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Acceptability and adherence to a Mediterranean diet in the postnatal period to prevent type 2 diabetes in women with gestational diabetes in the UK: a protocol for a single-arm feasibility study (MERIT)

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ABSTRACT

Introduction Women with gestational diabetes are at increased risk of developing type 2 diabetes later in life. In at-risk general populations, Mediterranean-style diet helps prevent type 2 diabetes. But its effect on postnatal women with a history of gestational diabetes is not known. Prior to a full-scale trial on Mediterranean-style diet in the postnatal period to prevent type 2 diabetes, a feasibility study is required to assess the acceptability of the diet and evaluate the trial processes.

Methods and analysis MEditerranean diet for pReventIon of type 2 diabeTes is a single-arm feasibility study (65 women) with qualitative evaluation of women who have recently given birth and had gestational diabetes. The intervention is a Mediterranean-style diet supplemented with nuts and olive oil, with dietary advice and an action plan. A dedicated Health Coach will interact with participants through an interactive lifestyle App. Women will follow the intervention from 6 to 13 weeks post partum until 1 year post partum. The primary outcomes are rates of recruitment, follow-up, adherence and attrition. The secondary outcomes are maternal dysglycaemia, cost and quality of life outcomes, and acceptability of the intervention to participants, and to healthcare professionals delivering the intervention. Feasibility outcomes will be reported using descriptive statistics.

Ethics and dissemination Ethical approval was obtained through the South Central—Berkshire Research Ethics Committee (19/SC/0064). Study findings will be disseminated via publication in peer-reviewed journals, as well as via newsletters made available to participants and members of Katie's Team (a women's health patient and public advisory group).

Trial registration number ISRCTN40582975.

Strengths and limitations of this study

- The study is designed to provide robust information on feasibility of trial processes, preliminary information on rates of clinical outcomes, and health economic data to inform a large-scale trial.
- The study procedures, including delivery of intervention, are planned to replicate processes in a future randomised trial.
- The study design includes a detailed qualitative assessment to determine the facilitators and barriers of study procedures and intervention (including the acceptability of the Mediterranean diet) to women and healthcare professionals.
- The setting of the study in an inner city UK trust is designed to include a high proportion of minority-ethnic participants, a first for this type of intervention.
- Intervention delivery and uptake may be affected by digital literacy of participants.

INTRODUCTION

Gestational diabetes is a condition characterised by glucose intolerance first identified in pregnancy. Up to half of all women with gestational diabetes progress to type 2 diabetes in the first 5 years after delivery;[1] the risk of progression is particularly increased in women who receive pharmacological treatment in pregnancy to maintain normoglycaemia.[2]

Current UK guidelines recommend that women diagnosed with gestational diabetes are followed up after birth and offered an Oral Glucose Tolerance Test (OGTT) 6–13 weeks after birth, or HbA1c testing after 13 weeks, to exclude diabetes.[3] Women with negative test results are offered yearly HbA1c testing in primary care for detection of type 2 diabetes[3]; however, only 20% of

women engage with services and complete their HbA1c testing.[4] If these women enter a subsequent pregnancy with undiagnosed type 2 diabetes, they are at a higher risk of miscarriage, stillbirth and congenital abnormalities.[5] Furthermore, 35%–50% of women with gestational diabetes have recurrent disease in future pregnancies.[6 7]

The postnatal period offers a viable time-window to implement interventions that prevent progression to type 2 diabetes in women with gestational diabetes. The Mediterranean diet, which consists of high consumption of vegetables and fruit, olive oil and nuts, and low intake of red meat and processed foods, significantly reduces type 2 diabetes and cardiovascular adverse events in the non-pregnant high-risk population.[8] The Mediterranean diet in pregnancy reduces the risk of gestational diabetes.[9] In a cohort study of women with previous gestational diabetes, women in the highest versus lowest quartile of Mediterranean diet adherence had 40% reduced risk of type 2 diabetes.[10] However, there are no studies in the immediate postnatal period, where the interventions should be tailored to fit around women's busy lives and unpredictable schedules.[11 12]

Our aim is to evaluate the feasibility of introducing a simple, targeted dietary intervention with a Mediterranean-style diet, to prevent the progression to type 2 diabetes after childbirth in women with gestational diabetes. Prior to a large-scale definitive multicentre randomised trial, we plan to assess the feasibility of evaluating the intervention in an NHS (National Health Service) setting, and assess the acceptability of the study and interventions, in the postnatal period, to women and healthcare professionals.

