal damage, kidney and liver disease. It is one of the largest public health issues in the developing world today, and therefore the focus of public health initiatives (12-14).
Insulin resistance resulting from obesity may be preventable with a lifestyle intervention (15), so most preventative programs concentrate on weight loss through dietary modification and increased physical activity (12). Yet the prevalence of T2DM in the Australian population has increased to 4.2% of the total population (16). The financial burden of T2DM is increasing each year worldwide, particularly in developed countries such as Australia and the United States (17, 18). Preventing T2DM is a far more logical and cost effective approach rather than waiting for it to manifest and relying on pharmacologic treatment (19).

During pregnancy, insulin resistance develops as part of the normal physiologic adaptation to advancing gestation. In the face of this challenge, the woman's pancreatic beta cells must respond appropriately by increasing endogenous insulin secretion. If this compensation is inadequate, hyperglycemia (generally recognised clinically during an OGTT and labeled as ‘GDM’) develops. The diagnostic criteria used at this time consisted of a 75 g OGTT with Fasting Plasma Glucose (FPG) ≥5.5 mmol/L and/or a two-hour plasma glucose ≥8.0 mmol/L (9). The prevalence of GDM in Australia is reported as ranging between five to eight per cent (20), with up to one third of all parous women who develop type 2 diabetes having had a previous history of GDM (21). Therefore, the diagnosis of GDM during pregnancy is an important marker for women at risk of developing diabetes.

For a woman who has been diagnosed with GDM, her antenatal course is one of additional advice, support and monitoring to ensure the optimal outcome for both herself and her baby (22). Following the birth, women can feel abandoned, as they have been given constant advice throughout the pregnancy which stops as soon as they go home (23, 24). Best practice, clinical, postnatal follow-up guidelines include an OGTT between 6–12 weeks postpartum to exclude T2DM. This should be repeated annually for early detection of the onset of T2DM if other risk factors are present or the woman is planning to conceive within the next 12 months. Otherwise bi-annual testing is recommended (25).
Intervention trials designed to reduce risk factors by increasing physical activity to support weight loss in women with prior GDM have been conducted with mixed success (26, 27), but there is evidence to support combined physical activity and dietary programs to decrease the risk of developing T2DM in high risk populations (15).

The most successful intervention study to prevent T2DM to date was the Diabetes Prevention Program (DPP) (15) which showed that lifestyle changes were more effective than treatment with oral hyperglycaemic medication (Metformin). The intensive lifestyle intervention of the DPP study was considered successful based on the outcome measures of weight loss (seven per cent body weight from baseline weight) and increased physical activity (at least 150 minutes/week). A sixteen-lesson curriculum delivered by case managers included behaviour modification with diet (low calorie, low fat diet) and exercise goals (brisk walking). Further sessions (either group or individual) were designed to reinforce the behaviour changes. The participants in the lifestyle intervention group lost an average of 5.6 kg over a 24-month period, and 50 per cent of participants met the target of increased physical activity (15). However, implementation, dissemination and local adaptions of lifestyle interventions for women with previous GDM have met with mixed success (26, 27).

In Brisbane, South East Queensland, a pilot study was conducted in 2012 and subsequently substantially informed the development of the work reported in this thesis. This trial involved women in the early postpartum period (approximately six weeks post-birth) and achieved a clinical improvement in the primary outcome of increased physical activity in women with young babies (27). Anecdotal participant feedback suggested that a better time to commence a lifestyle intervention would be when the baby is older, and that the addition of a dietary component to the intervention might be beneficial. Another study by Kim et al. also suggested that a combination of physical activity and a dietary component would be more effective than either intervention on its own (26).
The design and implementation of a lifestyle intervention to change health related behaviours to prevent disease is complex. The Behavioural Epidemiology Framework developed by Sallis et al (2000) provides a five phase step process, each phase leading to the next (28) (Table 1).

Table 1. Phases of the Behavioural Epidemiology Framework

<table>
<thead>
<tr>
<th>Phase</th>
<th>Process</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase 1</td>
<td>Establish links between behaviours and health</td>
</tr>
<tr>
<td>Phase 2</td>
<td>Develop methods for measuring the behaviour</td>
</tr>
<tr>
<td>Phase 3</td>
<td>Identify factors that influence the behaviour.</td>
</tr>
<tr>
<td>Phase 4</td>
<td>Evaluate interventions to change the behaviour</td>
</tr>
<tr>
<td>Phase 5</td>
<td>Translate research into practice</td>
</tr>
</tbody>
</table>

This framework guided the development of the studies included within this thesis. In response to Phase 1, a literature review was undertaken to establish the links between lifestyle and the risk of T2DM following GDM. It confirmed the strong link between GDM and T2DM, as well as identifying interventions that have had positive results in decreasing modifiable risk factors of developing T2DM, such as obesity and decreased physical activity. Phase 2 was addressed by developing a website with an interactive pedometer, which measured steps walked by participants, and utilising surveys designed to measure physical activity with both planned and incidental activity (Appendix 3). This was combined with nutrition coaching, targeting dietary and lifestyle change using effective behaviour change techniques, and measured by utilising surveys designed to report on eating behaviours and food choices (Appendix 4, 6). Tools reporting on self-efficacy and eating behaviours were used. Phase 3 has been addressed by the identification and application of a theoretical framework namely Social Cognitive Theory (29) to inform the development of an intervention study aimed at behaviour change. Phase 4 has been
addressed through designing and conducting a randomised controlled trial. Phase 5 was partially addressed within this research, through the use of qualitative investigation which explored factors which might influence translation.

Randomised controlled trials are considered the highest level of experimental research (30) and this method fits the purpose of the intervention section of the study. A feature of this research method is that it allows a hypothesis or treatment to be tested without bias, as participants are allocated to a treatment (with intervention) or a control (without intervention) in a random fashion. This increases the likelihood that any changes noted between groups can be attributed to the treatment offered to the intervention group, rather than to chance. If randomisation is concealed, or ‘blinded’, selection bias can be prevented, assuming the participants in each group are similar in characteristics (31). Limitations of this experimental research can include non-compliance of participants in the treatment arm, therefore decreasing the effectiveness of the interventions, withdrawal of participants before hypothesised outcomes are measured. Additionally, RCTs are not designed to provide information relating the participants’ experience or feelings (31).

The aim of the RCT within this thesis was to evaluate and test strategies for women previously diagnosed with GDM with a BMI >25 kg/m$^2$ to delay or prevent T2DM. This study consisted of a pedometer-based intervention to encourage physical activity, combined with a group-based nutrition coaching targeting dietary and lifestyle change using effective behaviour change techniques, aiming to decrease the risk of T2DM. The primary outcome was weight loss, with secondary outcomes of; (1) improved insulin sensitivity; (2) increased physical activity; (3) improved diet quality and self-efficacy; (4) decreased waist and hip measurements; and (5) a decrease in free fat mass (FFM).

The study was evaluated using mixed methods research. Mixed methods research involves research data that are collected and analysed, using both qualitative and quantitative approaches (32). A key focus of this research methodology is that the importance of the scientific evidence relating to data can be strengthened by the
addition of the human experience (33). Positivist research can provide information and scientific theories that can be repeated in a similar population, while the interpretivist research method provides understanding surrounding behaviours and perceptions of people within a particular setting (34). The study evaluation was informed by this theoretical background, and took advantage of the opportunity for use of a mixed-method paradigm that combines interpretivist and positivist approaches.

Information emerging from mixed-methods research is potentially influential and robust, and the method can overcome the strengths and weaknesses of one method alone (35). In this thesis, the use of mixed-methods is able to provide evidence from the RCT and qualitative interviews employing quantitative methods with a primary outcome of weight loss, and secondary outcomes of increasing physical activity and improving diet quality and improved insulin sensitivity, as well as insight into women’s experiences of the behavioural interventions. Qualitative research explores the lived experiences of people through interviews, focus groups and discussions. Thematic analysis allows the researcher to analyse the data into patterns or themes identifying common thoughts or experiences between the participants (36, 37). This may inform future researchers of barriers and enablers and potentially encourage participation in similar intervention trials. Thus, the recommendations which emerge may be used to inform Phase 5, the translation of research into practice in the future, although this is beyond the scope of this thesis.

1.1. Research questions

1) Which interventions may be potentially effective in decreasing the risk of T2DM in women previously diagnosed with GDM?

2) Does a pedometer-based intervention combined with nutrition coaching result in increased weight loss, improved insulin sensitivity, increased physical activity, improved diet quality and self-efficacy, decreased waist and hip measurements, and a decreased FFM when compared to standard care?
3) What are the experiences of undergoing a pedometer intervention combined with nutrition coaching for women with a previous history of GDM?

1.2. Hypotheses

1) A pedometer-based intervention combined with nutrition coaching will result in increased weight loss, improved insulin sensitivity, increased physical activity, improved diet quality and self-efficacy, decreased waist and hip measurements, and improved anthropometric measurements in the intervention group compared with the control group.

1.3. Overview of the thesis

This thesis will be presented in three studies that reflect the research questions above and contains six chapters. Figure 1 provides a schematic representation of the thesis.
Chapters two, three and four each contain a manuscript written for submission for publication. Preceding each manuscript the section describes the research context, provides a more detailed explanation of research methods, reports additional results, and elaborates on discussion not included in the manuscript.

Chapter 2 - the literature review describes the relationship between GDM and T2DM, and critically reviews the evidence on previous interventions to prevent T2DM, specifically in women previously diagnosed with GDM. Analysis of studies in the review is based on three questions:

1) What interventions were effective to prevent or delay T2DM in women previously diagnosed with GDM?
2) What are the barriers, enablers to and predictors of women engaging in interventions to delay or prevent T2DM?
3) What is the role of the midwife in care of a woman with GDM?

This chapter includes; Peacock AS, Bogossian FE, Wilkinson SA, McIntyre HD. A review of interventions to prevent Type 2 Diabetes after gestational diabetes. Women and Birth. Forthcoming 2015.

Chapter 3 reports the development, methodology, implementation and quantitative findings of the ‘Walking for Exercise and Nutrition to prevent Diabetes for You’ (WENDY) RCT. The study was designed to test an intervention for women previously diagnosed with GDM to delay or prevent the onset of T2DM. This chapter includes; Peacock AS, Bogossian FE, Wilkinson SA, Gibbons K, Kim C, McIntyre HD. A randomised controlled trial to delay or prevent type 2 diabetes after gestational diabetes. International Journal of Endocrinology. Forthcoming 2015.

Chapter Four reports the development, methodology, and qualitative findings examining the women’s experiences of participating in the RCT. This chapter includes; Peacock AS, Bogossian FE, McIntyre HD, Wilkinson SA. What Now? Women’s experiences post gestational diabetes engaging in an intervention to prevent Type 2 Diabetes mellitus. Manuscript submitted for publication.
Chapter Five draws together the findings of the studies in the preceding chapters. These findings are discussed in context of the wider literature and the strengths and limitations are discussed.

Chapter Six concludes the thesis by summarising the key findings of the thesis and makes recommendations to inform future interventions and research in this arena.

Acknowledgements of sources and references have been incorporated into the thesis document in two ways. Firstly where references form part of a manuscript submitted for publication they are included in the manuscript. Additionally a reference list for the thesis in its entirety is included.

1.4. Definition of variables

The following definitions for variables and key concepts have been applied throughout the thesis:

**Gestational Diabetes Mellitus (GDM)**

Glucose intolerance of variable severity with onset or first recognition during pregnancy (38).

**Type 2 Diabetes Mellitus (T2DM)**

Type 2 diabetes results from the body’s ineffective use of insulin. Type 2 diabetes comprises 90% of people with diabetes around the world, and is largely the result of excess body weight and physical inactivity (13).

**Oral Glucose Tolerance Test (OGTT)**

A fasting blood sample (participants were advised to fast for 10–12hrs prior to test), a 75 g carbohydrate load, and further blood samples taken at one hour and two hours(38).
Fasting blood glucose sample

A fasting blood sample taken following a fasting period of 10–12 hours.

Homeostasis Model Assessment. (HOMA-IR)

An estimate of insulin resistance in the fasting state, was calculated as (fasting plasma insulin (FPI) - [mU/L] x Fasting plasma glucose (FPG) [mmol/L]/22.5 (39).

Age

Age was calculated in years at baseline from the recorded date of birth.

Ethnicity

Participant’s self-identification of culture and traditions.

Gravidity

The number of previous pregnancies as self-reported by the participant.

Parity

The number of babies born as self-reported by the participant.

Health insurance status

The variable related to the health insurance status and included public (no health insurance, with all maternity care in the public health system) and private (all maternity care managed by private obstetrician and endocrinologist).

Diabetic control

The variable included three treatment options;

  1) Diet – hyperglycaemia was managed through diet modification alone in relation to blood sugar levels

  2) Oral medication – hyperglycaemia was managed through oral hyperglycaemic medication

  3) Insulin – hyperglycaemia was managed through insulin therapy

Self-reported height and weight

The participant reported this variable at the time of initial phone contact prior to baseline weight measurement.
**Height and weight**

Height was measured (cm) using a stadiometer and weight (kg) was measured using calibrated scales within the antenatal clinic of the research hospital.

**Body Mass Index (BMI)**

The formula to determine BMI is weight divided by height squared (BMI = kg/m²).

**Hip and waist measurement**

Hip and waist measurements were taken using a standard tape measure.

**Body fat (percentage)**

This variable was measured using bio-impedance technology (Body Stat 1500) in the fasting state prior to OGTT and fasting samples.

**Australian Women’s Activity Survey (AWAS)**

The AWAS was developed for the assessment of health-enhancing physical activity among women with children, and assesses past-week physical activity on weekdays and weekend days across a number of domains (40).

**Fat & Fibre Behaviour Index**

Diet quality was assessed using the Fat & Fibre Behaviour Index, a self-reporting tool that reflects components of participant’s diet over the previous month (41).

**The Health and Wellbeing Self-Efficacy Survey (WEL)**

This survey was designed to measure self-efficacy around eating behaviours. A total score, as well as scores in domains: Availability; Negative Emotions; Social Pressure; Physical Discomfort; and Positive Activities (42), are calculated following the completion of the surveys.

**Kessler (K10) scale**

Mental health was assessed using the Kessler Psychological Distress scale (K10) (43).
This chapter has provided an introduction to the problem and an overview of the thesis content. The following chapter will describe the methodology and findings of the literature review.
2. Literature review

“….the question is how best to deliver interventions in this population?”
Cheung et al. (2011)

2.1. Introduction

The previous chapter provided an introduction of the thesis, and a background to the significance of GDM in relation to T2DM. This chapter will describe the impact of GDM and T2DM nationally and globally, and provide a background to the literature review included.

Systematic reviews, are considered the ‘gold standard’ of research evidence (44). Key components of a systematic review are that all available literature on a clearly defined clinical question is synthesised by two or more authors (this may or may not include a statistical meta-analysis) and it uses a specified framework to report on findings (31). A systematic review aims to overcome bias by following a rigorous methodology for all stages of the review, including pre-defined search criteria, retrieval and appraisal of research (45). Using a systematic approach to reviewing the literature also allows the researcher to fully understand the literature already published in their field, as well as identifying gaps in research that need to be addressed (31, 35).

Diabetes has become a global issue, and the World Health Organisation (WHO) has predicted that diabetes will be the 7th leading cause of death globally by 2030 (46). Kim et al. (2002) reviewed articles from 1965 to 2001 specifically related to testing for GDM then subsequent testing for T2DM, and found there was up to 70% incidence of T2DM in women previously diagnosed with T2DM (21). This finding was significant as it showed a strong link between GDM and T2DM, and led to public health considerations for future preventative programs relating to this high risk group (19, 47). More research showed not only was the risk of women with previous GDM translating to the development of T2DM increased, there was an opportunity to delay
or prevent T2DM through lifestyle modifications that had been proven in similar populations in other studies (15, 48).

Over 27% of women in Australia in 2012 were obese, with one in twenty diagnosed with GDM (49), with statistics showing an increase each year. The retention of postpartum weight has been studied (50) in an effort to support weight loss as the risk of T2DM is higher if the women are overweight or obese (51). A recent Cochrane review by Amorim and Linne (2013) (52) suggested the combination of diet and exercise may support weight loss in this cohort compared to dieting alone.

Investigating health beliefs and risk perception of developing T2DM in women previously diagnosed with GDM, showed a number of barriers to long term lifestyle changes, and a large percentage of this population group did not perceive themselves at increased risk despite education and information on lifestyle changes (53, 54). Further systematic reviews and meta-analyses by Baptiste- Roberts et al. (2009) (51) reinforced this increased risk and provided evidence of specific risk factors such as increased anthropometric measurements and indicated that the use of insulin therapy during the pregnancy would statistically increase the chances of developing T2DM (51, 55). As more evidence emerged, it became clear that lifestyle interventions targeting risk factors to delay or prevent the onset of T2DM in women previously diagnosed with GDM were not only feasible, they were a sensible public health initiative (56).

This solution to this public health issue was not as easily rectified as the researchers who had studied this concept proposed. Intervention trials aimed at increasing physical activity and diet modifications showed only small changes to lifestyle were achieved following the birth of a baby, and most recommendations included more intensive follow-up and support in the postpartum period (57-60).

A wide variety of intervention trials conducted world-wide have met with mixed success in reaching the aims of modifying behaviour to support the increased
physical activity and diet modifications recommended. A Cochrane review is currently in progress, which will provide a synthesis of past and current studies in the arena of diet and exercise interventions to prevent T2DM in women previously diagnosed with GDM (61).

In this thesis a systematic literature review was undertaken in response to the clinical question: Which interventions may be potentially effective in decreasing the risk of T2DM in women previously diagnosed with GDM?

Inclusion criteria were: women previously diagnosed with GDM (population); behavioural and pharmacological interventions intended to reduce maternal risk of T2DM (interventions); delay or prevention of development of T2DM (outcomes); English (language); peer reviewed publications or professional publications (source); and between 1998 and 2013 (publication time period).

The preliminary search yielded one hundred and twenty-two articles. These were reviewed and commentaries, reviews and research that did not fulfil research criteria were discarded. Full text articles were assessed for eligibility by all authors and, following this, thirty articles remained (Figure 1, page 45). The reporting quality of the articles was assessed using the Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) protocol using the Consolidated Standards of Reporting Trials (CONSORT) and STrengthening the Reporting of OBservational studies in Epidemiology STROBE guidelines by study type (Appendix 1) (62). Each study was reported by study type, and a score of 1 given for each section within the guidelines. Studies were included in the Literature Review if the score was 80% of the total possible score or higher to ensure the articles were high quality evidence.

Analysis and reporting of findings reflected three research areas:

1) Interventions that identify effective strategies and programs to decrease the risk of T2DM in women who experience GDM.

2) The barriers and enablers to participation in interventions.
3) The opportunities for midwives to assist women in prevention.

2.2. Summary of Findings

2.2.1. Interventions that identify effective strategies and programs to decrease the risk of T2DM in women who experience GDM

Of the thirty publications selected for review, thirteen studies included interventions to delay or prevent T2DM (Table 1, page 48). Of these, eight were RCTs and five were observational studies. Three RCTs and one observational study also involved a pharmacological intervention. Of the thirteen studies, the effectiveness of the interventions varied, and outcomes measured included dietary behaviour change, weight loss and increased physical activity.

In summary, from the eight RCTs, five (Buchanan et al, Ferrara et al, Knowler et al, Ratner et al, and Reinhardt et al.) reported positive results in the intervention groups, and within the five observational studies; three (Fehler et al, Retnakaran et al, and Xiang et al), reported positive changes.

Five of the studies identified (Chueng et al., Ferrara et al., Kim et al., McIntyre et al., and Reinhardt.) used non-pharmacological interventions and subsequently informed the design of the RCT in this thesis. All of these studies used either a pedometer or accelerometer as a tool for both goal setting and a measure of physical activity. Physical activity was assessed through questionnaires, with two studies (McIntyre et al. and Reinhardt et al.) measuring all domains of life such as work, transport, home life and leisure time. McIntyre et al. specifically used The Australian Women’s Activity Survey (AWAS) (40) for assessment of physical activity. Self-efficacy was self-reported in food frequency questionnaires and all interventions involved motivational counselling and were delivered by either by telephone or in-person.

Although telephone counselling was appropriate in one study due to the rural cohort, in-person counselling was considered a strength in the remaining studies. Informed by these studies the RCT in this thesis was developed to include goal setting (with
pedometers) with the addition of both an Internet program to deliver motivational tools, as well as face-to-face nutrition coaching.

2.2.2. Barriers and enablers to participation in interventions

Of the publications selected for review, fourteen studies identified barriers to women who had GDM taking up interventions to prevent or delay T2DM, particularly in relation to instigating and sustaining programs designed for lifestyle change (Table 2, page 55)

Six of these studies (Bennett et al., Doran et al., Graco et al., Nicklas et al., Smith et al., and Symon Downs et al.) reported common themes such as lack of child care, work, transport issues, lack of motivation and perceived insufficient time as reasons for non-participation in intervention trials in this cohort. Overall, women reported difficulty in making lifestyle changes during this life phase. When designing the RCT for this thesis consideration for these factors was made, such as providing paid parking, the ability to bring children to the nutrition coaching sessions if desired, and the introduction of an Internet-based activity program designed to be used at the woman’s convenience

2.2.3. The opportunities for midwives to assist in prevention

Of the thirty articles selected for review, three articles (Devsam et al., Irwin J., and Jones S.) explored the role of the midwife, in particular the need to enhance the role in order to improve the quality of care for women with GDM (Table 3, page 61).

Devsam et al. (2013) identified women newly diagnosed with GDM who have described their frustration with the transition to the multidisciplinary team approach from a midwifery model of care, finding the care fragmented with little psychological support from the different healthcare providers (23). The positive effects of continuity-of-care during the childbirth journey have been well described, and women identify that they prefer that their pregnancy is ‘normalised’ after the diagnoses of
GDM was made (23), which may be achieved with a collaborative midwifery and multidisciplinary team approach.

2.3. Discussion

This population group (women with a history of GDM) have proven risk factors for the development of T2DM, and further research is required to evaluate how these risks can be decreased. It makes sense to explore all options that prevent T2DM, rather than treat the disease later in life. Although there are barriers for women to take up lifestyle and behaviour change, this target cohort is considered ‘high-risk’ for development of T2DM within 10–15 years (21).

A recent Cochrane review has shown that screening and testing postpartum for T2DM has not increased through the use of reminders and further research should be performed to identify possible motivating factors for women to undertake suggested screening (38, 63).

The birth of a new baby is a profoundly life changing experience. Issues such as lack of childcare, work, transport, lack of motivation and perceived insufficient time were common themes and resulted in difficulty in recruitment and engagement in intervention programs. Health care programs aimed at this group need to find a ‘common ground’ where behaviour change to delay or prevent T2DM can be affected without women feeling that their family life or responsibilities are compromised. Education of women about strategies that may prevent the long term risks of GDM, such as breastfeeding (64), by midwives during the antenatal period may encourage women to consider adopting lifestyle changes.

This literature suggests the need to develop a behaviour change program specifically targeting women previously diagnosed with GDM, in order to decrease the risk of T2DM. Several studies have shown that interventions can be successful and, providing lifestyle change options for women who are still relatively young, may
prevent development of T2DM long-term; as preferable to treatment of the disease itself.

Previous research has shown that weight loss and increasing physical activity can prevent the development of T2DM, and these interventions were the natural choice to base the theoretical framework of behaviour change and self-efficacy with the intention of instilling a long-term healthy lifestyle.

The next chapter describes the development of an intervention designed to support weight loss and increased physical activity for women previously diagnosed with GDM with a BMI >25 kg/m².
2.4. Publication: A review of interventions to prevent Type 2 Diabetes after gestational diabetes.


1 School of Nursing and Midwifery, Faculty of Health Sciences, The University of Queensland, Herston Campus, Edith Cavell Building, Herston QLD 4006
2 Mater Clinical School, The University of Queensland; Head of Mothers and Babies Research Theme, Mater Research, Mater Health Services, Raymond Terrace, South Brisbane, Qld 4101
3 Mothers and Babies Theme, Mater Research, Mater Health Services, Raymond Terrace, South Brisbane, Brisbane, QLD 4101
4 Department of Nutrition & Dietetics, Mater Health Services Raymond Terrace, South Brisbane, Brisbane, QLD 4101

Introduction

Worldwide, the incidence of gestational diabetes mellitus (GDM) has been increasing over the last 15 years along with increasing obesity rates\(^1\). The incidence of GDM in Australia was 5% in 2008\(^2\), however under new diagnostic criteria the rate could be as high as 13%\(^3\). With escalating rates of diagnosis midwives will play an increasingly important role in the care of women with GDM, collaborating with the specialist care team of endocrinologists, obstetricians, diabetes educators and dietitians.

Gestational diabetes mellitus is carbohydrate intolerance recognised or first diagnosed during pregnancy\(^4\). The original identification of GDM by O'Sullivan in the 1960s using the oral glucose tolerance test (OGTT) was the first step in recognising the importance of this condition in pregnancy\(^5\). Since then the Hyperglycaemia and Adverse Pregnancy Outcome (HAPO) study has reinforced the associations between elevated maternal blood glucose control and adverse neonatal outcomes including increased birth weight, fetal adiposity and umbilical cord blood C-peptide
levels. The results of this landmark study have led to a greater understanding of glucose metabolism during pregnancy and the revision of diagnostic criteria for blood glucose levels for GDM.

It is important for midwives to understand the relationship between GDM and Type 2 diabetes mellitus (T2DM), the impact on the index pregnancy, and the effect on future health of mothers and their infants in order to provide women with relevant evidence-based care and advice for the long-term wellbeing of themselves and their families. The relationship between the diagnosis of GDM and the onset of T2DM has been the focus of numerous reports, studies and reviews over the last decade, and GDM has emerged as one of the strongest predictors of T2DM with the cumulative incidence of T2DM ranging from 2.6%–70% from six weeks to 28 years postpartum.

Documented risk factors for GDM are similar to those for T2DM, and include older maternal age (>35), obesity (BMI>30kg/m²), family history of Type 1 or Type 2 diabetes, and a diet high in saturated fat. Common risk factors in the development of GDM and T2DM underlie the temporal relationship between these two conditions, leading to a high risk of development of T2DM following the GDM pregnancy.

The identification of women who face the consequent risk of developing T2DM during their pregnancy provides midwives with an opportunity to individually, and with other members of the multi-disciplinary team, initiate education and support women in interventions to decrease modifiable risk factors such as high BMI, excess gestational weight gain, and insufficient physical activity. The opportunity to intervene is not restricted to the antenatal period but extends into the postnatal period and to the pre-conception phase of a subsequent pregnancy. The Australasian Diabetes in Pregnancy Society (ADIPS) guidelines recommend follow up care in collaboration with General Practitioners, and include an OGTT at 6 to 12 weeks postpartum, with diagnosis of T2DM according to WHO criteria and then 1 to 2 yearly depending on risk factors. Women planning to conceive again should have an annual OGTT to exclude T2DM prior to conception. While the OGTT is an
essential diagnostic and screening tool compliance with guidelines has been sporadic at best\textsuperscript{15,16}.

Obesity is an independent risk factor for the development of T2DM, so the identification of women with both GDM and obesity is important to allow tailored and targeted delivery of information and programs to support this population\textsuperscript{17}. Despite this recognition, lifestyle changes in new mothers to prevent or delay the onset of T2DM have been difficult to deliver or to engage women\textsuperscript{18}. In addition to the long-term increased risk of T2DM, the infant/child of a GDM pregnancy has a two-fold increase of being overweight\textsuperscript{19}. Animal models have also shown increased obesity and altered glucose metabolism in offspring of mothers who had GDM\textsuperscript{20}, and developing and promoting interventions to the population of mothers with young children both in the antenatal and immediate postpartum period may lead to a “whole of family” approach and to the prevention of a suite of chronic diseases\textsuperscript{20}. Midwifery intervention, referral and/or collaboration with appropriate multi-disciplinary team members during pregnancy may have a profound effect not only on the current pregnancy outcomes, but also on the future health of the mother, her infant and family.

Although women may be aware of the risks of future development of T2DM, they may not always act on this knowledge and initiate lifestyle changes suggested by health practitioners\textsuperscript{21}. Tiredness, lack of access to childcare and work commitments are commonly cited by women as deterrents of their engagement in intervention programs to delay or prevent T2DM after GDM\textsuperscript{22}. There are, however, strategies that midwives can initiate in the immediate postpartum that can lead to long-term health changes such as the encouragement and support of breastfeeding.

Breastfeeding is beneficial in the prevention of T2DM in obese women and in those women diagnosed with GDM\textsuperscript{23,24}. The benefits of breastfeeding depend on the length and intensity of lactation, as longer duration of lactation (up to 9 months) improves glucose metabolism and insulin sensitivity and reduces T2DM risk after GDM diagnosis\textsuperscript{23}. Difficulties surrounding the establishment of breastfeeding and lactation in both obese and GDM women have been documented\textsuperscript{23}.
Midwives are ideally positioned to implement strategies including promotion of early breastfeeding, maintaining supply and long term postpartum breastfeeding support\textsuperscript{25,26} that may lower a woman’s risk of T2DM and may be beneficial for long term health\textsuperscript{24}. Continuity of care by a midwifery team has also shown to enhance screening of at risk women identified while pregnant, as well as providing opportunistic education relating to long term lifestyle changes that may delay or prevent T2DM\textsuperscript{27}.

Poorly managed GDM not only results in negative maternal and infant outcomes but also has future fiscal implications if it leads to T2DM. The health care cost of T2DM to society has been examined in the United States where the national economic burden in 2007 attributed to diabetes was approximately $US218 Billion\textsuperscript{28}. An Australian study, using a micro-simulation model, demonstrated that the most cost-effective intervention option to decrease T2DM risk is a combined diet and exercise program aimed at high risk populations with the focus on prevention of T2DM development\textsuperscript{29}. This recommendation has been strengthened by cost benefit studies which suggest that interventions in this group to delay or prevent the development of T2DM are cost effective\textsuperscript{30,31}. In summary, the literature indicates that the prevalence of the GDM is increasing and the link between GDM and T2DM is has been clearly demonstrated, and makes ethical and economic sense to pursue interventions that may decrease the risk of T2DM in women with GDM.

In order to do so we posed three research questions: How effective are interventions to delay or prevent T2M in women previously diagnosed with GDM?, what are the barriers to participation, and the opportunities for midwives to assist women in prevention?

\textbf{Methods}

The aim of this review is to identify effective strategies and programs to decrease the risk of T2DM in women who experience GDM, the barriers to participation, and the opportunities for midwives to assist women in prevention.
A three-stage approach was employed in order to answer the research questions. Firstly a systematic review of the literature was undertaken, included studies were then appraised for quality and finally findings of the studies were thematically analysed.

Between February 2011 and November 2013 we searched CINAHL, Medline and PubMed databases. Key search terms were used, including gestational diabetes, gestational diabetes mellitus, diabetes mellitus, type 2 diabetes, epidemiology, prevalence, incidence, risk factors, barrier *, intervention*, strategy*, prevent*, program*, diet, exercise, midwives, nurse* and breastfeeding. A secondary hand search of the reference lists of retrieved articles yielded further papers for evaluation. Publications dates were limited to the previous 15 years, because this period represents the largest concentration of contemporary research.

Inclusion criteria were: women previously diagnosed with GDM (population), behavioural and pharmacological interventions intended to reduce maternal risk of T2DM (interventions), delay or prevention of development of T2DM (outcomes), English (language), peer reviewed publications or professional publications (source); and 1998 to 2013 (publication time period).
The preliminary search, based on title and abstract, yielded 122 articles. The first author (AP) then reviewed these articles and discarded commentaries, reviews and research that focused on populations other than women who had been diagnosed with GDM. Full text articles were then assessed for eligibility, and included reviews were then assessed by FB (second author). Following this, 30 articles remained (Figure 1). The reporting quality of the RCTs was assessed using the CONSORT algorithm\(^3\), to which a numerical score was assigned and those articles having a score of 90% or better were included in further analysis. Because the included studies lacked homogeneity, we could not justify a meta-analysis and undertook a thematic approach to data synthesis\(^3\). Analysis of studies was based on the research questions namely, interventions to prevent or delay T2DM in women previously diagnosed with GDM – summarised in Table 1, barriers, enablers to and predictors of women engaging in interventions to delay or prevent T2DM

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**Figure 1. Flow Diagram outlining search strategies and results**

Records identified through database searching (n=22)  
Records after duplicates removed (n=122)  
Records screened (n=122)  
Records excluded (n=46)  
Full-text articles assessed for eligibility (n=75)  
Full-text articles excluded, did not meet study criteria (n=46)  
Studies included in quantitative synthesis (n=30)
summarised in Table 2, and the role of the midwife in care of a woman with GDM in Table 3.

Results

Interventions to delay or prevent T2DM in women previously diagnosed with GDM

Of the 30 publications selected for review, 13 studies included interventions to delay or prevent T2DM (Table 1). Of these, eight were randomised controlled trials (RCTs) and five were observational studies. Three RCTs and one observational study also involved a pharmacological intervention\textsuperscript{34-37}. Of the 13 studies, the effectiveness of the interventions varied, and outcomes measured included dietary behaviour change, weight loss and increased physical activity.
<table>
<thead>
<tr>
<th>Author and Year</th>
<th>Study Design</th>
<th>Setting</th>
<th>Sample Studies</th>
<th>Intervention</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Buchanan, T.A., Xiang, A.H., Peters, R.K., Kjos, S.L., Marroquin, A., Goico, J., Ochoa, C., Tan, S., Berkowitz, K., Hodis, H.N., Azen, S.P. (2002)</td>
<td>RCT</td>
<td>USA</td>
<td>n=266</td>
<td>Randomised to receive Troglitazine 400mg/day or placebo</td>
<td>Diabetes incidence rate was decreased in the intervention group (5.4%) compared with the placebo group (12.1%) ((p&lt;0.001))</td>
</tr>
<tr>
<td>Cheung, N., Smith, B., van der Ploeg, H., Cinnadaio, N., &amp; Bauman, A. (2011)</td>
<td>RCT</td>
<td>Australia</td>
<td>n=43</td>
<td>12 month patient centred counselling self-management education techniques to change physical activity behaviour</td>
<td>No increase in physical activity to baseline measurement was achieved</td>
</tr>
<tr>
<td>Author and Year</td>
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<td>Intervention</td>
<td>Outcomes</td>
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<tr>
<td>Ferrara, A., Hedderson, M., Albright, C., Ehrlich, S., Quesenberry, C. (2011)</td>
<td>RCT</td>
<td>USA</td>
<td>n=17</td>
<td>Dietary intervention by phone based on the DPP guidelines</td>
<td>Greater percentage of weight loss in the intervention group, however greater weight loss in the BMI &lt;25kg/m² (46.9%) than the BMI &gt; 25kg/m² (30.0%) at 12 months postpartum</td>
</tr>
<tr>
<td>Kim, C., Draska, M., Hess, M. L., Wilson, E. J., &amp; Richardson, C. R. (2012)</td>
<td>RCT</td>
<td>USA</td>
<td>n=49</td>
<td>13 week walking programme that provided web-based education, pedometer, text message reminders, and an internet forum</td>
<td>There were no significant differences in physical activity and weight loss noted</td>
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</table>


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<tr>
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<th>Sample Studies</th>
<th>Intervention</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ratner, R. E., Christophi, C. A., Metzger, B. E., Dabelea, D., Bennett, P. H., Pi-Sunyer, X., Fowler, S., Kahn, S. E. (2008).</td>
<td>RCT</td>
<td>USA</td>
<td>n=1776</td>
<td>Compared outcomes of women who had GDM who had participation in (DPP) Lifestyle intervention program, the use of Metformin, or standard care</td>
<td>Lifestyle intervention ($p=0.002$) and Metformin ($p = 0.006$) reduce the risk of T2DM compared to placebo and control</td>
</tr>
<tr>
<td>Reinhardt, J., van der Ploeg, H., Gregrzulka, R., Timperley, J. (2012)</td>
<td>RCT</td>
<td>USA</td>
<td>n=38</td>
<td>6 month phone based motivational interviewing program aimed at positive lifestyle change</td>
<td>Weight reduction in the intervention group (95% CI: -7.6 to -0.5) + changes in dietary intake.</td>
</tr>
<tr>
<td>Author and Year</td>
<td>Study Design</td>
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<td>Sample Studies</td>
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<tr>
<td>Cheung, N. W., Smith, B. J., Henriksen, H., Tapsell, L. C., McLean, M., &amp; Bauman, A. (2007)</td>
<td>Observational</td>
<td>Australia</td>
<td>n=20</td>
<td>One year group based lifestyle behaviour change program</td>
<td>Reduction in weight in participants ($p = 0.03$)</td>
</tr>
<tr>
<td>Fehler, K. L., Kennedy, L. E., McCargar, L. J., Bell, R. C., &amp; Ryan, E. A. (2007)</td>
<td>Observational</td>
<td>Canada</td>
<td>n=11</td>
<td>Dietary intervention</td>
<td>Eating patterns were changed during the index GDM pregnancy ($\uparrow$ protein $p = 0.01$, fibre $p = 0.002$) but not sustained postpartum</td>
</tr>
<tr>
<td>Gates, D. J., &amp; Mick, D. (2010)</td>
<td>Observational</td>
<td>USA</td>
<td>n=7</td>
<td>Assessing participants perceptions of healthiness though the exercise Qiong</td>
<td>Group sessions demonstrated a potential to improve perceptions of healthiness in women</td>
</tr>
<tr>
<td>Retnakaran, R., Qi, Y., Sermer, M., Connelly, P. W., Zinman, B., &amp; Hanley, A. J. (2010)</td>
<td>Observational</td>
<td>Canada</td>
<td>n=238</td>
<td>Assessing behaviour change post GDM</td>
<td>Leisure time activity was increased, but poorly defined</td>
</tr>
<tr>
<td>Author and Year</td>
<td>Study Design</td>
<td>Setting</td>
<td>Sample Studies</td>
<td>Intervention</td>
<td>Outcomes</td>
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<tr>
<td>Xiang, A. H., Peters, R. K., Kjos, S. L., Marroquin, A., Goico, J., Ochoa, C., Buchanan, T. A. (2006).</td>
<td>Observational</td>
<td>n=89</td>
<td>3 years administration of Pioglitazone</td>
<td>The results supported a class effect of Thiazolidinedione drugs to enhance insulin sensitivity, reduce insulin secretory demands and preserve pancreatic β-cell function, with a relatively low rate of T2DM in Hispanic women with prior GDM</td>
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</table>
The Diabetes Prevention Program (DPP) RCT studies, with \( n = 3234^{34} \) and \( n = 1776^{35} \), demonstrated the effectiveness of a lifestyle intervention in preventing the development of T2DM. In 2002, the DPP Research Group used a three arm trial to compare participation in a lifestyle intervention program (intervention 1) or the use of Metformin (intervention 2) with standard care (control group) to reduce the incidence of T2DM in high risk populations, where a history of GDM was one risk factor\(^{34}\). The control group received general written information, highlighting the importance of the US Food Guide Pyramid, and general advice to increase physical activity. The lifestyle intervention, which included a 16-lesson curriculum covering diet, exercise, and behaviour modification was found to be more effective than Metformin in reducing the risk of developing T2DM. When outcomes for women with a history of GDM were compared with those who did not it was found that both the lifestyle and Metformin intervention reduced the incidence of T2DM by approximately 50% compared with the placebo group\(^{35}\). The intensive lifestyle intervention was more effective in the non-GDM group and the GDM group were not able to sustain the lifestyle changes over time\(^{35}\). A smaller study (\( n=17 \)) that delivered the DPP dietary-principles via telephone counselling demonstrated success with weight loss in a high-risk population\(^{38}\). The combination of increased risk, less physical activity and consistent weight gain in the GDM group highlights the importance of an intense intervention and long-term follow-up in this group of women\(^{35}\).

