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Effectiveness of a customised mobile phone text messaging intervention supported by data from activity monitors for improving lifestyle factors related to the risk of type 2 diabetes among women after gestational diabetes: protocol for a multicentre randomised controlled trial (SMART MUMS with smart phones 2)

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ABSTRACT

Introduction Gestational diabetes (GDM) contributes substantially to the population burden of type 2 diabetes (T2DM), with a high long-term risk of developing T2DM. This study will assess whether a structured lifestyle modification programme for women immediately after a GDM pregnancy, delivered via customised text messages and further individualised using data from activity monitors, improves T2DM risk factors, namely weight, physical activity (PA) and diet.

Methods and analysis This multicentre randomised controlled trial will recruit 180 women with GDM attending Westmead, Campbelltown or Blacktown hospital services in Western Sydney. They will be randomised (1:1) on delivery to usual care with activity monitor (active control) or usual care plus activity monitor and customised education, motivation and support delivered via text messaging (intervention). The intervention will be customised based on breastfeeding status, and messages including their step count achievements to encourage PA. Messages on PA and healthy eating will encourage good lifestyle habits. The primary outcome of the study is healthy lifestyle composed of weight, dietary and PA outcomes, to be evaluated at 6 months. The secondary objectives include the primary objective components, body mass index, breastfeeding duration and frequency, postnatal depression, utilisation of the activity monitor, adherence to obtaining an oral glucose tolerance test post partum and the incidence of dysglycaemia at 12 months. Relative risks and their 95% CIs will be presented for the primary objective and the appropriate regression analysis, adjusting for the baseline outcome results, will be done for each outcome.

Strengths and limitations of this study

- A scientifically rigorous single-blinded randomised controlled trial.
- Uses linked modern technology targeting the education and motivation of women diagnosed with gestational diabetes to provide support and improve lifestyle risk factors, allowing the assessment of these technologies in clinical practice.
- This trial investigates the feasibility of incorporating a text messaging intervention into routine clinical care across three ethnically diverse health districts among new mothers.
- It has limited follow-up of 6–12 months that will only allow assessment of impact on surrogate near-term measures of lifestyle risk factors rather the long-term outcome of type 2 diabetes.
- Due to limited numbers is not powered to detect changes in dysglycaemia but can be used to help design larger studies and provide information on feasibility and magnitude of impact on surrogate lifestyle risk factors and an indication of the impact on dysglycaemia at 12 months.

Ethics and dissemination Ethics approval has been received from the Western Sydney Local Health District Human Research Ethics Committee (2019/ETH13240). All patients will provide written informed consent. Study results will be disseminated via the usual channels including peer-reviewed publications and presentations at national and international conferences.

Trial registration number ACTRN12620000615987; Pre-results.

INTRODUCTION

In Australia, 15%–30% of pregnant women develop gestational diabetes (GDM), and up to 40% of pregnant mothers from high-risk ethnic subgroups.[1 2] In a meta-analysis of six controlled follow-up studies with 2230 women, those with GDM had six times the risk of developing type 2 diabetes (T2DM) compared with women who did not have GDM (95% CI 4.1 to 8.8).[3] A recent systematic review and meta-analysis found that women with a history of GDM appear to have a nearly 10-fold higher risk of developing T2DM than those with a normoglycaemic pregnancy.[4] In the Western Sydney hospital catchment area, where there is a diverse multiethnic population, 45% of women with a GDM pregnancy develop impaired glucose tolerance (IGT) or T2DM over a mean follow-up of 5.5 years.[5] Women with GDM are therefore a high-risk group, with the long-term risk of developing T2DM being around 50%.[3–5]

Trials in at-risk patient populations with IGT, including women who have had past GDM, demonstrate that prevention or delay of T2DM is possible with intensive lifestyle intervention.[6 7] A meta-analysis of eight randomised controlled trials (RCTs) conducted among women who have had GDM showed that lifestyle interventions in the postpartum period suggested a reduction in T2DM incidence but failed to reach statistical significance (relative risk 0.75, 95% CI 0.55 to 1.03).[8] The largest post-pregnancy trial is the gestational diabetes' effects on Moms (GEM) study, where 2280 women with GDM were cluster randomised to receive an intensive intervention or usual care over 6 months.[9] Intervention participants were more likely to meet weight goals, retain less weight (mean difference 0.64 kgs) or have greater increases in physical activity (PA) at 6 months. No difference in the incidence of T2DM was demonstrated, but this was limited by the short duration of the study.