Aims and objectives

Primary Objective

Our main objective is to obtain real time data to assess the feasibility of recruitment, adherence to a Mediterranean-style dietary intervention, and follow-up after childbirth for women with previous gestational diabetes.

Secondary objectives

- To explore the factors associated with acceptability of and adherence to the intervention.
- To examine reasons for participation and non-participation in the trial, trial attrition and non-adherence.
- To determine preliminary estimates on glycaemic effects to inform the definitive trial.
- To determine the level of and factors relating to adherence to the study protocol with healthcare professionals.
- To establish the support required in hospitals for staff to ensure successful recruitment and delivery of the intervention.

METHODS AND ANALYSIS

Study design

The Mediterranean diet for prevention of type 2 diabetes (MERIT) study is a multisite, single arm feasibility study to inform a larger study on the effects of a Mediterranean-style diet to prevent type 2 diabetes after gestational diabetes. A nested qualitative component will explore the views of women and healthcare professionals through interviews. This study will also explore the acceptability and use of a mobile App in delivering the intervention.

Study setting

The study is set within Barts Health NHS Trust, a large London trust with a diverse, multiethnic population (around 70% of pregnant women who deliver here are from non-white background). Women will be recruited from the joint obstetric diabetes clinic in two maternity units: Royal London Hospital and Whipps Cross Hospital. Interviewees for qualitative research will be recruited from participating women and healthcare staff involved in recruitment and intervention delivery. The MERIT study will be conducted from June 2019 to February 2021.

Participants

We plan to recruit eligible women that fulfil the criteria below when they attend the antenatal clinics. Pregnant women will be recruited over a period of 6 months. We will aim for 65 women to start the intervention, at the 6–13 weeks postnatal visit. The inclusion criteria are women: diagnosed with gestational diabetes as per the National Institute for Health and Care Excellence criteria at the time of consent and who are treated with metformin and/or insulin in pregnancy; willing to receive an intervention of a Mediterranean-style based diet up to 1 year after delivery; smartphone user, and willing and able to use an App for the intervention; able to provide written informed consent in English language; aged 16 years or over at the time of consent. The exclusion criteria are women: diagnosed with pre-existing type 1 or 2 diabetes; with body mass index ≤18.5 kg/m^2 or ≥50 kg/m^2 at booking; who are unable to follow a Mediterranean-style diet for religious or other reasons, for example, nut allergies in themselves or other living in the house (NB: vegetarian or vegan women need not be excluded, as dietary advice can be adapted); participating in another dietary interventional study at recruitment, and/or another planned interventional study during the postnatal period; with poor understanding of written and spoken English.

Screening and recruitment

Eligible participants will be identified initially and primarily by the clinical team and the local research team. Identification will involve reviewing and screening patient medical records, obstetric diabetic clinic lists, and the laboratory results of OGTTs to identify potential women who meet the inclusion criteria. Women attending the obstetric diabetes clinic will receive a patient information sheet about the study (see online supplemental file 1),

accompanied with a letter from the principal investigator informing patients that they may be approached about the trial at their hospital visit.

Pregnant women are usually seen every 2 weeks in this clinic. Participants will be recruited by trained members of the research team, including research midwives and research assistants. Eligible women will be approached in the clinic and consent (see online supplemental file 2) will be obtained at any point from diagnosis of gestational diabetes up to delivery. Ideally, however, most women will be approached in the third trimester, after 32 weeks of gestation, to avoid too much lag time between recruitment and start of the intervention. All women who are approached about the study will be entered onto a screening log. Outcome of recruitment and reasons for ineligibility or refusal will be entered onto this log, if available.