Smaller RCTs with between 20 to 40 women have demonstrated success with weight loss and dietary change\(^{39}\) and mixed success with changing physical activity levels. McIntyre and colleagues’ evaluation of developing an individualised physical activity program for women following a GDM pregnancy found that the average physical activity time increased by 60 minutes/week when women undertook a program that mainly comprised of walking, when compared with standard care\(^{18}\), while neither Cheung (2011), nor Kim were able to demonstrate increases in physical activity levels in their interventions\(^{40,41}\).

Despite Cheung and colleagues’ (2006) success in increasing physical activity through walking in an observational study delivering a group-based healthy lifestyle program to women previously diagnosed with GDM\(^{42}\), the group’s subsequent RCT based on a structured, behavioural physical activity intervention in women with recent GDM found a small increase in physical activity in the intervention group, but the aim of reaching the
target of 10,000 steps/day was not met by the majority of women in the study. Kim and colleagues’ study examining a program designed to increase physical activity using a web-based pedometer programme in women recently diagnosed with GDM detected little difference in clinical measurements between the two groups. However, it was noted by the authors that the addition of a dietary intervention to their program might have been more effective.

Observational studies add further support to these findings. In addition to Cheung’s study, Gates et al. (2010) introduced Qigong, an oriental movement exercise, to a group of woman (with young children) at risk of T2DM, and Retnakaran et al investigated the maintenance of women’s pre-pregnancy leisure time activity and dietary patterns in the year immediately postpartum following the diagnosis of GDM. Gates et al showed participants reported attendance at the Qigong sessions beneficial, increasing their perception of healthiness, and Retnakaran et al (2010) had success with increasing their leisure time activity in the year after pregnancy compared with women who did not have GDM. However, the definition of leisure-time activities was limited to walking and television watching, so the inclusion of sedentary activities does not provide clear evidence of the effectiveness of physical activity.

In contrast, the problem with sustaining dietary changes made during pregnancy into the postpartum period was highlighted by Fehler et al. Lifestyle advice, including dietary and physical activity recommendations provided at the time of diagnoses of GDM, were not continued into the postpartum period in a study where 60% of participants failed to return to their pre-pregnant weight, with physical activity levels low or unchanged.

Studies that primarily looked at pharmacological treatments evaluated in their effectiveness at preventing the development of, or progression to, T2DM were also considered. In 1998, the TRIPOD study recruited high risk Hispanic women with prior history of GDM and demonstrated a significant decrease in T2DM incidence (12.1% in the intervention group compared with 5.4% in the placebo group) following the use of Troglitazone. However the drug was removed from use due to adverse hepatic effects. In the follow up study (PIPOD), researchers used Pioglitazone to evaluate β-cell function, insulin resistance and the incidence of T2DM in women who had completed the TRIPOD study. The researchers found that Pioglitazone stopped the decline of β-cell function and
concluded that Thiazolidinedione drugs could enhance insulin sensitivity, reduce insulin secretory demands, and preserve pancreatic β-cell function, all in association with a reduced rate of progression to T2DM, in Hispanic women with prior GDM.\(^{36}\)

In summary, from the 8 RCTs, 5 (Buchanan et al., Ferrara et al., Knowler et al., Ratner et al., and Reinhardt et al.) reported positive results in the intervention groups, and within the 5 observational studies, 3 (Fehler et al., Retnakaran et al., and Xiang et al.), reported positive changes.

**Barriers and enablers to and predictors of women engaging in interventions to prevent or delay the onset of T2DM**

Of the total 30 publications selected for review, 14 studies identified barriers to women who have had GDM taking up interventions to prevent or delay T2DM, particularly in relation to instigating and sustaining programs designed for lifestyle change, such as those presented above. Researchers have examined behaviours, beliefs and issues that may prevent or support this cohort maintaining long term lifestyle changes to prevent or delay the onset of T2DM.
Table 2. Summary of thematic findings of studies regarding barriers, enablers and predictors to women previously diagnosed with GDM participating in effective interventions to delay or prevent Type 2 Diabetes

<table>
<thead>
<tr>
<th>Author and Year</th>
<th>Study Design</th>
<th>Setting</th>
<th>Sample Studied</th>
<th>Method</th>
<th>Thematic findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bennett, W. L., Ennen, C. S., Carrese, J. A., Hill-Briggs, F., Levine, D. M.,</td>
<td>Thematic analysis</td>
<td>USA</td>
<td>n=22</td>
<td>Semi-structured interviews to identify barriers to post GDM follow up</td>
<td>Themes; emotional stress adjusting to motherhood, fear of receiving a diagnoses of T2DM</td>
</tr>
<tr>
<td>Doran, F., &amp; Davis, K. (2011)</td>
<td>Quantitative</td>
<td>Australia</td>
<td>n=72</td>
<td>Surveys identifying barriers and enablers to physical activity</td>
<td>Themes; lack of child care , time constraints, illness, lack of family support; enjoyment and perception of health promotion enhanced activity</td>
</tr>
<tr>
<td>Evans, M., Patrick, L., Wellington, C.M., (2010)</td>
<td>Descriptive, interpretive analysis</td>
<td>Canada</td>
<td>n=16</td>
<td>Semi-structured interviews and surveys to elicit information regarding general health and health behaviours</td>
<td>Themes; Being on one’s own, Feeling uncertain/not off the hook, Staying healthy/making changes, Moving on. Sustaining lifestyle changes described as difficult</td>
</tr>
<tr>
<td>Author and Year</td>
<td>Study Design</td>
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<tr>
<td>Kieffer, E. C., Sinco, B., &amp; Kim, C. (2006)</td>
<td>Cross sectional; quantitative</td>
<td>USA</td>
<td>n=177,420</td>
<td>Telephone surveys assessing physical activity, fruit and vegetable intake, and smoking</td>
<td>Women with a history of GDM were less likely to meet fruit and vegetable guidelines ($p=0.05$) and more likely to smoke ($p=0.05$)</td>
</tr>
<tr>
<td>Koh, D., Miller, Y. D., Marshall, A. L., Brown, W. J., &amp; McIntyre, D. (2008)</td>
<td>Cross sectional; quantitative</td>
<td>Australia</td>
<td>n=331</td>
<td>Telephone survey assessing physical activity, psychosocial correlates of physical activity,</td>
<td>Health enhancing physical activity was low, suggests increasing social support and self-efficacy</td>
</tr>
<tr>
<td>Author and Year</td>
<td>Study Design</td>
<td>Setting</td>
<td>Sample Studied</td>
<td>Method</td>
<td>Thematic findings</td>
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<tr>
<td>Razee, H., Hp, Blignault, I., Smith, B. J., Bauman, A. E., McLean, M., &amp; Wah Cheung, N. (2010)</td>
<td>Thematic analysis</td>
<td>Australia</td>
<td>n=57</td>
<td>Semi structured telephone interviews on women’s experiences and perceptions of GDM and risk of developing T2DM</td>
<td>Themes; differing cultural needs, mental health, social support.</td>
</tr>
<tr>
<td>Smith, B. J., Cheung, N. W., Bauman, A. E., Zehle, K., &amp; McLean, M. (2005)</td>
<td>Cross sectional; quantitative</td>
<td>Australia</td>
<td>n=226</td>
<td>Telephone surveys assessing physical activity, self-efficacy, social support and barriers to participation in interventions</td>
<td>Barriers identified; lack of child care, insufficient time, and lack of encouragement</td>
</tr>
<tr>
<td>Stage, E., Ronneby, H., &amp; Damm, P. (2004)</td>
<td>Cross sectional quantitative;</td>
<td>Denmark</td>
<td>n =121</td>
<td>Mailed survey with structured questions on diet, weight loss and exercise</td>
<td>Theme; Not able to change lifestyle following GDM</td>
</tr>
<tr>
<td>Swan, W. E., Liaw, S., Dunning, T., Pallant, J. F., &amp; Kilmartin, G. (2010)</td>
<td>Cross sectional; quantitative</td>
<td>Australia</td>
<td>n= 77</td>
<td>Mailed questionnaire on stage of behaviour change, physical activity level, and dietary fat intake</td>
<td>Reported readiness for change, weight remained increased</td>
</tr>
<tr>
<td>Author and Year</td>
<td>Study Design</td>
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<tr>
<td>Symons Downs, D., &amp; Ulbrecht, J. S. (2006)</td>
<td>Cross-sectional quantitative</td>
<td>USA</td>
<td>n= 28</td>
<td>Mailed survey on self-reported exercise beliefs and behaviours</td>
<td>Themes; initial feelings of abandonment post-partum, lifestyle changes are difficult</td>
</tr>
</tbody>
</table>
Women described in the studies (Table 2), who have had GDM in a previous pregnancy, were more likely to be overweight, not meeting recommended fruit and vegetables intake, smokers and have low levels of physical activity\textsuperscript{47,48} compared with women who did not have a diagnosis of GDM. These findings suggest women may not be successful in changing their lifestyles despite the increased risk of T2DM and may need greater assistance in changing these specific behaviours.

A woman’s ability to follow a healthy lifestyle is dependent on her psychological wellbeing, as well as social and cultural support. The difficulty balancing household expectations and leading a healthy lifestyle\textsuperscript{49} and the complexities of women’s motivations behind these decisions are highlighted in the studies in Table 2. Evans et al. (2010) studied women with a history of GDM to explore their health behaviours and their perceived health status compared with their actual experiences in healthy lifestyle changes\textsuperscript{50}. Important issues to the mother such as ‘the feeling of abandonment’ by health care providers and the hospital following the birth of their baby in contrast to the intensive monitoring during their pregnancy, and the recognition that lifestyle changes are difficult were noted\textsuperscript{50}. Zehle et al. (2008) examined psychosocial factors related to diet, concluding that most women felt that a healthy diet (more vegetables and fewer fried foods) was too great a change from their current behaviours to maintain\textsuperscript{51}. In a study investigating postnatal lifestyle changes following GDM, despite reporting their concern about progression to T2DM women were not observed to increase their levels of physical activity or lose weight as advised during their pregnancies\textsuperscript{52}.

Symons Downs & Ulbrecht (2006) noted that most women they surveyed exercised in pregnancy to control their blood glucose levels, whereas during the postpartum period exercise was perceived as important only to assist weight loss. Only 7% of women believed that exercising postpartum would decrease their risk of T2DM, despite the education provided during pregnancy\textsuperscript{53}. A proportion of women in this population group were in the ‘pre-action’ phase for both undertaking sufficient levels of physical activity and taking steps to lose weight. Many reported readiness-to-change behaviour to prevent T2DM; however the majority remained overweight or obese\textsuperscript{54,55} indicating that further assistance is required to motivate women to achieve healthier, chronic disease preventing behaviours and lifestyles.
Factors that negatively influence initiation and engagement in physical activity, follow up care following GDM, and specific approaches to encourage women adopt healthy lifestyle changes have been reported by numerous authors (Table 2)\textsuperscript{22,56,57}. Studies report barriers to physical activity including lack of assistance with child care, insufficient time, financial constraints, fatigue, work issues, and lack of social support, all of which prevented women undertaking sufficient physical activity\textsuperscript{22,51,57-59}.

Women also expressed their preference for a program of support that allowed access from home (e.g. internet based) and/or support from ‘lifestyle coach’\textsuperscript{22}. Studies targeting women with GDM in the immediate postpartum period using a telephone intervention have attempted to overcome accessibility issues, have been effective, and well received\textsuperscript{38,39}. Women in both of these studies experienced a greater percentage of weight loss and lifestyle behaviour changes in the intervention group (when compared with usual care). Increased social support and facilitating increased physical activity self-efficacy, as well as a ‘family friendly’ approach, may help increase the proportion of women meeting lifestyle recommendations in this population\textsuperscript{55,59}.

\textit{The role of the Midwife in the care of women with GDM}

Of the 30 articles selected for review, three articles explored the role of the midwife (Table 3), in particular, the need to enhance the role in order to improve the quality of care for women with GDM. The cornerstone of midwifery care has always been women-centred, holistic delivery of safe, evidence-based care, regardless of the individual woman’s level of risk. However, following a diagnosis of GDM, women transition to a ‘high-risk’ model of care involving the multidisciplinary team\textsuperscript{4,60}. Women newly diagnosed with GDM have described their frustration with the transition to the multidisciplinary team approach, finding the care fragmented and little psychological support from the different healthcare providers\textsuperscript{61}. The positive effects of continuity-of-care during the childbirth journey have been well described, and women identify that they prefer that their pregnancy is ‘normalised’ after the diagnoses of GDM was made \textsuperscript{61}, which may be achieved with a collaborative midwifery and multidisciplinary team approach.
Table 3. Summary of included studies identifying the role of the midwife regarding women diagnosed with GDM

<table>
<thead>
<tr>
<th>Author and Year</th>
<th>Study Design</th>
<th>Sample Studies</th>
<th>Title</th>
<th>Outcomes</th>
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<tbody>
<tr>
<td>Irwin, J. (2010)</td>
<td>Review</td>
<td></td>
<td>Addressing the midwifery role in relation to women diagnosed with GDM</td>
<td>A specialist midwifery role could have an impact on improving care antepartum and postpartum</td>
</tr>
<tr>
<td>Jones S., &amp; Wilson, C. (2010)</td>
<td>Cohort</td>
<td>n=291 GDM women in UK</td>
<td>Comparing outcomes of midwifery – led antenatal care to those who received specific multidisciplinary team care</td>
<td>Low risk GDM women previously managed by acute primary teams can be cared for in primary care clinics, and allowed for other service components such as postnatal screening and lifestyle intervention advice can be developed.</td>
</tr>
</tbody>
</table>
In order to normalise care for women diagnosed with GDM, midwives require specialist knowledge. Irwin’s (2010) review\textsuperscript{62} has suggested the option of a diabetes specialist midwife, who has the qualifications and experience to incorporate both diabetes and midwifery care. Such a role could have an impact on improving care during both the antenatal and postnatal periods and support will become more important as more women who are diagnosed with GDM seek midwifery combined with medical care\textsuperscript{27,62}.

A cohort study demonstrated the benefits of caring for women postpartum using a midwife-led GDM care clinic in London, particularly in overcoming the poor uptake of postnatal follow up. The postpartum screening clinic increased the number of women who attended for their post GDM screening test, as well as providing opportunistic discussions on long term lifestyle changes to delay or prevent T2DM\textsuperscript{27}.

Discussion
This literature review identified thirty studies that varied in their methodological approaches, rigor and findings, thus it is not possible to draw firm conclusions about interventions to prevent Type 2 Diabetes following gestational diabetes. Our synthesis of the findings suggests that lifestyle interventions including behaviour modification programs directed towards weight loss and physical activity may be effective delay or prevention of T2DM following in women previously diagnosed with GDM\textsuperscript{34}. However, there are barriers to the uptake and adherence to lifestyle advice and midwives may be ideally placed to assist with resolving this disconnect.

This population group have risk factors for the development of T2DM, and further research is required to evaluate how these risks can be decreased long term. It makes sense both clinically and financially to explore options that prevents T2DM, rather than treat the disease later in life. If the new diagnostic guidelines are introduced\textsuperscript{14} (and it is beyond the scope of this paper to examine their sensitivity and specificity) this may increase the rate of GDM diagnosis and treatment and have a profound effect on the number of women identified as ‘at risk’ of developing T2DM.

Although this review has shown there are barriers to recruit, retain and engage women in interventions relating to lifestyle and behaviour change, this target cohort is considered
‘high risk’ for development of T2DM within 10–15 years. The birth of a new baby is a profoundly life changing experience. Issues such as home responsibilities, work and lack of time were cited as reasons for non-participation and further pregnancies, lack of childcare, work, cultural considerations, and family obligations were common themes and resulted in difficulty in recruitment and engagement. Health care programs aimed at this group need to find a ‘common ground’ where behaviour change to delay or prevent T2DM can be affected without women feeling that their family life or responsibilities are compromised.

Discussion and education of women regarding the long-term risks by midwives, dietitians and diabetes educators during the antenatal period may encourage women with GDM to consider continuing the lifestyle changes suggested. However, to ensure women remain aware of the ongoing increased risk of T2DM, postnatal programs need to be developed. These should include reminders and a specified follow up schedule and the design of accessible, preventative health, evidence-based programs that are systematically delivered to support women in attaining these health goals. An effective behaviour change program for women who have had GDM should be easily accessible, engaging, and provide, social and institutional support to recruit and maintain this group of the population who are at very high risk of developing T2DM without appropriate health care support.

**Conclusion**

Although the literature relating to the role of the midwife in the care of women with GDM is limited, it is clear that this is an emerging role that will be required increasingly in the future, and adapting to a changing maternity care landscape has been the mainstay of the midwifery profession. Midwives are in the unique position of caring for women when risk factors for T2DM are often first recognized. Although the midwives’ role is completed following the birth and immediate postpartum period, reinforcement of the relationship between GDM and T2DM during the childbirth journey may encourage women to engage in lifestyle changes postpartum that support long term health. Education programs for midwives that expand their knowledge on the prevention, diagnoses, treatment and management of diabetes will support midwives to provide women in their care with evidence-based information to encourage long term lifestyle changes to delay or prevent T2DM.
Acknowledgements

The authors would like to acknowledge the Mater Health Services Gold Casket Midwifery Research scholarship, and Mater Research Institute –The University of Queensland for administrative support.

References


19. Clausen T, Mathiesen ER, Hansen T, et al. Overweight and the Metabolic Syndrome in Adult Offspring of Women with Diet-Treated Gestational Diabetes Mellitus or


3. The Randomised Controlled Trial; Walking for Exercise and Nutrition to Prevent Diabetes for You (WENDY)

“…all women with GDM should be encouraged to engage in preventative measures such as increased physical activity, healthy diets and maintenance of normal weight”

Kim et al. (2002)

3.1. Introduction

The literature review has demonstrated that an evidence practice gap exists regarding interventions to decrease known risk factors for the development of T2DM in women previously diagnosed with GDM. Obesity has been recognised as a risk factor for the development of T2DM (24), yet obesity rates continue to increase in Australia (49). Supporting weight loss in overweight or obese women, who also have the added risk of a previous diagnosis of GDM, may be an effective way to decrease the risk of developing T2DM. A combination of diet and exercise may support weight loss in this population (52), however, women have shown to experience barriers to engaging in lifestyle intervention programs (65).

Adopting a theoretical construct prior to developing an intervention that can direct behaviour change will identify core techniques that may affect behaviour (66) and overcome this evidence practice gap. However, integrating theories of behaviour change into practical interventions can be difficult if not approached in a logical manner. The use of a step-wise approach, with each step leading naturally to the next in the development of an intervention, can provide both a theoretical and practical framework (28, 67, 68). Examining previous research for effectiveness was achieved through systematically reviewing the literature regarding this subject. Using the deductive reasoning approach (69), a hypothesis was generated, and a research study designed to test the hypothesis.

Examining how interventions work by identifying behaviour change techniques can provide information to enable adjustment of treatments for maximum benefit. Bandura’s (1986) Social Cognitive Theory explains how a behaviour is influenced by complex interactions between a person’s actions, thoughts and their surroundings. Within this theory, self-
efficacy is an important construct that defines a person’s confidence to perform an action and achieve a desired outcome (29, 70). Self-efficacy determines how a person will adopt coping mechanisms, how much effort is required and how changes in behaviour are sustained.

There are four principal components of information that influence self-efficacy; performance attainment, vicarious experience, verbal persuasion, and physiological state (29). Performance attainment is the most powerful source of efficacy information as it is based on actual experience of achievement and mastery. Success in achievement increases self-efficacy and is made stronger through repeated successes and few failures, particularly in the early stages of behaviour change.

Vicarious experience increases self-efficacy, observing other’s successes and enabling personal achievements by modelling behaviour based on those observations. Verbal persuasion can be described as encouragement and support for a behaviour, delivered by another person (70), and can enhance performance attainment. Physiological state provides personal feedback regarding successes and generally, there is less negative emotions such as stress or tension with successful achievements. The perception of success of failure, or the personal interpretation about whether outcomes were due to personal achievements (self-efficacy) or external (environmental) events (29) depend on how information is processed by the individual. Techniques such as goal-setting, self-monitoring, peer support and education to enhance coping skills, have all been identified as supportive of encouraging self-efficacy (66). Incorporating this theory into the interventions within this program of study included the pedometer-based physical activity component of self-monitoring and goal setting, with nutrition coaching utilising activities that incorporated goal setting, self-monitoring, peer support, health professional support and feedback.

A pedometer program with an internet component that allowed for goal-setting capability was developed by Professor Catherine Kim at the University of Michigan, (USA). Professor Kim had previously researched a pedometer-based exercise program in women with prior GDM (26) and, following discussions with one of my supervisors, was keen to collaborate
in a further research study combining pedometers and a nutrition component. The program content was designed in collaboration with the University of Michigan, based on the previous research (26), and the content of the website used in that study was reviewed and tailored to the Australian audience by including local additions such as walking trails and resources in the Brisbane area. As the website targeted an American audience, the language used was reviewed and tested prior to use to enhance validity in the Australian context. This included substitution of American terms such as ‘mom, sidewalks, walking through the woods’ for ‘mum, footpaths and bushwalking’.

The nutrition coaching sessions were an evidence-based four one-hour session program targeting dietary and lifestyle change using effective behaviour change techniques facilitated by an Accredited Practicing Dietitian (APD). Each session was conducted in a group environment, and continuity of an APD enabled rapport between participants and the presenter to be built. The classes were run in four-week blocks, and relationships within the group allowed for sharing of experiences and feelings. Dietary tools and reference materials, designed to reinforce behaviour modification and support portion control, were supplied as part of the course and included a reference book detailing portion sizes (“this=that”) required for weight loss in pictures (71), as well as a plate with with visual cues for appropriate portion size for protein, carbohydrate and vegetables (72).

RCTs are considered Level II of experimental research (30, 73) and this method fits the purpose of the intervention phase of the study. To examine the ‘cause and effect’ of an intervention, a control group and a group receiving the experimental research are required (35). Assigning groups is done randomly, and using a control group that does not receive the intervention or treatment, any difference in outcomes between the groups after the experiment can be attributed to the intervention, assuming that both groups are similar apart from the variable of the intervention (35). The risk of bias is decreased with randomisation of participants to either group, and the CONSORT guidelines should be used in the design of the study (74).
3.2. Aim

The aim was to develop, implement, and evaluate a low intensity short-term exercise and nutrition coaching program for women who were diagnosed with GDM during a prior pregnancy and who had a BMI in the overweight or obese range (>25 kg/m²) in the postpartum period to assist with weight loss, improve insulin sensitivity, increase physical activity, improve diet quality self-efficacy relating to eating behaviours, decreased waist and hip measurements, and a decrease in Fat Free Mass (FFM) that may decrease their risk of developing T2DM.

3.3. Hypothesis

3.3.1. Primary hypothesis

The use of a pedometer based exercise programme combined with nutrition coaching in women with prior GDM and BMI >25 kg/m² would result in increased weight loss when compared with standard care.

3.3.2. Secondary hypothesis

Compared with women in the control group, we hypothesised that women in the intervention group would experience or develop: (1) lower glucose and Homeostasis Model Assessment (HOMA-IR); (2) increased minutes of physical activity/week; (3) improved diet quality measured by a self-reported survey; (4) improved eating behaviour self-efficacy and domain scores; (5) decreased waist and hip measurements; and (6) lower body fat mass (FM) and significantly higher FFM.

3.4. Methods

3.4.1. Study design

This multidisciplinary study was conducted as an RCT. Women diagnosed with GDM during a pregnancy between six months and two years previously and who had a BMI >25 kg/m², were randomly allocated to an intervention or control group. This time frame was chosen as participant feedback from the pilot study (27) suggested this time frame was preferred by women. The primary outcome of the intervention programme considered changes
between measures at baseline (at recruitment), and at the end of the three month intervention, compared between the intervention and control groups. Further follow up data were to be collected at six months.

3.4.2. Study setting/location

The study took place at Mater Mothers’ Hospital (MMH), Mater Health Services (MHS) campus from June 2011 to December 2012 in Brisbane, South East Queensland. Participants were asked to attend the hospital for three visits (baseline, three months and six months), and for four weekly nutrition coaching sessions. Parking was subsidised at each visit and public transport was easily accessible.

Ethics approval was granted by the Human Research Ethics Committee, Mater Research Institute- The University of Queensland, and the Human Medical Research Ethics, The University of Queensland.

3.4.3. Study population

We aimed to recruit a total of 102 women for participation in this study (51 in each experimental group). Based on preliminary data from similar studies at MMH and University of Michigan (75), we considered a relative decrease in weight of 3% between control and intervention groups to be both reasonably likely and clinically important. Using this relative change of 3% (SD 4%) with an alpha significance level of 0.05 to achieve a power of 0.8, thirty-nine participants were required in each group. We allowed for likely attrition of 30%; therefore, the aim was to recruit 51 participants in each group.
3.4.4. Eligibility criteria

Inclusion criteria

Women eligible for inclusion were those who:

- were >18 years old
- had been diagnosed and treated for GDM in the preceding pregnancy
- had given birth in the previous six months to two years
- had a BMI >25 kg/m\(^2\)
- had routine access to a computer and possess adequate computer skills to navigate websites and e-mail
- understood that the primary physical activity would be walking.

Exclusion criteria

Women ineligible for inclusion are those who were:

- currently pregnant
- diagnosed with T2DM
- not sufficiently fluent in spoken and written English to be able to fully participate in the study
- taking medications which interfere with glucose metabolism
- suffering from any mental or physical disability which would have interfered with their participation in the study.
3.4.5. Study outcomes

Primary outcome

The primary outcome was weight loss.

Secondary outcomes

Secondary outcomes were: (1) glucose and Homeostasis Model Assessment (HOMA-IR); (2) minutes of physical activity/week; (3) diet quality measured by a self-reported survey; (4) eating behaviour self-efficacy and domain scores; (5) waist and hip measurements; and (6) body fat mass (FM) and fat free mass (FFM).

3.4.6. Statistical analysis

Analyses were conducted using the intention-to-treat principle with comparisons between the control and intervention groups. Continuous data were checked for normality, and normally distributed variables subsequently underwent parametric analyses. Non-normally distributed data were analysed using non-parametric methods. Analysis of the primary outcome (examining absolute weight loss between the control and intervention groups) and continuous secondary outcomes used an unpaired t-test (or Mann-Whitney U test if not normally distributed). Statistical significance was set at 0.05 (two tailed) for all analyses.

3.4.7. Data collection

Data were collected at baseline and three months. Baseline observations included assessments of anthropometrics, body composition, serum insulin and OGTT performance, surveys of dietary and physical activity, and mental health. Weight was measured to the nearest 0.1 kg using a spring balance scale, and height was measured with a wall mounted stadiometer to the nearest 0.5 cm. Hip and waist measurements were taken with a standard tape measure, and estimation of body composition (fat mass and lean body mass) was assessed using using a multi-frequency bioelectrical impedance analyser (BodyStat 1500MDD, Bodystat, United Kingdom) with a measured resistance at a fixed frequency of 50 Hz.
Dietary quality was assessed using the Fat & Fibre Behaviour Index (41), and eating behaviour self-efficacy was assessed using The Health and Wellbeing Self-Efficacy Survey (WEL) (76). Physical activity was assessed using Australian Women's Activity Survey (AWAS) with the Health Enhancing Physical Activity Score (HEPA) (40), and mental health was assessed using the Kessler Psychological Distress scale (K10) (43). HOMA-IR, a widely used estimate of insulin resistance in the fasting state, was calculated as; HOMA-IR = (fasting plasma insulin (FPI) \cdot [\text{mU/L}] \times \text{Fasting plasma glucose (FPG)} [\text{mmol/L}]/22.5 (39).

The Fat & Fibre Behaviour Index is a questionnaire that reported on general food patterns and addressed eating and food behaviours by domains and has been validated by previous research (41, 77). These domains (20 items) included frequency of ingestion of high fat and fibre foods, cooking and food choices such as dairy or bread, as well as fruit and vegetable intake. Scoring quantified amounts of fruit and fibre in a subscale, and food considered 'unhealthy' was reverse scored (41).

Self-efficacy around eating behaviours was assessed using The Health and Wellbeing Self-Efficacy Survey (WEL). A total score, as well as scores in domains: Availability: Negative Emotions; Social Pressure; Physical Discomfort; and Positive Activities (42), were calculated following the completion of the surveys. This survey has been extensively used following its proven validity ($p = 0.01$) (76). Physical activity was assessed objectively in the intervention group using pedometers and was supplemented with self-reported physical activity using the AWAS (40). The AWAS was developed for the assessment of health-enhancing physical activity among women with children, and assesses past-week physical activity on weekdays and weekend days across a number of domains. Previous research demonstrated good validity and test-re-test reliability (ICC = 0.80 (0.65-0.89) (40) of the AWAS for the assessment of physical activity among women with young children, and recommended interviewer administration to maximise the validity of responses and reduce missing data. Therefore, the AWAS was administered during each assessment session (40). The HEPA was calculated by summing data from the...
intensity levels that are widely accepted as sufficient to confer health benefit (i.e., brisk walking, moderate and vigorous-intensity activity reported in the Planned Activity or Transport Domains). This HEPA total is consistent with recommendations for treating data collected using other existing self-report measures (Active Australia Survey, Behavioural Risk Factor Surveillance System physical activity module, International Physical Activity Questionnaire) (40).

Changes in insulin resistance were compared using the HOMA-IR. HOMA-IR estimates of insulin resistance from a single fasting sample have high correlation with the gold standard euglycaemic clamp technique (R=0.77, p<0.005) (39). The first measurements of fasting plasma insulin and glucose were taken from the basal (fasting) samples of the baseline OGTT. At the same time, the glucose values during this OGTT were used to categorise the women into normal glucose tolerance, impaired fasting glucose (IFG) or impaired glucose tolerance (IGT), and Type 2 diabetes (T2DM) categories, using Australian criteria (25). Any woman found to have frank T2DM at the time of the baseline OGTT was excluded from the study and referred for appropriate clinical care. As the baseline and OGTT measurements were the first visit for the participants, all women were randomised at the time of the baseline and OGTT visit, and subsequently excluded from the study if T2DM was diagnosed.

The K10 is a scale measuring non-specific psychological distress and consisted of 10 questions to measure the level of current anxiety and depressive symptoms a person may have experienced in month prior to the interview (78). According to the Australian Bureau of Statistics, there is no consistent scoring system within Australia (79); therefore, in this study, a score of 20 and above was considered a reason to initiate discussion relating to anxiety with the participant. This scoring system is used in Primary health care settings in Australia, and will more likely monitor distress, rather than identification of a disorder (80). As per the study protocol, the score was revealed to each participant at the completion of the survey and they were referred to their primary health care provider for further management if necessary (81). These participants were was also asked to reconfirm continuing with the study.
3.4.8. Recruitment of participants

Initially, women with GDM who were diagnosed and treated at MMH in the preceding six months to two years were contacted and invited to participate in the study, as feedback from previous research showed this time frame was optimal for intervention as women felt they would be more able to include changes in their life after the birth of their baby (27). Contact details and confirmation of eligibility by previous diagnoses of GDM was obtained from the MHS obstetric patient database, and information retrieved from this database included name, date of birth, address, confirmation of GDM diagnoses, date of delivery of affected pregnancy, pre-pregnancy BMI, ethnicity, land-line home phone number and mobile phone number. Initial participant screening excluded women who lived out of the hospital catchment area, or interstate, as previous research had shown these women were less likely to attend the three or more visits to MMH (27). Attempts were then made to contact eligible women by phone.

A standard phone recruitment protocol script was followed:

"Hello this is Ann from Mater Mothers Hospital, is (insert name) there? To reassure and inform you I am from the Mater Hospital, I have information that states your last baby born here was on (insert date)?"

No information regarding previous diagnoses or pregnancy was disclosed until identification of the participant was confirmed, and confidentiality was established by verifying their birth date with the hospital database. The participant was again asked if they wish to continue, "I am a midwife and I am involved in a project looking at the relationship of GDM and T2DM". The study was explained and, if the woman decided to participate, she was asked to provide an email address and self-reported height and weight to allow calculation of current BMI and updated contact details. This method allowed the researcher to: (1) determine if contact details were correct at time of recruitment, and the participant was willing to be involved with the study, (2) determine the participants computer/Internet access and skills and, (3) confirm that BMI eligibility criteria were met. The women who were eligible, and expressed interest, were sent a Participant Information letter via email or post and re-contacted after one week (at a mutually agreed time) to confirm or decline further participation and allow an opportunity to clarify any concerns and answer any questions. If, at the time of contact, the woman was happy to continue with the
study, an appointment was made for the initial OGTT. Any woman who declined participation was thanked for her time and not contacted further.

Phone contact for each potential participant was attempted at three different time points (using both landline and mobile phone contact details), and notation made at each attempt if: (1) not contacted; (2) disconnected; (3) refused; or (4) unable to contact. The final variable of unable to contact was used following three unsuccessful attempts to contact. Comments were also noted on the database, including reasons for refusal if stated by the woman. As the study evolved, the recruitment rate of participants was slower than projected. Two further data extractions from the database were obtained and phone contacts were attempted with the expanded list of possible participants. Subsequently, further ethical approval was obtained to include potential participants who had not birthed at MMH but fulfilled the other eligibility criteria (as recruitment remained slow when limited to women who delivered solely at MMH).

Collaboration with external agencies such as Diabetes Australia (Queensland [QLD]) was developed, and their dedicated website to GDM (You2) provided an avenue to advertise the study to an audience tailored to the project. An article on the RCT was published in two editions of the online newsletter, as well as in the ‘Research’ section of the ongoing website. A key component of the Diabetes Australia (QLD) program is the mail out to women previously diagnosed with GDM at one year to remind them to attend their GP and the recommended annual OGTT to exclude T2DM (25). An information sheet advertising the study including contact details of research staff was included in the paper mail out.

Following minimal response to this exposure to the study, further advertising was initiated, including notices advertising the project using the Mater Mothers’ Hospital internal research intranet site, a post on the hospital’s Facebook page, University newsletter, a media release, and a five-minute television feature on the statewide news bulletin. Contact was attempted with 320 women, which resulted in a total of 31 women being enrolled. Recruitment is presented in the CONSORT diagram of the study (Appendix 2).
3.4.9. Randomisation

Randomisation status was determined through sealed opaque envelopes (supplied by a independent source), based on a computer generated sequence, and were numbered and distributed sequentially following stratified randomisation procedures to one of two treatment groups. The envelopes were stored in a locked, secured container (held by the researcher) until baseline measurements had been completed and the eligibility of participants was established.

Blinding was not possible because the researcher was the sole contact for the study, and the participants required education about the website and explanation of appointment times and contact points at the time of randomisation. Contact between the researcher and the participants was uniform across both intervention and control groups, and was limited to follow up for return appointments, and collecting data at appropriate time points. Short message service (SMS) text messaging was utilised as a contact point and as a reminder for appointments.

3.4.10. Study procedure

Those eligible women who provided email and verbal consent were offered an appointment time to attend MMH to provide baseline observations, and to complete the Participant Consent Form on arrival, prior to any testing or measurements.