While there is some evidence that lifestyle interventions can reduce lifestyle risk factors, there is also evidence that this cohort naturally has less healthy eating and lower PA so has greater room for improvement. In one study of 226 women with GDM, it was shown that women with GDM often have unhealthy lifestyles with 26.5% classified as sedentary based on PA, and only 33.6% reported sufficient PA.[10]

Although the above studies suggest a benefit of lifestyle modification for the prevention of T2DM following a GDM pregnancy, they have not been translated into routine care. These lifestyle interventions all involve personal educational interactions with individuals and hence are resource intensive, high cost and not aligned with current models of healthcare delivery post partum. Lower cost, accessible interventions that can be scaled up to a population level are needed. Digital health interventions (DHI) may fill this gap due to the ease of implementation, potentially minimal cost and widespread reach,[11] but their effectiveness needs to be examined at scale in large multicentre, health service embedded clinical trials.

Studies have shown that DHI, such as text messages, can improve low density lipoprotein cholesterol (LDL-C), blood pressure, body mass index (BMI) and increase PA.[11] These interventions have been similarly effective in people with T2DM, with BMI reducing after a 6-month texting intervention programme (BMI: −0.89 kg/m^2 (95% CI −2.74 to 0.95, p<0.0001).[12] Additionally, text messaging programmes have been shown to be cost-effective[13] and easy to understand by patients.[14]

Some intervention programmes have integrated the use of activity monitors with text messaging. Jakicic *et al*[15] and Maturi *et al*[16] found evidence for an improvement in weight loss through PA using activity monitors as part of their lifestyle intervention. We recently conducted a feasibility study of 60 women with GDM, randomised to receive a 6-month postpartum intervention comprising text messaging and an activity monitor, or no intervention.[17] An adaptive step algorithm was developed using step data from the activity monitors to inform the text messaging engine, such that dynamic step targets, dependent on the participant's recent activity, could be set and relayed back to the participant by text messaging. A pool of some 150 text messages, in the domains of PA, healthy eating and parenting, with customisation for specific factors was implemented. The majority gave positive feedback on this text messaging intervention.

It is important to detect whether the T2DM persists after pregnancy, so that appropriate management occurs, particularly for women who may have another pregnancy.[18] In an Australian survey of 1372 women with GDM, only 56% reported having done their recommended postpartum glucose tolerance test (GTT).[19] Australian studies have found that neither a national mail out reminder[20] nor a stand-alone series of text reminders[21] increased the rate of attendance for the postpartum GTT. Text reminders, as part of an integrated DHI, may improve patient adherence to a 12-week postpartum T2DM reassessment with a timely GTT.

Breast feeding is not just important for the health of the offspring, but there is evidence that breast feeding improves glucose metabolism in the mother and it has been associated with reduced T2DM risk for the mother.[22 23] Assessing the influence of DHI on the duration and intensity of breast feeding is important for the long-term T2DM risk.

There is evidence of an association between postnatal depression and GDM as shown in a recent study in China.[24] There is also evidence that postnatal depression can be helped by digital interventions. Baumel *et al*[25] and Niksalehi *et al*[26] found a statistically significant reduction in Edinburgh Postnatal Depression Scale (EPDS) among women with postpartum depression using a DHI. It will be useful to assess whether the support provided by the DHI influences the development of postnatal depression.

Given the existing evidence of adverse outcomes after a GDM pregnancy, our goal is to implement a translatable

lifestyle intervention and assess its effectiveness in reducing T2DM risk among women who have given birth after a diagnosis of GDM. We will do this using simple everyday technologies and examine if the intervention reduces broader indices of dysglycaemia at 12 months. The primary aim of our study is to determine if a text messaging support programme, integrated with feedback from activity monitors, will improve the key T2DM risk factors, namely PA, healthy diet and weight management, following a GDM pregnancy. Secondary aims include the assessment of the text messaging support programme on postnatal depression, adherence to recommended postpartum GTT and breastfeeding patterns.

METHODS AND ANALYSIS

Study design

This is a multicentre randomised controlled effectiveness trial of a digital health lifestyle intervention versus active control, among 180 women diagnosed with GDM, to commence shortly after completion of the pregnancy. The three participating hospitals are Westmead, Campbelltown and Blacktown hospitals in Western Sydney. Investigator meetings will be conducted monthly to align processes and recruitment and communicate any protocol amendments. The DHI is usual care plus customised education and support delivered via text messaging linked with feedback from an activity monitor. The active control is usual care with an activity monitor, but no text messaging. The primary outcome will be assessed at 6 months with an extension to further assess secondary outcomes at 12 months (figure 1). As no harm is anticipated from this intervention, we do not require a data safety monitoring board. This trial is registered on the Australian New Zealand Clinical Trails Registry and has ethics approval with ethics approval number 2019/ETH13240.