Intervention

The intervention is made up of multiple components: Mediterranean-style dietary advice provided by the health coach, supplemented with nuts and olive oil. A health coach will deliver the intervention through face-to-face interaction and through an interactive lifestyle App.[13–17] The health coach is a separate member of the research team trained to support participants to motivate them to achieve their health goals, and will also provide regular information and support regarding the Mediterranean diet. Participants will receive dietary advice on how to follow a Mediterranean-style diet (see figure 1) in two dietary education sessions, delivered one-to-one in person and electronically through the Liva App (by Liva Healthcare UK). All women will be supplied with extra virgin olive oil and sachets of nuts (walnuts, hazelnuts and almonds) at the start of the intervention (6–13 weeks postnatally) and at regular intervals throughout their participation in the study, until 1 year after delivery. Women will be advised to consume 30 g of nuts per day, 2–4 tablespoons of olive oil per day and cook their meals using olive oil.

The Liva App is a registered NHS digital library App that allows participants to interact with the coach, and vice versa, through text messaging or video messages.

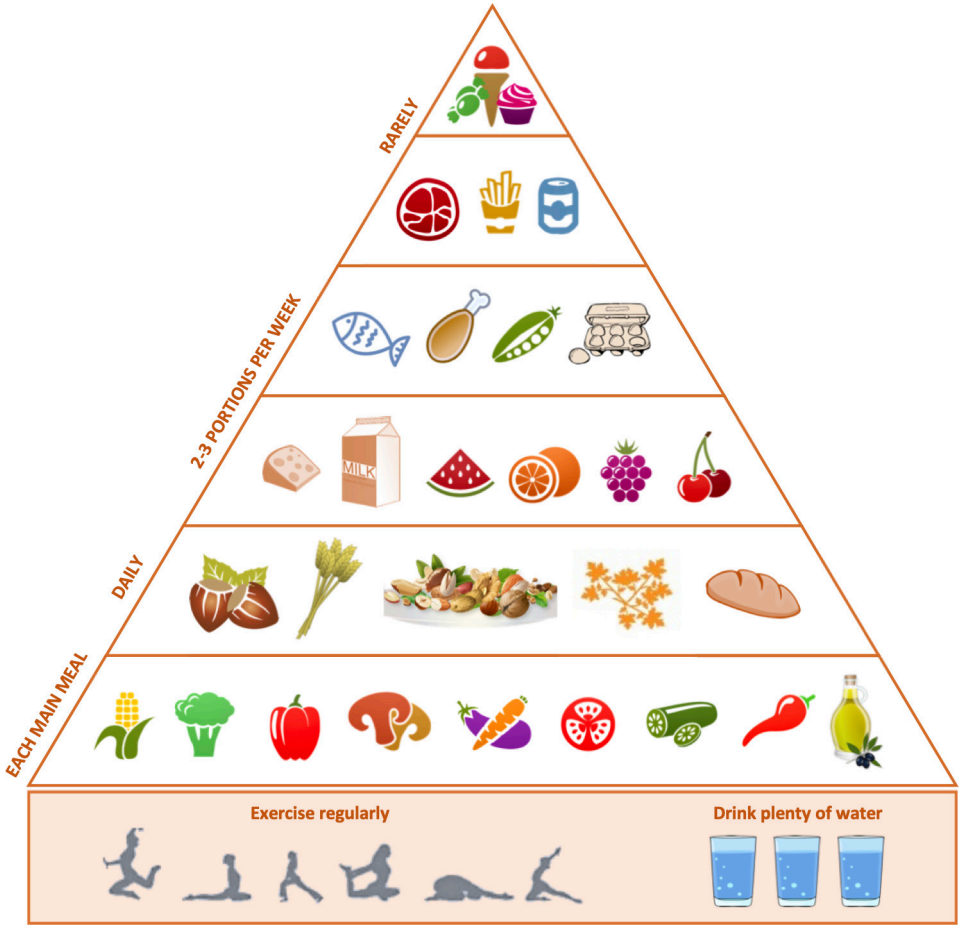

Figure 1 An infographic summarising the Mediterranean dietary advice provided.[8 31] The Mediterranean diet consists of: a high intake of vegetables, nuts, non-refined grains, legumes and fruits; a moderate to high consumption of fish; a small to moderate intake of poultry and dairy products such as yoghurt and cheese; low consumption of red meat and processed meat; an avoidance of sugary drinks, fast food and high fat food; high fibre; intake of nuts including walnuts and almonds that are rich sources of monounsaturated and polyunsaturated fatty acids (30 g/day); and olive oil to cook and dress salads as the main source of fat (0.5 L/week).