Baseline observations included:

- a fasting two-hour 75 g OGTT, including measurement of the serum insulin concentrations in the fasting state
- measurement of height and weight
- waist and hip measurements
- estimation of body composition (fat mass and lean body mass) using ‘Bio-impedence’ measurements
- completion of validated questionaires, the AWAS, the Fat and Fibre Index, the Health and WEL survey, and K10
Eligibility criteria was reapplied in light of baseline assessment. Any women who were found to have diabetes (fasting plasma glucose ≥7.0 mmol/L and/or two-hour plasma glucose ≥11.1 mmol/L [NHMRC guidelines]) were referred to their health care provider to receive follow-up confirmatory diagnosis, standard diabetes care and excluded from the trial. As this project involved general nutrition advice, the specific requirements of of a newly diagnosed patient with diabetes could not be included within the scope of this study. All participants who were eligible at time of baseline observations, were randomised during this baseline visit to allow for education about the use of the pedometers and website if allocated to the intervention group. Within this cohort one woman who was randomised as per protocol proved to be ineligible. This stage of the protocol was designed to decrease the number of times required by the participants at the hospital, as feedback from the pilot study highlighted numerous visits as a barrier (27).

**Control group procedure**

Women allocated to the control group received feedback on their baseline test results, were informed about group assignment and a tentative appointment for three months time. They did not receive any further intervention or advice on physical activity beyond the usual care offered by their general practitioner (as per current clinical practice). They were only contacted to schedule the post-intervention measurement visit (three months following the initial visit). A ‘waiting-list control’ design for this study was used to engage the control group, as following the three month assessment, which formed the basis of the randomised comparison, they were then offered the nutrition coaching course.

![Baseline and 3 months time line](image)

Figure 2. Control group time line
**Intervention group procedure**

Social Cognitive Theory (29) was adopted when designing the intervention, using the behaviour modelling of; mastery using goal setting, with feedback and support; vicarious learning through group sessions with peers in the nutrition coaching session; and social persuasion by encouraging messages through the website and the nutrition coaching.

Education for the intervention group included provision of a username and password to allow access to the website *Stepping up to Health*, and a Universal Serial Bus (USB) equipped pedometer was provided. The pedometer was issued with an occlusive sticker over the digital step count display. This provided an unbiased baseline step count, as the participants were not influenced to increase their activity by their readings. Other instructions were not to wear the pedometer in or near water, to wear it on the right (R) hip if possible and, at least five out of the seven days of the week (with at least one of those days being on the weekend) for a minimum of eight hours a day. The participants were requested to continue wearing the pedometer until advised otherwise or until they returned for their three month assessment.

![Figure 3. Intervention group time line](image-url)
The specially designed pedometer allowed the user to upload their data via USB connection to a tailored web based program that offered tips, ideas and motivation to the participants over the three month intervention. Participants were encouraged to log on weekly and would receive weekly goals, feedback on their walking progress, and messages and ‘tips’ regarding diet and exercise, targeted at diabetes prevention. The participant also received motivational messages and alerts to the email address they had previously specified.

The program was designed to run for 12 weeks, with a different message, tip or hint available via the website each week. Each participant was encouraged to upload their pedometer at the same time each week, at which time the program projected the next week’s goal. This goal was based on the previous week’s steps, with increments increased by 1000 steps/day until 10,000 steps/day was reached. The program was individualised; for example, if the participant did not meet the goals set from the week before, the step count remained the same, allowing the participant to reach the goal before a new (higher) goal was set. This approach allowed for the individual participants to progress through the program at their own pace.

The nutrition coaching program included in the intervention group, designed and delivered by dietitians from MHS, was presented by an APD and held over a four-week period, with weekly attendance by the participant. Each session was one hour, paid parking was offered, and children were made to feel welcome with children’s activities supplied.

The sessions consisted of:

- **Session 1**: *Steps to success—a wellbeing focus to goal setting*, aimed at introducing the program and assessing the participants ‘readiness for change’ by goal setting and instigating self-efficacy through beginning of behaviour change.
- **Session 2**: *It’s all about me—making diet and exercise work for you* aimed at introducing exercise and education of healthy eating through core food groups and portion control.
- **Session 3**: *Food for thought—getting in the right frame of mind* aimed at discussion of how thoughts and feelings impact on weightloss through Social Cognitive Theory.
• Session 4: *Making a healthy dollar go further* aimed at increasing confidence in the lifestyle change through education of budgeting and healthy food choices while shopping.

*Session one: Steps to success—a wellness focus to goal setting*

This session introduced the concept and philosophy of nutrition coaching. The ‘readiness for change’ by the participant was determined by reinforcement of positive behavioural goals and the use of self-reflection comparing change to current lifestyle compared with no change. Goals such as realistic weight loss goals, activity goals and behaviour changes were discussed with an emphasis on individual expectations. Ways of increasing confidence (self-efficacy) relating to food behaviours were discussed through self-reflection activities and strategies to promote self confidence. The concept of self-monitoring was introduced to support and increase awareness of behaviours. A daily food and activity diary (including thoughts and emotions felt at the time) was provided for the participant to use in the next week.

*Session two: It’s all about me—making diet and exercise work for you*

This session reinforced the concepts from Session one, introducing *The Australian Guide to Healthy Eating*, and developing a personal exercise program. Key principles such as education of the five core food groups, portion sizes and self-reflection on their food diary was covered with the participants. Further information on ‘energy dense’ foods and snacks were delivered i.e. the use of tools such as a plate indicating recommended portion sizes of protein, carbohydrates and vegetables. The benefits of exercise were explored, with self-reflection and activities relating to the benefit of increasing exercise as a routine habit. Goal setting of modest exercise targets was encouraged and weekly diaries were reviewed.
Session three: Food for thought—getting in the right frame of mind

This session built on the previous sessions and added the impact of thoughts and feelings on weight loss and lifestyle change underpinned by the theoretical framework of the Social Cognitive theory (29). Recognition of how strong emotions can trigger unhealthy eating habits were explored, and strategies to support self-efficacy were discussed, underpinned by the relationship between the self-efficacy concepts (Figure 4)

![Figure 4. Relationship between self-efficacy concepts](image)

These concepts work together, with each affecting the others, However it is easier to change actions than thoughts or emotions, but these can subsequently change with a change in the behaviour. Positive reinforcement was given through identification of and dealing with, lapses in motivation.

Session four: Making a healthy dollar go further

This session empowered participants to make healthy food choices by helping them to feel confident when shopping for food. Explanations regarding the cost of food, and the use of written reference material to help budget for a healthy diet was covered in this session. To assist with portion control an illustrated book (“this = that”) depicting actual serving sizes (71) and the Portion Plate (72) was also provided. A summary of all sessions was given, with the opportunity for questions and queries before the conclusion.
Following the three month intervention period, all participants were re-contacted and asked to attend a further appointment at the hospital, where the following measures were repeated to assess the effectiveness of the intervention:

- A fasting blood glucose sample, including measurement of the serum insulin concentrations in the fasting state.
- Measurement of weight.
- Waist and hip measurements.
- Estimation of body composition (fat mass and lean body mass) using ‘Bio-impedance’ measurements.
- Completion of validated questionnaires, the AWAS, the Fat & Fibre Index, the Health and WEL survey, and K10.

With the aim to assess if the lifestyle changes instigated in the study were able to be maintained, the intervention group participants were offered a maintenance program for a further three months. After this additional time, anthropometric observations, fasting blood tests and questionnaires relating to diet, activity and lifestyle were to be repeated. All participants were contacted for a further six month appointment. However, only four participants returned. Due to the limited number of participants who attended at six months and the low probability of detecting clinical or statistical difference at this time point, this data was not included in further analysis. In any case, the pre-defined primary outcome changes at three months formed the basis of this report.

3.5. Results

Of 576 women assessed as eligible contact was attempted with 320. Of those 208 did not meet inclusion criteria and 81 declined participation. Thirty-one women were randomised, with 23 women completing the three month primary outcome measurements. Twenty-one women also initially agreed to be part of the study; however, they withdrew prior to randomisation.
Five participants in the intervention group discontinued over the course of the three month period for reasons outlined in Appendix 2. One control participant was diagnosed as T2DM following randomisation as a result of baseline OGTT and two other participants withdrew for unspecified reasons. Eleven participants in the intervention group (69%) and twelve participants in the control group (80%) completed both baseline and three month assessments.

Demographic and anthropometric characteristics of the study participants are presented in Table 2. The age range for the sample was 28-44 years. There were more multigravidas in the intervention group, and an equal proportion of women had public and private health insurance. Ethnicity was predominately Caucasian, with three women of Asian descent. The majority of women (67%) had required insulin therapy to control their glucose levels during pregnancy, followed by diet (26%) then metformin (13%). None were taking glucose lowering medications at the time of the study. At baseline there was no significant differences between the intervention and control group (Table 2).
Table 2. Demographic characteristics of participants

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<tr>
<td>Treatment for GDM during pregnancy</td>
<td>Insulin</td>
<td>9 (56%)</td>
<td>10 (67%)</td>
<td>19 (61%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Metformin</td>
<td>3 (19%)</td>
<td>1 (7%)</td>
<td>4 (13%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Diet</td>
<td>4 (25%)</td>
<td>4 (27%)</td>
<td>8 (26%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age at OGTT*</td>
<td></td>
<td>34.8 (3.1)</td>
<td>37.3 (5.4)</td>
<td>36.0 (4.5)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Range 28-39</td>
<td>Range 28-44</td>
<td>Range 28-44</td>
<td></td>
</tr>
<tr>
<td>Self-reported weight*</td>
<td></td>
<td>83.9 (18.4)</td>
<td>86.2 (17.4)</td>
<td>85.0 (17.7)</td>
<td>p = 0.798</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Range 57-118</td>
<td>Range 62-125</td>
<td>Range 57-125</td>
<td></td>
</tr>
<tr>
<td>Self-reported BMI^</td>
<td></td>
<td>29.4 (6.6)</td>
<td>31.2 (9.9)</td>
<td>29.4 (8.2)</td>
<td>p = 0.740</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Range 25.3-47.1</td>
<td>Range 25.5-44.8</td>
<td>Range 25.3-47.1</td>
<td></td>
</tr>
</tbody>
</table>

* mean (SD) ^ median (IQR)
Baseline assessment of characteristics of the intervention and control group relating to anthropometric and glucose measures revealed no significant differences (Table 3).

Table 3. Visit one baseline characteristics by group

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Intervention n=16</th>
<th>Control n=15</th>
<th>p-value</th>
<th>Total n=31</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight*</td>
<td>84.9 (18.5)</td>
<td>86.5 (17.1)</td>
<td>0.798</td>
<td>85.7 (17.5)</td>
</tr>
<tr>
<td>BMI(^\dagger)</td>
<td>30.0 (7.6)</td>
<td>31.2 (9.6)</td>
<td>0.740</td>
<td>30.3 (8.2)</td>
</tr>
<tr>
<td>Waist*</td>
<td>101.0 (10.8)</td>
<td>100.4 (13.2)</td>
<td>0.885</td>
<td>100.7 (11.8)</td>
</tr>
<tr>
<td>Hip*</td>
<td>117.4 (14.9)</td>
<td>115.8 (13.6)</td>
<td>0.757</td>
<td>116.6 (14.1)</td>
</tr>
<tr>
<td>Body fat %(^*)</td>
<td>37.5 (7.5)</td>
<td>37.3 (6.9)</td>
<td>0.940</td>
<td>37.4 (7.1)</td>
</tr>
<tr>
<td>Lean mass %(^*)</td>
<td>53.0 (6.9)</td>
<td>52.0 (5.6)</td>
<td>0.661</td>
<td>52.5 (6.2)</td>
</tr>
<tr>
<td>Fasting glucose(^\dagger)</td>
<td>4.7 (0.4)</td>
<td>4.9 (0.9)</td>
<td>0.030</td>
<td>4.8 (0.8)</td>
</tr>
<tr>
<td>Fasting insulin(^\dagger\infinity)</td>
<td>9.1 (5.0)</td>
<td>8.4 (9.0)</td>
<td>0.683</td>
<td>8.7 (6.0)</td>
</tr>
<tr>
<td>two-hour glucose(^\dagger)</td>
<td>5.6 (2.3)</td>
<td>5.5 (3.2)</td>
<td>0.572</td>
<td>5.5 (2.8)</td>
</tr>
</tbody>
</table>

\(^*\) mean (SD), independent samples t-test \(^\dagger\) median (IQR), Mann-Whitney U test
\(^\dagger\infinity\) 4 cases missing (1 intervention; 3 control)

3.5.1. Primary outcomes

Weight loss was greater in the intervention group, with a median loss of 2.5kg (SD1.4) compared with a static weight in the control group (p=0.002), corresponding to a reduction in BMI of 0.9kg/m\(^2\) (SD 0.7) (p=0.002) in the intervention group.

3.5.2. Secondary outcomes

Changes in hip circumference were also significant with a median loss of 3cm (5.0) in the intervention group compared with 0cm (4.8) (p=0.006). Intervention group waist circumference decreased by a mean of 3cm (SD 4.0) compared with 0.5 cm (SD4.8) (p=0.037) (Table 5).
There was a slight decrease in body fat and increase in lean body mass in the intervention group, but these changes were not statistically significant. Fasting glucose at baseline was slightly lower in the Intervention group (difference 0.2 mmol/L; \(p=0.03\)) and the change in fasting glucose over the three months of the study differed slightly between the two groups. This latter difference was in the opposite direction to what might have been predicted (slight rise in glucose in the intervention group and slight fall in the control group), but did not achieve statistical significance (\(p=0.052\)). There was no change in insulin resistance as measured by HOMA-IR.

Table 4. Visit two three month characteristics by group

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Intervention</th>
<th>Control</th>
<th>(p)-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n=11</td>
<td>n=12</td>
<td></td>
</tr>
<tr>
<td>Weight^</td>
<td>80.5 (38.5)</td>
<td>83.8 (24.9)</td>
<td>0.833</td>
</tr>
<tr>
<td>BMI^</td>
<td>28.2 (13.8)</td>
<td>31.2 (11.1)</td>
<td>0.413</td>
</tr>
<tr>
<td>Waist^</td>
<td>95.0 (26.0)</td>
<td>99.8 (20.0)</td>
<td>0.347</td>
</tr>
<tr>
<td>Hip^</td>
<td>107.0 (30.0)</td>
<td>114.5 (23.0)</td>
<td>0.449</td>
</tr>
<tr>
<td>Body fat %(^\infty)</td>
<td>32.6 (12.8)</td>
<td>39.9 (13.7)</td>
<td>0.280</td>
</tr>
<tr>
<td>Lean mass %(^\infty)</td>
<td>55.2 (10.8)</td>
<td>53.5 (6.7)</td>
<td>0.631</td>
</tr>
<tr>
<td>Fasting glucose(^\infty)</td>
<td>5.0 (1.0)</td>
<td>4.7 (1.0)</td>
<td>0.315</td>
</tr>
<tr>
<td>Fasting insulin^#</td>
<td>11.5 (6.9)</td>
<td>8.5 (7.6)</td>
<td>0.400</td>
</tr>
</tbody>
</table>

^ median (IQR), Mann-Whitney U test
\(\infty\) 3 cases missing (1 intervention; 2 control)
^# 4 cases missing (1 intervention; 3 control)
Table 5. Changes in characteristics between three months and baseline by group

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Intervention</th>
<th>Control</th>
<th>( p )-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>( n=11 )</td>
<td>( n=12 )</td>
<td></td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>-2.5 (1.4)</td>
<td>0.0 (2.3)</td>
<td>0.002*</td>
</tr>
<tr>
<td>BMI (kg/m(^2))</td>
<td>-0.9 (0.7)</td>
<td>0.0 (0.8)</td>
<td>0.002*</td>
</tr>
<tr>
<td>Waist (cm)</td>
<td>-3.0 (4.0)</td>
<td>0.5 (4.8)</td>
<td>0.037*</td>
</tr>
<tr>
<td>Hip (cm)</td>
<td>-3.0 (5.0)</td>
<td>0.0 (4.8)</td>
<td>0.006*</td>
</tr>
<tr>
<td>Body fat %(^\infty)</td>
<td>-1.1 (4.5)</td>
<td>-0.3 (1.3)</td>
<td>0.393</td>
</tr>
<tr>
<td>Lean mass %(^\infty)</td>
<td>0.9 (3.3)</td>
<td>0.0 (2.6)</td>
<td>0.436</td>
</tr>
<tr>
<td>Fasting glucose(^\infty)</td>
<td>0.3 (0.5)</td>
<td>-0.1 (0.6)</td>
<td>0.052</td>
</tr>
<tr>
<td>Fasting insulin(^#)</td>
<td>-0.5 (2.4)</td>
<td>0.173</td>
<td>0.830</td>
</tr>
<tr>
<td>K 10 Total Score(^\wedge)</td>
<td>0.0 (4.0)</td>
<td>1.0 (4.0)</td>
<td>0.193</td>
</tr>
<tr>
<td>WEL Total Score</td>
<td>27.8 (20.1)</td>
<td>13.9 (37.4)</td>
<td>0.290</td>
</tr>
<tr>
<td>Negative emotions</td>
<td>5.5 (2.9)</td>
<td>3.5 (8.5)</td>
<td>0.472</td>
</tr>
<tr>
<td>Availability</td>
<td>7.1 (5.5)</td>
<td>1.0 (7.0)</td>
<td>0.036*</td>
</tr>
<tr>
<td>Social pressure</td>
<td>6.1 (5.4)</td>
<td>4.1 (9.4)</td>
<td>0.545</td>
</tr>
<tr>
<td>Physical discomfort</td>
<td>4.5 (6.7)</td>
<td>4.5 (8.4)</td>
<td>0.978</td>
</tr>
<tr>
<td>Positive activities</td>
<td>4.6 (4.9)</td>
<td>0.9 (7.6)</td>
<td>0.188</td>
</tr>
<tr>
<td>HEPA</td>
<td>135 (225)</td>
<td>0 (418)</td>
<td>0.190</td>
</tr>
<tr>
<td>Fat</td>
<td>0.2 (0.4)</td>
<td>0.2 (0.5)</td>
<td>0.824</td>
</tr>
<tr>
<td>Fibre</td>
<td>-0.04 (0.8)</td>
<td>0.1 (0.4)</td>
<td>0.576</td>
</tr>
<tr>
<td>Total</td>
<td>0.1 (0.5)</td>
<td>0.2 (0.4)</td>
<td>0.682</td>
</tr>
</tbody>
</table>

All results mean (SD) unless other stated. \(^\wedge\) median (IQR), Mann-Whitney U test

\(^\infty\) 3 cases missing (1 intervention; 2 control)

\(^#\) 5 cases missing (1 intervention; 4 control)
The intervention group increased their daily activity by 135 minutes/week at the three month time point compared to the control group (Table 6). Although this difference was not statistically significant, this trend may be clinically important as it demonstrates a tendency towards increased physical activity.

Table 6. Changes in Health Enhancing Physical Activity (HEPA) by group

<table>
<thead>
<tr>
<th>Visit</th>
<th>Intervention</th>
<th>Control</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline∞</td>
<td>63 (161)</td>
<td>120 (420)</td>
<td>0.358</td>
</tr>
<tr>
<td>Three months#</td>
<td>240 (315)</td>
<td>175 (405)</td>
<td>0.608</td>
</tr>
<tr>
<td>Change</td>
<td>135 (225)</td>
<td>0 (418)</td>
<td>0.190</td>
</tr>
</tbody>
</table>

^ median (IQR), Mann-Whitney U test * n (%), Fisher’s exact test
∞ Intervention N = 16, Control = 15, Total N = 31
# Intervention N = 11, Control = 12

The WEL results showed participants in the intervention group at three months feeling empowered when presented with opportunity for poor food choices (p=0.36) and, although not statistically significant, trends towards improvements in the domains of negative emotions, social pressure, physical discomfort and positive activities were noted, all relating to the participants’ feelings regarding food and food choices (Table 7).
Table 7. Weight Efficacy Lifestyle Questionnaire (WEL) sub scales and total scores at baseline and three months by group

<table>
<thead>
<tr>
<th>Visit</th>
<th>Scores</th>
<th>Intervention</th>
<th>Control</th>
<th>(p)-value</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline(\infty)</td>
<td>Negative Emotions</td>
<td>20.4 (6.2)</td>
<td>20.4 (7.1)</td>
<td>0.992</td>
<td>20.4 (6.5)</td>
</tr>
<tr>
<td>Baseline(\infty)</td>
<td>Availability</td>
<td>19.8 (5.8)</td>
<td>18.7 (7.2)</td>
<td>0.666</td>
<td>19.3 (6.4)</td>
</tr>
<tr>
<td>Baseline(\infty)</td>
<td>Social Pressure</td>
<td>22.6 (6.3)</td>
<td>21.2 (7.3)</td>
<td>0.565</td>
<td>21.9 (6.7)</td>
</tr>
<tr>
<td>Baseline(\infty)</td>
<td>Physical Discomfort</td>
<td>25.2 (6.5)</td>
<td>23.5 (6.4)</td>
<td>0.481</td>
<td>24.4 (6.4)</td>
</tr>
<tr>
<td>Baseline(\infty)</td>
<td>Positive Activities</td>
<td>26.8 (6.4)</td>
<td>24.5 (6.1)</td>
<td>0.319</td>
<td>25.7 (6.3)</td>
</tr>
<tr>
<td>Baseline(\infty)</td>
<td>Total Score</td>
<td>114.8 (23.0)</td>
<td>108.4 (25.4)</td>
<td>0.471</td>
<td>111.7 (24.0)</td>
</tr>
<tr>
<td>3 months#</td>
<td>Negative Emotions</td>
<td>25.2 (6.8)</td>
<td>20.8 (9.0)</td>
<td>0.213</td>
<td>-</td>
</tr>
<tr>
<td>3 months#</td>
<td>Availability</td>
<td>26.0 (6.0)</td>
<td>17.4 (7.5)</td>
<td>0.008</td>
<td>-</td>
</tr>
<tr>
<td>3 months#</td>
<td>Social Pressure</td>
<td>28.7 (5.1)</td>
<td>24.8 (7.0)</td>
<td>0.151</td>
<td>-</td>
</tr>
<tr>
<td>3 months#</td>
<td>Physical Discomfort</td>
<td>28.8 (4.6)</td>
<td>27.1 (4.9)</td>
<td>0.401</td>
<td>-</td>
</tr>
<tr>
<td>3 months#</td>
<td>Positive Activities</td>
<td>30.6 (4.1)</td>
<td>25.4 (7.2)</td>
<td>0.048</td>
<td>-</td>
</tr>
<tr>
<td>3 months#</td>
<td>Total Score</td>
<td>139.4 (22.0)</td>
<td>115.5 (31.0)</td>
<td>0.050</td>
<td>-</td>
</tr>
<tr>
<td>Change</td>
<td>Negative Emotions</td>
<td>5.5 (2.9)</td>
<td>3.5 (8.5)</td>
<td>0.472</td>
<td>-</td>
</tr>
<tr>
<td>Change</td>
<td>Availability</td>
<td>7.1 (5.5)</td>
<td>1.0 (7.0)</td>
<td>0.036</td>
<td>-</td>
</tr>
<tr>
<td>Change</td>
<td>Social Pressure</td>
<td>6.1 (5.4)</td>
<td>4.1 (9.4)</td>
<td>0.545</td>
<td>-</td>
</tr>
<tr>
<td>Change</td>
<td>Physical Discomfort</td>
<td>4.5 (6.7)</td>
<td>4.5 (8.4)</td>
<td>0.978</td>
<td>-</td>
</tr>
<tr>
<td>Change</td>
<td>Positive Activities</td>
<td>4.6 (4.9)</td>
<td>0.9 (7.6)</td>
<td>0.188</td>
<td>-</td>
</tr>
<tr>
<td>Change</td>
<td>Total Score</td>
<td>27.8 (20.1)</td>
<td>13.9 (37.4)</td>
<td>0.290</td>
<td>-</td>
</tr>
</tbody>
</table>

All results mean (SD), independent samples t-test

\(\infty\) Intervention N = 16, Control = 15, Total N = 31

\# Intervention N = 11, Control = 11
The Fat & Fibre Behaviour Questionnaire assessed dietary behaviours that influence fat and fibre intake and has been used in previous research (41, 77). This questionnaire was analysed using the total score from each participant at baseline and at the three month time point. There was no statistical difference in the values within this study; however this may be due to the small number of study participants (Table 8).

Table 8. Fat & Fibre Behaviour Questionnaire scores at baseline and at three months by group

<table>
<thead>
<tr>
<th>Visit</th>
<th>Measure</th>
<th>Intervention</th>
<th>Control</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline**</td>
<td>Fat</td>
<td>3.38 (0.62)</td>
<td>3.15 (0.69)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Fibre</td>
<td>2.71 (0.79)</td>
<td>2.29 (0.66)</td>
<td></td>
</tr>
<tr>
<td>Three months #</td>
<td>Fat</td>
<td>3.38 (0.92)</td>
<td>3.38 (0.62)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Fibre</td>
<td>2.57 (0.86)</td>
<td>2.57 (0.55)</td>
<td></td>
</tr>
<tr>
<td>Change in three months</td>
<td>Fat</td>
<td>0.15 (0.46)</td>
<td>0.23 (0.46)</td>
<td>0.392</td>
</tr>
<tr>
<td></td>
<td>Fibre</td>
<td>0.00 (0.71)</td>
<td>0.14 (0.43)</td>
<td>0.739</td>
</tr>
</tbody>
</table>

All results median (interquartile range), Mann-Whitney U test

**Intervention N = 16, Control = 15, Total N = 31

# Intervention N = 11, Control = 12

The K10 results revealed seven women at each time point who returned a score over 20, and each were managed as per the protocol outlined (Table 9). It was not within the scope of this study to diagnose or treat anxiety issues, and it was not known whether the participants were already being treated for depression prior to enrolment. All the women with whom the results discussed were receptive to and aware of their score, and stated they were willing to seek help, if required. There were no differences in factors relating to depression or mood changes between groups at the three month time point (Table 10).
Table 9. Participants referred to health care provider at baseline and three months by group

<table>
<thead>
<tr>
<th>Visit</th>
<th>Intervention</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>4 (25%)</td>
<td>3 (20%)</td>
</tr>
<tr>
<td>Three months</td>
<td>3 (27%)</td>
<td>4 (36%)</td>
</tr>
</tbody>
</table>

Table 10. Kessler Psychological and Distress (K10) scores at baseline and three months by group

<table>
<thead>
<tr>
<th>Visit</th>
<th>Intervention</th>
<th>Control</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline*</td>
<td>16.5 (7)</td>
<td>16.0 (6)</td>
<td>0.827</td>
</tr>
<tr>
<td>Three months#</td>
<td>15 (7)</td>
<td>17 (6)</td>
<td>0.391</td>
</tr>
</tbody>
</table>

median (IQR), Mann-Whitney U test
*Intervention N = 16, Control = 15, Total N = 31
# Intervention N = 11, Control = 12

The average frequency of pedometer downloads in the intervention group was 90 times over the three months, ranging between 39 and 145 (Table 11). This included all uploads of the pedometer, e.g. when the participant uploaded weekly, then there would be seven data entries for that week. The average number of steps/day was 5,916 and seven participants reached the target of 10,000 steps/day at least once. Seven participants uploaded their steps for 12 consecutive weeks, and four participants did not (Table 12). The average number of nutrition coaching workshops attended was three out of four sessions (Table 11).
Table 11. Pedometer uploads and steps and nutrition coaching workshop attendance for intervention group

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Mean (SD)</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of times pedometer data uploaded</td>
<td>90 (31)</td>
<td>39-145</td>
</tr>
<tr>
<td>Number of steps per day</td>
<td>5,916 (2,878)</td>
<td>0 -16,645</td>
</tr>
<tr>
<td>Number of nutrition coaching workshops attended</td>
<td>3 (1.3)</td>
<td>0-4</td>
</tr>
</tbody>
</table>

Table 12. Consecutive weeks uploaded and steps per day by participants in the intervention group

<table>
<thead>
<tr>
<th>Participant</th>
<th>Number of consecutive weeks uploaded by individual participants</th>
<th>Steps/day completed per week</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>6 weeks</td>
<td>0-8352</td>
</tr>
<tr>
<td>2</td>
<td>8 weeks</td>
<td>0-8996</td>
</tr>
<tr>
<td>3</td>
<td>9 weeks</td>
<td>0-8875</td>
</tr>
<tr>
<td>4</td>
<td>10 weeks</td>
<td>0-1376</td>
</tr>
<tr>
<td>5</td>
<td>12 weeks</td>
<td>658-12979</td>
</tr>
<tr>
<td>6</td>
<td>12 weeks</td>
<td>0-1645</td>
</tr>
<tr>
<td>7</td>
<td>12 weeks</td>
<td>0-10555</td>
</tr>
<tr>
<td>8</td>
<td>12 weeks</td>
<td>0-14104</td>
</tr>
<tr>
<td>9</td>
<td>12 weeks</td>
<td>0-14230</td>
</tr>
<tr>
<td>10</td>
<td>12 weeks</td>
<td>0-12974</td>
</tr>
<tr>
<td>11</td>
<td>12 weeks</td>
<td>0-9146</td>
</tr>
</tbody>
</table>
3.6. Discussion

Although women with GDM are at increased risk for T2DM and a significant proportion will develop the condition within the decade after their GDM delivery, interventions successfully targeting women during this time are few. There is a need to adopt effective programs to local settings and service capabilities. In this study, we demonstrated that an intervention consisting of a web-based activity component and four sessions of nutrition coaching could successfully support weight loss. Although not statistically significant, the clinical implications of the increased physical activity of 135 minutes/week and self-efficacy in eating behaviours shown in this study confirm a positive trend towards improved lifestyle behaviours. However, this study also demonstrates the challenges of engaging women with young children in an intervention aimed at changing lifestyle behaviours, as willingness to participate in the intervention was low.

Obesity is a primary risk factor for the development of T2DM (55), and at least two systematic reviews (52, 82) have suggested that a combination of diet and exercise rather than diet alone may be more efficacious for postpartum weight loss (52, 82, 83). A previous report using only the web-based pedometer component targeting physical activity did not demonstrate significant weight loss (26), suggesting that both diet and exercise components are necessary. Of note, the pattern of clinically significant changes in physical activity with smaller, non-significant diet quality changes, were also observed in recent dietary and physical intervention underpinned by similar behaviour-change strategies for high BMI women in the postpartum period (50).

The findings from this RCT also suggest that the combination of an in-person counseling and web-based activity component may be more effective for behaviour change in this specific at-risk group of women than the web-based program alone as previous research using pedometers alone did not result in behaviour change (26). Other interventions targeting obesity and risk reduction of T2DM have noted that behaviour may be successfully modified by counseling sessions only (15), but participant populations in those studies were older and had different motivators and enablers of behaviour change.
3.6.1. Strengths

The strengths of this study lie in the physical and lifestyle changes achieved in the intervention group of the sample. The pedometer and website designed to increase physical activity was an established website that was adapted to a local setting, an aspect that may increase participation in future programs. The nutrition coaching program had a strong theoretical underpinning based on Social Cognitive Theory (29) and informed by previous research. Measurements and survey delivery were performed on all participants by one researcher ensuring validity by decreasing the risk of possible differences in measurement methodology.

Confidence in reliability of outcomes following an RCT lie in the determination that characteristics of both the intervention and control groups are similar at the commencement of the study (69). This similarity will strengthen the hypothesis that any difference in outcome is a result of the intervention (69). This study was a wait-list RCT, with no statistical difference between intervention and control groups. Random allocation of groups potentially distributes potential confounders known and unknown in an even fashion between groups (69), and this method was utilised in this RCT.

The feedback from the participants on the combination of the pedometer and website was positive and the delivery and content of the nutrition workshop was well received. The ability to provide the intervention in a central location was also a strength as most women found the hospital a familiar environment.

3.6.2. Limitations

Despite efforts to recruit a larger number of participants, actual recruitment was low, therefore the statistical power to detect significant differences between intervention and control arms was limited. Despite small numbers of recruits to the study, statistical significance was achieved in respect of the primary outcome. Statistical significance was shown in several areas of outcomes, with results of clinical importance achieved in secondary outcomes such as increased physical activity and self-efficacy relating to food choices.
Furthermore, the women not recruited to the study may have had different characteristics from those who did participate. As it was not possible to measure non-participant characteristics, it may limit the generalisability of some results. Moreover, the women in this study were predominately caucasian, and in their mid-thirties, and thus these results may not apply to women of other ages or racial/ethnic groups. Younger women may have lower perceptions of risk and less motivation to alter behaviour (54, 84), and women of other races/ethnicities may have different perceptions and understanding of lifestyle changes required to decrease their risk of developing T2DM (85).

Blinding of the treatment groups to the researcher was not possible within this study. Education regarding the website and use of the pedometer was required, and as there was one researcher it was necessary for this to occur at time of randomisation. Although this may be considered a limitation, there was no systematic difference between groups in the follow-up contact between the researcher.

Adherence by the participants randomised to the intervention group relating to the pedometer program was mixed. Seven of the participants in the intervention program completed and uploaded steps in 12 consecutive weeks into the website, however four participants did not. The goal within the program was to meet 10,000 steps/day by the end of the intervention period, and although eight participants met this goal at least once during the study period, the average of the total step counts did not meet this target.

Recruitment of women in the early postpartum phase has been proven to be difficult. Although we demonstrated promising weight and behaviour changes amongst participants, it is also notable that the participation was low and needed extensive advertising and outreach to obtain the small numbers enrolled in this study. Common themes encountered by other intervention studies in this population, such as lack of time, no childcare, and difficulties ‘fitting the changes’ into the family, were also a factor in this study and affected all stages of the the project from recruitment of possible participants, attrition during the trial to poor follow-up attendance (26, 86, 87). These barriers precluded the possibility of long term follow up of the participants, although eleven participants agreed to further
contact should a new study be developed. While the intervention was designed to reduce barriers to behaviour change, experience suggests that additional methods, such as specific delivery formats and different ways to encourage engagement needed to be explored in order to successfully change behaviour in this group of young mothers. This is explored in detail in the next section, dealing with qualitative analysis of participant’s experiences.

3.7. Conclusion

Although encountering barriers to recruitment and retention of participants similar to those seen in other intervention trials, results from this study demonstrate that a web-based pedometer intervention, in combination with nutrition coaching underpinned by behaviour change theory, can lead to overall weight loss and increased physical activity over a three month period. The implementation of a program that combines these features, in a suitably delivered format, to engage women previously diagnosed with GDM, in a larger scale trial or full scale clinical program has the potential to delay or prevent T2DM in this high risk group. The adaption of this program to the local context through the tailored website and face-to-face nutrition coaching in a familiar location may be part of the reason for the positive outcomes described here.

This chapter reported the Walking for Exercise and Nutrition to prevent Diabetes for You (WENDY) RCT, including methodology, protocols and evaluation of the intervention. Quantitative research methods were detailed, including study design recruitment strategies, sample size, estimates based on statistical power calculations with allowance for attrition, outcome measures, data handling and storage, statistical evaluation of results of the trial, and discussion relation to implications for future interventions.

The next chapter (4.0) will describe the qualitative study designed to examine the experiences of the participants of the RCT relating to engagement in the study, the study characteristics, the risk perception of T2DM, and the ability to sustain lifestyle changes long term.
3.8. **Publication:** A randomised controlled trial to delay or prevent type 2 diabetes after gestational diabetes.


1 School of Nursing and Midwifery. The University of Queensland, Brisbane, Queensland Australia
2 Mater Research Institute – The University of Queensland, Brisbane, Australia
3 Mater Health Services, Brisbane, Australia
4 University of Michigan, Ann Arbor, Michigan, United States of America
5 School of Medicine, The University of Queensland, Brisbane, Australia

**Introduction**

Gestational diabetes mellitus (GDM) is a well-established predictor for the development of Type 2 diabetes (T2DM) [1]. The incidence of GDM has been increasing over the last fifteen years [2], and with the introduction of updated clinical guidelines for the diagnosis and management of GDM, the prevalence in Australia could be as high as 13% [3]. Worldwide, the prevalence of T2DM following GDM may be as high as 70% [4-8].

In 2007 the economic burden of T2DM was estimated at approximately $US218 Billion [9]. The global burden of T2DM is immense [10] with one potential solution being a targeted delay or prevention of progression to T2DM in high-risk populations [11-14]. However, programs designed to target women following GDM have met with varied levels of success [15]. Lifestyle intervention trials incorporating dietary modification and promoting increased physical activity to support weight loss have been successful in preventing T2DM [15-18], demonstrating a reduced risk of progression to T2DM in high risk groups by up to 58% [19, 20], with a continuing influence up to eight years after the intervention [21].

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In a secondary analysis of the US Diabetes Prevention Program study, women with documented prior GDM had a 71% greater chance of progressing to T2DM three years later, a risk which was reduced by 50% through lifestyle intervention [17]. However, women were over a decade from their delivery, and it was not known whether this last delivery was in fact their GDM delivery. Therefore, although interventions successfully reduced the incidence of diabetes, the onset of diabetes likely occurred after subsequent pregnancies. Surveys of women with GDM suggest that six months to two years is an optimal time to offer a lifestyle modification intervention as women felt they would be more able to include changes in their life after the birth of their baby [22], and earlier intervention would also offer the chance to reduce the risk of glucose intolerance during subsequent pregnancies. Targeting these reproductive-aged women with recognised risk factors with programs that both engage and provide education for long-term healthy behaviour may provide the optimal prevention strategy for both maternal and fetal outcomes.

A recent systematic review examined types of physical activity and found the most successful exercise programs in postpartum women were those with objectively set goals usually incorporating devices such as pedometers [23]. Previous studies that specifically used pedometers in the postpartum population report an increase in physical activity [24, 25]. Both studies relied on self reporting of step counts from the pedometer, with no indication as to whether the women would have preferred web-based storage of the step data. Kim et al suggested the combination of internet based support combined with a more traditional approach may be more successful than the internet support alone [26].