Participant eligibility

Woman are eligible if they have GDM diagnosed for their current pregnancy based on their local GTT criteria, using either the International Association of Diabetes in Pregnancy Study Groups[27] or the 1998 Australasian Diabetes in Pregnancy Society criteria,[28] own a smart phone with internet access, are over 18 years old and have adequate English literacy to read text messages. They are excluded if they are already using a standalone activity monitor, have previously been diagnosed with diabetes or have a GTT result in the 'diabetes mellitus in pregnancy' range[29] in the first 20 weeks of pregnancy (fasting glucose ≥7.0 mmol/L or 2 hour glucose ≥11.1 mmol/L), are on medications which affect glucose metabolism which are likely to continue after pregnancy, are expecting twins or multiple pregnancy, if their baby has a significant fetal disorder likely to require high level care in first 6 months post partum (eg, major malformation, major inheritable disorder), if they are planning to spend >1 month overseas within 6 months post partum or they are unable to walk regularly due to physical limitations. Some of the exclusion criteria were incorporated because in these situations the text messaging programme would either be inappropriate or impractical to deliver.

Recruitment and setting

Participants will be recruited during pregnancy, from diabetes in pregnancy clinics at the three participating hospitals. Women will be provided an activity monitor and given instruction regarding their use. This free device is expected to be highly attractive for recruitment. Research assistants will review patient's eligibility and obtain written informed consent (see the patient consent form in the online supplemental material).

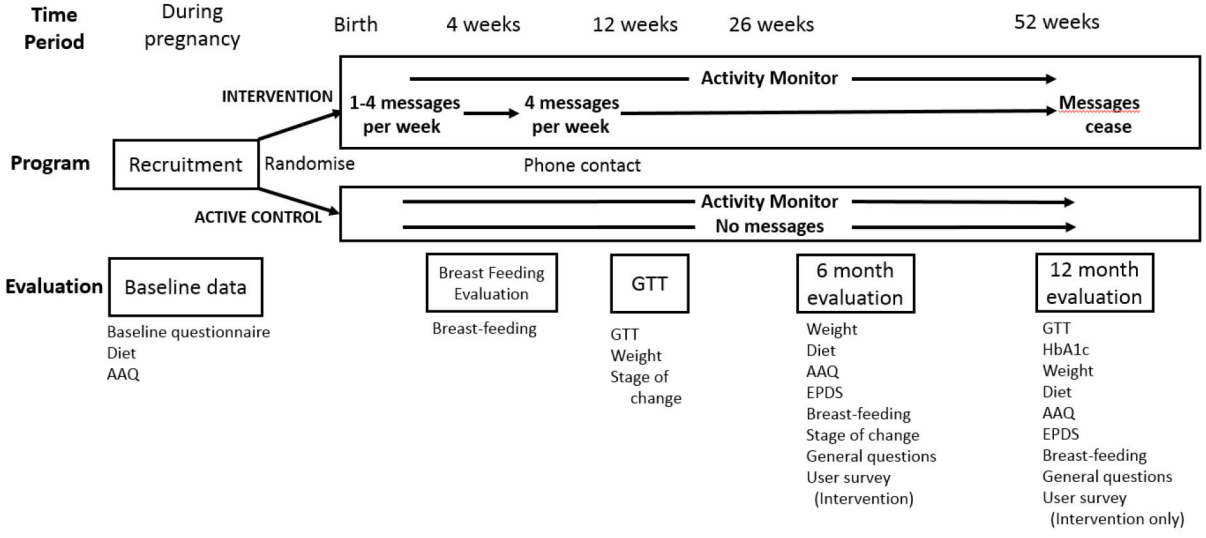

Figure 1 Study design for the SMART MUMS2 trial. AAQ, Active Australia Questionnaire; EPDS, Edinburgh Postnatal Depression Scale; GTT, glucose tolerance test; HbA1c, glycated haemoglobin test.

Intervention development

The intervention comprises a patient-centred lifestyle programme via semi-personalised and customised mobile phone text messages, facilitated by the use of an activity monitor which is integrated with the texting through the use of activity data. The text messages provide advice, motivation, information and support for disease management, monitoring of risk factors and tips and links to engage in healthy behaviours.