The App is centred around the setting of lifestyle goals (such as diet change, weight change and exercise) that both the participant and the coach can customise, and which participants can log adherence to on a daily basis. All women will be contacted on a regular basis (every 2–4 weeks) by the health coach, either through the App or by telephone in case of lack of response, to provide encouragement and motivation to achieve goals and adhere to the diet. The App will be used to deliver personal dietary advice and materials such as recipes and factsheets at scheduled time points (see also figure 2). The App also provides a forum where participants can share experiences with other MERIT participants; this will be facilitated by the health coach.

Outcome measures

Primary outcomes

- The proportion of screened women who are eligible for participation, the proportion of eligible women who consent to participate in the study, and the proportion of consented women who commence the intervention at 6–13 weeks.
- Rates of follow-up at 6 months and 1 year postnatal.
- The proportion of women who adhere to the intervention of a Mediterranean-style diet. Adherence will be measured as follows:
  - Proportion of women who engage with the health coach (in an intervention session, and/or through interaction with the App).
  - Proportion of women who consume nuts and olive oil as self-reported.
  - Mediterranean-style diet adherence as self-reported through the ESTEEM (effect of simple, targeted diet in pregnant women with metabolic risk factors on maternal and fetal outcomes) diet questionnaire (see online supplemental file 3).[18]

Secondary outcomes

- Proportion of women who engage with the lifestyle App, and frequency of engagement (on the App, engagement is defined as interaction for example, logging a goal or sending a message).
- Women's views relating to factors influencing their initial participation, the acceptability and adherence to the intervention, and the interaction with the App.
- Robustness of the trial processes (measured as frequency of protocol deviations, data queries, issues with nuts and oil supplies and major monitoring findings).
- Healthcare professionals' views of the acceptability of delivering the intervention and adhering with the study protocol.
- Proportion of women with normoglycaemia, and dysglycaemia (impaired fasting glucose, impaired glucose tolerance, high risk of type 2 diabetes, type 2 diabetes—see online supplemental file 4) at 6 and 12 months after delivery. Participants will undergo the 75 g OGTT and HbA1c test at 6–13 weeks post delivery and at 1 year. HbA1c levels will be measured also at 6 months postnatally. All samples will be processed by NHS laboratories.
- Weight change at 6 months and 1 year after delivery.
- Preliminary relevant cost data to inform future economic evaluation.

Participant follow-up

After starting the intervention at 6–13 weeks, participants will be followed up at 6 months and 1 year. These appointments will be scheduled in the hospital and HbA1c, maternal outcomes, breast feeding status, adverse events, EQ-5D-5L questionnaire and diet questionnaires will be collected. At the 6–13 weeks postnatal visit, the participants will receive the first dietary intervention by the health coach and they will undergo the 75 g OGTT (fasting and 2 hour). At 1 year postnatally, the participants will undergo another 75 g OGTT. Participants who do not engage with the diet or the App will nevertheless be invited for study visits to assess outcomes. For patients not attending study visits or engaging with the App, routinely collected data (eg, HbA1C at 1 year by their General Practitioner, available in clinical records) will still be recorded, unless patients have explicitly withdrawn their consent from the study. Figure 2 provides information on trial processes and procedures.

Patient and public involvement

We will engage women throughout each stage of the study as one of our success criteria. Members of our patient and public advisory group, 'Katie's Team', have been involved in many aspects of the research process: design of the research (eg, reviewing protocol and participant related documents, deciding the optimal timing for recruitment and start of the intervention, testing the App, commenting on recipes), management of the research (including participation in trial committees) and dissemination of findings (eg, at conferences and meetings). Interview schedules will be developed with patient and public involvement (PPI) collaboration.