**Objectives**

This study aimed to develop, implement and evaluate a low intensity, exercise and diet program for women who were diagnosed with GDM during a prior pregnancy and had a body mass index (BMI) > 25 kg/m² in the postpartum period. Our primary hypothesis was that the women in the intervention group would achieve significantly more weight loss than the control group. Our secondary hypotheses were that compared with women in the control group, women in the intervention group would have significantly: (1) better diet quality and self-efficacy; (2) more minutes of physical activity/week; (3) lower fasting glucose and insulin levels; and (4) lower body fat mass (FM) and significantly higher fat
free mass (FFM). The study was named: Walking for Exercise and Nutrition to prevent Diabetes for You (WENDY).

**Method**

The intervention took place at a tertiary maternity hospital in Brisbane, Australia from June 2011 to December 2012. The study was approved by Mater Health Services Human Research Ethics Committee, and The University of Queensland Medical Research Ethics Committee.

We evaluated the intervention using a randomised controlled trial. Women were eligible if they were aged 18 years of age or over, and had been diagnosed and treated for GDM, six months to two years postpartum, had a self reported BMI > 25 kg/m², had routine access to a computer, computer skills to navigate websites and email, and understood that the primary physical activity would be walking. Women were ineligible if they were currently pregnant, had T2DM, not fluent in English, used hypoglycaemic medications, or had any mental or physical disabilities which would have hindered participation in study activities. Randomisation was stratified according to BMI (25–30 kg/m²; >30 kg/m²).

Women were recruited through several venues, including telephone contact obtained from the hospital database of women with GDM diagnoses, hospital-based electronic resources, advertisements placed through the Australian National Diabetes Services Scheme (NDSS) [27] dedicated website to GDM (You2), and television advertisements.

Participants were contacted by the research team, with three attempts at contact (fixed and mobile phones). Women not contactable after three attempts were classified as ‘unable to contact’. Those who were contacted and refused had their reasons for refusal noted. For those who agreed to participate, an email address and basic data such as height and weight to allow calculation of current BMI and updated contact details were collected, and an oral glucose tolerance test (OGTT) was performed to exclude T2DM.

**Randomisation**
An independent service generated a stratified, variable block, computer-generated randomisation schedule and sealed the individual allocations in opaque envelopes. The envelopes were stored in a locked, secured container until eligibility was established. Once eligibility was established through baseline measurements (BMI, no T2DM on OGTT), the next envelope for the appropriate stratum was opened.

Women allocated to the intervention group received a pedometer linked to a tailored web-based program “Step Up to Health” and a four-week nutrition coaching workshop. The women in the control group formed a wait-list group and were offered the nutrition workshop following the three month assessment.

The pedometer had an opaque sticker that covered the digital display and was worn continuously for the first week, without providing feedback to record baseline steps. Once the baseline steps were uploaded via USB, the sticker was removed, and the step count was visible. The web-based program generated weekly goals based on the previous weeks steps. As the steps were uploaded each week, the goals were gradually increased, until the maximum of 10,000 steps/day was reached [26]. The user was encouraged to log on weekly to receive updated weekly goals, feedback on their walking progress, messages and ‘tips’ regarding diet and exercise targeted at diabetes prevention.

The nutrition coaching workshop was delivered by accredited practising dietitians. The workshop consisted of four one-hour group sessions incorporating evidence-based strategies to facilitate behaviour change aimed at healthy sustainable weight loss [28], and to build self-efficacy such as goal setting and self monitoring and use of group activities to model recommended behaviour and engender peer support. Resources provided to all women included tools designed to encourage portion control [29, 30].

Data collection and outcome measures

Data were collected at baseline and three months. Baseline observations included survey-based assessments of dietary and physical activity, mental health assessments, assessments of anthropometrics, body composition, serum insulin and OGTT performance. Weight was measured to the nearest 0.1 kg using a spring balance scale, and height was measured with a wall mounted stadiometer to the nearest 0.5 cm. Hip and
waist measurements were taken with a standard tape measure, and estimation of body composition (fat mass and lean body mass) was assessed using using a multi-frequency bioelectrical impedance analyser, (BodyStat 1500MDD, Bodystat, United Kingdom) with a measured resistance at a fixed frequency of 50Hz.

Dietary quality was assessed using the Fat & Fibre Index [31], eating behaviour self-efficacy was assessed using The Health and Wellbeing Self-Efficacy Survey (WEL) [32], physical activity was assessed using Australian Womens Activity Survey (AWAS) [33], and mental health was assessed using the Kessler Psychological Distress scale (K10) [34]. Any results indicative of anxiety or depression were discussed with the participant and referred to relevant health care providers if necessary [35]. The homeostasis model assessment of insulin resistance (HOMA-IR), a widely used estimate of insulin resistance in the fasting state, was calculated as \((\text{Fasting plasma insulin (FPI)} \, [\text{mU/L}] \times \text{Fasting plasma glucose (FPG)} \, [\text{mmol/L}]/22.5\) [36].

**Outcome measures**

The primary outcome was weight loss from baseline to three months, reported as absolute weight loss for each participant.

Secondary outcomes were change in measurements from baseline to three months for (1) hip and waist measurements; (2) diet quality measured by a self reported survey; (3) WEL overall and domain scores; (4) minutes of physical activity/week (as Health Enhancing Physical Activity, HEPA); (5) glucose and HOMA-IR; and (6) body FM and FFM.

**Statistical methods**

Analysis was by intention-to-treat with all analyses comparing the control and intervention groups. Analysis was undertaken with blinding to study assignment.

Data were checked for normality of the distributions of continuous variables. Normally distributed variables underwent parametric analyses; continuous non-normally distributed data were analysed using non-parametric methods and categorical data were analyzed using chi-squared or Fishers exact test. Analysis of the primary outcome used an
Results

Demographic and anthropometric characteristics of the study participants were similar in each group (Table 1). There were more multigravidas in the intervention group, and an equal proportion of women and public and private health insurance. Ethnicity was predominately Caucasian women, with three women of Asian descent. The majority of women had required insulin therapy (control n=10 [67%], intervention n=9 [56%]) to control their glucose levels during pregnancy, followed by diet (control n=4 [27%], intervention n=4 [25%]) then metformin (control n=1 [7%], intervention n=3 [19%]).
Table 1. Demographic characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Group</th>
<th>Intervention</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>N=16</td>
<td>N=15</td>
</tr>
<tr>
<td>Ethnicity</td>
<td>Caucasian</td>
<td>14 (88%)</td>
<td>14 (93%)</td>
</tr>
<tr>
<td></td>
<td>Other</td>
<td>2 (12%)</td>
<td>1 (7%)</td>
</tr>
<tr>
<td>Gravidity</td>
<td>1</td>
<td>4 (25%)</td>
<td>2 (13%)</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>5 (31%)</td>
<td>6 (40%)</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>4 (25%)</td>
<td>3 (20%)</td>
</tr>
<tr>
<td></td>
<td>4+</td>
<td>3 (19%)</td>
<td>4 (27%)</td>
</tr>
<tr>
<td>Parity</td>
<td>0</td>
<td>3 (19%)</td>
<td>3 (20%)</td>
</tr>
<tr>
<td></td>
<td>1</td>
<td>6 (38%)</td>
<td>7 (47%)</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>4 (25%)</td>
<td>1 (7%)</td>
</tr>
<tr>
<td></td>
<td>3+</td>
<td>3 (19%)</td>
<td>4 (27%)</td>
</tr>
<tr>
<td>Insurance</td>
<td>Public</td>
<td>8 (50%)</td>
<td>9 (60%)</td>
</tr>
<tr>
<td></td>
<td>Private</td>
<td>8 (50%)</td>
<td>6 (40%)</td>
</tr>
<tr>
<td>Diabetic control</td>
<td>Insulin</td>
<td>9 (56%)</td>
<td>10 (67%)</td>
</tr>
<tr>
<td></td>
<td>Metformin</td>
<td>3 (19%)</td>
<td>1 (7%)</td>
</tr>
<tr>
<td></td>
<td>Diet</td>
<td>4 (25%)</td>
<td>4 (27%)</td>
</tr>
<tr>
<td>Age at OGTT*</td>
<td></td>
<td>34.8 (3.1)</td>
<td>37.3 (5.4)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Range 28-39</td>
<td>Range 28-44</td>
</tr>
<tr>
<td>Self-reported Weight*</td>
<td></td>
<td>83.9 (18.4)</td>
<td>86.2 (17.4)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Range 57-118</td>
<td>Range 62-125</td>
</tr>
<tr>
<td>Self-reported BMI^</td>
<td></td>
<td>29.4 (6.6)</td>
<td>31.2 (9.9)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Range 25.3-47.1</td>
<td>Range 25.5-44.8</td>
</tr>
</tbody>
</table>

* mean (standard deviation), independent samples t-test
^ median (interquartile range), Mann-Whitney U test
& 4 cases missing (1 intervention; 3 control)
We attempted to contact three hundred and twenty women (Fig. 1). Thirty-one women were randomised, with 23 women completing the three month primary outcome measurements.

Five participants in the intervention group discontinued over the course of the three month period for differing reasons (Fig. 1). One control participant (who was randomised in error prior to OGTT results) was diagnosed as T2DM following baseline OGTT and two other participants withdrew for unspecified reasons. Eleven participants in the intervention group (69%) and 12 participants in the control group (80%) completed both baseline and three month assessments.
Figure 1: Consort diagram of the study
Weight loss was greater in the intervention group, with a median loss of 2.5 kg (1.4) compared with a static weight in the control group ($p=0.002$), leading to a reduction in BMI of 0.9 kg/m$^2$ (IQR 0.7) ($p=0.002$) in the intervention group (Table 2).

**Secondary outcomes**

Changes in hip circumference were also significant with a median loss of 3 cm (5.0) in the intervention group compared with 0 cm (4.8) ($p=0.006$). Intervention group waist circumference decreased by a median of 3 cm (4.0) compared with 0.5 cm (4.8) ($p=0.037$).

There was a slight decrease in body fat and increase in lean body mass in the intervention group, but this was not statistically significant. Fasting glucose taken at both data collection points showed a small difference between the two groups that had borderline statistical significance ($p=0.052$), however, there was no change in HOMA-IR.

The intervention group increased their daily activity by one hundred and thirty-five minutes/week at the three month time point compared to the control group, although this difference was not statistically significant. The WEL results showed participants in the intervention group at three months feeling empowered when presented with opportunity for poor food choices ($p=0.036$). Although not statistically significant, trends towards improvements in the domains of negative emotions, social pressure, physical discomfort and positive activities were noted, all relating to the participants’ feelings regarding food and food choices (Table 2). There were no differences in factors relating to depression or mood changes between groups.
Table 2. Change between three month and baseline measurements

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Intervention</th>
<th>Control</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n=11</td>
<td>n=12</td>
<td></td>
</tr>
<tr>
<td>Weight^ (kg)</td>
<td>-2.5 (1.4)</td>
<td>0.0 (2.3)</td>
<td>0.002</td>
</tr>
<tr>
<td>BMI^ (kg/m^2)</td>
<td>-0.9 (0.7)</td>
<td>0.0 (0.8)</td>
<td>0.002</td>
</tr>
<tr>
<td>Waist^ (cm)</td>
<td>-3.0 (4.0)</td>
<td>0.5 (4.8)</td>
<td>0.037</td>
</tr>
<tr>
<td>Hip^ (cm)</td>
<td>-3.0 (5.0)</td>
<td>0.0 (4.8)</td>
<td>0.006</td>
</tr>
<tr>
<td>Body fat %^&amp;</td>
<td>-1.1 (4.5)</td>
<td>-0.3 (1.3)</td>
<td>0.393</td>
</tr>
<tr>
<td>Lean mass %^&amp;</td>
<td>0.9 (3.3)</td>
<td>0.0 (2.6)</td>
<td>0.436</td>
</tr>
<tr>
<td>Fasting glucose^&amp;</td>
<td>0.3 (0.5)</td>
<td>-0.1 (0.6)</td>
<td>0.052</td>
</tr>
<tr>
<td>Fasting insulin^#</td>
<td>-0.5 (2.4)</td>
<td>0.173</td>
<td>0.830</td>
</tr>
<tr>
<td>K 10 Total Score^ (measure of distress and anxiety over the previous month)</td>
<td>0.0 (4.0)</td>
<td>1.0 (4.0)</td>
<td>0.193</td>
</tr>
<tr>
<td>WEL Total Score (measure of attitudes, feelings and efficacy relating to food and eating behaviours)</td>
<td>27.8 (20.1)</td>
<td>13.9 (37.4)</td>
<td>0.290</td>
</tr>
<tr>
<td>Negative Emotions</td>
<td>5.5 (2.9)</td>
<td>3.5 (8.5)</td>
<td>0.472</td>
</tr>
<tr>
<td>Availability</td>
<td>7.1 (5.5)</td>
<td>1.0 (7.0)</td>
<td>0.036</td>
</tr>
<tr>
<td>Social Pressure</td>
<td>6.1 (5.4)</td>
<td>4.1 (9.4)</td>
<td>0.545</td>
</tr>
<tr>
<td>Physical Discomfort</td>
<td>4.5 (6.7)</td>
<td>4.5 (8.4)</td>
<td>0.978</td>
</tr>
<tr>
<td>Positive Activities</td>
<td>4.6 (4.9)</td>
<td>0.9 (7.6)</td>
<td>0.188</td>
</tr>
<tr>
<td>HEPA</td>
<td>135 (225)</td>
<td>0 (418)</td>
<td>0.190</td>
</tr>
<tr>
<td>Fat</td>
<td>0.2 (0.4)</td>
<td>0.2 (0.5)</td>
<td>0.824</td>
</tr>
<tr>
<td>Fibre</td>
<td>-0.04 (0.8)</td>
<td>0.1 (0.4)</td>
<td>0.576</td>
</tr>
<tr>
<td>Total</td>
<td>0.1 (0.5)</td>
<td>0.2 (0.4)</td>
<td>0.682</td>
</tr>
</tbody>
</table>

All results mean (standard deviation) unless other stated. ^ median (interquartile range), Mann-Whitney U test
^ 3 cases missing (1 intervention; 2 control) # 5 cases missing (1 intervention; 4 control)
Website “Stepping up to Health”

All women randomised to the intervention group accessed the website during the three month intervention. The mean number of participant pedometer uploads was 90 (SD 31). The mean recorded steps/day was 5,916 (SD 2,878, Range 5 – 16,645) in the three month period (Table 3).

Table 3. Pedometer and nutrition workshop data

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Mean (SD)</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of times pedometer data uploaded</td>
<td>90 (31)</td>
<td>39-145</td>
</tr>
<tr>
<td>Number of steps per day</td>
<td>5,916 (2,878)</td>
<td>5-16,645</td>
</tr>
<tr>
<td>Number of nutrition workshops attended</td>
<td>3 (1.3)</td>
<td>0-4</td>
</tr>
</tbody>
</table>

SD standard deviation

Discussion

Although women with GDM are at increased risk for diabetes and a significant proportion will develop T2DM within the decade after their GDM delivery, interventions successfully targeting women during this time are few. In this study, we demonstrated that a simple, brief intervention consisting of only four sessions of counselling and a web-based activity component could successfully reduce weight, increase physical activity and improve constructs associated with improved lifestyle behaviours. Such a program has the potential to be delivered in multiple care settings for limited cost. However, our study also demonstrated the challenges of engaging women with young children in an intervention aimed at changing lifestyle behaviours, as willingness to participate in the relatively ‘simple’ intervention was low.

Obesity is a primary risk factor for the development of T2DM [1]. At least two systematic reviews [38, 39] have suggested that a combination of diet and exercise, rather than diet alone, may be more efficacious for postpartum weight loss [23, 38, 39]. A previous report using only the web-based pedometer component targeting physical activity did not
demonstrate significant weight loss [26], suggesting that both diet and exercise components are necessary, even though we did not note significant changes in dietary quality. Of note, the pattern of clinically significant changes in physical activity with smaller, non-significant diet quality changes, were also observed in recent dietary and physical intervention underpinned by similar behaviour-change strategies for high BMI women in the postpartum period [40]. The results for the secondary outcomes in our study, such as the trend of increased incidental activity and improved self-efficacy in food behaviour in the intervention group, may be a collateral effect of goal setting behaviour. The value of increased physical activity in all domains is an important factor in overall lifestyle change.

Our study also suggests that an in-person counseling component may be more effective for behaviour change in this specific at-risk group of women than the web-based program alone. The mean attendance in the four counseling sessions was three (range 0–4 sessions) (Table 3) with the majority of participants attending all four group sessions. These results suggest that the primary impact of the intervention was mediated through the in-person counseling session. Other interventions targeting obesity and risk reduction of T2DM have noted that behaviour may be successfully modified by counseling sessions only [16], but participant populations in those studies were older and had different motivators and enablers of behaviour change.

Recruitment of participants in the early postpartum phase has been proven to be difficult. Although we demonstrated promising weight and behaviour changes amongst participants, it is also notable that the participation was low and needed extensive advertising and outreach to obtain the small numbers enrolled in this study. Common themes encountered by other intervention studies in this population such as lack of time, no childcare, and difficulties ‘fitting the changes’ into the family were also a factor in this study, and affected all stages of the the project from recruitment of possible participants, attrition during the trial to poor follow-up attendance [26, 41, 42]. While the intervention was designed to reduce barriers to behaviour change, this experience suggests that additional motivators will need to be explored in order to successfully change behaviour in this group of young mothers.

The strengths of our study lie in the physical and lifestyle changes achieved in the intervention group of our sample. The feedback from the participants on the combination of
the pedometer and website was positive and the delivery and content of the nutrition workshop was well received. The ability to provide the intervention in a central location was also a strength as most women found the hospital a familiar environment.

There were limitations in this project. Despite our efforts to recruit a larger number of participants, actual recruitment was low, therefore the statistical power to detect significant differences between intervention and control arms was limited. Moreover, the women in this study were predominately Caucasian, and in their mid-thirties, and thus our results may not apply to women of other age or racial/ethnic groups. Younger women may have lower perceptions of risk and less motivation to alter behaviour [43, 44], and women of other races/ethnicities may have different perceptions and understanding of lifestyle changes required to decrease their risk of developing T2DM [45].

Conclusion

Although encountering similar barriers to recruitment and retention of participants as in other intervention trials, results from this study demonstrate that the combination of a web-based pedometer intervention in combination with a nutrition program underpinned by behaviour change theory based on long term behaviour change can lead to overall weight loss and increased physical activity (known risk factors for the development of T2DM) over a three month period. The availability of a program that combines these features in a suitably delivered format to engage women previously diagnosed with GDM in a larger scale trial may delay or prevent T2DM in this high-risk group.

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Figure and table legend

Figure 1. Consort diagram

Table 1. Demographic characteristics of women in intervention and control groups

Table 2. Change between three month and baseline measurements

Table 3. Pedometer and nutrition workshop data

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4. Qualitative study

“Despite the theoretical advantage of commencing diabetes prevention at an earlier stage of pathophysiology, practical barriers may make women more resistant to change at this stage of the life cycle…” McIntyre (2012)

5.1. Introduction

A key challenge in the effectiveness of interventions to delay or prevent T2DM following GDM was recruitment and engagement of participants in this cohort for varying reasons. The literature review (Chapter 2) highlighted that, although there was evidence lifestyle interventions were effective, there is difficulty in recruitment and engagement of this population. This qualitative research aims to add to the body of knowledge to inform further research by examining the experiences of the women who participate in the RCT (Chapter 3) to assist with engagement of women through appropriate delivery of interventions that could meet women’s needs.

The purpose of qualitative research is to explore and explain the intervention or phenomena being studied (69). There is not a single qualitative methodology, and a range of theories have been developed, including grounded theory, phenomenology, ethnography and narrative discourse (88). Thematic analysis has been described as “a method for identifying, analysing and reporting patterns (themes) within data” (37). Thematic analysis can be used within both realist and constructionist methods, which examines experiences of participants, as well as the meaning of these experiences on society as a whole (37). Braun and Clarke (2006) found a deductive or theoretical approach to analysis of the data allows the researcher to apply a specific interest to the data in order to answer a question (37), with the identification of broad themes, and continually reviewing the data until the final themes or common ideas have emerged from the data (37).
Qualitative research also allows participants to express their feelings and experiences of an intervention, provides a human counterpoint to the quantitative data already collected and extends the researchers’ knowledge of the strengths and limitations of the research studied (89).

Using the Interpretive model, aiming to interpret meanings through experiences, thoughts and feelings, can lead to a deeper understanding of how they can affect a person’s life (90). By interviewing the women who had participated in an intervention trial, thoughts, feelings and perceptions of their experience can inform further research within this context.

The use of an interview to collect information is a common approach to gathering data in a qualitative way (34). By using the interview approach, information such as feelings, opinions, and ideas for the future can be gathered from people relating to a subject in question (90). The use of focus groups can provide valuable information as data is generated through social interaction amongst the participants (90) and may provide more information as confidence within the group may encourage the expression of feelings and thoughts within a comfortable setting. The use of interviews can also provide this environment, and may give the participant more opportunity to disclose feelings and thoughts at their own pace (90). However a limitation can be difficulty in gathering a group together at a time suitable for all participants. Face-to-face interviews offer the advantage of a personal rapport to be established between the researcher and participant, and subtle actions such as facial gestures and body language can be observed (90). Telephone interviewing provides flexibility and is immediate, and both parties can respond to each other (34).

Data collected through semi-structured interviews involves an interview guided by a set of questions, while allowing the people to express their own thoughts and feelings within the question framework (35, 90). Conducting the interview in a place and time suitable for the participant adds to the strength to the discussion as the participant will be more likely to share valuable information if they are comfortable. Mutual respect and trust between interviewer and participant also contributes to information sharing, and can be even more valuable if a rapport and confidentiality has already been established between both parties.
This approach was supported in this study, as the participants throughout the original trial knew the interviewer through contact as the study progressed.

Through the use of semi-structured interviews there was a broad direction to data flow. However, it was important that the themes manifested as the participant shared their experiences of the trial, their feelings towards sustaining lifestyle change and their perception of risk of developing T2DM. When using deductive thematic analysis, it is important for the researcher to be open to all ideas, so that concepts and themes become apparent reviewing the data, although sensitivity to the data and the area of interest will guide the researcher as the interview evolves (90). This was indeed the case, as the researcher who conducted the interviews also coordinated the original trial, and so had intimate knowledge of the intervention the women experienced.

5.2. Aim

The aim was to gather and interpret qualitative data from the participants of the RCT in this thesis relating their experiences, perceptions and thoughts of participating in an intervention trial to prevent T2DM.

5.3. Methods

Data collection, coding and categorising were conducted under research processes in line with deductive thematic analysis framework. After discussion and review between the researcher and supervisors, questions were formulated to provide a broad framework and allow for a flow of conversation and information between the researcher and the participant. These questions were in a semi-structured format were discussed at each interview (Appendix 13).
5.3.1. Sample

The framework of theoretical sampling aims to select participants who can expand on emerging or new ideas on the topic that is studied. This selection and collection of data continues until no new theories are discovered or shared by the participants (90). All participants in the original trial and their perceptions, feelings and thoughts were particularly relevant in this context.

Following completion of the RCT section of the study, the researcher attempted to contact all participants (n=31) to invite them to participate in the qualitative evaluation of the program. Twenty participants were unable to be contacted, or did not return phone enquiries, and eleven agreed to participate (35%). Of the eleven women agreed to participate in the interviews, the mean age was 37 years, and all but one women had more than one child, with family size ranging from one to five children.

5.3.2. Data collection

Although focus groups are considered a respected way of collecting feelings and thoughts of a group (36), anecdotal discussion with the RCT participants revealed they were reluctant to attend too many appointments, and led to the decision to hold semi-structured interviews by phone. This method allowed the interview to be held in their own home which was preferable to most participants. Ten participants consented to phone interviews, with one participant preferring a face-to-face interview due to convenience.

After gaining verbal consent for the taping, the interview was conducted by phone by the researcher who coordinated the original RCT. Each interview took approximately 30 minutes to one hour, with no time restriction imposed to allow free verbal expression of thoughts and opinions. Each participant was asked the same questions (Appendix 13), and all participants were able to express their opinions as the interview developed. The interviews were transcribed verbatim by an external typist, and accuracy of interview content was checked by the interviewer post transcription.
5.3.3. **Data analysis**

Coding or the identification of themes within the deductive thematic analysis framework is a process where data are reviewed and transformed into categories that are named (34, 90). The first, or provisional, codes can be modified over the analysis process, and the data should be reviewed line-by-line by more than one reviewer to allow for a broad selection of themes (90). All transcripts in this study were reviewed independently by three researchers (AP, FB, and SW) to identify common themes and significant responses. Themes identified were discussed and broad themes were constructed. Interviews were re-coded by the researchers, allowing for refinement of themes using constant comparison of the data. Constant comparison of the data allows for checking of the ‘fittingness’ of all data into the established categories (90), so all possible themes have been explored. The general themes and sub themes were discussed between all members of the research team until no new themes emerged and data saturation was reached. In-text quotes relating directly to the themes/sub themes were identified and approved by all members of the research team.

5.4. **Results**

5.4.1. **Themes**

Analysis of the data revealed four major themes: (1) Engagement, (2) Perspectives on Program Characteristics, (3) Sustaining Change, and (4) Risk Awareness. Each theme is subsequently described and illustrated with quotes. All names have been substituted with pseudonyms. Full explanation and supporting quotations are within the manuscript submitted for publication.

5.4.2. **Engagement**

Engagement refers to the initial reaction and factors that encouraged interest in the program, and contained three sub-themes that reflected initial contact, practical considerations, and the timing for engagement of other women in the future.

The timing of initial contact was received favourably, with all the participants stating they preferred the personal contact more motivating than generic reminders through the post or
internet. Components of the RCT such as parking concessions and the timing of the hospital visits and nutrition coaching within school hours were seen as helpful and encouraged them to continue with the program. When asked about the best time to approach new mothers who had been diagnosed with GDM, most women felt that the immediate postpartum or even antenatally was the best time to start to think about the long term impact GDM would have on their health.

5.4.3. Perspectives on Program characteristics

The program was seen as helpful and positive. Although the information provided was not new to most of the participants, they felt it reinforced their knowledge in relation to practical ways to incorporate health changes to their lifestyle such as portion size and shopping for healthy choices. The group setting with the same APD promoted stability and trust, which in turn encouraged sharing of ideas and feelings within the group. This proved to be difficult for some mothers however as they felt that having their children with them precluded them from joining in as much as they would have liked. Some mothers’ however liked having their children with them and stated that if they had to find someone to care for them, this would have provided another barrier to attendance.

The use of the website and pedometer worked well for some participants and not for others. The participants who stated they liked the pedometer also appreciated the website capability as a whole, including the graph showing their steps, and the tips and messages they received. Reasons the participants gave for the pedometer not being as useful included the bulkiness of the actual pedometer and not utilising the website as much as they might have.

5.4.4. Sustaining change

This theme explored if there were changes the women had adopted during the RCT and if they had maintained them following completion of the program. Most women felt that during the RCT, instant feedback for the pedometer program allowed them to balance their food intake and exercise, and for some had become a part of their lives. Resources they
received during the nutrition coaching ("this= that" book and Portion Plate) helped them stay “on track”, and although some women struggled to maintain the changes after the program finished, they felt they had the tools to “re-visit” the program in the future. Some women however noted they had increased their incidental exercise without realising it and spoke positively regarding this change.

5.4.5. Risk awareness

Understanding the risk of developing T2DM was explored through examining the source of information the women obtained, as well as their personal perception of their own risk. Most women were aware of their increased risk, and had received education and information form a variety of sources, including health care workers and their own research. Although some were making lifestyle changes in reaction to this risk, others were openly talking about how difficult the changes were and how other life factors such as family and work take precedence over exercise.

5.5. Discussion

Lifestyle interventions aimed at increasing physical activity and improving diet quality can prevent the development of T2DM (15). A systematic review looking at the effects of physical activity alone or in conjunction with nutrition interventions found that although the weight loss and increased physical activity was supported by the combination of both, more motivational factors were required such as personal goals, and supervised diet interventions (91). The participants of this qualitative study were part of a larger randomised controlled trial that combined both interventions. Despite the overwhelming evidence, interventions aimed at the cohort of women recently diagnosed with GDM have met with differing success, mainly relating to low recruitment and engagement (92). By interviewing women who have participated in an intervention, information such as experiences, perceptions and thoughts of participating in an intervention trial to prevent T2DM can inform further programs to tailor a program to meet the needs of the women in this cohort.
Using Social Cognitive Theory as a theoretical framework allows a person’s behaviour to be influenced by their surroundings and interactions with others (29). The concept of self-efficacy as part of this theory is dependent on the confidence an individual receives to be able to achieve the goal they seek through development of coping strategies. The theoretical constructs of vicarious experience, verbal persuasion, performance attainment and physiological state as described by Bandura (1977) provides a platform to encourage behaviour modification through increased self-efficacy (29). When applying the findings from the interviews of the women’s experiences to this construct, the concepts related to self-efficacy were supported. The group experience of the nutrition coaching allowed participants to observe others successes as well as sharing their own experiences. The presentation of the program within this arena promoted self-efficacy as most women felt the group gave them confidence and felt comfortable to discuss both successes and failures, providing personal feedback to support their behaviour.

The inclusion of practical tools to enhance physical activity such as the pedometer (with a digital display as well as the internet component) proved to be motivational for goal setting, self-monitoring, and instant feedback, all of which can lead to self-efficacy (70). Most women who used the pedometer found it motivating, and enjoyed the visual feedback they received from the pedometer and website.

The feeling of abandonment that has been found on other studies following a GDM pregnancy (24) was supported by the women interviewed for this study. However this feeling seemed to be alleviated by the initial contact coming from the maternity hospital, perhaps providing credibility to the program. The time frame to approach new mothers regarding the risk has also been suggested in the antenatal and immediate postpartum period (93), and again the women in this study agreed.

Although most women stated they had been given information relating to the risk of developing T2DM during their pregnancy, most felt that a program to support the lifestyle changes they learnt through the affected pregnancy after the birth of the baby would reinforce and encourage long term changes required that may prevent T2DM.
5.5.1. **Strengths**

Scientific rigor was strengthened by discussion of broad themes leading to the semi-structured interview script by all members of the research team, which provided confirmability (90). Using theoretical sampling (90) in this context, i.e. women who had participated in an intervention trial to prevent T2DM, resulted in specific information relating to this research question. Confirmability was achieved through open, independent review of the interviews by three researchers, ensuring the data reported fitted into the appropriate identified themes. The consistency of the interviewing researcher provided dependability, as all interviews were conducted in as similar a manner as possible, allowing for individual participant interaction (90). Data saturation cannot always be achieved (34); however, all researchers in this project reviewed the data, and agreed there were no further gaps in information or categories to be identified.

5.5.2. **Limitations**

However the study is not without its limitations. The homogeneity of the participants may mean the experiences of this cohort may not translate to the larger community, especially differing cultural groups.

The findings from the qualitative study may inform further intervention programs with components suited to new mothers. They should include:

1) education and introduction of post GDM and the risks of development of T2DM guidelines in the immediate postpartum period, with support and follow-up contact with a health professional.

2) invitation to face-to-face diet interventions in group setting of women with young children, or further investigation regarding service delivery to suit this cohort e.g. remote or internet engagement.

3) introduction of a program to encourage physical activity using modern technologies.

The birth of a new baby is a time consuming, emotionally intense life phase. However the risk of T2DM following GDM remains, and there is a wide consensus that a suitable intervention, which would become part of the women’s life aimed at weight loss and increased physical activity, would delay or prevent T2DM in this cohort.
This section described a detailed description of development, methodology, recruitment and thematic analysis results of the qualitative study following the completion of the RCT. The implications and extensive examples provided clarity relating to participation of women with young children previously diagnosed with GDM in intervention trials.
5.6. Manuscript: What Now? Women’s experiences post Gestational Diabetes engaging in an intervention to prevent Type 2 Diabetes Mellitus.


Ann S. Peacock¹,³, A/Prof Fiona Bogossian¹, Professor H. David McIntyre ²,³, Dr Shelley Wilkinson ³,⁴.

¹ School of Nursing and Midwifery, Faculty of Health Sciences, The University of Queensland, Herston Campus, Edith Cavell Building, Herston QLD 4006

² Mater Clinical School, The University of Queensland; Head of Mothers and Babies Research Theme, Mater Research, Mater Health Services, Raymond Terrace, South Brisbane, Qld 4101

³ Mothers and Babies Theme, Mater Research, Mater Health Services, Raymond Terrace, South Brisbane, Brisbane, QLD 4101

⁴ Department of Nutrition & Dietetics, Mater Health Services Raymond Terrace, South Brisbane, Brisbane, QLD 4101

Introduction

The likelihood of progression of Type 2 Diabetes Mellitus (T2DM) following a pregnancy complicated with Gestational Diabetes Mellitus (GDM) is linked (1) with lifestyle factors such as being overweight and obesity (2). The risk of T2DM manifesting in women increases with each year, and indications are that 25% of women in Australia previously diagnosed with GDM will go on to develop T2DM within 10 years (3). Interventions to modify lifestyle factors aimed at delaying or preventing T2DM would seem a logical solution, and a high-risk group such as those with a previous diagnosis of GDM would appear to be an ideal cohort to target from a public health perspective.

The relationship between maternal diabetes, childhood obesity and possible subsequent T2DM has also been demonstrated (4), suggesting the need for a family wide holistic approach to reduce the risk of T2DM. Intervention programs have been tailored for women with young children, although engagement and retention has been a challenge (5-7).
Previous studies have found that lack of time, work commitments, and family obligations have been reasons women have not participated (8) in prevention programs, and an understanding of the implications of GDM and the development of T2DM have not been a priority to them (9).

Interventions for women previously diagnosed with GDM have included; increasing physical activity through walking, or group exercise (5, 6, 10), modifying dietary input, specifically fat and/or fibre content (11), and addressing readiness for lifestyle changes required to decrease diabetes risk (12). However the reality of poor recruitment and participation in post-partum interventions has been common and addressed in previous studies (13, 14).

Following a diagnosis of GDM women have described the remainder of their pregnancy as stressful, highly managed and frequently monitored (15). However once their baby has been born, they have reported feelings of abandonment and confusion due to the lack of future direction or expectations relating to diabetes (15, 16). The Australian guideline for postnatal follow up of women with GDM consists of a 6-12 week post-partum Oral Glucose Tolerance Test (OGTT) to exclude T2DM (17). The recommended practice is that this should be repeated annually in the presence of risk factors such as obesity, a strong family history, the use of insulin during the pregnancy or if the woman is planning a pregnancy in the next year. Otherwise a bi-annual OGTT should be performed as a means of early detection of T2DM (17). There is currently little information given to women to decrease the risk of T2DM other than generic healthy lifestyle advice (16, 18). Building on previous research which examined women’s experiences of diagnosis of GDM (15), the objective of this study was to describe the experiences, feelings and future risk perceptions of women previously diagnosed with GDM who engaged in a research trial of an intervention to delay or prevent T2DM. The goal was to obtain information to inform future interventions so that they better engage this at risk group in long-term lifestyle changes.

Methods

The theoretical framework of Symbolic Interactionism (SI) provides the researcher with an insight to the perceptions of the participants in relation to a lived experience, and provides a reality and meaning to a person’s life, and helps shape opinions and social interactions (19). Using SI in this research context provided valuable insights relating to the women’s’ feelings and experiences regarding the intervention to inform how the process can be changed or modified to be more effective.
By interviewing the women who participated in the intervention trial, thoughts, feelings and perceptions of their experience may inform further research within this context (19). The semi-structured interview method provided a format of questions, while allowing the participants to express their own thoughts and feelings within the question framework (20, 21). Conducting the interview in a place and time agreeable to the participant encouraged valuable information to be shared as they chose a location where they felt comfortable (19). Mutual respect and trust between interviewer and participant also contributes to information sharing, and can be even more valuable if a rapport and confidentiality has already been established between both parties (19). This approach was supported in this study, as the participants throughout the original trial knew the interviewer through contact as the study progressed. Telephone interviewing provides flexibility and is immediate, and both parties can respond to each other (22). Limitations can include the inability to read facial gestures or body cues by the interviewer (21), however the convenience to the participant, especially in this instance with small children, was preferred.

Study Sample

Ethics approval was sought and granted by Human Research and Ethics Committee, Mater Health Services, and Medical Research Ethics Committee, The University of Queensland.

The women recruited for this study were participants in the Walking for Exercise and Nutrition to prevent Diabetes for You (WENDY) intervention trial (23). The WENDY trial was conducted at a large metropolitan hospital in Brisbane and incorporated a randomised controlled trial (RCT) of a physical activity and dietary intervention. To be included in the trial women needed to have a have given birth in the last 6 months to 2 years, have been diagnosed and treated with GDM in the preceding pregnancy, have a Body Mass Index (BMI) >25kg², have not already been diagnosed with T2DM, and be fluent in both written and spoken English (23).

Full details of the trial have been reported elsewhere (23). However in brief, the intervention consisted of two parts; a web site linked USB pedometer and a nutrition program. The participant uploaded their pedometer step counts each week, and the web site generated individualised, weekly goals based on the steps the week before, as well providing tips and messages aimed at encouraging increased physical activity. The nutrition program consisted of a group based nutrition workshop held once a week for four weeks on health behaviour modification, with each session conducted by the same
dietician. Participants received practical tools to encourage portion control consisting of a reference book and a plate depicting portion sizes (24).