Message delivery will be managed by computerised mHealth software (TextQStream, Python V.3.6 using Pycap V.1.02 library), selecting messages randomly from the message banks, customised based on patient's data entered into Research Electronic Data Capture (REDCap). Participants receive messages through a telecommunications gateway at no cost to the subject.

All participants will be offered a brief training at enrolment on how to read a text message and how to delete or save messages. Both intervention and control participants will be encouraged to receive usual care for their health conditions from their regular health professionals.

Text messages

Following delivery, participants randomised to intervention will receive up to four messages a week, and this will continue until 12 months post partum. Messages will be sent at random times between 09:00 and 17:00 during weekdays. These will mostly be unidirectional, in that participants will be sent messages without expectation that they respond back or discuss their specific health issues with the study team. Where there are return messages which are of a clinical nature, the message will be escalated to a medical doctor investigator for review. Participants may request to stop the text message intervention at any time.

Content of messages

The four messages each week will be related to (1) PA, (2) healthy eating, (3) parenting, breast feeding and infant health and (4) the activity monitor. Initial messages will focus more on issues relevant to early parenting and promoting adoption of healthy lifestyle behaviour, shifting more to long-term maintenance of healthy lifestyle. The PA messages will gradually motivate the women to achieve at least 5 days of >10 000 steps/day each week, and 30 min of at least moderate-intensity activity on most days. The dietary messages will support the Australian Dietary Guidelines[30] and healthy eating to reduce weight and T2DM risk. Parenting and infant health messages will address issues such as breast feeding, weaning, infant care, sleep, allergies and mental health support. There will be two reminders to undertake the GTT prior to 12 weeks.

Message customisation

Customisation will occur at two different levels. (1) Initial customisation will be on whether the woman is breast feeding. This will be based on breastfeeding status immediately post partum, but may be modified by a change in status and (2) PA coaching will be individually customised through the activity monitor feeding data to the text messaging engine, so that the women will receive a weekly text message with adaptive step targets, encouragement and reminders based on their activity monitor data, as successfully tested in our pilot study. For the first 10 weeks post partum, the daily step target will be set at 3500. Adaptive goal setting has been successful in research using pedometers to facilitate weight loss, and demonstrated to be effective in shaping behaviour change.[31 32] Using a rank order percentile algorithm, adaptive incremental steps targets will be set weekly based on the step counts from the previous 2 weeks. The maximum target is 10 000 steps a day. Text messages will also remind women to wear or synchronise their activity monitor if needed. Emojis have been included within the text messages to modernise our digital intervention as they have been shown to help bridge cultural diversity and convey positive feedback more effectively.[33]

Active control

All active control participants will receive usual care and be given an activity monitor, but no other intervention nor messaging related to their activity monitor. They will receive a welcome message and surveys for evaluations over the 52 weeks. They will also receive the 'Life After GDM' booklet which is routinely sent to all women registered in the National Diabetes Services Scheme as having GDM by Diabetes Australia after their pregnancy.[34] This is a comprehensive 30-page guide encouraging healthy lifestyle. The Australian Breastfeeding Association also routinely offers a free phone helpline or web-based lactation advice communicated at hospital discharge to all women.

Activity monitor

All participants will receive a wrist-worn activity monitor prior to delivery. A difficulty found in the feasibility study[17] was battery life so a replacement battery set is sent to participants, to ensure continuity of data. Assistance will be provided on how to download and use the phone activity monitor application. Data from the activity monitors will be uploaded from the application and captured for customisation of messages and analysis.

Patient and public involvement

Text messages were co-designed with involvement of multidisciplinary stakeholders including consumer representatives. From participant feedback in the feasibility study,[17] we will place even greater focus on maternal support in the messages, particularly in the initial few weeks of the programme, and the dietary surveys have been dramatically simplified as they were onerous influencing completion rates.

Randomisation

Although recruitment will occur during pregnancy by the research nurse, randomisation will not occur until after

delivery. An automatically generated email will be sent to the project manager to randomise patients via the secure web-based REDCap database web application. In the event of stillbirth, or a major maternal or fetal/neonatal complication whereupon the receipt of text messages would be inappropriate, no text messages will be sent and the participant will be discontinued from the study prior to randomisation.

Randomisation will be to intervention or control on a 1:1 basis stratified by site and using permuted blocks of sizes 4 and 6. The REDCap database web application will be used for participant registration and data collection and will implement a randomisation list generated by the statistician from the randomizeR package in R.[35] The study team, statistician and research nurses are blinded to treatment allocation, with one research assistant unblinded to monitor any text message stop requests.