Withdrawal criteria

Any participant has the right to withdraw their consent from the trial at any time for any reason without prejudice to their medical care and without an obligation to provide a reason for their withdrawal. It is important to note that a participant's refusal to follow Mediterranean-style diet advice or to engage in dietary intervention sessions or the App is not in itself a study withdrawal—efforts will be made to clarify whether a woman is happy to continue with scheduled study visits and data collection. Women who develop type 2 diabetes postnatally will be withdrawn from the study and receive no further olive oil and nuts supplement. They will be referred to their GP for management of type 2 diabetes.

Sample size

Recommendations for sample sizes for feasibility studies range from 12 individuals[19] per group to 50[20] or 60–100[21]

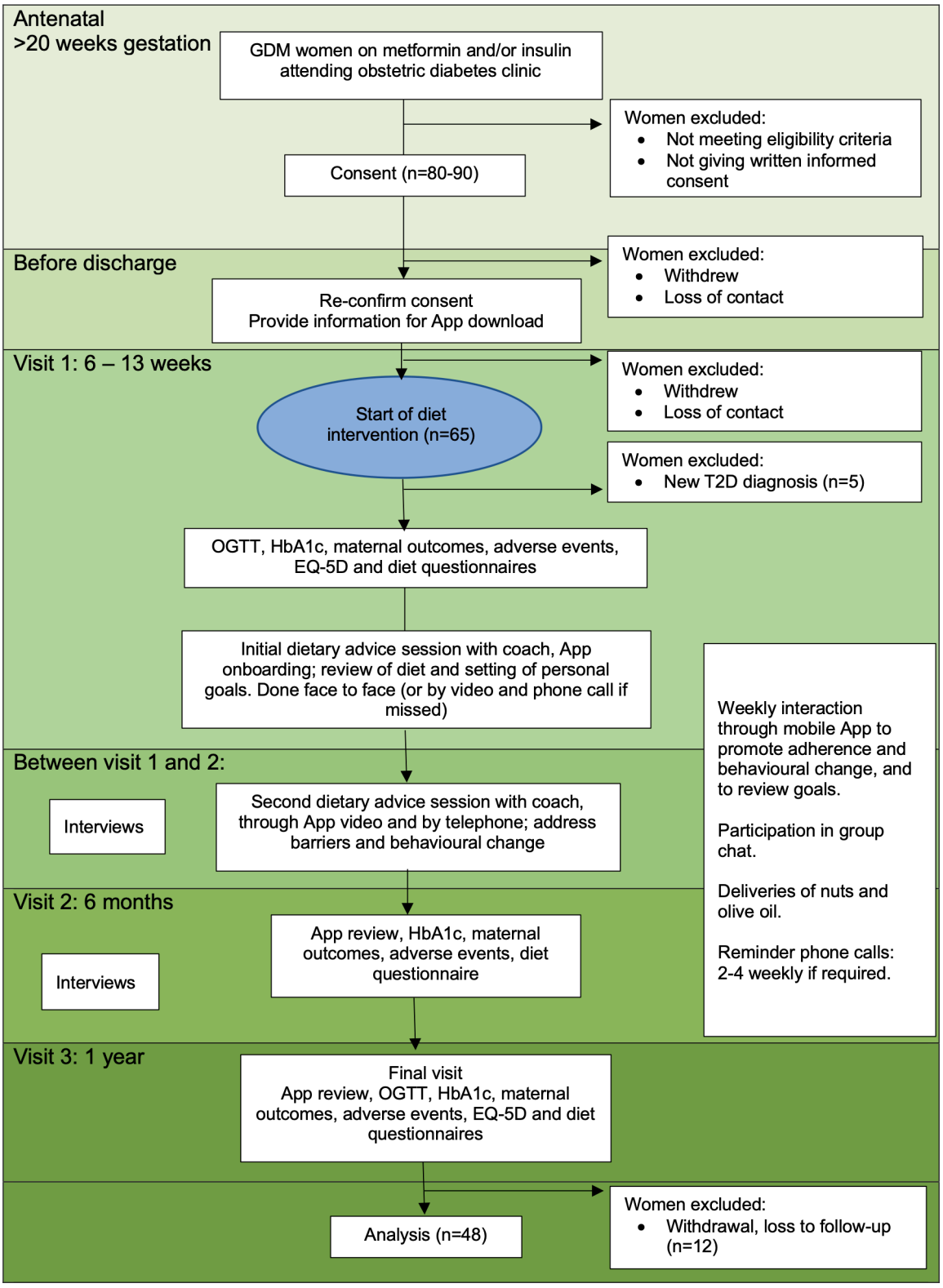

Figure 2 Study flow chart. After recruitment during pregnancy, women will start the intervention at 6–13 weeks post partum, and will then be followed up at 6 months and 1 year post partum. Women will have regular interaction with the Health Coach between study visits. OGTT (Oral Glucose Tolerance Test), GDM (Gestational Diabetes Mellitus)