Following completion of the trial, the researcher attempted to contact all participants (n=31) to request participation in this qualitative component of the study. Eleven agreed to participate (35%) and twenty participants were unable to be contacted or did not return phone calls.

Data collection

Women who agreed to the trial were offered either telephone or face to face interviews. The majority of participants (n=10) preferred the telephone option (due to family responsibilities, work and transport issues) and one participant opted for the face to face interview method. The interviews were conducted by the same person who was the researcher for the initial intervention trial. They lasted 30-60 minutes and allowed the participant time to express their feelings and opinions with no time constraints. The face-to-face interview was held at the research hospital as the participant was an employee and this was more convenient.

The semi-structured interview introduced four broad concepts, their thoughts and feelings relating to initial engagement in the program, their experience of the intervention program, how they are planning to sustain any lifestyle changes they may have made, and their risk awareness relating to developing T2DM. The interview guide used by the interviewer is presented in Appendix 1. The purpose of the study was explained to each woman and their informed consent was obtained and recorded, prior to the commencement and audio recording of the interview.

Data Analysis

The data was analysed using thematic analysis method. Braun’s six phase process (25) allows the data to be analysed within a systematic framework that has been used in other qualitative research (21). Phase One, knowing and understanding the data; Phase Two, identification of initial codes; Phase Three, identification of themes; Phase Four re-evaluation of themes; Phase Five, stating final themes and; Phase Six, reporting results (25).

All interviews were audiotaped and transcribed verbatim (Phase one). A theme or code represents a guided response or meaning within the data (25), and the transcripts were reviewed to identify preliminary coding independently by three researchers (AP, FB, and
SW) (Phase two). These initial themes were then debated and broad themes were constructed (Phase three) and approved by all members of the research team. These broad themes included; mindfulness (being mindful or thinking about lifestyle change), distraction (issues or thoughts that distract from lifestyle change), risk (risk assessment of future health – an understanding of issues that affect thoughts), and engagement (issues or thoughts that encourage or enable engagement). General themes and sub themes were debated between all researchers until a consensus was reached there were no new themes and data saturation was reached (Phase four-five), and the final themes were selected. All members of the research team selected and approved quotes relating directly to the final themes/sub themes.

Results

Eleven women agreed to participate in the interviews, and their ages ranged from 32 to 44 with a mean age of 37 years. All but one woman had more than one child, with family sizes ranging from 1-5 children. Ten of the women identified as Caucasian, and one was of Asian descent. Each woman was assigned a pseudonym for the purposes of reporting findings.

Analysis of the data revealed four major themes (1) Engagement, (2) Program Characteristics, (3) Sustaining Change, and (4) Risk Awareness including a number of related sub-themes outlined below.

Engagement

Engagement referred to the initial reaction and factors that encouraged interest in the program, and contained three subthemes that reflected initial contact, practical considerations, and the timing of the approach to engage other women in the future. Without exception, all the women interviewed expressed satisfaction with timing and method of the initial contact regarding the study. They felt that contact originating from the maternity hospital was a positive aspect, and legitimised the contact.

“No, I thought it was fine cause it was linked to the hospital…” (Abbey; 35 yrs, 4 children).

“So it seemed kind of logical to me so… it was fine because you’ve indicated to the hospital that you are ok to be contacted if any further opportunities came up so to me it seemed the logical link”. (Cathy; 42 years, 2 children).
They felt the personal phone call was more engaging than a letter or generic information:

“I mean I got e-mails, letters from the Diabetes Foundation but you get it then file it way somewhere so I think that contact with people is more motivating” (Tina; 44 years, 2 children).

“yeah so if it had been a letter I probably would have read the letter then put it down……would have forgotten about it with a new baby and everything that is going on” (Sally; 39 years, 5 children).

Practical considerations, which were built into the intervention such as paid parking, the timing of the nutrition workshop during school hours, and the ability to bring their children to the workshop were seen as reasons to continue engagement.

“the fact you paid for parking was a real bonus that really helped out coz yeah, that would have been a bit costly if I had to pay for that” (Alice, 37 years, 3 children).

”and the timing was ok too because I was able to drop the older child off at Kindy (kindergarten) and then come in…. “ (Tina).

“but I could bring the girls with me…..So I found it not a hassle at all” (Cathy).

Overall, the participants felt that for future programs women should be contacted antenatally or in the immediate postpartum period. Most women recognised that the postpartum was a busy time with a new baby; however they felt that information providing guidance to encourage healthy habits would be better received at this time.

“maybe contact mums before they have the baby or just in the initial postpartum period. I know mums are very overwhelmed, but if they could be contacted in a way that was going to be supported……I think that might be something which would be fairly positive” (Tina)

“Straight after giving birth because no one seemed to care when I went in that I had GDM, it didn’t seem to be a big deal and there was no follow up. So yes, I definitely think it would have helped to have extra information and may be go over the diet etc., and the risks then.” (Paige, 32 years, 2 children)
Program characteristics

Overwhelmingly, women spoke positively about the program, some identifying that it reinforced their current knowledge, and enjoyed participating in the intervention. Women described the characteristics of the nutrition and physical activity aspects of the intervention separately. In relation to the nutrition component, they considered that the information delivered was practical and very helpful, especially relating to shopping and healthy choices.

“it made it even more important that I try and sort everything out” (Julie; 39 years, 1 child)

“I think this is the best diet advice that I’ve ever been given. “ (Emily; 36, 4 children)

“And yes, the plate has also given me more idea about portion sizes” (Alice)

Because the nutrition workshops were conducted by the same dietitian for the duration of the intervention, trust and rapport was established, and women felt they were listened to and their concerns were addressed.

“So that was fantastic …knowing that if I did have any questions that I could just e-mail through or just call you (the researcher)” (Julie)

“Our nutrition coach was excellent and was open to questions, feedback, was really, really good with us…” (Hayley, 35 years, 2 children)

The group setting gave the women a chance to share ideas and talk with others in the same position, an opportunity that was welcomed by the majority of participants. They liked the idea of a group as they were comfortable and felt able to ask questions in a safe environment.

“But it was a good atmosphere having this little group where you could just sort of talk and ask questions” (Stephanie; 36 years, 2 children)

“I really like the face-to-face interaction and be able to talk with people and discuss it. That was one of the things I liked about it.” (Alice)
Children were welcome to the nutrition workshop and although for some this made attendance easier, not all women felt comfortable with attending with their children. Some women found having toddlers and babies there was a distraction, and saw it as a barrier to attending. The group time was seen by these mothers as a time for them and those who came without their children stated that they would not have been able to concentrate with their children present.

“I found it ok when I had no child. With a child, it was virtually impossible”
(Paige)

“Um just some of the ones I had to bring the kids with me …..that was probably more of a distraction” (Abby)

Likewise, regarding the use of the pedometer and website, women voiced mixed opinions. Most women reported using the website predominantly for uploading their steps and charting their progress on the provided graph, as well as receiving their new step goals for the week.

“the best way to use the pedometer ever was to track it online and have it give you your goal for the next week…..I found it really motivational having the pedometer and when I lost the pedometer, half my motivation went out the window I think” (Emily)

However, women reported that they did not fully utilise the extra information and messages available on the website.

“I probably could have used the website more than what I did” (Hayley)

“I didn’t go in and look weekly, usually I went in every couple of weeks….but yeah I did find some of them encouraging and helpful” (Alice).

The practicality of wearing the pedometer every day proved to be a barrier for some women.

“Yeah.. I didn’t find it (the pedometer) comfortable to wear it just looked bulky and sat out from under my clothes, I didn’t like that bit” (Alice)
Sustaining change

Women spoke of the lifestyle changes they had attempted and implemented during and subsequent to the lifestyle intervention, and two sub-themes emerged namely how they stayed on track, as well as barriers to change and their reflections on these. The pedometers were returned and access to the web-site were ceased once the trial had been completed, however, techniques were described by women both during the trial and after completion to help them stay on track included tracking their progress and adjusting goals and behaviour accordingly.

“I loved how it (the pedometer) broke it down hour by hour, how many steps I was doing throughout the day……and then so I’d tried to adjust that the following week” (Emily)

Many women described an increased consciousness and awareness of what they were buying, eating, and doing when adapting their lifestyles. Some mentioned keeping the skills and knowledge of food selection in the back of their mind when shopping and preparing meals since the trial. Using the resources they received helped in this process.

“looking at, you know, what, where, how, breaking down your shopping list to see what was good foods, and you know, not so good foods”(Emily)

“you think you’re on the right track… then you take the time…work out the portions” (Julie)

Those who reported making progress and successful changes to their lifestyles during the trial tracked foods eaten against recommended serves or calories, balanced their intake and exercise, and a number used the pedometer and website program, tracking their progress online, day by day with instant feedback allowing them to reflect on their progress, activity/inactivity and adjust the subsequent days.

“I liked looking at the pedometer and seeing how seeing how many steps I had done and it was a motivator to do some more……It’s [now] part of my way of life” (Sally)

“I think being able to see how many steps you’ve taken made you, sort of made me want to say, well I’ve done that many today let’s see if I can do more tomorrow” (Hayley)
Some women struggled to change or, did not make as many changes as they would have liked. Women highlighted the balancing act between caring for their children and often, “putting themselves last”. Others described “slipping back” into old habits. However, women noted their change in mindset.

“And I feel that that sometimes that the kids are more important than my health” (Hayley)

“you can get yourself into a bit of a rut…because it’s (exercise) not you know, fits in with the baby” (Sally)

“I’m aware of things, like with the book it was the portion sizes and the equivalence, and taking those French fries out and putting something else on your plate” (Stephanie)

Others mentioned they had not started an exercise routine, but had increased their incidental activity, highlighting the small, but positive changes they had made.

“[I do] every day activities. I’m not an exercise person” (Tina).

Risk awareness

Risk awareness refers to the women’s perceptions of their risk of developing T2DM and two sub-themes emerged in this theme. These were the source of information about women’s T2DM risk and women’s personalisation and identification with this risk. A variety of sources emerged regarding information about risk, from their general practitioner (GP), obstetrician or endocrinologist, their diabetes educator, midwife, and/or their dietitian. Some women had done their own research from professional websites (e.g. Diabetes Australia) and one stated she was unaware of her elevated risk of progression to T2DM.

“yeah, once I had it (GDM) my obstetrician and my endocrinologist, and the diabetes midwife all told me I could get Type 2 diabetes later” (Sally)

“I did go online and found the Queensland Diabetes website especially on GDM really useful” (Paige)

“when it comes to that I didn’t know I was an increased risk (for Type 2 diabetes) you know…..” (Alice)

Many women were already aware of their T2DM risk and were trying to make changes. Their motivations were based around improving elements of health behaviours related to T2DM risk.
“I wanted to exercise regularly, trying to get into the healthy weight range, losing weight is a lifelong goal, and specifically to decrease my risk of T2DM”
(Julie)

and some women mentioned being motivated by family

“I wanted to be fit and healthy for the girls or set a good example for the kids”.
(Alice)

Other women were aware of risk, but realise they were in ‘denial’.

“No, I think because I was pretty aware of the risks and everything else. I guess it’s more that I ignore it rather than not be aware of it, because it really was it was a part the gestational diabetes” (Stephanie)

“… a lot more awareness of those things like you know being overweight kind of creeps up [on people] and you become quite complacent about it…” (Tina).

The four identified themes of Engagement, Program Characteristics, Sustaining Change, and Risk Awareness have provided an insight into these women’s experience within the intervention trial. Contact through the maternity provider by a personal phone call was viewed positively, as was the group nutrition workshop sessions although women differed in whether allowing children to attend was beneficial or distracting. The pedometer was seen as a motivator; however the reality of wearing it every day was also seen as a barrier. The idea of maintaining the lifestyle changes the women had made during the trial was met with uncertainty; however most felt they would try, as they were aware of the risks of developing T2DM later in life. In general all the women in this trial knew they had to change their lifestyle to delay or prevent T2DM, were happy to try, and welcomed the opportunity and education the trial gave them.

Discussion

The aim of this study was to describe the experiences of women previously diagnosed with GDM who engaged in a lifestyle intervention to delay or prevent T2DM. The intervention was designed to engage and retain the participant by adapting a combination of both physical activity and diet modification, key factors that have shown to decrease T2DM in previous research (26, 27). The findings of this study suggest that women’s experiences of this intervention post GDM to prevent T2DM are predominantly positive. This is an important finding because lifestyle interventions aimed to increase physical activity and improve diet quality can prevent the development of T2DM (26). However, despite the
overwhelming evidence, interventions aimed at the cohort of women recently diagnosed with GDM have met with differing success, mainly relating to low recruitment and engagement (9, 14). Our results show that initiating contact via the maternity hospital gave credence to the intervention program, and provided insights as to the time women should be approached or reminded regarding lifestyle modifications to decrease the risk of T2DM.

A recent Cochrane review found a limited effect of reminder letters to encourage women to attend screening post-partum to exclude T2DM (28), However Kelley et al. (2010) previously found that reminder letters to both the women and their primary care giver were beneficial (29). Wilkinson et al. (2014) reported there is currently no clear pathway for women GP’s for GDM to postpartum screening and suggested a joint approach of increased communication between hospital and Primary Care givers (16). More research may also identify if there is a link between increased testing rates and participation in intervention trials (28).

Other researchers have found that following the diagnoses of GDM women fell more motivated to make healthy lifestyle choices during the antenatal period in order to increase the chances of an uncomplicated pregnancy (14, 30). In the pregnancies that required more intensive management such as insulin treatment, there was a feeling of abandonment following the birth, leading to a decreased risk perception secondary to perceived changes in health care providers attitudes (13, 15). McIntyre et al (2011) found the women in their study felt that 6 weeks post-partum was too soon, however they would have appreciated information on discharge (10). This was supported by our results, where the immediate post-partum period was identified for opportunistic teaching and provision of information. Additionally individual follow up via a phone call or reminder was suggested acknowledging the intensely busy time it is following the birth of a baby and the large amount of postpartum advice also given at this time.

The use of the internet in health care has been increasing as technology becomes more sophisticated and access to the internet by either home computers or other devices has become more common (31). Nicklas et al. (2014) found the use of a web-based intervention following GDM successful, with the intervention group having a mean loss of
2.8kg after 12 months (32). The web-based component of the intervention was based on the Diabetes Prevention Program (27), and included regular contact with a personal lifestyle coach, provision of laptop computers, internet access, scales, measuring cups and gym memberships (32). Although these results are promising and would seem to be able to be translated into larger populations, the financial cost of this program may preclude it’s dissemination to all clinical settings. A key component of the trial the women in this study participated in was a web-based pedometer program that offered opportunistic health promotion such as tips, hints, messages and information when they logged on relating to increasing physical activity and incorporating lifestyle changes to decrease the risk of developing T2DM they could access at any time of the day. Walker et al (2012) found that the use of internet based programs, did not always result in uptake of web-based information and that usage was based on the person’s interest in that program at the time (33). An inclusion criterion for the WENDY trial was routine access to a computer and the ability to access websites and e-mail, so it was assumed that participants would be regular internet users. They were however selective in their use on the trial website, preferring to use it primarily for uploading of steps, and receiving the next week’s goal, rather than accessing the health messages provided. Overall however, the user friendliness of the project was positively received.

The use of “goal setting” and “self-monitoring” physical activity programs, specifically the use of pedometers, has been extensive (34), and this concept has been re-enforced in our study. The participants found the feedback and visual cues such plotting their steps on a web site graph helpful and reported that this increased their motivation. The pedometer (Omron Model HJ-720ITC) was waist mounted and slightly larger than others that were available at the time and was reported to be awkward to use, so a more streamlined design or the use of wrist-worn physical activity trackers may be a consideration for further trials. Recently there has been an increase in the personal tracking technology with physical activity trackers that interact with smart phone technology/applications (35) that may prove more user friendly than the pedometers used in our intervention. The pedometer was complemented by the face-to-face component of the personal visits, assessments and nutrition workshops, and the combination of the personal approach of the women being approached and interacting with a health care provider, rather than a reminder letter or e-mail was a key consideration from this research.
A systematic review looking at the effects of physical activity alone or in conjunction with a diet intervention found that although the weight loss and increased physical activity was supported by the combination of both, more motivational factors were required such as personal goals, and supervised diet interventions (36), such as what was incorporated into the original trial. The women returned the pedometers and did not have access to the website after their final assessments were taken, and some women reported they had bought their own pedometer in an effort to extend the motivation gained from the trial. Other research with this cohort of women has found issues such as a perceived lack of time to increase physical activity, commitments such as work and family expectations, and transport difficulty as reasons for not maintaining or making lifestyle changes (37). The perception of “putting myself last” has been a common theme sustaining lifestyle changes made during the pregnancy affected by GDM has been shown to be difficult (9), and although some of our participants reported they has “slipped back” to old habits, most felt they had more information to help them make improved health life choices since participating in the trial. Education in most antenatal settings for women with GDM covers diet, exercise and increased risk of developing T2DM, however there is little evidence that these changes are maintained after the birth of the baby (38, 39). Although the women in our study reported they had received the information either during their pregnancy or in the post-partum period, most felt that that a program with support would encourage them to realise the increasing risk and consequently change lifestyle behaviours to delay the development of T2DM.

A strength of this study is the innovative approach of the subject topic. Exploring the experiences of women who have participated in an intervention trial designed to support weight loss through lifestyle change following GDM has not been a common source of information from this cohort and has provided an insight into how future programs can be modelled. The benefits of promotion of the long term health of women with GDM are recognised, along interventions to support weight loss in obese women post-partum. A combined approach to these issues may complement each other and provide practical solutions to the current obesity and diabetes population concerns. Scientific rigour was strengthened by discussion of general questions to be included in the interview scripts in the broad area to be studied by all members of the research team strengthened reliability.
Using purposive sampling (21) in this context, i.e. women who had participated in an intervention trial to prevent T2DM, resulted in specific information relating to this research question. Objectivity was achieved through open, independent review of the interviews by three researchers, ensuring the data reported fitted into the appropriate identified themes. The consistency of the interviewing researcher provided reliability, as all interviews were conducted in as similar as possible, allowing for individual participant interaction. All researchers in this project reviewed the data, and agreed there were no further gaps in information or categories to be identified, and data saturation was achieved.

The study is not without its limitations. The small number of participants could be explained by difficulties engaging a potentially mobile population, a population with the competing priorities of child rearing, household tasks, work outside the home, and maintaining personal health and wellbeing, or a general lack of interest, as telephone contact was attempted on at least 3 occasions, and despite messages for return contact made, there was a smaller response than expected. The homogeneity of the participants may mean the experiences of this cohort may not translate to the larger community, especially differing cultural groups. All of the women interviewed had more than one child, and although a previous diagnosis of GDM was not included in this study, treatment and education relating to diabetes risk with previous pregnancies may have contributed to the motivation to be included in the original trial. Added to this, as it was a purposive sample the participants in this study also have been more motivated to participate as they had already agreed to the intervention trial.

The researcher who interviewed the women was also the point of contact for the original trial, and although there was a risk of social acceptability bias, participants were assured that they were able to speak freely and their opinions (both favourable and non-favourable) were important to the outcome of future trials.

Conclusions

The results of this study provide a promising insight to women’s experiences of participation in an intervention post GDM, and further testing of these findings in a larger population cohort a future may provide a possible template for future programs. Education and introduction of post GDM guidelines was optimum in the immediate postpartum period, with follow up contact from a health professional, with a diet and exercise program based on goal setting and behaviour modification. The use of the internet and other
devices such as pedometers and smart phone applications may provide the framework to encourage increased physical activity, and an option of a group nutrition workshop that offered the option of children attending or mothers only may support dietary changes required to support weight loss. Further research needs to include strategies to improve communication between the maternity and primary care givers, with a clear “pathway” of follow up care developed. This may include a specific professional group assuming responsibility, ideally with a national approach and coordination. GP’s currently provide screening for women previously diagnosed with GDM; however the process is reliant on the women seeking medical help or referral. Coordinating and collaboration the flow of information following the birth of the baby to the community in a common theme that has been reported (16, 40), and this may increase the profile of post-partum screening and risk of T2DM following GDM, and in turn encourage participation in interventions.

The birth of a new baby is a time consuming, emotionally intense life phase. However the risk of T2DM following GDM remains, and there is a wide consensus that a suitable intervention that would become part of the women’s life aimed at weight loss and increased physical activity would delay or prevent T2DM in this cohort.

References


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6. Discussion

This thesis has been presented in six chapters, expanding on the three key research questions.

In order to understand how best to delay or prevent the development of T2DM in women previously diagnosed with GDM, three research studies were conducted. These included:

1) A review of the literature surrounding the effectiveness of previous interventions to prevent T2DM (Chapter 2)

2) An RCT introducing the combination of a pedometer program aimed at increasing physical activity, and nutrition coaching through behaviour modification aimed at improving self-efficacy in relation to food choices; with a primary outcome of weight loss, and secondary outcomes of (1) lower glucose and HOMAR-IR; (2) increased minutes of physical activity/week;(3) better diet quality measured by a self-reported survey; (4) better eating behaviour self-efficacy and domain scores; (5) decreased waist and hip measurements; and (6) higher FFM (Chapter 3).

3) A study using qualitative methods to understand the experiences, barriers and enablers of women participating in an intervention study (Chapter 4).

Findings have been presented as three manuscripts prepared for peer-review publications

This chapter will consolidate chapters two, three and four, summarise the key findings, and examine these findings in light of the extant literature.

The overall aim of this study was to develop, implement and evaluate a program to support behavioural lifestyle changes for women who have experienced GDM with a Body Mass Index (BMI) >25 kg/m² to delay or prevent development of T2DM.
The literature review was reported as a systematic review, following the PRISMA reporting guidelines. Gaps in current knowledge surrounding interventions following GDM to delay or prevent T2DM were identified and led to the design of the RCT intervention study. The intervention was designed according to the SCT (29), particularly the construct of self-efficacy. Sessions were structured to facilitate behaviour modification by: using goalsetting activities (to achieve mastery); feedback and support; group attendance and discussion and feedback from the dietitian and peers; vicarious learning through group sessions with peers in the nutrition coaching sessions; and social persuasion by encouraging messages through the website and the nutrition coaching.

The findings of the RCT confirmed selected findings of the Literature Review with respect to recruitment and engagement of the cohort. This led to and informed the qualitative study, which was designed and analysed using thematic analysis (37), with semi-structured interviews providing the broad framework of data collection.

The use of the triangulation method to integrate findings from mixed-method research can provide clarification of the relationship between the quantitative and qualitative findings (106, 107). The findings from the studies in this thesis could be described as ‘complementary’, as the results from each study add to the other (106). The findings from the RCT, (that weight loss and increased physical activity can be achieved in women previously diagnosed with GDM), together with the results from the interviews, (that the group based nutrition coaching, and the face-to-face contact to initiate the intervention were valuable), highlights that it is the combination of both factors that may support compliance within further programs.
6.1. Summary of key findings

The findings from the Literature Review were that there are lifestyle interventions based on behaviour modifications aimed at weight loss and increasing physical activity that have been proven to be effective in reducing the risk of T2DM. There has been a mixed success in the high risk cohort of women previously diagnosed with GDM, and barriers and enablers have been identified to participation in intervention programs by these women. Midwives and health carers may have an increasing role in education and support in the antenatal and immediate postpartum period which may lead to maintaining behaviour modification to delay or prevent T2DM.

The findings for the RCT were that a program that combined a pedometer with a web-based interaction, and nutrition coaching can lead to weight loss, decreased waist and hip measurements, increased physical activity and higher self-efficacy in relation to healthy food choices. Recruitment and engagement of this cohort in intervention studies is a challenge and requires further research to find ways to increase participation.

Interpretation of the experiences, perceptions and thoughts from the qualitative interviews reinforced previous research relating to barriers such as childcare, tiredness, work commitments and family priorities as reasons women provide for lack of engagement in lifestyle changes. Positive findings such as the use of the pedometer as a goal setting tool, the positive feedback regarding the group nutrition coaching sessions and the suggestion of approaching women in the immediate postpartum period with follow-up were found. However the paradox of the success of the face-to-face nutrition coaching with some participants yet proved to be a barrier for others is a factor that requires further research. This could be contributed to the premise that the priority at this time of the women’s life is the new baby, family commitments and other lifestyle factors. Future studies that adopt a more “family friendly” choices in intervention delivery, such as the choice of programs with or without children, or both face to face and internet based programs.
The diagnosis of GDM is a recognised and increasing risk factor for the subsequent development of T2DM (21). Other established modifiable risk factors such as obesity, diet quality, and physical activity below recommended guidelines can be addressed with interventions (15). However, a number of barriers proved to be a common factor in the cohort of new mothers in preventing women meeting recommended guidelines for health behaviours (20).

In the Diabetes Prevention Program study, the participants in the lifestyle invention group lost an average of 5.6 kg over a 24 month period, and 50% of participants met the target of increased physical activity (15). This study’s RCT design provided individually tailored physical activity goal setting with the step count goals program following uploading of steps, and the nutrition coaching provided personal delivery of dietary and lifestyle education which followed the DPP framework. Despite the shorter intervention period, participants in the RCT lost a median of 2.4 kg and increased their weekly physical activity to a similar level to those participants within the DPP. These results may be reflective of the face-to-face interaction with the dietitians in the RCT, as was the case in the DPP.

The intervention within the RCT combined a physical activity program incorporating goal setting and Internet interaction and feedback, with nutrition coaching underpinned by activities designed to facilitate behaviour modification. The pedometer and nutrition coaching intervention successfully decreased weight, waist and hip measurements. This was also effective in increasing physical activity, and self-efficacy relating to healthy eating choices. Potentially, the nutrition coaching was more effective than the pedometer, as results from the qualitative study showed the peer support and face-to-face aspect of the study was seen as an incentive. Most women liked coming to the nutrition coaching session, and although the website was reported as being helpful, this aspect of the study proved to be less successful than originally hoped. The pedometer itself was difficult to wear for some participants, and the use of goal-setting through uploading of their steps was not utilised as much as predicted as in previous research involving pedometers (26).
Recruitment and engagement of women with babies and young children was a challenge within this study, and participation in interventions such as these has been noted in other studies. Infanti et.al. noted a lower than expected rate of participation in women with previously diagnosed GDM in a lifestyle intervention study and found that women over 34 years and not managed with insulin therapy during their pregnancy were more likely to participate (65). The participants in this RCT also were similar in age; however a difference in this study was the majority had been managed with insulin therapy during their pregnancy. Multiple strategies were used to encourage recruitment including personal phone contact, advertising and television coverage. Despite these methods, women still made the choice not to take part in the project citing the common reasons given previously.

The studies by McIntyre et al. (2012) and Cheung et al. (2011) also aimed to increase physical activity in women previously diagnosed with GDM and, although the participants in one study showed increased activity, it was predominately walking (27). The RCT in this thesis showed an increase of 135 minutes/week in overall activity in the intervention group, and though participant numbers precluded statistical significance, clinically the result is a significant and close to the national guidelines of 150 minutes/week (108).

The use of web-based support has been suggested as the future of intervention delivery (101) and the pedometer linked website in the RCT was received favourably by participants. Kim et al (2012) found there was no increase in physical activity in their pedometer based study (26), and the website used in RCT study was further developed from this model in conjunction with the University of Michigan, following modification for the Australian audience. Yet, the intervention group in the RCT increased their overall physical activity by 135 minutes/week. The measurement of activity within the RCT included the AWAS survey, of both planned exercise and incidental activity. The increase in activity may be an indication of the increased awareness by the intervention group of how changes in daily routine can positively influence daily activity.

The physical wearing of the pedometer was a barrier to its regular use for some participants. The use of newer technologies such as smart phones, physical activity
bracelets or a slimmer style pedometer which have become available since the study may overcome those issues. However a recent systematic content analysis (109) showed a number of new technologies include well established behaviour change techniques such as goal setting and feedback, but there was few with problem solving capability included in the website of this study. Findings from the qualitative interviews showed that although participants did look at the tips, hints and e-mails messages embedded in the web site, they did not find them as motivating as the goal setting capability of the pedometer and physical attendance at the nutrition coaching.

The inclusion of the nutrition coaching sessions in the RCT were informed by previous research that suggested the combination of physical activity and nutrition coaching would be effective (27), and is a key point of difference between this study and from other intervention studies. The use of dietary modifications to support weight loss has been used extensively to treat obesity world-wide, and in high risk populations such as women previously diagnosed with GDM (15, 27, 87, 95). As previously described, women diagnosed with GDM adhere to suggested dietary modification during their pregnancy generally well, although it has also been suggested that this is due to concern for their baby and the wish for an uncomplicated pregnancy, rather than long term life changes (23, 85). Overall, participants received the nutrition coaching sessions positively, with most attending at three out of four sessions. The face-to-face component of the sessions was considered a strength by participants, although some suggested the idea of podcasts or an on-line component would add to the program. The dietary tools included in the program (a “this=that” book and Portion plate) designed as visual cues for portion size (71, 72), as well as written reference material were considered helpful and may be used to reinforce behaviour modification after the cessation of the program.

Barriers preventing women from engaging in interventions have been well documented and were also encountered in this study. Reasons for not participating included time, distance from the hospital, language barriers, some had already enrolled in a weight-loss/gym program, and a current pregnancy or T2DM diagnoses. Overwhelmingly, the
major difficulty in recruitment to the study lay in establishing initial contact with potential participants, with a large proportion of the telephone number in the hospital's database disconnected. However, 31 women were randomised, and eight participants declined participation after randomisation.

6.2. Strengths

Scientific rigor was strengthened during this study by adopting optimal research methodology. Mixed methods methodology was utilised with both quantitative and qualitative data collected. The study was informed by a systematic review of the literature, identifying effective interventions to delay or prevent T2DM, as well barriers to participation by women previously diagnosed with GDM. By conducting an RCT the risk of bias or participant harm was reduced through the use of adherence to an ethically approved protocol. The intervention within the study used high level pedometers and interactive web-site, in combination with nutrition coaching underpinned by a strong behaviour change theoretical framework. A qualitative study was conducted using a validated interview method of semi-structured interviews and was reported using thematic analysis. The study was funded by a competitive peer reviewed funding source, in conjunction with a peer reviewed scholarship achieved by the researcher. Nationally recognised ethical guidelines were followed by ensuring all amendments to the original protocol were also ethically reviewed and approved during the course of the study.

A strength may be that the website and nutrition coaching could be potentially customised to suit the target population, in particular population groups other than caucasian, by including the use of interpreters and the development of culturally appropriate diet suggestions.

6.3. Limitations/future directions

When using a mixed methods approach, the concurrent collection of both quantitative and qualitative data is best (108), however due to the extension related to recruitment of the RCT, the qualitative interviews for this study were conducted at a later time frame than initially projected.
The literature review was conducted to inform further research at the commencement of this study, and the most recent research was included within this thesis.

The numbers recruited in the study imply potential limitations in the generalizability of results, as does the predominately Caucasian population involved. Previous research has shown that participation in lifestyle intervention studies is based on the person’s wish to improve their health (110) and this was the case within the RCT cohort as revealed in the qualitative interviews. As financial constraints have been reported as a barrier to participation in other studies (110) parking concession was offered to all participants in the study, a factor that was welcomed by enrolled participants, but did not prove enough incentive for other potential eligible women.

There is evidence to suggest that specific populations/ethnic groups are at higher risk of progression to diabetes following GDM; for example Vietnamese and women from the subcontinent (25, 85). Women who identified themselves in these groups proved difficult to recruit in this study; initial phone contact without an interpreter meant that information about the intervention could not be delivered as effectively as it should. Also, cultural considerations, such as the paternal dominance in some cultures, did not encourage the women participating without family approval (85). Transport issues within these cultural cohorts, where the women may not have a drivers licence, was given as a reason not to attend and the recruitment strategy in this study meant the risks of T2DM could not be discussed with women with English as their second language.

Verbal consent was obtained for further contact following the completion of the RCT for the qualitative study incorporating the semi-structured interview; however eleven (35%) women agreed to participate. The aim of integration of both methods of data collection is for one to complement the other (111), and data collected from the participants who did not agree may have offered further insight as to reasons for non-participation. There was also a lack of continued engagement beyond the three month primary outcome visit, thus the inability to explore longer term outcomes and follow up were precluded.
As already discussed, an unanticipated factor was the difficulty in initial contact. As most women provided a mobile phone number on admission to the maternity hospital, it was assumed that this would be the ideal form of contact. This did not prove correct, with the majority of successful contacts made through home land-line telephones. A reason for this may be the choice of not answering a phone call if the number is not recognised as it is through mobile phone technology. Time was a limitation also as the single research midwife was responsible for all facets of the trial, including recruitment, follow up, study methodology, day to day running of the trial, data collection, input and storage.

6.4. Significance

This study was one of the first mixed methods study to examine interventions to prevent T2DM post GDM. It demonstrated that programs such as this can influence weight loss, waist and hip measurements, increase physical activity and improve self-efficacy relating to healthy eating behaviours.

It used a unique combination of interventions strategies and was guided by a strong theoretical framework in Social Cognitive Theory that includes self-efficacy as a construct using goal setting to increase physical activity, coupled with the behaviour modification from the nutrition coaching program, and has the potential to promote long-term lifestyle changes in women previously diagnosed with GDM. Life style changes aimed at factors known to prevent or delay the onset of T2DM such as weight loss (in obese women) and increased physical activity can potentially be targeted at populations with non-modifiable risk markers including previous GDM or strong family history. Understanding barriers and enablers of influencing participation in interventions such as this gives insight to further studies to encourage initial engagement and longer term lifestyle changes. Following the completion of this trial, the participants felt they were more prepared to address the risk of developing T2DM using the tools and education they gained. Awareness that behaviour change is a lifelong mission and adjustment of lifestyle factors in a manner designed to reduce risk factors were key components of this study.
6.5. Recommendations

The women in this trial found the combination of a pedometer with goal setting ability and interaction using a dedicated website and group setting nutrition coaching useful and supported weight loss and increased physical activity.

Although most women stated that they understood their personal risk of developing T2DM, they also felt they were not equipped with sufficient education or lifestyle tools to make the changes they felt they needed before their participation in this study. Approaching women diagnosed with GDM antenatally and in the early postpartum period offering lifestyle tools, such as a pedometer and the offer to attend nutrition coaching sessions specially aimed to facilitate behaviour change that may prevent T2DM and may provide the impetus for a change in self-efficacy (24). A follow-up by a General Practitioner or Midwife at 6–12 weeks postpartum (the recommended time frame for the OGTT designed to exclude T2DM) could be integrated into routine care. At a later time point, perhaps the one year anniversary of the baby’s birth (when a repeat OGTT should be conducted), mothers could be offered a pedometer and a nutrition workshop to reinforce the lifestyle changes needed.

Lie et al. (2013) found that women preferred the group environment for the delivery of diet and nutrition advice postpartum (24). It must be noted that these needs differ from the advice they had previously been provided with during their GDM pregnancy, due to the need to allow for breastfeeding and family dynamics (24). This concept was reinforced in our study as the participants who produced the most successful weight loss attended the group-based nutrition workshops offered within the RCT.

Offering incentives such as car parking vouchers or gratuities to encourage recruitment was a key factor in some of the participant’s reasons for maintaining participation in the RCT. Although not economically feasible for all participants in future trials, consideration of subsidies or incentives for low income or socially disadvantaged women may provide the incentive for attendance at the workshops, which has been also recognised in other research (24).
Education aimed at midwives and other obstetric care providers involved in the care of women diagnosed with GDM regarding the increased risk of later T2DM may lead to integration of a preventative plan into routine care following the birth of the baby. This could potentially be commenced during the antenatal period and may allow improved direction for women currently not receiving any type of education. Other studies have found that postpartum care for women previously diagnosed with GDM is fragmented, with no clear direction or consistent frameworks of primary care (93). The integration of ante and postnatal care may alleviate the feelings of neglect and abandonment that has been described in other studies (23), as well as providing education opportunity for women previously diagnosed with GDM, and commencement of lifestyle change as early as possible in the postpartum period. Future research relating to depression scores or emotional profiles of women previously diagnosed with GDM that find lifestyle change difficult may provide further insights to tailor interventions to suit these women.

Although the primary aim of this study did not include examining the role of the midwife, the results imply a ‘health care’ gap that maybe addressed (at least partly) by the midwife. The literature review showed how the role of the midwife during the antenatal course needs to include a high level of knowledge in relation to GDM, and that midwives are in a unique position to begin discussions and education aimed at behaviour modification of lifestyle choices during pregnancy. Consistency of information provision and support may encourage behaviour that may continue following the birth of the baby (112). In the immediate postpartum period, routine midwifery care for women diagnosed with GDM may include routine education and support previously the domain of the specialist diabetes educator.

Support of programs to delay T2DM may be as simple as multi-disciplinary education and support relating the benefits of breastfeeding in relation to insulin resistance and the effect on the infants (64, 113). As the qualitative study showed, the early postpartum period is the optimum time for the introduction of management strategies for lifestyle changes. Reinforcement of the life-long vigilance required to delay or prevent T2DM should begin following diagnoses of GDM, and midwives are in the perfect position to initiate this behaviour.
The women in this study did not want to develop T2DM, and were happy to be educated regarding the risks (although this attitude from the women requires a degree of motivation, this motivation has not been translated into action as judged from other studies). Using self-efficacy concepts such as the relationship between thoughts, actions and emotions, (figure 4) may guide further interventions that suit this cohort of new mothers.