Study outcomes

Primary outcomes

The primary outcome of the study is a composite of weight, dietary and PA outcomes, to be evaluated at 6 months.

We have defined a 'Healthy Lifestyle Outcome' (HLO) for this study to be achieving two of the following three components:

1. Weight: Reaching pregravid weight if pregravid BMI was <25 or losing 5% of pregravid weight if pregravid BMI was ≥25.
2. PA: Whether Australian guidelines of 150 min of moderate intensity PA each week have been met using the Active Australia Questionnaire (AAQ).[36]
3. Fruit and vegetables: Whether one serve of fruit and three serves of vegetables are consumed per day, and discretionary foods (junk food, sweets, takeaway food) are consumed ≤14 times a week.

The weight criteria have been adopted from that of the GEM study.[9] Our diet criteria are less ambitious than the health guidelines[30] as local research has shown that reaching those levels is unlikely.[37] Only 5.4% of women reached five or more vegetables while 28.6% reached three or more vegetables per day. Similar results were found in our feasibility study[17] where only 1 in 60 subjects recorded more than four serves of vegetables and two serves of fruit and less than two discretionary items.

Secondary outcomes

1. Component 1 of the HLO: Weight: Reaching pregravid weight if pregravid BMI was <25 or losing 5% of pregravid weight if pregravid BMI was ≥25.
2. Component 2 of the HLO: PA: Whether Australian guidelines of 150 min of moderate intensity PA each week have been met.
3. Component 3 of the HLO: Fruit and vegetables: Whether one serve of fruit and three serves of vegetables are consumed per day, and discretionary foods are consumed ≤14 times a week.
4. BMI.
5. Weekly minutes of moderate and vigorous PA, measured by the self-completed AAQ.[36]
6. Whether Australian Dietary Guideline recommendations of consumption of ≥2 serves of fruit, ≥5 serves of vegetables and of discretionary foods ≤14 times a week have been met.
7. Duration of breast feeding measured by the breastfeeding survey.
8. Postnatal depression as assessed by the EPDS.[38]
9. Sustainability of activity monitor use.
10. Step count from the activity monitor.
11. Whether a postpartum GTT has been performed by 12 weeks as per Australian guidelines.
12. Dysglycaemia at 12 months. This is defined as the presence of any of the following:
    a. Impaired fasting glucose, diagnosed on the basis of a fasting glucose level ≥6.1 mmol/L.
    b. IGT, diagnosed on a 2-hour glucose level of 7.8–11.0 mmol/L on a 75 g oral GTT.
    c. Pre-diabetes, diagnosed by the American Diabetes Association criteria of the glycated haemoglobin test (HbA1c) 39–47 mmol/mol (5.7%–6.4%).[39]
    d. Diabetes, diagnosed by standard criteria of fasting glucose ≥7.0 mmol/L, or 2-hour glucose ≥11.1 mmol/L on a GTT, or HbA1c ≥48 mmol/mol (6.5%).

Data collection and management

Data are collected at baseline, 4 weeks post delivery, 12 weeks post delivery, 26 weeks post delivery and 52 weeks post delivery. Baseline data will include demographic information, pregnancy history, breastfeeding history, previous diagnoses including gestational diabetes history, AAQ, diet information and basic clinical information. For every time point except baseline, participants will self-report their data via a weblink which is sent to them via a text message.

Sample size

Based on our earlier study,[17] we estimate that 21% of control participants will meet the HLO at 6 months. With 180 participants we will have 80% power to detect an increase of 20% in the proportion meeting the HLO primary outcome, at a significance level of 0.05, with 10% dropout. This is the primary focus of the study, but it is also of interest to assess the outcome of dysglycaemia as a secondary objective. Grigis *et al*[5] found that 20% of Australian women with GDM had developed diabetes mellitus within 2 years and found evidence of this being higher in some ethnicities. Gupta *et al*[40] observed dysglycaemia as high as 72% within a median of 14 months among women in India. Therefore, with a highly diverse Australian population we can expect rates of 10%–40% dysglycaemia within 6 months. If we found 30% with dysglycaemia then our sample size would be sensitive enough to detect a drop to 13% with 80% power and a 10% drop out rate. It is not expected that a significant difference in the incidence of dysglycaemia will be observed as the duration is

too short and sample size too small to achieve a reduction in incidence of dysglycaemia. However, this may provide data towards the design of a larger trial in the future.