Implementation of a consistent program of postpartum care for women with prior GDM would require funding and engagement of community stakeholders who are committed to decreasing the incidence of T2DM such as government bodies and healthcare providers. However, early recognition, with support and encouragement from a variety of health care providers, may inform women and incorporate healthy lifestyle changes in time to delay or prevent the development of T2DM.
7. Conclusion

This mixed method study aimed to answer the following questions:

1) Which interventions may be potentially effective in decreasing the risk of T2DM in women previously diagnosed with GDM?
2) Does a pedometer-based intervention combined with nutrition coaching result in weight loss, increased physical activity, improved diet quality, and improved insulin sensitivity when compared to standard care?
3) What are the experiences of undergoing a pedometer intervention combined with nutrition coaching for women with a previous history of GDM?

The literature review showed an evidence-practice gap where interventions had not been easily translated to women previously diagnosed with GDM to prevent T2DM. The literature also highlighted an increased opportunity for midwives caring for women with GDM, to provide information relating to the increased risk of developing T2DM, as well as possible lifestyle changes that may delay the onset of the disease.

The findings from the mixed methods study add to the body of research in this clinical arena by proving a short-term intervention study that can support weight loss and increased physical activity in women previously diagnosed with GDM. The findings from this study also support other research in relation to the difficulty in recruitment of women in this cohort. The difficulty in contacting eligible women was a key factor in the RCT, and the use of mobile phone technology did not increase the number of women able to be contacted.

However, the women who did participate showed that a program that incorporated a pedometer based activity intervention in conjunction with nutrition coaching was effective, as a median of 2.4 kg was lost in the intervention group. The finding of 135 minutes/week of increased activity is an encouraging trend, as is the result that the same women showed increased self-efficacy in eating behaviours.
The qualitative study provided insights of participants in interventions such as these in relation to barriers and enablers to further engagement. Although the use of modern communication methods has been thought to be more convenient for women with small children, the women in this study preferred face-to-face follow-up with a health care worker as they felt they would act on the health care workers’ recommendations more than an anonymous message. Findings from the qualitative interviews also revealed that the optimum time to contact women is the immediate postpartum period, which also supports previous research.

The prevention of T2DM in women previously diagnosed with GDM has been the focus of research for a number of years, and successful programs have been identified. The results of this RCT study makes a unique and significant contribution to the continuing efforts around reducing the risk of T2DM for a cohort increase in number in Australia (and potentially globally) following a change in the GDM diagnostic criteria (38). In this context intervention programs such as those tested in this thesis may hold the key to delay the development of T2DM for some women.

The barriers to recruitment and engagement in this cohort need to be overcome. The risk of development of T2DM has not diminished, therefore programs such as this need to be offered in a systematic way, accompanied by rigorous assessment of outcomes. This research has statistically and clinically important findings, which may contribute to positive improvements in the care of women following a pregnancy complicated by GDM.
8. References


52. Amorim Adegboye AR, Linne YM. Diet or exercise, or both for weight reduction in women after childbirth. Cochrane Database of Systematic Reviews. 2013(7).


73. NHMRC Levels of Evidence and Grades for Recommendations for Developers of Guidelines NHMRC (National Health and Medical Research Council); 2009.


### Appendix 1: Quality Assessment of studies included in the Literature Review

Table 13. Quality assessment of RCTS included in the Literature Review using CONSORT guidelines

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Table 14. Quality assessment of observational studies describing interventions included in the Literature Review using STROBE guidelines

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Table 15. Quality assessment of observational studies describing barriers to participating in interventions included in the Literature Review using STROBE guidelines

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Appendix 2: WENDY CONSORT diagram

Enrollment

Assessed for eligibility n = 576

Not meeting inclusion criteria n = 208
- BMI < 25 n = 71
- currently pregnant n = 35
- current diabetes n = 8
- maternal death n = 1
- limited English n = 22
- IUFD n = 1
- baby > 2yrs n = 58

Participants contacted n = 320

Randomized n = 31

Declined to participate n = 81
- too far from hospital n = 27
- too busy n = 11
- not interested n = 27
- already in a program n = 4
- didn't have GDM n = 6
- working n = 3
- other n = 3

Intervention n = 16

Three month visit n = 11 (69%)
Discontinued intervention n = 5
- too busy n = 2
- work commitments n = 1
- unable to re-contact n = 2

Control n = 15

Three month visit n = 12 (80%)
Discontinued Control n = 3
- current diabetes n = 1
- became pregnant decided to withdraw n = 1
- too busy n = 1
Appendix 3: Australian Women’s Activity Survey

Australian Women’s Activity Survey

The first category is about any **PLANNED ACTIVITY** you do. There are five intensity levels in this category; sitting, light effort, brisk walking, moderate effort which doesn’t include brisk walking and vigorous effort.

1. In a typical week do you do any planned activities while **SITTING** such as watching TV or reading?

   1 [ ] yes

   0 [ ] no → Move to next question.

1a. If **Yes**. Just thinking about the **weekdays** from Monday to Friday.

   How many days would you do this activity?

   On an average weekday how long would you spend doing this activity?

   \[
   \leq 5
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   \]

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   \hspace{2cm}
   \]

   # days hrs/day mins/day

1b. Just thinking about the **weekend** from Saturday to Sunday.

   How many days would you do this activity?

   On an average weekend day how long would you spend doing this activity?
2. In a typical week do you do any planned activities of **LIGHT EFFORT** such as slow walking, stretching, fishing, playing in water or playing golf with a cart?

   1  [ ] yes

   0  [ ] no  →  Move to next question.

2a. **If Yes.** Just thinking about the **weekdays** from Monday to Friday.

   How many days would you do this activity?

   On an average weekday how long would you spend doing this activity?

   \[
   \leq 5
   \]

   \[
   \begin{array}{ccc}
   \text{# days} & \text{hrs/day} & \text{mins/day} \\
   \end{array}
   \]

2b. Just thinking about the **weekend** from Saturday to Sunday.

   How many days would you do this activity?

   On an average weekend day how long would you spend doing this activity?

   \[
   \leq 2
   \]

   \[
   \begin{array}{ccc}
   \text{# days} & \text{hrs/day} & \text{mins/day} \\
   \end{array}
   \]
3. In a typical week do you do any planned activities that involve **BRISK WALKING** such as walking for exercise or walking the dog?

1 [ ] yes

0 [ ] no  → Move to next question.

3a. **If Yes.** Just thinking about the **weekdays** from Monday to Friday.

How many days would you do this activity?

On an average weekday how long would you spend doing this activity?

\[ \leq 5 \]

\[ \begin{array}{ccc}
\# \text{ days} & \text{hrs/day} & \text{mins/day} \\
\end{array} \]

3b. Just thinking about the **weekend** from Saturday to Sunday.

How many days would you do this activity?

On an average weekend day how long would you spend doing this activity?

\[ \leq 2 \]

\[ \begin{array}{ccc}
\# \text{ days} & \text{hrs/day} & \text{mins/day} \\
\end{array} \]
4. In a typical week do you do any planned activities **MODERATE EFFORT** that do not include brisk walking such as social sports, tai chi, doubles tennis, slow cycling, low-impact aerobics, ballroom dancing or play golf without a cart?

1 ☐ yes

0 ☐ no → Move to next question.

4a. **If Yes.** Just thinking about the **weekdays** from Monday to Friday.

How many days would you do this activity?

On an average weekday how long would you spend doing this activity?

≥ 5

# days ☐ ☐ ☐

hrs/day ☐ ☐ ☐

mins/day ☐ ☐ ☐

4b. Just thinking about the **weekend** from Saturday to Sunday.

How many days would you do this activity?

On an average weekend day how long would you spend doing this activity?

≥ 2

# days ☐ ☐ ☐

hrs/day ☐ ☐ ☐

mins/day ☐ ☐ ☐

5. In a typical week do you do any planned activities **VIGOROUS EFFORT** such as running, jogging, swimming laps, singles tennis, competitive sports, rowing or high-impact aerobics?
1 □ yes

0 □ no → Move to next question.

5a. **If Yes.** Just thinking about the **weekdays** from Monday to Friday.

How many days would you do this activity?

On an average weekday how long would you spend doing this activity?

≤ 5

<table>
<thead>
<tr>
<th># days</th>
<th>hrs/day</th>
<th>mins/day</th>
</tr>
</thead>
</table>

5b. Just thinking about the **weekend** from Saturday to Sunday.

How many days would you do this activity?

On an average weekend day how long would you spend doing this activity?

≤ 2

<table>
<thead>
<tr>
<th># days</th>
<th>hrs/day</th>
<th>mins/day</th>
</tr>
</thead>
</table>
The second category is the **WORK-RELATED ACTIVITY CATEGORY**. There are two separate sections to this category, one relating to employment and one relating to childcare.

6. Are you currently working, volunteering or studying?

   1 [ ] yes

   0 [ ] no  →  Move to the Childcare Section (Question 11).

7. In a typical week do you do any work-related activities while SITTING such as desk work or sitting at a computer?

   1 [ ] yes

   0 [ ] no  →  Move to next question.

7a. If Yes. Just thinking about the **weekdays** from Monday to Friday.

How many days would you do this activity?

On an average weekday how long would you spend doing this activity?

   \( \leq 5 \)

   [ ] # days  [ ] hrs/day  [ ] mins/day

7b. Just thinking about the **weekend** from Saturday to Sunday.

How many days would you do this activity?

On an average weekend day how long would you spend doing this activity?
8. In a typical week do you do any work-related activities of **LIGHT EFFORT** such as mostly standing at a counter or standing at a photocopier?

   1  yes

   0  no  →  Move to next question.

8a. **If Yes.** Just thinking about the **weekdays** from Monday to Friday.

   How many days would you do this activity?

   On an average weekday how long would you spend doing this activity?

   ≤ 5

   

8b. Just thinking about the **weekend** from Saturday to Sunday.

   How many days would you do this activity?

   On an average weekend day how long would you spend doing this activity?

   ≤ 2

   


9. In a typical week do you do any work-related activities of **MODERATE EFFORT** such as mostly brisk walking like teaching, nursing or waiting tables?

1  yes

0  no  →  Move to next question.

9a. If Yes. Just thinking about the **weekdays** from Monday to Friday.

How many days would you do this activity?

On an average weekday how long would you spend doing this activity?

≤ 5

<table>
<thead>
<tr>
<th># days</th>
<th>hrs/day</th>
<th>mins/day</th>
</tr>
</thead>
</table>

9b. Just thinking about the **weekend** from Saturday to Sunday.

How many days would you do this activity?

On an average weekend day how long would you spend doing this activity?

≤ 2

<table>
<thead>
<tr>
<th># days</th>
<th>hrs/day</th>
<th>mins/day</th>
</tr>
</thead>
</table>

10. In a typical week do you do any work-related activities of **VIGOROUS EFFORT** such as manual labour, moving furniture or loading trucks?

1  yes
10a. **If Yes.** Just thinking about the **weekdays** from Monday to Friday.

How many days would you do this activity?

On an average weekday how long would you spend doing this activity?

- ≤ 5
- 
  - # days
  - hrs/day
  - mins/day

10b. Just thinking about the **weekend** from Saturday to Sunday.

How many days would you do this activity?

On an average weekend day how long would you spend doing this activity?

- ≤ 2
- 
  - # days
  - hrs/day
  - mins/day
11. Do you **CURRENTLY LOOK AFTER CHILDREN**, whether they’re your own, your partner’s or fostered?

- [ ] 1 yes → For the childcare section there are four intensity levels; sitting, light effort, moderate effort and vigorous effort.

- [ ] 0 no → Move to Domestic Activities section (Question 16).

12. In a typical week do you do any childcare activities while **SITTING** such as breastfeeding or reading to your children?

- [ ] 1 yes

- [ ] 0 no → Move to next question.

12a. **If Yes.** Just thinking about the **weekdays** from Monday to Friday.

How many days would you do this activity?

On an average weekday how long would you spend doing this activity?

- \( \leq 5 \)
  - [ ] # days
  - [ ] hrs/day
  - [ ] mins/day

12b. Just thinking about the **weekend** from Saturday to Sunday.

How many days would you do this activity?

On an average weekend day how long would you spend doing this activity?
13. In a typical week do you do any childcare activities of **LIGHT EFFORT** such as bathing, feeding or playing with your children inside or picking up toys?

1  yes

0  no  →  Move to next question.

13a. **If Yes.** Just thinking about the **weekdays** from Monday to Friday.

How many days would you do this activity?

On an average weekday how long would you spend doing this activity?

194

13b. Just thinking about the **weekend** from Saturday to Sunday.

How many days would you do this activity?

On an average weekend day how long would you spend doing this activity?
14. In a typical week do you do any childcare activities of MODERATE EFFORT such as lifting or carrying your child, pushing prams or playing with children outside?

1 yes

0 no → Move to next question.

14a. If Yes. Just thinking about the weekdays from Monday to Friday.

How many days would you do this activity?

On an average weekday how long would you spend doing this activity?

≤ 5

# days hours/day minutes/day

14b. Just thinking about the weekend from Saturday to Sunday.

How many days would you do this activity?

On an average weekend day how long would you spend doing this activity?

≤ 2

# days hours/day minutes/day
15. In a typical week do you do any childcare activities of **VIGOROUS EFFORT** such as carrying your child upstairs, carrying you child whilst shopping or playing strenuous games with children outside?

   1 □ yes

   0 □ no  →  Move to next question.

15a. **If Yes.** Just thinking about the **weekdays** from Monday to Friday.

   How many days would you do this activity?

   On an average weekday how long would you spend doing this activity?

   $\leq 5$

   □ □ □

   # days  hrs/day  mins/day

15b. Just thinking about the **weekend** from Saturday to Sunday.

   How many days would you do this activity?

   On an average weekend day how long would you spend doing this activity?

   $\leq 2$

   □ □ □

   # days  hrs/day  mins/day

The third category is the **DOMESTIC-RELATED ACTIVITY CATEGORY**. There are four intensity levels in this category; sitting, light effort, moderate effort and vigorous effort.
16. In a typical week do you do any domestic responsibilities while SITTING such as sewing, mending or knitting?

1  yes

0  no  →  Move to next question.

16a. If Yes. Just thinking about the weekdays from Monday to Friday.
How many days would you do this activity?
On an average weekday how long would you spend doing this activity?

≤ 5

# days   hrs/day   mins/day

16b. Just thinking about the weekend from Saturday to Sunday.
How many days would you do this activity?
On an average weekend day how long would you spend doing this activity?

≤ 2

# days   hrs/day   mins/day

17. In a typical week do you do any domestic responsibilities of LIGHT EFFORT such as preparing meals, laundry, washing dishes, grocery shopping or watering plants?
17a. **If Yes.** Just thinking about the **weekdays** from Monday to Friday.

How many days would you do this activity?

On an average weekday how long would you spend doing this activity?

<table>
<thead>
<tr>
<th>≤ 5</th>
<th># days</th>
<th>hrs/day</th>
<th>mins/day</th>
</tr>
</thead>
</table>

17b. Just thinking about the **weekend** from Saturday to Sunday.

How many days would you do this activity?

On an average weekend day how long would you spend doing this activity?

<table>
<thead>
<tr>
<th>≤ 2</th>
<th># days</th>
<th>hrs/day</th>
<th>mins/day</th>
</tr>
</thead>
</table>

18. In a typical week do you do any domestic responsibilities of **MODERATE EFFORT** such as vacuuming, mopping, raking, cleaning windows, cleaning the bath, washing the car, cleaning gutters, digging in garden or painting walls?
18a. **If Yes.** Just thinking about the **weekdays** from Monday to Friday.

How many days would you do this activity?

On an average weekday how long would you spend doing this activity?

\[ \leq 5 \]

\[ \underline{\phantom{0}} \underline{\phantom{0}} \underline{\phantom{0}} \]

# days hrs/day mins/day

18b. Just thinking about the **weekend** from Saturday to Sunday.

How many days would you do this activity?

On an average weekend day how long would you spend doing this activity?

\[ \leq 2 \]

\[ \underline{\phantom{0}} \underline{\phantom{0}} \underline{\phantom{0}} \]

# days hrs/day mins/day

19. In a typical week do you do any domestic responsibilities of **VIGOROUS EFFORT** such as moving furniture, carrying groceries upstairs or pushing the lawn mower?

1 \[ \underline{\phantom{0}} \] yes

0 \[ \underline{\phantom{0}} \] no → Move to next question.
19a. **If Yes.** Just thinking about the **weekdays** from Monday to Friday.

How many days would you do this activity?

On an average weekday how long would you spend doing this activity?

\[ \leq 5 \]

\[
\begin{array}{ccc}
\# \text{ days} & \text{hrs/day} & \text{mins/day} \\
\end{array}
\]

19b. Just thinking about the **weekend** from Saturday to Sunday.

How many days would you do this activity?

On an average weekend day how long would you spend doing this activity?

\[ \leq 2 \]

\[
\begin{array}{ccc}
\# \text{ days} & \text{hrs/day} & \text{mins/day} \\
\end{array}
\]

The final category is the **TRANSPORT CATEGORY**. There are five intensity levels in this category; sitting, light effort, brisk walking, moderate effort which doesn’t include brisk walking and vigorous effort.

20. In a typical week do you do any transport-related activities while **SITTING** such as driving a car or sitting on a bus or train?

1 [ ] yes

0 [ ] no → Move to next question.
20a. If Yes. Just thinking about the **weekdays** from Monday to Friday.

How many days would you do this activity?

On an average weekday how long would you spend doing this activity?

<table>
<thead>
<tr>
<th>≤ 5</th>
<th># days</th>
<th>hrs/day</th>
<th>mins/day</th>
</tr>
</thead>
</table>

20b. Just thinking about the **weekend** from Saturday to Sunday.

How many days would you do this activity?

On an average weekend day how long would you spend doing this activity?

<table>
<thead>
<tr>
<th>≤ 2</th>
<th># days</th>
<th>hrs/day</th>
<th>mins/day</th>
</tr>
</thead>
</table>

21. In a typical week do you do any transport-related activities of **LIGHT EFFORT** such walking slowly?

1 [ ] yes

0 [ ] no → Move to next question.

21a. If Yes. Just thinking about the **weekdays** from Monday to Friday.
How many days would you do this activity?

On an average weekday how long would you spend doing this activity?

\[ \leq 5 \]

\[ \boxed{} \quad \boxed{} \quad \boxed{} \]

\# days \quad hrs/day \quad mins/day

21b. Just thinking about the **weekend** from Saturday to Sunday.

How many days would you do this activity?

On an average weekend day how long would you spend doing this activity?

\[ \leq 2 \]

\[ \boxed{} \quad \boxed{} \quad \boxed{} \]

\# days \quad hrs/day \quad mins/day

22. In a typical week do you do any transport-related activities that involve **BRISK WALKING** such as walking to get places or walking to the bus?

1 \[ \boxed{\text{yes}} \]

0 \[ \boxed{\text{no}} \quad \text{Move to next question.} \]

22a. If **Yes**. Just thinking about the **weekdays** from Monday to Friday.

How many days would you do this activity?

On an average weekday how long would you spend doing this activity?

\[ \leq 5 \]

\[ \boxed{} \quad \boxed{} \quad \boxed{} \]
22b. Just thinking about the **weekend** from Saturday to Sunday.

How many days would you do this activity?

On an average weekend day how long would you spend doing this activity?

\[ \leq 2 \]

\[ \begin{array}{ccc}
\# \text{ days} & \text{hrs/day} & \text{mins/day} \\
\end{array} \]

23. In a typical week do you do any transport-related activities of **MODERATE EFFORT** such as riding a bike or riding a push scooter?

1 \[ \square \] yes

0 \[ \square \] no \[ \Rightarrow \] Move to next question.

23a. **If Yes.** Just thinking about the **weekdays** from Monday to Friday.

How many days would you do this activity?

On an average weekday how long would you spend doing this activity?

\[ \leq 5 \]

\[ \begin{array}{ccc}
\# \text{ days} & \text{hrs/day} & \text{mins/day} \\
\end{array} \]
23b. Just thinking about the **weekend** from Saturday to Sunday.

How many days would you do this activity?

On an average weekend day how long would you spend doing this activity?

\[ \leq 2 \]

<table>
<thead>
<tr>
<th># days</th>
<th>hrs/day</th>
<th>mins/day</th>
</tr>
</thead>
</table>

24. In a typical week do you do any transport-related activities of **VIGOROUS EFFORT** such as running or jogging to get somewhere?

1 [ ] yes

0 [ ] no  \(\rightarrow\) Move to next question.

24a. **If Yes**. Just thinking about the **weekdays** from Monday to Friday.

How many days would you do this activity?

On an average weekday how long would you spend doing this activity?

\[ \leq 5 \]

<table>
<thead>
<tr>
<th># days</th>
<th>hrs/day</th>
<th>mins/day</th>
</tr>
</thead>
</table>
24b. Just thinking about the **weekend** from Saturday to Sunday.

How many days would you do this activity?

On an average weekend day how long would you spend doing this activity?

≤ 2

<table>
<thead>
<tr>
<th># days</th>
<th>hrs/day</th>
<th>mins/day</th>
</tr>
</thead>
</table>

End of Survey - Thank you
## Appendix 4: Fat and Fibre Behaviour Index

### FAT & FIBRE BEHAVIOUR INDEX

These questions relate to your eating habits over the last month:

<table>
<thead>
<tr>
<th>Items</th>
<th>Subscale</th>
<th>Response Options [Scoring]</th>
</tr>
</thead>
<tbody>
<tr>
<td>4. How often do you eat red meat? Red meat includes beef, lamb, liver and kidney, but not pork or ham. It includes all minimally processed forms of red meat such as chops, steaks, roasts, rissoles, hamburgers, mince, stir fries, and casseroles.</td>
<td>Fat</td>
<td>Items reverse scored: 10, 11</td>
</tr>
<tr>
<td>5. How often do you eat meat products such as sausages, frankfurters, Belgium, devon, salami, meat pies, bacon or ham?</td>
<td>Fat</td>
<td></td>
</tr>
<tr>
<td>6. How many days a week do you eat take-away or ‘fast foods’ (such as fish and chips, hamburgers, fried or BBQ chicken, pizza, sausage rolls, meat pies, Chinese)? (Include meals and snacks from McDonalds, Hungry Jacks, Pizza Hut, Red Rooster etc as well as local take-away places)</td>
<td>Fat</td>
<td></td>
</tr>
<tr>
<td>7. How often do you eat potato crisps, corn chips or nuts?</td>
<td>Fat</td>
<td></td>
</tr>
<tr>
<td>8. How often do you eat pastries, cakes, sweet biscuits or croissants? Do not include low fat cookies.</td>
<td>Fat</td>
<td></td>
</tr>
<tr>
<td>9. How often do you eat sweets such as chocolates or lollies?</td>
<td>Fibre</td>
<td></td>
</tr>
<tr>
<td>10. How often do you eat legumes, such as baked beans, lentils, split peas, dried beans, four bean mix?</td>
<td>Fibre</td>
<td></td>
</tr>
<tr>
<td>11. How often do you eat a high-fibre breakfast cereal?</td>
<td>Fibre</td>
<td></td>
</tr>
<tr>
<td>13. How often do you, or the person who cooks your food, remove the skin from the chicken before it is cooked?</td>
<td>Fat</td>
<td></td>
</tr>
<tr>
<td>14. When eating bread (as toast, sandwiches, or a snack) how often do you spread butter or margarine on it?</td>
<td>Fat</td>
<td></td>
</tr>
<tr>
<td>15. How often do you choose low or reduced fat milk in preference to the full cream milk?</td>
<td>[missing]</td>
<td></td>
</tr>
<tr>
<td>16. How often do you choose low or reduced fat varieties of cream, sour cream and ice-cream in preference to full cream varieties?</td>
<td>Fat</td>
<td></td>
</tr>
<tr>
<td>17. How often do you choose low or reduced fat cheddar-type cheese in preference to regular cheese?</td>
<td>Fat</td>
<td></td>
</tr>
<tr>
<td>18. How often do you choose wholemeal spaghetti or pasta in preference to regular spaghetti or pasta?</td>
<td>Fat</td>
<td></td>
</tr>
<tr>
<td>19. How often do you choose brown rice in preference to white rice?</td>
<td>Fibre</td>
<td></td>
</tr>
<tr>
<td>20. How often do you choose wholegrain or wholemeal bread in preference to white bread?</td>
<td>Fibre</td>
<td></td>
</tr>
</tbody>
</table>

**Scoring of Subscale and Total Indices**

- Fat: (sum Fat items)/n with valid responses (i.e. not missing)
- Fibre: (sum Fibre items)/n with valid responses (i.e. not missing)
- Total: (sum all items)/n with valid responses (i.e. not missing)
Appendix 5: Kessler Psychological Distress Scale (K10)

<table>
<thead>
<tr>
<th>Question</th>
<th>None of the time</th>
<th>A little of the time</th>
<th>Some of the time</th>
<th>Most of the time</th>
<th>All of the time</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. During the last 30 days, about how often did you feel tired out for no good reason?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. During the last 30 days, about how often did you feel nervous?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. During the last 30 days, about how often did you feel so nervous that nothing could calm you down?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. During the last 30 days, about how often did you feel hopeless?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. During the last 30 days, about how often did you feel restless or fidgety?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. During the last 30 days, about how often did you feel so restless you could not sit still?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. During the last 30 days, about how often did you feel depressed?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8. During the last 30 days, about how often did you feel that everything was an effort?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9. During the last 30 days, about how often did you feel so sad that nothing could cheer you up?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10. During the last 30 days, about how often did you feel worthless?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Nutrition Coaching - Weight Efficacy Life-Style Questionnaire

This survey describes some typical eating situations. Everyone has situations which make it very hard for them to keep their weight down. The following are a number of situations relating to eating patterns and attitudes. This form will help you to identify the eating situations which you find the hardest to manage.

Read each situation listed below and decide how confident (or certain) you are that you will be able to resist eating in each of the difficult situations. In other words, pretend that you are in the eating situation right now. On a scale from 0 (not confident) to 9 (very confident), choose ONE number that reflects how confident you feel now about being able to successfully resist the desire to eat. Write this number down next to each item.

<table>
<thead>
<tr>
<th>Not confident</th>
<th>Very confident</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 1 2 3 4 5 6 7 8 9</td>
<td></td>
</tr>
</tbody>
</table>

1. I can resist eating when I am anxious (nervous).

| 0 1 2 3 4 5 6 7 8 9 |

2. I can control my eating on the weekends.

| 0 1 2 3 4 5 6 7 8 9 |

3. I can resist eating even when I have to say “no” to others.

<p>| 0 1 2 3 4 5 6 7 8 9 |</p>
<table>
<thead>
<tr>
<th>Item</th>
<th>Confidence</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
</tr>
</thead>
<tbody>
<tr>
<td>4. I can resist eating when I feel physically run down.</td>
<td></td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>7</td>
<td>8</td>
<td>9</td>
</tr>
<tr>
<td>5. I can resist eating when I am watching TV.</td>
<td></td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>7</td>
<td>8</td>
<td>9</td>
</tr>
<tr>
<td>6. I can resist eating when I am depressed or down.</td>
<td></td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>7</td>
<td>8</td>
<td>9</td>
</tr>
<tr>
<td>7. I can resist eating when there are many different kinds of food</td>
<td></td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>7</td>
<td>8</td>
<td>9</td>
</tr>
<tr>
<td>available.</td>
<td></td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>7</td>
<td>8</td>
<td>9</td>
</tr>
<tr>
<td>8. I can resist eating even when I feel it’s impolite to resist a</td>
<td></td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>7</td>
<td>8</td>
<td>9</td>
</tr>
<tr>
<td>second helping.</td>
<td></td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
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<td>9. I can resist eating even when I have a headache.</td>
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<td>Item</td>
<td>Not confident</td>
<td>Very confident</td>
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<td>10. I can resist eating when I am reading.</td>
<td>0 1 2 3 4 5 6 7 8 9</td>
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<td>11. I can resist eating when I am angry (or irritable).</td>
<td>0 1 2 3 4 5 6 7 8 9</td>
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<tr>
<td>12. I can resist eating even when I am at a party.</td>
<td>0 1 2 3 4 5 6 7 8 9</td>
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<td>13. I can resist eating even when others are pressuring me to eat.</td>
<td>0 1 2 3 4 5 6 7 8 9</td>
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<td>14. I can resist eating when I am in pain.</td>
<td>0 1 2 3 4 5 6 7 8 9</td>
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<td>15. I can resist eating just before going to bed.</td>
<td>0 1 2 3 4 5 6 7 8 9</td>
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<td>16. I can resist eating when I have experienced failure.</td>
<td>0 1 2 3 4 5 6 7 8 9</td>
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<td>17. I can resist eating even when high-calorie foods are available.</td>
<td>0 1 2 3 4 5 6 7 8 9</td>
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<tr>
<td>18. I can resist eating even when I think others will be upset if I don’t eat.</td>
<td>0 1 2 3 4 5 6 7 8 9</td>
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<td>19. I can resist eating when I feel uncomfortable.</td>
<td>0 1 2 3 4 5 6 7 8 9</td>
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<td>20. I can resist eating when I am happy.</td>
<td>0 1 2 3 4 5 6 7 8 9</td>
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Appendix 7: Participant information form

Introduction

Thank you for your interest in joining the Walking for Exercise and Nutrition to prevent Diabetes for You (WENDY) Study. The researchers involved in this study are from the Mater Medical Research Institute, (Mater Health Services), and the School of Nursing and Midwifery (The University of Queensland).

Women with history of diabetes during pregnancy (gestational diabetes) are at higher risk of developing Type 2 Diabetes Mellitus (T2DM). Studies have shown that the risk of T2DM can be greatly reduced with regular physical activity and dietary management. This study will help women can increase their physical activity and support healthy dietary habits.

This study will be conducted over a period of 6 months. The main part of the study will be carried out in the comfort of your own home and will involve the use of e-mail and the internet to access the webpage required for this project. The glucose (blood sugar) tests and other measurements will be conducted at the Mater Hospital.

Aims of Study

This study aims to determine the best way support women with recent diabetes during pregnancy with information to increase physical activity and healthy nutrition to improve lifestyle and to prevent Type 2 Diabetes. This study also aims to determine the effect of increased physical activity and nutrition coaching on measurements related to weight loss, diabetes, including blood sugar, insulin levels and body weight changes.

What We Would Like You to Do

1) Ask any questions you may have (and discuss with family and / or your local doctor if needed), then if you agree to participate in this study, contact the research staff to arrange your first appointment.

2) Attend three feedback/measurement sessions at the Mater Hospital:

   a) After you agree to be part of the project, you will be invited to the Mater Hospital where you will have the standard post-natal Oral Glucose Tolerance Test (OGTT), a
“Bioimpedance Analysis” (painless measurement of body fat and muscle mass), body weight and height measurements, and complete a survey relating to your activity levels. These measurements and surveys will be repeated at 3 months and 6 months, but the blood test at that time will be a simple fasting test. Your parking fees will be provided for all visits to the Mater Hospital campus.

All participants will be assessed at the beginning of the study, at 3 months and at 6 months.

3) You will then be randomly allocated into one of two groups. One group will be given advice from Health Professionals, and also printed materials, on how to manage the risk of developing T2DM later in life. The other group will also be given a pedometer, which can be linked to a dedicated web program where you can upload your pedometer readings weekly, and receive regular updates, hints and tips to help increase your exercise. This website also allows for feedback, blogs and general information relating to a healthy lifestyle. In addition, this group will be invited to a Nutrition Coaching course offered by the Health and Wellness Centre at Mater Health Services. This course consists of 4 group sessions relating to healthy nutrition, recipes, shopping tips and strategies for long term healthy living, and are held at the Mater Hospital Campus. The aim of the study is to compare these two approaches. However, if you were not part of the group that took part in the workshops at the commencement of the study, following the 3 month measurement you will be offered the Nutrition coaching course in the next 3 months, and the measurements repeated at 6 months. All participants will receive at least as much care and attention as would usually be received by patients with previous GDM.

**Oral Glucose Tolerance Test (OGTT)**

This is a recommended test for all women with GDM, generally done at around 6 weeks after birth and then annually. It is similar to the test which you had to diagnose GDM during your pregnancy. The only preparation for this test is fasting (at least 10 hours), no food or drinks (except plain water) after 10pm the night before the test. First, a blood sample will be obtained with a needle from a vein in your arm. You will then be given 75g of glucose in 350mL (about 2 medium glasses) of water. You will need to finish this sweet drink within 10
minutes. A repeat blood sample will be taken at one and again two hours later. We will also use samples for insulin analysis.

**RISKS:**

The risk of standard blood tests are minimal (bleeding, bruising, discomfort). A trained pathology blood taker (phlebotomist) will take the blood samples to limit and/or prevent these problems and treat them if they happen. Total amount of blood taken will be 10mL (three tablespoons). Taking this amount of blood is not thought to be a risk for most people. Most people have no problems drinking water sweetened with 75g of glucose, as the sugar content of this drink is equal to about two cans of Coke. Some people may feel a bit sick after the drink, but vomiting is rare.

**Fasting Blood Glucose Test (FBG)**

This test requires fasting for at least 10 hours, no food or drinks (except water) after midnight the night before the test. This test only requires a single blood sample, which will be taken from a vein in your arm. The same blood sample will be used for insulin analysis.

**RISK:**

The risks of standard blood draws are routine and minimal (bleeding, bruising, discomfort). A trained phlebotomist will take the blood sample to limit and/or prevent these problems, and treat them as they happen. The total amount of blood taken will be 10mL (three tablespoon). Taking this amount of blood is not thought to be a risk for most people.

**Bio-impedance Analysis (BIA)**

Bio-impedance analysis is a painless procedure that uses a very low level electric current which passes between stick-on electrodes on your arms and legs to measure your amount of muscle mass and body fat. Preparation for this test includes (a) no alcohol consumption within 24 hours prior to taking the test; (b) no exercise, caffeine or food taken within 4 hours
prior to taking the test; (c) drink 2-4 glasses of water 2 hours prior to the test. This test will be performed following the blood test as you will already be fasting.

**RISKS:**

The bio-impedance analysis has been clinically proven to be safe. The test current is below the level that your nervous system can detect. Therefore the test is completely painless.

---

### Wearing the Pedometer

If you are allocated to the group that is given a pedometer, we will provide you with full instructions on how to use both the pedometer and the website at the first visit.

---

### Survey and Measurement of Body Weight & Height

A questionnaire survey will be administered by an interviewer and no preparation is necessary. There are no specific preparation for the measurement of weight and height. You will be required to remove your shoes for these two measurements.

**RISKS:**

There is no risk in completing the survey, or the measurement of body weight and height.

---

### Benefits

Your participation in this study will contribute to the development of long term health care strategies for women with diabetes during their pregnancy. However, if you were found to have diabetes, you and your doctor at the Mater Hospital will be alerted to this problem. If
your test shows that you have “pre-diabetes” [impaired glucose tolerance or impaired fasting glucose], you and your doctor will be informed of this increased health risk. By knowing your body composition, you will be able to identify your future health risks and discuss this with your doctor. All this will give you a head start with your doctor to reduce your risk of developing diabetes and other future health problems.

At the end of the third measurement session, you will be given tools to maintain healthy dietary habits as an appreciation for your time and patience in completing this study. We will also pay your parking for all your visits, as this is in addition to routine care.

The results of this project will hopefully be published in a medical journal, with the hope that the findings will help guide treatment for women in the future.
Confidentiality

Your identity and personal details provided for this study will be kept strictly confidential and accessible only to the researchers directly involved. The findings in this study will only be used to describe group changes in physical activity, body weight, body composition, blood glucose levels and insulin sensitivity. No individual data will be disclosed to the public. We will tell you about your own results for all tests.

Any or all of publications of the findings of this project will not include patient details, and will describe group findings only.

Voluntary Participation

Participation in this research is entirely voluntary. You may take your time to consider your participation in this study. You may wish to discuss the study with family, friends or your local doctor. Your refusal to participate in this research will not result in any penalty or loss of any benefits. You can stop participation at any point without losing any of your rights for medical attention or services provided by Mater Health Services.

Consent and Participation

This study has been cleared by the Human Research Ethics Committee of the University of Queensland in accordance with the National Health and Medical Research Council's guidelines. You are of course free to discuss your participation in this study in person with project staff:

1) Ann Peacock- ph 3169 2874 , 0478310931, or apeacock@mmri.mater.org.au
2) Prof. David McIntyre - Ph: (07) 3163  6358

This study has also been approved by the Mater Health Services Human Research Ethics Committee. If you should have any complaints about the conduct of the research, or wish to
raise any concerns, and would like to speak to an officer not involved in the study, you may contact:

1) The Mater Research Secretariat. Ph: 07 3163 1585 or The patient representative 07 3163 8303

2) The University of Queensland Research & Research Training Division, Ph: (07) 3365 9324

To participate in this study, please provide all information requested on the attached consent form, including a signature and the date.

Please keep this information sheet for future reference.
Appendix 8: Participant consent form

Walking Exercise and Nutrition to reduce Diabetes Risk for You (WENDY)

Investigators:

<table>
<thead>
<tr>
<th>Name</th>
<th>Role and Institution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ms Ann Peacock</td>
<td>Research Midwife&lt;br&gt;PhD candidate, The University of Queensland&lt;br&gt;Mater Health Services</td>
</tr>
<tr>
<td>Professor David McIntyre</td>
<td>Head of Mater Clinical School&lt;br&gt;The University of Queensland&lt;br&gt;Director of Endocrinology and Obstetric Medicine&lt;br&gt;Mater Health Services&lt;br&gt;South Brisbane</td>
</tr>
<tr>
<td>Associate Professor Fiona Bogossian</td>
<td>Director of Research&lt;br&gt;School of Nursing and Midwifery&lt;br&gt;Edith Cavell Building&lt;br&gt;The University of Queensland, Herston campus</td>
</tr>
<tr>
<td>Dr Shelley Wilkinson</td>
<td>Research Dietitian&lt;br&gt;Mater Health Services&lt;br&gt;Brisbane</td>
</tr>
</tbody>
</table>

I have:

- Read and understood the information package;
- Had any questions or queries answered to my satisfaction;
  - I understand that I will be randomly (like the toss of a coin) placed in one of two groups
  - I understand that I will be required to attend 3 visits to the Mater Hospital for measurements; the first is a 2 hr Oral Glucose Tolerance Test, the following consisting of a fasting blood test, as well as Bio-Impedance measurements and surveys relating to diet and activity.
  - I may be issued with a pedometer and will be given instruction for its use and logging on to the website. I will be offered a Nutrition Coaching course held at the Mater Health and Wellness Clinic as a part of the program, either in the initial 3 months or after 3 months.

Been informed of the possible risks or side effects of the tests or procedures being conducted;
- Understood that the project is for the purpose of research and not for treatment;
- Understood that the project may involve randomisation of participants;
- Been informed that the confidentiality of the information will be maintained and safeguarded;
- Given permission for access to my medical records, for the purpose of this research;
- Given permission for medical practitioners, other health professionals, hospitals or laboratories outside this hospital, to release information concerning my disease and treatment which is needed for this trial and understand that such information will remain confidential;
- Been assured that I am free to withdraw at any time without comment or penalty; and
- Agreed to participate in the project.

Signatures: ............................................................Date __/__/____

...................................................................................................

Witness/Date
Appendix 9: WENDY patient instructions

Wendy

Walking for Exercise and Nutrition to prevent Diabetes for You

Welcome to Wendy - Thank you for taking part in this important project.

Your appointment is………………………………………………………………………………

Please note the following instructions and map before you attend the first appointment and your blood test. Please print them out for reference: Please be aware that this test takes approx 2 hrs and 3 blood samples- your parking will be provided. Please park in the main Water St car park (not Raymond Tce)

Glucose Tolerance Test Instructions

• Follow your usual diet and usual activity for at least 3 days before the test.
• Nothing to eat or drink for 8-10 hours before test
  You may have water but no food, tea/coffee, alcohol, chewing gum etc
• Do not take usual medications on the morning - bring them with you to take after the test is completed.
• Bring all prescription medication to the visit
• Do not take any asthma / allergy inhalers/puffers after bedtime the night prior to the test
• Do not smoke the morning of the appointment
• Do not engage in vigorous physical activity for 10hrs before the test
• If you have been ill within three days of the appointment e.g. chills, Vomiting or Diarrhoea, please ring the research staff as the test may have to rescheduled
If you are unable to attend, please ring/text 0478310931 or 31632874 to reschedule.

Please follow directions arranged with the researcher - or the address is The University of QLD Clinical School entrance; Level 1 Original Mater Mothers Hospital (Directly opposite the ramp entrance to Mater Mothers Hospital)

If you have any questions:

e-mail wendy.project@mmri.mater.org.au
Appendix 10: Human research ethics approval—UQ MREC

(The University of Queensland Medical Research Ethics Committee)

THE UNIVERSITY OF QUEENSLAND
Institutional Approval Form For Experiments On Humans
Including Behavioural Research

Chief Investigator: Mrs Ann Peacock

Project Title: Human Ethics Application, Walking For Exercise And Nutrition To Prevent Diabetes For You (WENDY)

Supervisor: A/Prof Fiona Bogossian, Prof David McIntyre

Co-Investigator(s): A/Prof Fiona Bogossian, Prof David McIntyre, Dr Shelley Wilkinson

Department(s): School of Nursing and Midwifery; UQ Clinical School, Mater Campus

Project Number: 2011000500

Granting Agency/Degree: The Golden Casket Nursing and Midwifery Scholarship, Mater Foundation, Mater Health Services

Duration: 31st December 2014

Comments:

Expedited review on the basis of approval from the Mater Health Services HREC, dated 07/04/2011.

Name of responsible Committee:-
Medical Research Ethics Committee

This project complies with the provisions contained in the National Statement on Ethical Conduct in Human Research and complies with the regulations governing experimentation on humans.

Name of Ethics Committee representative:-
Professor Bill Vicenzino
Chairperson
Medical Research Ethics Committee

Date: 28/4/2011  
Signature:
Human research ethics approval amendment—The University of Queensland

THE UNIVERSITY OF QUEENSLAND
Institutional Human Research Ethics Approval

Project Title: Human Ethics Application, Walking For Exercise And Nutrition To Prevent Diabetes For You (WENDY) - 20/12/2012 - AMENDMENT

Chief Investigator: Mrs Ann Peacock

Supervisor: A/Prof Fiona Bogossian, Prof David McIntyre, Dr Shelley Wilkinson

Co-Investigator(s): A/Prof Fiona Bogossian, Prof David McIntyre, Dr Shelley Wilkinson

School(s): School of Nursing and Midwifery; UQ Clinical School, Mater Campus

Approval Number: 2011000500

Granting Agency/Degree: The Golden Casket Nursing and Midwifery Scholarship, Mater Foundation, Mater Health Services; APA Scholarship

Duration: 31st December 2014

Comments:

Note: If this approval is for amendments to an already approved protocol for which a UQ Clinical Trials Protection/Insurance Form was originally submitted, then the researcher must directly notify the UQ Insurance Office of any changes to that Form and Participant Information Sheets/Consent Forms as a result of the amendments, before action.

Name of responsible Committee:
Medical Research Ethics Committee
This project complies with the provisions contained in the National Statement on Ethical Conduct in Human Research and complies with the regulations governing experimentation on humans.

Name of Ethics Committee representative:
Professor Bill Vicenzino
Chairperson
Medical Research Ethics Committee

Signature ____________________ Date 15/1/13
Appendix 11: Human research ethics approval—MHS HREC

(Mater Health Services Human Research Ethics Committee)

MATER HEALTH SERVICES HUMAN RESEARCH ETHICS COMMITTEE

7th April 2014

Ms Ann Peacock
Mater Medical Research Institute
Level 2, Quarter Building
Woolloongabba QLD 4102

Dear Ms Peacock

Re: Protocol Ref. 1683W Walking for Exercise and Nutrition to prevent Diabetes for You (WENDY)

I write to advise that the Mater Health Services Human Research Ethics Committee considers the above study to meet the requirements of the National Statement on Ethical Conduct in Human Research (2007) and has granted ethical approval for your research proposal. Please accept our very best wishes for the success of this study. In all future correspondence with the Committee please quote the Mater reference number.

Documents reviewed and approved include:

- Mater Ethics Application Form Dated 12th January 2011
- Participant Information and Consent Form
- Data Collection Form
- Mater Pathology quote Dated 15th December 2010
- Financial Costing Summary Form
- Curriculum Vitae

This approval is valid until 7th April 2014. Please note the following conditions of approval:

- Any departure from the protocol detailed in your proposal must be reported immediately to the Committee.
- When you propose a change to an approved protocol, which you consider to be minor, you are required to submit a written request for approval to the Chairperson through the Secretary. Such requests will be considered on a case by case basis and interim approval may be granted subject to ratification at the next meeting of the Committee.
- Whose substantial changes to any approved protocol are proposed, you are required to submit a full, new proposal for consideration by the Human Research Ethics Committee.
- You are required to advise the Research Ethics Coordinator immediately of any complaints made, or expressions of concern raised, in relation to the study, or if any serious or unexpected adverse events occur.
- Under the NHMRC National Statement on Ethical Conduct in Research Involving Humans, research ethics committees are responsible for monitoring approved research to ensure continued compliance with ethical standards, and to determine the method of monitoring appropriate to each project. You are required to provide written reports on the progress of the approved project annually, the first report being due on date and time on completion of the project. (The Progress Report is located at http://www.mater.org.au/Research/Human-Research-Ethics-Committee.aspx or can be accessed through the Mater Intranet. Applications, Research Registrar then refer the project name or alternatively can be emailed to you). Please inform the Committee of publications, presentations at Conferences, education and quality improvement outcomes from this study. The Committee may also choose to conduct an interim audit of your research.
Please be aware that all study procedures including follow up of participants and data analysis should be completed within the approval time frame or an extension should be requested.

Please contact the Executive Director in the participating hospital/hospitals prior to commencing the study. To access medical records, for the purpose of this study, please provide a copy of this approval letter to the Corporate Health Information Manager. I would also be grateful if you could confirm the date of commencement. (All correspondence should be directed to the Mater Research Ethics Coordinator.)

Yours sincerely

Dr Andrew Crowden
Chairperson
Mater Health Services Human Research Ethics Committee
Human research ethics approval amendment—Mater Health Services Human Research Ethics Committee

MATER HEALTH SERVICES HUMAN RESEARCH ETHICS COMMITTEE

20th December 2012

Ms Ann Peacock
Level 2
Quarters Building
Mater Medical Research Institute
South Brisbane
QUEENSLAND 4101

Dear Ms Peacock,

Re: Protocol Ref. No. 1685M: Walking for Exercise and Nutrition to Prevent Diabetes for You (WENDY)

I write to advise that the Mater Health Services Human Research Ethics Committee has granted ethical approval for the proposed amendments for the above study.

Documents reviewed and approved include:

<table>
<thead>
<tr>
<th>Documents submitted for HREC Review</th>
<th>Version</th>
<th>Date</th>
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</thead>
<tbody>
<tr>
<td>Research protocol – WENDY study</td>
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<tr>
<td>Research protocol – WENDY sub-study</td>
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<tr>
<td>Qualitative Interview</td>
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<td>Letter – response to HREC questions- received 18 December 2012</td>
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<tr>
<td>Semi-structured interview questions: WENDY – Participant A</td>
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<tr>
<td>Semi-structured interview questions: WENDY – Participant B</td>
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You are reminded that this letter constitutes ethical approval only. You must not commence this research project until authorisation from the Research Governance Office has been obtained.

Yours sincerely,

[Signature]

[Name]
Chairperson
Mater Health Services Human Research Ethics Committee
Appendix 12: Human research governance approval

From: Patricia Murray
Sent: Friday, 30 November 2012 1:59 PM
To: Ann Peacock
Subject: RE: Ammendmant 1685M

Dear Ann

Many thanks for sending the amendment documents through.

This study was approved by the HREC prior to Research Governance requirements being established at the Mater and as the proposed amendment does not impact on Research Governance items the research may continue as per the HREC approvals (original and amendment once this amendment is approved by the HREC).

Best wishes

Patricia

From: Ann Peacock
Sent: Wednesday, 21 November 2012 11:31 AM
To: Research Ethics
Cc: Research Governance
Subject: Ammendmant 1685M

Dear Ethics committee,

Re; 1685M Walking for Exercise and Nutrition to prevent Diabetes for You (WENDY)

Please find attached the relevant forms for my amendment application form as part of my study.

Kind Regards
Ann

Ann Peacock RN, RM, B Mid (Hons)
Research Co-ordinator, WENDY Project
PhD Candidate
UQ School of Nursing and Midwifery
Mater Medical Research Institute
P: +617 3163 2874
F: +617 3163 2134
mob 0478310931
apeacock@mmri.mater.org.au
www.mmri.mater.org.au
### Appendix 13: Semi-structured interview questions

<table>
<thead>
<tr>
<th>Questions</th>
<th>My notes/comments</th>
<th>Prompts</th>
<th>Other notes</th>
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<tbody>
<tr>
<td><strong>Intro</strong></td>
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<tr>
<td>You’ve taken part in WENDY.</td>
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<td>How did you feel when you were contacted regarding the study?</td>
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<td>Did you find easy to make contact with research staff. Do you have a</td>
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<td>preferred way of contacting you?</td>
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<td><strong>WENDY PROGRAM</strong></td>
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<td>What part of the WENDY project did you enjoy the most</td>
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<tr>
<td>What part of WENDY did you enjoy the least</td>
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<td>What were your experiences regarding the visits required for the study?</td>
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<td>Did you reach your personal goals in relation to the study?</td>
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<tr>
<td>Was the study what you were</td>
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<tr>
<td>Perception</td>
<td>How do you feel now about you and Type 2 diabetes?</td>
<td>Why/why not?</td>
<td>Would you have preferred a different way of obtaining information?</td>
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<td></td>
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<td>Did you find the Nutrition workshops helpful?</td>
<td>Did you find the pedometer and website easy to access and helpful? What did you enjoy the most/least?</td>
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<td></td>
<td></td>
<td>Have you noticed any behaviour changes?</td>
<td>Do you feel you will maintain any changes you have made during</td>
</tr>
<tr>
<td>GDM/T2DM risk</td>
<td>What information were you given regarding T2DM?</td>
<td>Who gave you the information (dr, diab educator, midwife, own reading). When were you given this information? Did you do any research yourself after you were diagnosed with GDM? What did you understand regarding the study? What is your understanding of the risks of developing T2DM since participation in the study?</td>
<td></td>
</tr>
</tbody>
</table>
the risks of T2DM?

| Closure | Is there any other information you would like to share regarding the program? Do you think there is another way the information could be given that may be easier? |  |  |  |
Appendix 14: Website screenshots
Getting Started

To get started with the Wendy Study:

1. Learn how to wear and care for your pedometer.
2. Learn how to register your pedometer (this needs to be done very soon).
3. Learn how to upload your step counts.

Please do not remove the sticker or adjust anything on the pedometer until you receive an email asking you to do so.

Step 1: Wear your pedometer every day. Keep the sticker on the front of the pedometer until you receive an email telling you it is okay to remove the sticker.

Step 2: To register your pedometer, connect the USB cable to the top of the pedometer and connect the other end of the USB cable to the USB port on your computer.

Log in to the study website and click the "Register Pedometer" button.

A small window will open and display the message "After upload, please remember to click the home button to load your updated graphics." Click "OK." Another small window will open to run the registration upload program. If you don't see the small window, it may have opened in another tab. If so, find and open it. You should see a message asking if you want to register the pedometer.

You will then see a message "Transferring Data." Please wait while the data is being uploaded. When it is complete you will get a message that says "Upload Complete." Your pedometer is now registered. You must wait to upload your step counts.

Step 3: To upload the step-counts stored in your pedometer, connect the USB cable to your pedometer and computer as in Step 2. Then click the "Upload Now" button on the "Home" page and follow the same procedure (above) as you did for registering the pedometer. Uploading takes the step-count data from your pedometer and transfers the data to the website and study team.

You must wear your pedometer for at least 5 hours a day for 7 days and upload your step counts to have full access to the Web site content. You will not be a participant of any study pools until you have completed these initial requirements.

"After the first upload, you can upload as often as you like, but at least once a week.

Omron Pedometer Instructions:

- Wear your Omron every day.
- Put on the Omron right after you get up in the morning, and do not remove it until you go to bed, except when showering, bathing, or swimming.
- When you take it off at night, put it where you will remember to wear if the next day, such as with your glasses, clock, or wallet.
- Place the Omron in the plastic holder and clip the pedometer onto your belt or the waistband of your pants using the plastic clip on the back of the holder.
- The Omron comes with a security strap. Secure the Omron to your clothing using the strap itself or the clamp that attaches to the waistband of your pants. Use this security strap at all times, without it, the device is too easy.
- The Omron is not waterproof and cannot be worn in the shower.
- Do not leave it in hot places such as on the dashboard of a car.
Week 2: Living Confidently

Return to List of Messages
Living confidently with a history of DSM
Welcome to Week Two. We are glad you have made a commitment to this program.

This week we would like to talk about things that are important to you. Do you feel that your energy level prevents you from doing things that are important to you? Are you feeling worried about what is important to you will have to make a decision in difficult times?

Everything can be more difficult when you are tired. Fatigue affects everyone differently, and being tired can really affect you. You wish you could get up and do things quickly. It makes it more difficult to do simple things, such as shop at the store.

The idea of walking to get all your thoughts might sound crazy, at first. Walking can make you more relaxed, right? Yes. It’s true, especially if you are not active right now. Fortunately, a gradual walking program can slowly improve your energy, making you more fit over time.

Does walking make you lose weight? Walking strengthens muscles used in breathing. As these muscles become stronger, breathing becomes easier.

As you participate in this walking program, please keep in mind some tips for safe walking and physical activity:

- Breathe in and out slowly.
- Choose a place that is moderate for your current condition.
- Walk at a pace that is comfortable for you and your fitness level.
- Gradually increase your activity level.
- Stretch and go slow.
- Keep it at a slow pace.

As you start to feel more energetic, your confidence will increase, and you will be more able to do things you enjoy.

Remember to talk with your health care provider if you have any concerns about the level of activity or if you experience any new symptoms while walking.

Week 3: Step by Step

Return to List of Messages
Slow and steadily wins the race.

It’s really to be excited and want to do the best you can to achieve your goal. However, it’s important to remember that waking up is a process that takes time. Changing your fitness level is difficult, but it is possible.

Keep in mind some tips for safe walking and physical activity:

- Be prepared.
- Check the weather.
- Choose a place that is moderate for your current condition.
- Walk at a pace that is comfortable for you and your fitness level.
- Gradually increase your activity level.
- Stretch and go slow.

As you start to feel more energetic, your confidence will increase, and you will be more able to do things you enjoy.

Remember to talk with your health care provider if you have any concerns about the level of activity or if you experience any new symptoms while walking.

Don’t want to make walking something you dread. Have some fun. If you can’t get motivated, try something different. As you reach each of your goals, however small, reward yourself in some way. You deserve it!
Week 4: Managing Your Busy Life

In life and play:
Congratulations on completing your first month in WENDY! We hope you are feeling more and feeling better.
Doing too busy is a major reason many stop walking. You can learn to integrate walking into your daily routine.

If you find you are simply too busy to set aside a period of time to walk, try to walk walking into your errands. You can park your car in the farthest corner of the parking lot so you have to walk across the parking lot. You can deliberately park so you simply have to walk one or two extra blocks. You can take the stairs instead of the elevator or escalator. You can also try to take several shorter walks instead of one long walk. Many studies have shown that these short periods of activity can be just as useful as longer periods of activity.

Here are some examples of what others have done to fit walking into their day:
- Spend extra time walking when inside public buildings such as shopping malls or the grocery store.
- When the weather is nice, get out and walk around the block.
- Combine walking with socializing – meet with a friend to walk and talk.
- Take a walk with friends or family before or after dinner.
- Take your dog, or someone else’s dog for a walk.
- Add leisure time activities that involve walking such as going to a park, museum, botanical garden, or the zoo.

These shorter periods of activity are especially useful with a baby or small child. While children can tolerate prolonged stretches of non-activity, infants and small children need short periods of stimuli. Especially if they are outside, children can get extra stimulation even though you are not doing the walking.

Week 5: Managing Stress

Have you ever felt overwhelmed?

Many, especially women who are busy, can feel stressed. It is normal to feel stressed when there’s a lot happening, but not if it interferes with plans for exercise and eating healthily. There are steps you can take to stay anxious before it overwhelms you. You can’t always control what’s happening to you, but you can learn to control your reaction to it.

Managing your stress and anxiety begins by identifying their major sources in your life and understanding how well you are responding to them. Understanding what makes you anxious is the first step to controlling your reaction to stress.

Knowing what to do and planning for stressful situations will help you to reduce your anxiety levels. One of the most powerful ways to stop stress is to relax your mind and body using relaxation techniques. Here are some helpful strategies:

- Stay present focused – automatic people tend to get caught up worrying about possible negative events in the future and expect the worst. Instead, focus on what you can control now.
- Practice a relaxation technique – like meditation, yoga, prayer, or listening to calming music.
- Do things you enjoy – try doing one thing you enjoy every day.
- Keep a positive attitude – negative thinking can block your ability to think clearly and get in the way of finding solutions to problems or sources of stress.
- Use humor – seek out people and things that make you laugh, smile, and help you maintain a positive attitude.
- If you feel anxious – ask questions to find out answers.
- Seek support from others – don’t try to deal with all of your daily stressors by yourself.
- Seek help from a health professional – if you feel impaired by your anxiety.

Life can be hard enough to deal with. Do not let it stress you out in your life.
Week 6: Managing Your Eating

Return to List of Messages

Just a few simple changes can make a big difference!

Key skills you will learn from WENDY include learning how to eat healthfully without eating too much. Many women are overweight, but don't eat very much. Other women are overweight, and occasionally overeat. Still other women are overweight, and consistently overeat. It can be hard to know which category you're in.

Do you not to eat? Do you eat until you feel full? Do you eat while watching television? Do you eat between meals? Do you eat when you're not hungry?

If the answer to any of these questions is yes, there's a good chance that you need to adjust one or more of them. If you can develop healthy eating habits, it will help you achieve and maintain a healthy weight.

Many women are worried about getting enough of certain types of foods, such as fruits and vegetables, calcium, vitamin D, or fiber. Overly restrictive diets can lead to a lack of nutrients, and can also make it more difficult to achieve and maintain a healthy weight. However, it's possible to get enough of these foods without overeating, as well as eating any food in a healthy way!

Here are some tips if you answered "yes" to any of the questions above:

- Do you eat to relax? Many people do. Eating can be an enjoyable experience, but if you consistently do it when you feel sad or when you feel highly emotional, it can be easy to overeat. When you feel yourself in this situation next time, instead of going to the refrigerator or to the cabinet, cut out on your walking shoes instead, or make yourself a cup of tea. Try to avoid taking in calories and doing something you'll regret later.
- Do you eat until you feel full? If you can't finish it until you can't eat anymore, especially when there's a special meal prepared for the holidays. Try to develop the habit of eating until you're not hungry, and stopping before you get full. Some folks are to eat more when they're not hungry, but their bodies are still not working at their usual speed.

Week 7: Overcoming Barriers

Return to List of Messages

Learn to break down obstacles.

You have made a smart decision to take part in WENDY. Along with your medications, walking and other exercises play an essential role in the reduction of your diabetes risk.

There are many personal or situational factors or barriers that can get in the way of achieving your walking goals. WENDY is designed to help you find ways to handle these barriers to walking, and safely increase your daily walking at a comfortable pace.

Everyone faces a variety of barriers to staying regularly active. Knowing your barriers is the first step to being able to handle them. Look at the list of common barriers and consider which interfere with your ability to meet your walking goals.

Common Barriers to Physical Activity:

- Get more rest and rest
- Fear of getting injured
- Don't have enough time
- Too stressed
- Lack of accessibility
- Don't have anyone to do it with
- Too tired to start
- Lack of access to a fitness facility
- Lack of confidence or skills
- Need for walking outdoors
- Too many obstacles
- Become fatigued quickly
- Trouble controlling energy
- Hot or cold weather
- Lack of exercise
- Start or stop
- Back/hips/pain will get worse
Week 8: Planning for Lifetime Success

Week 8: Planning for Lifetime Success

Planning for success.

Congratulations! You are now over two months into WENDY. By participating in this walking program you have made strides to improve your health and know that being physically active is important to you. To move and continue with your goal of walking to a healthier you, you need to be able to pace yourself each day.

Making changes in your health habits is hard. It is often even harder to maintain those changes. But it can be done! The key is to make a plan for change.

Some basic things to consider when planning ahead and working on action plans are clear, where, and when you will go about working towards your goal:

- What will I do?
- Why will I do it?
- When will I do it?
- Where will I do it?
- What are things that could make it hard for me to achieve my goal?
- What is my plan for overcoming those difficulties?
- How confident am I that I can make this change?

It is important to be confident that you can make these changes to your routine. On a scale of 1 to 10, with 1 being not confident at all and 10 being completely confident, if you feel less than 9 it is best to choose another plan you are more confident you can achieve. Use your personal and step counter graphs to help you. Find out how many steps you can take comfortably and confidently. From there, you can slowly increase the steps.

One example of an action plan could be:

Week 9: Take Charge of Your Health

Week 9: Take Charge of Your Health

Taking charge.

WENDY is based on the belief that you can lead a fulfilling and active life even if you are at high risk for diabetes. CDM is a condition that you can’t get rid of, but you can manage and control your condition. Many people feel powerless when diagnosed with a condition that makes it difficult for them to achieve their goals. You can take steps to understand your vulnerabilities and take control of how you can live a better life.

Even though your health care provider can diagnose your health problems and give you medical treatments, he or she cannot be with you on a day-to-day basis. You are the expert about your life and controlling what things can help or worsen your glucose levels.

So far in this program we have talked about a variety of techniques and skills that you can use to manage your health and activity. When participating in a walking program, it is important to be prepared to handle situations that may happen every day. We have discussed ways in which to manage a busy schedule (week 4), ways to control levels of stress and anxiety (week 5), ways to improve your eating habits (week 6) and ways to overcome barriers to activity (week 7). This information can help you manage your Diabetes and take control of your health. The more you can learn, the more you can take back control. Remember you are the expert on your life and know what works for you.

As you’ve learned to participating in WENDY, part of managing your diabetes risk is staying active through daily walking and careful, mindful eating. Other things you can do to manage your risk are:

- Managing stress and anxiety
- Finding time for exercise
- Eating an active plan to improve exercise and diet
Week 11: Making it Stick!

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Walking is now part of your daily life!
You have made it to the final week! Take a look back over what you have accomplished in just 3 months!
You have learned:

- A walking program can improve your emotional well-being, increase your energy, manage your weight and improve your overall health.
- Better health will allow you to participate more fully in that which is important to you.
- You have learned how to progress at a steady pace to avoid injury.
- You have learned healthy eating habits...and just eating less, but eating mindfully.
- You have practiced using the IDEA methods to help you identify and resolve barriers to physical activity and healthy habits.
- You have developed a plan of actions to improve your health.
- You have completed the walking program and have set a new personal best track.
- Managing stress can help you with lifestyle changes.
- You have found ways to fit more walking into your day, and how to rely on food loss.

Now you have the knowledge to move forward. Now is a good time to consider a plan to maintain your new walking program. Look for social support, book a time to walk each day, and keep a journal to monitor your progress. Make it a habit or don’t become boring. Look for new places to walk or new activities that involve walking. Look for recipes that involve healthy foods. Talk with your healthcare provider for support and developing a continued walking program, diet, and how best to challenge yourself with new goals.

What’s next? Sticking to your walking plan and healthy dietary habits are keys to continued improvement in your health.

Reflective journaling question: Develop a plan to maintain your gains.

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Educational Tips

The Walking for Exercise and Nutrition to Prevent Diabetes for You.
Wendy, provides educational and motivational information to help you stay engaged with the walking program.

Every other day, there is a new educational tip. Read as little or as much as you want!

Tip 2: Reasons to Walk

Tip 1: How Your Behaviours Affect Your Health

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<th>9</th>
<th>10</th>
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Contact Us

For any questions or changes in your medical condition you should always contact your primary healthcare provider first. We're always here to provide your medical care while you are participating in this research study. You should not contact research study staff till as there may be a delay between your reporting and our response.

After contacting your primary healthcare provider, we do want you to report any changes to your medical condition, injury, or illness to us at emailing wendy@imr.arts.uwa.edu.au or calling us at 08 9337 3374, so we know your current health status.

If you are experiencing any other problems, or have questions about the study, please email us at wendy@imr.arts.uwa.edu.au. For technical difficulties of the website, you can email us using the example. Internet Explorer 5.5, and what operating system you have used (for example, Windows 98).

Submit questions or comments to the study team:

- Obtain more information about the study.
- Ask a question about the study procedures.
- Leave the study before it is finished.
- Express a concern about the study.
- Who can I contact about this study?

Principal Investigators:

- Ann Rea, PhD

Mailing Address: Level 2, Quarters Building, Mater Medical Research Institute, Annerley Road, Woolloongabba, 4102
Ph: (07) 3163 2074 or mobile 0479318301

This study has been cleared by the Human Research Ethics Committee of the University of Queensland in accordance with the National Health and Medical Research Council's guidelines. You are of course free to discuss your participation in the study in person with project staff.

Accessing:

- Access is an Australian software company specialising in collaboration and development tools. The software is free for use by eligible non-profit organisation and charities. If you have any questions or concerns, please feel free to contact us.

Department of Family Medicine – University of Michigan Health System

- The Department of Family Medicine has provided technical development and support.

Onsite:

- Onsite has provided enhanced pedometrics at a substantial research discount, as well as access to the proprietary interface to help us to create software.

Research Funding:

- The research was supported by the Mater Foundation Golden Casket, Giving and Philanthropy Scholarship program, Mater Foundation Golden Casket Research Grants, Mater Health Services, Royal Randwick Hospital, South Sydney 4101.

Acknowledgments:

- Mater Medical Research Institute

Permissions:

- Onsite, Mater Medical Research Institute

Log Out

CRM
Appendix 15: Supporting publications

Clinical Study
Pilot Study of an Individualised Early Postpartum Intervention to Increase Physical Activity in Women with Previous Gestational Diabetes

Harold David McIntyre,1,2 Ann Peacock,1,2 Yvette D. Miller,1 Denise Koh,3 and Alison L. Marshall4

1 The University of Queensland, St. Lucia, QLD 4072, Australia
2 Mater Medical Research Institute, Raymond Terrace, South Brisbane, QLD 4101, Australia
3 The National University of Malaysia, Bangi, 43600 Selangor, Malaysia
4 Queensland University of Technology, Brisbane, QLD 4001, Australia

Correspondence should be addressed to Harold David McIntyre, david.mcintyre@matez.org.au

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Optimal strategies to prevent progression towards overt diabetes in women with recent gestational diabetes remain ill defined. We report a pilot study of a convenient, home-based exercise program with telephone support, suited to the early postpartum period. Twenty-eight women with recent gestational diabetes were enrolled at six weeks post-partum into a 12-week randomised controlled trial of Usual Care (n = 15) versus Supported Care (individualised exercise program with regular telephone support; n = 15). Baseline characteristics (Mean ± SD) were: Age 33 ± 4 years; Weight 80 ± 20 kg and Body Mass Index (BMI) 30.0 ± 9.7 kg/m². The primary outcome, planned physical activity (Median [Range]), increased by 60 (0–540) min/week in the SC group versus 0 (0–580) min/week in the UC group (P = 0.234). Walking was the predominant physical activity. Body weight, BMI, waist circumference, % body fat, fasting glucose and insulin did not change significantly over time in either group. This intervention designed to increase physical activity in post-partum women with previous gestational diabetes proved feasible. However, no measurable improvement in metabolic or biometric parameters was observed over a three month period.

1. Background

Strategies to prevent the progression from impaired glucose tolerance to overt (principally type 2) diabetes in middle-aged and older adults have been developed by a number of groups worldwide, drawing on the results of major randomised controlled trials [1-3]. Women with previous gestational diabetes (GDM) are known to be at high risk of progression to type 2 diabetes [4]. However, strategies for diabetes prevention for women with previous GDM in the period immediately following pregnancy are less well defined. The TRIPOD [5] and PIPPOD studies [6] demonstrated that thiazolidinediones (TZD) therapy could delay progression to diabetes in a high risk group of women. Some benefits have also been suggested for metformin by Ratner and colleagues [7] in women with previous GDM (mean age at study entry 43 years) who participated in the Diabetes Prevention Program (DPP). In women with previous GDM, metformin led to a 50% reduction of the risk of progression from impaired glucose tolerance to overt diabetes, whereas lifestyle intervention was associated with a 53% risk reduction. However, medication-based strategies may not be appropriate for women of child-bearing age and are unlikely to be feasible or desirable on a broader scale.

Anecdotally, the pressures of caring for a new baby tend to dominate the early postpartum period, with Australian women potentially experiencing difficulty focusing on their own long-term health, and specifically their exercise, in this context. This belief is supported by a recent qualitative study conducted in the USA that found that having young children/child was a major barrier to an active lifestyle in the first 12 months postpartum [8]. Our recent work [9] has
demonstrated that women with previous GDM frequently have ongoing deficits in health promoting physical activity. By contrast, the recent findings of Rotnakan et al. [16] were more positive, suggesting some improvement in physical activity following a GDM pregnancy.

Changes in lifestyle patterns at this time might potentially prove to be valuable in preventing longer term progression towards diabetes, as well as influencing the woman’s entire family towards adopting health promoting behaviours. However, Cheng et al. have reported little success with a group intervention that used patient-centred counselling [11] or more recently with a pedometer linked programme [12]. In contrast, several intervention studies based on the Social Cognitive Theory [13] have demonstrated success in increasing and even maintaining physical activity among individuals with type 2 diabetes [14]. This pilot study sought to evaluate the feasibility and efficacy of an individualised programme, based on the social cognitive theory, to assist women to be more physically active in the early postpartum period.

2. Research Design and Methods

The protocol was approved by Hospital and University Human Research Ethics Committees. Participants consented in writing after appropriate verbal and written explanation of the study. The study was registered with the Australian and New Zealand Clinical Trials Registry: ACTRN 12608000280003.

Seventy-two women were approached to join the trial prior to six weeks postpartum. Forty-three women refused participation and one was excluded due to detection of overt diabetes on the entry oral glucose tolerance test (OGTT), leaving 28 randomised participants. At six weeks after delivery of the index pregnancy complicated by GDM, participants underwent baseline assessment. Parameters assessed included a 75 g OGTT, fasting insulin, body weight and height using standardised instruments, and body composition using bioimpedance methodology. Insulin resistance was estimated using the HOMA-IR equation [15] (HOMA-IR = Fasting Insulin (mU/ml) \times Fasting glucose (mmol/L)/22.5). Physical Activity was assessed using the validated Australian Women’s Activity Survey [16].

Women were then randomly assigned to one of two groups. The Usual Care group (“UC”, n = 13) received brief printed materials outlining the importance of diet and exercise for the prevention of future diabetes. The Supported Care (“SC”, n = 15) group underwent an initial face-to-face consultation with an exercise physiologist where specific, individualised goals for initiating and maintaining regular health-enhancing physical activity were developed. Consistent with current physical activity guidelines a physical activity target of 150 mins/wk was set, to be achieved gradually over the 12 weeks intervention through activities acceptable to the individual. The exercise physiologist contacted each woman in the SC group weekly by telephone for the next four weeks and then every 2 weeks thereafter to assess progress, promote accountability, and to provide tailored expert support for recognising and overcoming experienced constraints to physical activity behaviour change.

Twelve weeks following baseline assessment (total 18 weeks postpartum), both groups underwent repeat examinations as noted above, except that samples for fasting glucose and insulin alone were taken without a repeat OGTT. The primary outcome measure was change in self-reported physical activity. Secondary outcomes were change in insulin resistance (HOMA-IR), change in weight, and changes in body composition.

Statistical analyses were performed using data from those women who completed both assessments n = 11 “UC” and n = 14 “SC” women. All comparisons between the UC and SC groups consider differences between these groups in the change or “Delta” (Delta = Val12 vs. weeks post partum - Val12 vs. weeks post partum) in each variable between six and 18 weeks postpartum. Statistical comparisons have been performed using unpaired t-tests for normally distributed variables and Mann Whitney U tests for nonnormally distributed variables. Categorical variables were analysed using Fisher’s exact test due to small cell sizes. Significance was accepted at the 5% level for two-tailed analysis for all variables.

3. Results

Typical of an Australian GDM cohort, the women were generally in their early thirties and their mean body mass index (BMI) at six weeks postpartum was in the obese range. Importantly there were no significant differences between the study groups demographic, physical activity or insulin resistance at baseline (see Table 1). Two UC and one SC participant dropped out of the study prior to the follow-up assessment.

Consistent with previous studies, the physical activity data were nonnormally distributed (see Table 2). Median (range) planned physical activity increased by 60 (0–540) mins/wk in the SC group versus 0 (0–580) mins/wk in the UC group, but this change was not statistically significant (P = 0.234, Mann Whitney U test). The change observed in the SC group’s physical activity comprised mostly increased planned walking. A pre defined categorical analysis examined differences between UC and UC groups in the proportion of women increasing planned physical activity by >60 mins/wk; 67% of women who received SC achieved this criterion compared to 31% of women who received UC. Despite this, most women regardless of group allocation failed to reach the recommended physical activity level of 150 mins/wk (see Table 2).

Metabolic assessments revealed no changes in weight or insulin resistance in either group (see Table 2). Body composition (% lean mass, % fat mass) was also unchanged. Breastfeeding status (full/partial/nill) was also noted at six and 18 weeks postpartum. Weight loss and other metabolic parameters did not differ between breastfeeding groups.

Open-ended feedback regarding the intervention programme was obtained from the SC group, whilst most women responded positively to the programme, many commented that the starting point of six weeks postpartum was
Table 1: Prestudy characteristics of women, at the baseline visit (six weeks postpartum), divided by treatment group.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Usual Care group (n = 15)</th>
<th>Supported Care group (n = 15)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age—years</td>
<td>Mean ± SD</td>
<td>Mean ± SD</td>
</tr>
<tr>
<td>Weight—kg</td>
<td>31.5 ± 3.9</td>
<td>34.6 ± 4.4</td>
</tr>
<tr>
<td>BMI—kg/m²</td>
<td>20.3 ± 17.4</td>
<td>79.3 ± 20.7</td>
</tr>
<tr>
<td>Waist circumference (cm)</td>
<td>30.3 ± 7.4</td>
<td>30.6 ± 8.5</td>
</tr>
<tr>
<td>% Body fat</td>
<td>96.0 ± 11.0</td>
<td>97.6 ± 15.2</td>
</tr>
<tr>
<td>Fasting glucose—mmol/L</td>
<td>32.7 ± 8.1</td>
<td>33.5 ± 8.3</td>
</tr>
<tr>
<td>Fasting insulin—µU/mL</td>
<td>4.7 ± 0.7</td>
<td>4.6 ± 0.7</td>
</tr>
<tr>
<td>HOMA—IR</td>
<td>8.4 ± 7.5</td>
<td>8.4 ± 7.5</td>
</tr>
<tr>
<td>Parity &gt; 1</td>
<td>n (%)</td>
<td>n (%)</td>
</tr>
<tr>
<td>Education &gt; high school</td>
<td>9 (69%)</td>
<td>9 (69%)</td>
</tr>
<tr>
<td>Planned physical activity (mins/wk)</td>
<td>Median (range)</td>
<td>Median (range)</td>
</tr>
<tr>
<td></td>
<td>0 (0–420)</td>
<td>0 (0–300)</td>
</tr>
</tbody>
</table>

Table 2: Changes in physical activity, weight, and insulin resistance of women between baseline (six weeks postpartum) and followup (18 weeks postpartum) by treatment group. All changes calculated as (Value at week post partum − Value at week post partum).