Statistical analysis

A separate statistical analysis plan will be finalised prior to data lock and unblinding. Analysis will follow the principle of intention-to-treat, with participants analysed in the arm they have been allocated. The primary analysis will be a multivariate log-binomial regression on the HLO at 6 months and the relative risk will be reported with a 95% CI. Secondary outcomes will be analysed using log-binomial regression for binary outcomes and linear regression analysis for continuous variables. Heterogeneity analyses will examine the effectiveness of the intervention in different prespecified subgroups, such as ethnicity, breast feeding and BMI.

Process evaluation

A user's survey will collect information about the acceptability and use of the text messages among intervention participants, and the use of the activity monitor by all study participants.

Trial commencement and completion

Commencement: October 2020.

Anticipated completion: July 2023

Current protocol V.5.0, May 2021.

Ethics and dissemination

Ethics approval has been received from the Western Sydney Local Health District Human Research Ethics Committee (2019/ETH13240). Protocol deviations will be reported to this ethics committee. All patients will provide written informed consent. Each study participant will be assigned a unique study identification number and their name and contact number are stored separately to their study data. Final study data will only be accessible by study investigators and the study statistician. Authorship will be considered according to the International Committee of Journal Editors guidelines. Study results will be disseminated via the usual channels including peer-reviewed publications and presentations at national and international conferences.

DISCUSSION

Healthy lifestyle programmes developed in intervention studies for women who have had GDM have been resource intensive with one-to-one consulting programmes and educational seminars and would not be easily accessible for many women at this stage of their lives. Our trial aims to use technology to establish a healthy lifestyle programme which is affordable, sustainable and potentially transferable to health services. Successful widespread implementation of the programme may have profound public health implications, and impact on maternal health and the population prevalence of T2DM. Our targeted lifestyle programme can be conducted at relatively little expense, but if T2DM can be prevented or delayed, it may result in significant reductions in morbidity and cost savings to the health system. This study is not powered to assess the effectiveness on the development of dysglycaemia but will provide an indication of the magnitude of lifestyle change from this intervention, thus enabling sample size calculations for a larger study to be undertaken.

Research has shown that similar DHI-based lifestyle programmes are effective in other patient cohorts. The Tobacco, Exercise and Diet Messages (TEXT ME) study delivered a similar text messaging programme to participants with coronary heart disease and demonstrated improvements in multiple clinical risk factor measures including LDL-C, blood pressure, BMI, PA and smoking cessation.[11] Recent publications of text messaging for people with diabetes, the Self-Management Support for Blood Glucose (SMS4BG) programme, the Cardiovascular Health and Text Messaging- Diabetes Mellitus (CHAT-DM) study and the Rapid Education/Encouragement and Communication for Health (REACH) programme have demonstrated small improvements in HbA1c of 0.3%–0.4% (3–4 mmol/mol).[41–43] There are studies showing the effectiveness of DHI interventions during pregnancy for weight management. For example, Guo *et al*'s[44] RCT showed evidence of less weight gain among those using a mobile medical application compared with control (3.2±0.8 vs 4.8±0.7, p<0.001). Our study will provide information regarding the effectiveness of DHI interventions in supporting healthy lifestyles early in the postpartum period after a GDM pregnancy. We envisage that healthier lifestyles may translate into a reduction in the incidence of dysglycaemia, however a large RCT is needed to provide evidence of prevention of progression to T2DM.

Activity monitors are readily available, popular and a natural enhancement to our texting intervention. Both control and intervention will receive these devices in our study, but in the intervention group they will complement the text messaging support. By using data from the activity monitor to inform the text messages, this may provide incentives and motivation to improve PA, and incorporation of the activity monitor into the DHI may increase the durability of activity monitor use.

The use of activity monitors also enables tracking and collection of sleep data. There is increasing evidence that various parameters of sleep including duration, fragmentation, latency, regularity and chronotype are associated with T2DM, glycaemic control and mortality.[45–48] Sleep is also related to PA[49] and diet[50] which are two pillars in lifestyle interventions in management of T2DM. Activity monitors can provide greater granularity and duration of data than has been achieved in previous studies using clinically validated actigraphy. This study allows for further investigation of these relationships and the interaction between sleep and study outcomes.

Cost-effective translatable interventions are needed to minimise the T2DM burden on the heath system. With 15%–30% of pregnant women developing GDM, and

50% of these women eventually developing T2DM, this is an identified high-risk group which can be readily targeted. Our research may provide a translatable and cost-effective DHI which forms part of a wider strategy to prevent or delay the development of T2DM among these women.

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