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Usual Care group (n = 11 at end of study)</th>
<th>Supported Care group (n = 14 at end of study)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Change in planned physical activity (mins/wk)</td>
<td>Median (range)</td>
<td>Median (range)</td>
</tr>
<tr>
<td>Change in planned walking (mins/wk)</td>
<td>0 (0–360)</td>
<td>60 (0–540)</td>
</tr>
<tr>
<td>Change in planned physical activity &gt; 60 mins/wk</td>
<td>%</td>
<td>%</td>
</tr>
<tr>
<td></td>
<td>31%</td>
<td>67%</td>
</tr>
<tr>
<td>Meets physical activity goal of 150 mins/wk</td>
<td>Never: 54%</td>
<td>Never: 53%</td>
</tr>
<tr>
<td></td>
<td>18 weeks only 31%</td>
<td>18 weeks only 60%</td>
</tr>
<tr>
<td></td>
<td>6 &amp; 18 weeks 15%</td>
<td>6 &amp; 18 weeks 7%</td>
</tr>
<tr>
<td>Change in Weight (kg)</td>
<td>Mean ± SD</td>
<td>Mean ± SD</td>
</tr>
<tr>
<td>Change in Waist circumference (cm)</td>
<td>0.22 ± 4.2</td>
<td>0.97 ± 3.7</td>
</tr>
<tr>
<td>Change in % Body Fat</td>
<td>−3.6 ± 7.3</td>
<td>−0.35 ± 5.8</td>
</tr>
<tr>
<td>Change in fasting glucose (mmol/L)</td>
<td>−1.2 ± 5.5</td>
<td>1.0 ± 4.4</td>
</tr>
<tr>
<td>Change in fasting insulin (µU/mL)</td>
<td>0.12 ± 0.42</td>
<td>0.25 ± 0.56</td>
</tr>
<tr>
<td>Change in HOMA IR</td>
<td>0.06 ± 3.89</td>
<td>1.49 ± 4.23</td>
</tr>
<tr>
<td></td>
<td>−0.08 ± 1.02</td>
<td>0.43 ± 1.28</td>
</tr>
</tbody>
</table>

too early for maximum benefit, as they were still adapting to life with a new baby and found it difficult to focus on personal lifestyle changes such as increasing physical activity at that time.

4. Discussion

This pilot study was designed to evaluate and refine a potential early postpartum intervention designed to increase physical activity in women with previous gestational diabetes for future dissemination and evaluation. Our findings suggest that a postpartum programme designed to encourage and assist women with prior GDM to be more physically active is feasible.

Specific strengths of our study included the randomized design and good overall retention of participants. Weaknesses included relatively poor recruitment rates, anecdotaly contributed to by the predominance of “baby-related” concerns in early postpartum period, short duration of followup, and small total study cohort.

As noted in Tables 1 and 2, there was great variability in physical activity both at baseline and at followup, with many women reporting essentially zero planned physical activity. The variance in all biophysical study measures was large,
in particular for HOMA-IR where the standard deviations approached or exceeded the mean values. In designing future studies, it may be worthwhile to stratify women according to BMI at entry, as this is likely to be a major factor influencing the degree of insulin resistance.

Notwithstanding the timing of commencement, the intervention was well received. Anecdotally, women were happier than their potential health problems were being addressed in an organised programme. Although changes in physical activity between groups did not reach statistical significance, the proportion of women increasing their physical activity by >60 mins/wk in the SC group was twice that of women in the UC group. If confirmed in a larger study sample and maintained over a longer period of time, this would provide significant health benefits [17].

Commencement of programmes designed to increase physical activity in the early postpartum period has some potential advantages in terms of capitalising on the increased motivation often seen in pregnancy. However, the focus of attention frequently shifts to the baby at this stage, making alterations in ingrained maternal behaviours potentially difficult to achieve. The emotional stress of adapting to a new baby and the fear of receiving a diagnosis of diabetes are key barriers to follow up care for GDM [18].

As noted previously, other studies of interventions in the postpartum period [10–12] have met with limited and variable success and the optimal timing and content of postpartum programmes remains undefined. Group-based programmes may help increase motivation [11, 12] but achieving “buy in” and maintaining participation appears challenging. Despite the theoretical advantage of commencing diabetes prevention at an earlier stage of pathophysiology, psychological barriers may make women more resistant to change at this stage of the life cycle.

Despite some evidence of increased physical activity, measures of glucose metabolism were not altered by this intervention over a three-month period. This was not unexpected given the small sample size and short duration of the study, but we noted absolutely no trends in favour of metabolic improvement. Weight and body composition were also unchanged. Although early postpartum breast feeding status did not appear to influence our findings, the potential importance of breast feeding in longer term diabetes prevention has also been noted in a recent review [18].

Alternatively, one could argue in favour of pharmacologic prevention of progression towards diabetes following GDM, citing the results of the TRIPOD [5], FIPOD [6], and DPP [7] studies. However, thiazolidinediones are rapidly disappearing from the pharmacotherapy of type 2 diabetes due to an unfavourable risk/benefit profile and their potential use in diabetes prevention appears severely limited. Metformin was reported to be equally efficacious as an intensive diet/lifestyle programme in women with previous GDM who participated in the DPP [7], but this finding relates to much older women (mean age 46 years at study entry), rather than those in the early postpartum period. For large scale intervention, lifestyle measures appear intrinsically more attractive, though metformin may still deserve consideration in those struggling to make effective lifestyle changes.

Further research is warranted to improve the physical activity levels and general health of women with previous GDM. We suggest that studies combining physical activity and dietary interventions may potentially offer greater benefits and we are currently planning such studies, using the pilot data reported in this paper. We hope that our findings will also assist other researchers in determining in the design and conduct of more definitive studies, in particular by allowing pre hoc power calculations to be performed in a more robust fashion.

Abbreviations

BMI: Body mass index
GDM: Gestational diabetes mellitus
HOMA: Homeostasis model assessment
IR: Insulin resistance
OGTT: Oral glucose tolerance test
SC: Supported care
UC: Usual care

Conflict of Interests

The authors declare that they have no competing interests.

Authors’ Contribution

All authors made substantial contributions to conception and design, analysis, and interpretation of data. All authors were involved in drafting the paper and revised it critically for important intellectual content and have read and approved the final paper.

Acknowledgments

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References

Review article

An interpretive review of women’s experiences of gestational diabetes mellitus: Proposing a framework to enhance midwifery assessment

Bianca U. Devsam, Fiona E. Bogossian, Ann S. Peacock

1 The University of Queensland, The School of Nursing and Midwifery, Building 12, Sir Thomas Brisbane, Herston, Queensland, Australia
2 The University of Queensland, The School of Nursing and Midwifery, Faith Cavan Building, Herston Campus, Herston, Queensland, Australia
3 Mater Misericordiae Research Institute, Level 2, Queensland Building, Mater Misericordiae, South Brisbane, Queensland, Australia

ABSTRACT

Background: Gestational diabetes mellitus (GDM) affects almost 5% of pregnancies in Australia, and within 15 years, 25% of affected women will go on to develop Type 2 Diabetes Mellitus (T2DM). The adoption of preventive health behaviours may be influenced by women’s experiences of GDM.

Question: This review sought to understand women’s beliefs, values, perceptions and experiences following diagnosis of GDM.

Methods: Peer reviewed and professional journals were searched for primary research, published between January 1991 and December 2011 that explored the beliefs, values, perceptions and experiences of peripartum or postpartum women with a diagnosis or history of GDM.

Findings: Nineteen studies met the inclusion criteria and the majority of these studies were qualitative (n=15). Each study was reviewed and synthesis revealed three emergent themes and core concepts related to each theme: Women (initial reaction to GDM diagnosis), negative thoughts following diagnosis, struggle to manage GDM, feelings of ‘loss of control’, changes to identity and adapting to change, Focus of Concern (concern for baby’s health, mother’s concern for her own health, perceived seriousness of GDM, perceived fear of T2DM) and influencing factors (cultural roles and beliefs, social stigma, social support, professional support, adequate and appropriate information, social roles and barriers to self-care).

Conclusion: The experiences of women with GDM are unique and personal however this review highlights common experiences evident in the existing research. The proposed framework may be used by midwives in clinical assessment and care of women diagnosed with GDM.

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1. Introduction

In Australia during 2005–07 gestational diabetes mellitus (GDM) affected approximately 4.7% of pregnancies.1 Within 10 years, 17% of Australian women diagnosed with GDM will develop Type 2 Diabetes Mellitus (T2DM), and within 15 years prevalence rises to 25%.2 To provide quality midwifery care to pregnant women with GDM, midwives need to understand the factors that influence women’s behaviours.3 Consequently, an understanding of the beliefs, values and perceptions of women with GDM, or a history of GDM, is essential for quality individualised care during the antenatal, intrapartum and postpartum periods. This interpretive review seeks to understand women’s beliefs, values and perceptions and how they influence the GDM experience following diagnosis.

2. Methods

An electronic database search was conducted using CINAHL, PubMed, Medline, Maternity and Infant Care and Informit. Keywords and truncations in various combinations included: gestational diabetes mellitus; experience; emotion; attitude; belief; feel; perceive; expect; mental health; psychosocial; wellbeing; lived experience; psychological; encounter; impact; and diagnosis. The inclusion criteria were:

Population: per-partum or postpartum women;
Exposure: diagnosis or history of GDM;
Outcomes: beliefs, values, perceptions, feelings, reactions, influencing factors and their impact on experiences;
Language: English;
Source: Peer reviewed or professional journals;

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3. Results

Nineteen articles were included in the review as summarised in Table 1. The resulting studies (n = 15) spanned three main approaches to qualitative research: grounded theory, ethnography and phenomenology. The remaining studies undertook either a quantitative (n = 2) or a mixed methods approach (n = 2). The majority of the studies were conducted in Sweden (n = 7), followed by Australia (n = 5), United States of America and Canada (n = 3 respectively) while one case study did not identify its setting. Primiparous and multiparous women from varied ethnic backgrounds were sampled in these studies.

Each study was reviewed in depth and three themes emerged: Responses; Focus of Concern; and Influencing Factors. Each theme encompassed core concepts synthesized in a framework (see Table 2).

3.1. Responses

This first theme relates to the emotional and psychological element of women’s experiences with GDM. Core concepts that construct this theme include: initial reaction to GDM diagnosis; negative thoughts following diagnosis; struggle to manage GDM; feelings of ‘loss of control’; changes to identity; and adapting to change.

3.1.1. Initial reaction to GDM diagnosis

Women reported feeling ‘shocked’; ‘upset’; ‘panicked’; ‘scared’; ‘numbed’; ‘depressed’; ‘fearful’; ‘terrified’; ‘disappointed’; ‘surprised’; ‘horribly sad’; ‘anxious’ and ‘worried’ when first diagnosed with GDM.6,27-30 The diagnosis was unexpected and stunned most women because they had a non-problematic pregnancy up until this time, making the reality of their condition difficult to conceive.6,27-30 Therefore, information provided at diagnosis became hard to understand, integrate and accept.6,27-30 Women expressed they felt unprepared and unable to assimilate this knowledge because everything was new and uncertain to them.6,27-30 The shock was not as great for women who had been diagnosed with GDM in previous pregnancies because they had considered this outcome when planning their pregnancy.6,27-30 Likewise, women who had experienced other complications during previous pregnancies displayed more subtle reactions to their diagnosis.6,27-30 Women were more shocked by their diagnosis if they had healthy diets and engaged in regular physical activity.6,27-30 Responses and reactions to a GDM diagnosis were also influenced by concurrent life problems faced at the time. If women were preoccupied with other troubles and issues in life, then a GDM diagnosis was considered to be just another addition to their difficult life situation.6,27-30 During the postpartum period, women who had a normal glucose tolerance test (GTT) were happy that they had not developed T2DM. However, women who had an abnormal GTT felt ‘low’, ’upset’, and ‘depressed’.6,27-30

3.1.2. Negative thoughts following diagnosis

One study found that women diagnosed with GDM expressed feelings of self-blame and guilt for not taking better care of themselves during their pregnancy. For one woman this included not quitting her stressful job earlier, while another woman revealed guilt for having a baby later in life, increasing her risks of GDM and possibly harming her child. Women repeatedly asked questions about the causes of their condition and often blamed themselves for it.6,27-30 After learning the long-term effects of GDM, women felt despair towards their future. They worried about what would happen later in life and envisioned themselves being disabled with their bodies not functioning properly and failing them, after a diagnosis of T2DM. These thoughts left women feeling depressed about their future.6,27-30

3.1.3. Struggle to manage GDM

Women described managing their GDM and following their prescribed regime as ‘challenging’; ‘hard work’; ‘a struggle’; ‘a pain’; ‘overwhelming’; ‘troublesome’; ‘absolutely dreadful’; ‘very stressful’ and ‘difficult’.6,27-30 Managing their GDM represented an enormous task that they would never be able to handle or take control of. Women conveyed the need to have significant willpower to make all the lifestyle changes required.6,27-30 It’s unclear. I never imagined that it would be this much work.6,27-30 Canadian Aboriginal women normally ate one big meal per day, and struggled to adhere to their prescribed diet of several small meals per day. These changes to the women’s normal routine caused frustration and irritation as they struggled to gain control.6,27-30 Similar feelings were experienced by women in other studies as they described the major adjustments they had to make to adhere to their prescribed diet. “I don’t snack...I have to remind myself to eat small meals. I like to eat big meals, but I can’t do that anymore”.6,27-30 One woman described the intrusiveness she experienced having to routinely monitor her blood glucose levels (BGs), “When I wake-up in the morning, I can’t just go downstairs and get something to eat. First I must get my fasting blood sugar. I can’t eat like other pregnant women.”6,27-30 Postpartum women with a history of GDM also described this similar hardship of managing and
<table>
<thead>
<tr>
<th>Author and year</th>
<th>Study design</th>
<th>Setting</th>
<th>Sample studied</th>
<th>Theme(s)</th>
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<tr>
<td>Bandypadhyay, Small, Davy, Oates, Fowler, Aptward (2011)</td>
<td>Qualitative: thematic analysis of face-to-face in-depth interviews</td>
<td>Tertiary maternity hospital, Australia</td>
<td>(9=17) 8=India 6=Bangladesh 2=Sl Lanka 1=Pakistan</td>
<td>Responses Focus of Concern</td>
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<td>Bennett, Enon, Carone, Hill-Biggs, Levine, Nicholson, Clark (2011)</td>
<td>Qualitative: thematic analysis of semi-structured interviews</td>
<td>High-risk obstetric clinical practice, United States of America</td>
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<td>Focus of Concern Influencing Factors</td>
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<td>Daniels, Gremery, Davis, Coleman, Burgess, Moore (2003)</td>
<td>Quantitative: prospective longitudinal study</td>
<td>A diabetes centre, Australia</td>
<td>(9=50) 17=Australian born 17=not Australian born</td>
<td>Responses</td>
</tr>
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<td>Dunn (2008)</td>
<td>Mixed methods: surveys supplemented by in-depth interviews</td>
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<td>(9=38)</td>
<td>Responses Focus of Concern Influencing Factors</td>
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<td>Qualitative: exploratory study: semi-structured interviews</td>
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<td>Responses Focus of Concern Influencing Factors</td>
</tr>
<tr>
<td>Nickles, Zep, Seddy, Abdul-Rahim, Rudloff, Lekeoff (2011)</td>
<td>Qualitative mixed methods: grounded theory approach and thematic analysis: focus groups and semi-structured telephone interviews</td>
<td>Women were recruited through flyers and internet postings, United States of America</td>
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<td>Persson, Widmark, Mogren (2010)</td>
<td>Qualitative: grounded theory approach: semi-structured interviews</td>
<td>Antenatal clinic, Sweden</td>
<td>(9=10) 9=Swedish origin 1=Foreign origin</td>
<td>Responses Focus of Concern Influencing Factors</td>
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</tbody>
</table>
coming to terms with change. "The risk of getting type 2 diabetes is in the back of your mind, you think about what to eat and to exercise, struggling to reduce weight. It is really that simple but also so hard".3,6

3.1.4. Feelings of ‘loss of control’

Another emergent concept was the ‘loss of control’ women experienced following GDM diagnosis. Initially, loss referred to the ‘loss of a normal pregnancy and ordinary lifestyle’, as well as loss of normality and their future health, since good health could no longer be taken for granted. Women felt lost, uncertain and vulnerable not knowing what to expect for their future and their baby’s future, adding to their perceived loss of control. Being spontaneous and light-hearted were no longer options because plans, routines and following a strict GDM management regime was now their way of life.7,10

Canadian Aboriginal women’s behaviours, insecurities and complexities surrounding food were established pre-pregnancy and made the management of their GDM overwhelming. Many of these women described feeling powerless to their emotional reactions towards food, often resulting in them seeking out ‘comfort foods’ when under stress because food was viewed as a ‘pacifier’ that could ‘alter mood and emotion’.9 These women believed that they had little control over their food choices while adhering to their treatment plan. They felt that they could not control their BGs to keep them within the normal range, ‘If I don’t eat anything, it will just go up!’.9 Another woman in this study with a history of bulimia spoke about binging while having GDM and then purging to control her BGs.

For other women, an inability to control their illness affected their self-perceptions, ‘When my insulin dosages are increased, I am more depressed, I feel worthless’;11 Women experienced a loss of personal control as their sense of personhood was undermined by the constant surveillance and scrutiny of others after their GDM diagnosis.11 Women from one study spoke about quitting their jobs or dropping out of school because they felt that it was interfering with their ability to control their GDM, as their condition was so unpredictable.11

3.1.5. Changes to identity and adapting to change

Following GDM diagnosis, women’s perception of themselves and their pregnant bodies was restructured.11 Their sense of identity changed from being that of a healthy person to being someone with GDM, with the possibility of a future diagnosis of T2DM.10,12 However, in order for women to successfully adapt to their GDM diagnosis, establish a balance in their lives and maintain a sense of normality, they had to move towards viewing themselves as actively managing and controlling their GDM, "you have an active role and you can take charge of what’s going on rather than just roll along".12 As women came to accept their condition rather than viewing it as a burden, they began to seek information and knowledge about GDM which alleviated feelings of uncertainty and vulnerability and made it easier to engage in GDM self-care.7,10 Women with experiences of GDM from previous pregnancies described that the process of adaptation became easier with each pregnancy.12 Unfortunately, those women who were unable to find their own individual balance for handling their diagnosis continued to view GDM as a daily struggle with shortcomings and increased worries.10

3.2. Focus of Concern

This second theme relates to women’s main concerns following GDM diagnosis with core concepts including concern for their baby’s health, concern for their own health, perceived seriousness of GDM and perceived fear of T2DM.

3.2.1. Concern for baby’s health

Three ethnically diverse studies reported that women were concerned about complying with the nutritional advice the dieticians gave them because they felt that restricting their diet would negatively impact the growth and well-being of their baby.7,10,14 Raeze et al. found that women were equally concerned about the effect of high sugar levels on the baby, hence found it hard to reconcile their dietary regime with the nutritional needs of the growing foetus. Additionally, some women did not follow advice to walk or exercise because they perceived these activities to put strain on the baby.14

Women with GDM were more concerned about their unborn child’s wellbeing than their own health.14 Women felt morally compelled to adhere to their recommended GDM regimes believing it was their duty to care for their child’s wellbeing was at risk.7,10 Women described their responsibility to manage their GDM because the baby was considered to be innocent in this situation and it was the mother’s obligation to protect their child.10 This responsibility and commitment intensified as women perceived it
to be their duty to endure whatever sacrifices and hardships were needed in order to manage their GDM.2,14-16 I had to do it. I have to think of not my own self but the baby. There’s no choice here.7

Canadian Aboriginal women spoke of being so concerned for their baby’s health that they drastically limited their food intake in order to control their BGLs to protect their baby, “no matter what I eat, it’ll skyrocket. So after a while, it just seemed easier just to drink [than eat].”7 One woman also described managing their GDM as stressful because of the added pressure and responsibility of their unborn baby’s health. However, after the birth of her child, she believed she did not have to agonise anymore over what she ate because she was not pregnant and I’m not going to hurt anybody inside me.”9

Since women felt obliged to not expose their unborn baby to the dangers of GDM, feelings of failure, guilt, shame and anxiety overcame women when unable to adhere to the recommended management regime, and they feared that their shortcomings would affect their baby, “well, a bit of a guilty conscience, I think. [. . .] not so much for my own sake, but for the baby.”10

The mother’s greater concern for their baby than for their own health was also seen in the postpartum period. Bennett et al17 found that the health of a newborn sometimes influenced a mother’s ability and willingness to attend GDM follow-up appointments, one woman never attending her appointment because her baby was still in the neonatal intensive care unit.

Women’s personal adjustments to their new or expanded role of caring for their infant affected their experiences of GDM postpartum. There was less time for women to practice self-care routines as they were preoccupied with dealing with the newborn’s demanding and unpredictable schedule.5,7,12 They also described this adjustment to the newborn baby as interfering with their ability to attend follow-up appointments.7

3.2.2. Mother’s concern for own health

Women with GDM were worried about their own health.12 Some women spoke about restricting future pregnancies due to feeling impaired by their experiences with GDM, “I’ve decided to not have any more children. If I have another baby, the diabetes will get worse, and it might not go away – because my need for insulin is so unstable, I fear that another pregnancy may kill me.”11

Some women believed that pregnancy caused them to struggle to adhere to strict diets used to manage their GDM. Women stated that they were always hungry and had a big appetite because of the food cravings they were experiencing during their pregnancy,12-15 “it was hard . . . when you’re pregnant you have these temptations to eat a lot.” Women also expressed that it was difficult and frustrating not being able to have their comfort foods, especially when experiencing food cravings.16,17 For other women, morning sickness was to blame for not being able to adhere to diet regimes as the smell of prescribed foods made them vomit15,18; for example, one woman expresses that “salads made me sick and I can’t drink milk.”9

Bennett et al.17 found that women who attended their GDM postpartum follow-up appointment perceived this visit as an opportunity for a final check-up, to make sure their incision from a caesarean section or episiotomy had healed, and that they were in good health to return to all pre-pregnancy activities, including going back to work. This study also found that women were motivated to attend their GDM follow-up appointment to discuss birth control options, rather than to discuss their T2DM risk.

3.2.3. Perceived seriousness of GDM

GDM was perceived as a serious condition17 with the fear of needing to inject insulin to control their condition motivating women to follow the recommended GDM management regime despite any perceived or actual inconveniences.18 This fear also made women more preoccupied with testing and maintaining good BGLs and remaining vigilant in monitoring which foods did not cause large spikes in their BGL readings.19 However, when insulin therapy did commence for some women they relaxed their diet and became less vigilant.11

Women who perceived themselves as a healthy individual who did not need to change their lifestyle usually did not attend postnatal follow-up appointments.20,21 Alternatively, women were motivated to attend postnatal care if they had concerns about GDM and valued the importance of follow-up glucose testing.22

Many women described their experience with GDM as a revelation with positive ramifications, their GDM diagnosis, and increased risk of developing T2DM in the future, enhanced their motivation to change their dietary habits and make lifestyle changes.22,23,24,25 Women would have ignored required changes if they had not encountered GDM during their pregnancy, GDM acted as a warning, raising women’s health awareness.26,27,28 Hence, women’s experiences with GDM increased their knowledge and awareness about their health and associated health risks, and acted as a catalyst for them to consider long-term personal and familial-related health changes.7

3.2.4. Perceived fear of T2DM

At one year following GDM diagnosis, T2DM risk was no longer a major concern to the women when compared to the first few weeks postpartum when it was one of their major concerns. Women had returned to their pre-pregnancy routines. One woman described having GDM as an interruption to her life that she could now put behind her and other women perceived their lifestyle, particularly by changing their diet, due to this knowledge.4 Other women vowed not to return to their old eating habits because they did not want to develop T2DM.

Studies found that some women, who were scared and worried about their risk of developing T2DM, continued to self-monitor their BGLs for the first few months postpartum.5,6 Some women found that this eased their worry.2 They just checked their BGLs for the sake of curiosity if they were feeling tired.5 Bennett et al.17 found that some women were too scared to self-monitor their BGLs after delivery because they were anxious about developing T2DM. Similarly, women’s fears of receiving a T2DM diagnosis prevented them from attending their GDM follow-up appointments, “they probably fear that . . . they’re gonna have to continue doing blood sugars, and, continue with their diets like they were during the pregnancy.”17 However, some women still attended their postpartum follow-up despite their fear of a T2DM diagnosis because they acknowledged how important it was for them to ‘be around for a long time’ for their children, so wanted to do whatever was needed to be done if they did have T2DM.17 This study also found that some women who did self-monitor their BGLs after delivery, did not attend their GDM follow-up appointments because they perceived that they were healthy and did not need this extra care since their self-monitored BGLs were within the normal range.17

3.3. Influencing Factors

This third theme relates to the social and environmental factors that influence women’s experiences with GDM.

3.3.1. Cultural roles and beliefs

Cultural expectations affected women’s experiences of GDM. One study found that Arabic speaking women’s ability to maintain a healthy diet was affected by the notions of hospitality in their culture; hence they felt obliged, out of respect, to eat whatever
their family and friends offered when they visited them. South Asian immigrant women from Australia expressed difficulty maintaining traditional diets because key elements of their normal diet were restricted according to the GDM nutritional plan they had received from their dietician. These women also had difficulty understanding the advice the dietician gave them because of unfamiliar food types and preparations not commonly used in their traditional meals. This study established that eating for two and putting on weight during pregnancy was viewed as favourable in these cultures because it suggested a growing baby. Furthermore, pregnant women from these cultures were usually encouraged to rest and limit physical exertion. Therefore professional advice these women received regarding diet and exercise conflicted with their own cultural beliefs associated with pregnancy health. This is a significant finding considering that Asian women are at an increased risk of developing GDM and in 2010 Australians born in Asian countries comprised of 9% of the population, or approximately 2 million people.

Similar conclusions were highlighted by Neufeld, as Canadian Aboriginal women’s perceptions and understandings of food during pregnancy are very different to that of the Western worldview. This difference between cultures and different views regarding pregnancy health led the Canadian Aboriginal women to experience frustration and confusion over the nutritional messages they received from health professionals. This lack of connection between the messages delivered by health professionals and the individual beliefs of women with GDM often resulted in the women rejecting the advice from their dietician and following the advice of their family and friends instead.

Raze et al. found that GDM management cannot be achieved without considering a women’s mental and emotional wellbeing. Arab speaking women in this study continually spoke of their psychological distress as negatively impacting their ability to adhere to their prescribed diet and participate in physical activity, “Sometimes I have motivation but sometimes I don’t want to do anything in the house at all just want to sit down and be quiet. It depends on someone’s psychological mood with this thing [GDM].” Their mental health was also related to their migrant experience, “And even this country affects one’s psychological health as well. Psychological condition can affect everything. If one is staying by themselves and away from their own country.”

3.3.2. Social stigma

Women often felt socially isolated due to their GDM diagnosis. They felt that very few people knew about GDM and that it was an unknown condition because the disease is “invisible.” Women highlighted that GDM caused inconveniences in social situations where the food that was being served was not always appropriate or served at a suitable time according to women’s dietary regimes. Some women would hide their condition and eat the food and hope for no negative consequences while other women chose to reveal their condition as they felt obliged to protect their unborn child, even if this meant drawing attention to their condition and lifestyle.

Canadian Aboriginal women described deceptive behaviours they participated in following their diagnosis of GDM. Instances of overeating or binging on unhealthy foods in secret were reported, as women would often, “go shop for themselves to take back home, and they go look in their bags and find some sweet stuff; they go hide in their room or in the stores to go eat it.” Women stated that these behaviours were performed in secret as they were attempting to adhere to their healthcare professional’s recommendations. However, findings from this study reflect the population of Canadian Aboriginal women, making these findings less generalisable to other populations. Nonetheless, other types of secretive and deceptive behaviours carried out by women with GDM, or a history of GDM, were described in other studies. For example, Evans and O’Brien found that, for some women, having GDM presented a negative stigma which was embarrassing and labelled them as unhealthy individuals. Hence, women took actions to keep their condition hidden from others to reduce the embarrassment and protect themselves from the adverse reactions of others. “I took my blood at Lamaze classes, and it was interesting because I wanted to hide it... I could not reveal to others that I was having an abnormal pregnancy by testing my blood. I tested my blood in a bath room stall where no one could see what I was doing.”

3.3.3. Social support

Support from family members and friends influenced women’s ability to engage in healthy lifestyle choices, as these people assisted women by decreasing the burdens associated with GDM self-care measures. For example, women with family support were able to participate in more physical activity because they had people they trusted caring for their children. Being supported allowed the women to feel in control, relaxed and cared for; however, insufficient support left women feeling vulnerable and decreased the women’s ability to maintain a healthy lifestyle. One study found that some women were given advice about diabetes by well-meaning, but uninformed friends with inaccurate information. This created additional stressors for the women by increasing their fear and anxiety levels, for example, one woman initially refused insulin because one of her friends had told her it was addictive and another woman got scared when her father told her about a man whose leg had to be amputated because of diabetes.

Women’s feelings of being controlled by family members and healthcare professionals influenced their experiences of GDM. Authority figures provided women with a sense of security; however, they enhanced the women’s feelings of uncertainty and failure. Surveillance from these figures added pressure to women to adhere to self-care measures, such as diet and exercise, in order to maintain normalised BGs. Women reported that it was usually their spouse that monitored and commented on their behaviour to ensure they adhered to the recommended regime, “He [the spouse] becomes a little like this... Are you really going to eat that? Then it rather gives you an even more guilty conscience.” The study by Evans and O’Brien also found that GDM had affected women’s relationships with others too, as they felt that their friends and other family members were scrutinising their day-to-day activities.

3.3.4. Professional support

The professional support women received also influenced their experiences of GDM. Women who were adequately supported by their health professionals felt that the availability of them making long-term lifestyle changes had improved. However, not all women had positive encounters with healthcare professionals. Some women expressed frustration in the way healthcare professionals informed them of their diagnosis. They felt that they were not reassured by their healthcare provider; that they were unsympathetic and demonstrated a lack of psychological support. Women also stated that it was frustrating and difficult to comply with the dietary regime they were given, when they had not received adequate nutritional education. Some women felt that the clinicians had made a lot of assumptions about their lifestyle choices, leaving them feeling judged, “Any meeting with them [clinicians] started with, ‘now you have to change your lifestyle,’ and I thought, you don’t know what my lifestyle is, so how do you know what is bad or what needs to change. I may already know and be changing what I need to in order to be healthy. I am not a child.” In addition, women felt chastised by their healthcare providers for not conforming to their prescribed GDM regime.
woman also expressed feelings of frustration and like she was not doing well enough, despite trying her hardest, because of negative reactions from her doctor during visits when her BGLs were high. Some women attributed busy clinics with long waiting times, and a lack of continuity of care, as negatively influencing their decision to attend CDM screening and postpartum follow-up care. Women were more inclined to attend appointments if they had developed positive relationships with the healthcare team and office staff. Furthermore, women felt a sense of abandonment by healthcare providers during the first few weeks postpartum. Women expressed the transition from close monitoring and control by the healthcare team during the pregnancy, to minimal contact after the birth, as immediate. Women felt that, because they did not have a CDM diagnosis after the delivery, the healthcare system was no longer interested in them even though they wanted additional follow-up and information on preventing T2DM. Women were advised to seek follow-up care from their primary healthcare providers, which may have contributed to the lack of continuity of care between the prenatal and postpartum periods.

3.3.5. Adequate and appropriate information

Swedish women perceived a gap between their initial diagnosis and their next appointment two weeks later, where they felt that they did not receive adequate information. They described negative feelings and reactions that arose when the midwife first informed them of their CDM diagnosis without providing information on how to manage CDM or the possible consequences of CDM. The women stated that their anxieties and concerns were not eased until their appointment two weeks later, at the specialised diabetes clinic, where they were given adequate information. Women sought to adapt to this situation by gathering information regarding the management of CDM from books and the internet. Women stated that contact with the endocrinologist during this period was appreciated and helped them relax.

Canadian Aboriginal women often misunderstood nutritional advice given about hereditary lifestyle factors throughout her ongoing care. This left the women confused and led them to develop a level of mistrust towards healthcare professionals and reject counselling messages. While these findings cannot be generalised, they highlight how easily mistrust can tarnish the therapeutic relationship if the information provided to women is not culturally or clinically appropriate. Lawson and Rajaraman reported on women's experience of having their own CDM management regimes, "I believe that doctors know absolutely nothing about nutrition, I had to learn the importance of fibre to stabilise my blood glucose levels on my own." Similarly, in the study by Doran, women had not agreed with the advice their dietitian gave them, "she was telling me to eat carbs with every meal. I knew it wouldn't control my BSL... hadn't they read the latest research about a high protein diet being more beneficial that a high carb diet?"

3.3.6. Social roles

Returning to work was another social factor influencing women's CDM experiences postpartum. Women stated that busy work schedules meant that they did not have time to prepare healthy meals for themselves and often resorted to unhealthy fast food and frozen food. Going back to work was also a barrier to exercise, "I couldn't find the time when I went back to work - [I was] discouraged by gaining weight back in..." Another woman also explains, "I was exhausted and already feeling guilty for being away from my child while I was working, so I did not exercise.

Women's roles as a mother, partner and homemaker were of the highest priority in women's lives. Carrying out domestic chores and looking after their children took precedence over their own health and made it hard for women to engage in physical activity and follow a healthy diet. Women described their dissatisfaction with childcare services, stating that they were either expensive or inaccessible. Limited access to childcare was a barrier to self-care measures, such as physical activity participation. Women also felt that prearranged child care made it easier for them to attend postpartum follow-up appointments.

3.3.7. Barriers to self-care

Barriers to care reported in the literature related to women's abilities to engage in self-care activities postpartum and included: fatigue, financial issues, poor weather, transportation issues, lack of time, household chores, availability of healthy foods, food costs, food preparation, family food preferences and the presence of unhealthy foods at home intended for other family members. Following CDM diagnosis, the unique and personal nature of women's experiences with CDM highlights the need for midwives to provide individualised care, advice and education to these women.

This review demonstrates the range of women's responses to the diagnosis of CDM. The midwife should observe the woman's initial reaction to the diagnosis and be alert for the development of negative thoughts and feelings of loss of control as these may jeopardise the CDM management regime and could lead to ongoing mental health issues. Midwives should support the woman and as she adapts to changes in identity and assist her to actively manage her CDM. The psychological impact, of the diagnosis of CDM, on women emerged as an important issue. Continuity of care may provide more psychological support for women so that they can adopt the correct mindset and attitude to help them adapt to their CDM diagnosis and overcome it.

This review revealed that a lack of information contributed to women's feelings of uncertainty and vulnerability, as they did not fully understand the impact of the diagnoses of CDM. Improved communication and provision of information between the midwife and women with CDM also has the potential to alleviate many of women's fears. Midwives should provide individually tailored and culturally appropriate information to women diagnosed with CDM, regarding dietary and exercise advice, to help women comply with their CDM regimes, effectively manage their CDM and reduce their risk of T2DM. Instead of providing general advice and care, midwives should aim to assist women in the development of a CDM management regime that fits in with the
contexts of the woman's life and is compatible with the woman's values and preferences.

Midwives need to be mindful of the individual woman's 'Focus of Concern' regarding her GDM because, this review illustrates that, women with GDM do not always feel equal priority to their own health. Alarmingly, concern for their baby's health can be used to motivate women, midwives should be aware that this concern can impact negatively. Perceptions of the seriousness of GDM and fear of T2DM should also be assessed and misconceptions corrected, through clear, simple and consistent health promotion efforts.

It is perhaps through mediating the ' Influencing Factors' where midwifery care could most profoundly impact women's experiences. This review has identified the positive effect of support from professionals and the importance of adequate and appropriate information in the successful management of GDM. Midwives are ideally placed to provide continuity of care and the flexible care arrangements required to support screening, remove barriers to self-care and enhance ongoing follow-up, in collaboration with the health care team. The transition and postpartum follow-up of women who have GDM is an area of ongoing research in relation to risk reduction for T2DM, and enhancing communication between perinatal and primary health care provision.

An important finding of this review is the stigmatization of GDM, which suggests that wider community education may be required. Targeted education should be provided to the family members of the woman with GDM, so that they can provide appropriate social support to the woman. The impact of social and cultural roles also needs to be assessed for each individual woman with GDM so that midwives can address the concerns of the individual woman by providing support, care, advice and education tailored to her needs.

5. Conclusion

In order to enhance the quality of care provided to women with GDM, midwives need to understand the experiences of women diabetes mellitus, GDM, or who have a history of GDM, as well as the experiences of individual women with GDM are unique and personal, this review has identified a framework drawn from common themes in the literature, which midwives may use to assess individual women's responses to the diagnosis of GDM, and throughout her ongoing care. The findings emphasise the requirement for more individualised and culturally appropriate midwifery care for women with GDM. Offering quality midwifery care and support to these women, in collaboration with the diabetes team, is essential in order to secure the health of both the mother and the foetus during the pregnancy and in the long-term.

References