per group, while others recommend aiming for between 3%[22] and 9%[23] of the sample size of the full-scale trial intended. The sample size of this single-arm study will be at least 65 women commencing the intervention, and thus in line with these recommendations for minimum sample size. This should amply meet the NIHR (National Institute for Health Research) standards in terms of precision.[24] Women who withdraw between recruitment and

starting with the intervention will be replaced, although they will be accounted for in the feasibility outcomes calculations. Assuming an attrition rate of 25% between consent and the start of the intervention, we aim to recruit about 90 women to the dietary intervention part of the study, to ensure that at least 65 will commence the intervention. We will stop recruitment once we have 65 women who commence the intervention. Of the women who progress to the intervention phase of the study, we expect about 5 to be diagnosed with type 2 diabetes, and of the remaining 60 participants, we expect 80% to remain on the study and comply with the study process (48/60).

Qualitative evaluation

Qualitative data will be collected via semistructured interviews and anonymised transcripts of the chat in-app conversations. The health coach delivering the intervention will also keep an on-going reflective diary which will be analysed by a qualitative researcher to help inform the identification of the optimal support required to ensure robust trial processes in a full-scale trial. Semistructured interviews will be conducted with around 10–15 women participating in the study (until data saturation is achieved). During the trial consent process, participants will be asked if they are willing to be contacted to take part in an additional qualitative interview. A qualitative researcher will contact women for interviews, seeking to obtain a purposive sample based on adherence data to ensure a range of experiences and insights will be captured. Interviews will be held with participants at different points of the intervention; early on at approximately 2–3 months into the intervention and then in a different subset of participant later at 5–8 months into the intervention. This is to gain insights relating to participants understanding, acceptability and adherence over the duration of the intervention after the intervention has begun. Interviews will also explore participants' views on taking part in the trial (eg, consent processes and completing questionnaires). Interview schedules will be developed with PPI collaboration. Interviews will be expected to last approximately 30–60 min and will be audio-recorded on an encrypted device written informed consent. Participants will be offered a £10 voucher for each interview, as reimbursement for their time.

We will also conduct interviews with approximately 5–10 healthcare professionals (until data saturation is achieved), who have been involved in delivering the intervention or involved in the care of women with gestational diabetes and women who develop diabetes in the postnatal period. This may include research midwives, diabetologists, obstetricians and other healthcare professionals. The interviews with healthcare professionals will explore perspectives and experiences with the delivery of the intervention in practice, and perceived barriers and facilitators to the feasibility of its application in the postnatal period. Interviews with healthcare professionals will be expected to last approximately 60 min and will be audio recorded as above.

Qualitative interview data will be transcribed and analysed through thematic analysis to examine the key themes associated with the acceptability and adherence to the intervention as well as relating to the participation and non-participation, trial attrition and non-adherence to trial protocol. All participants will also be informed that the research team will collect data from the health App relating to their general use and engagement, which will include the group chat function. Group chat transcripts will be extracted, anonymised then analysed through a content analysis to examine the strengths, challenges and barriers to adhering to the diet and the role of support networks and modelling behaviours.

Statistical analysis

Data will be analysed using descriptive statistics to inform trial feasibility and process. This is a single-arm study and hence it is not possible to assess the effect of the intervention on outcomes. Therefore, hypothesis testing is not proposed. We will summarise feasibility outcomes using estimation of proportions and 95% CI. A detailed statistical analysis plan will be presented to the Project Steering Committee (PSC) prior to locking the database for analysis. Any changes from the original statistical plan will be approved by the PSC and reported to the sponsor.

Economic evaluation

A preliminary cost analysis of the intervention 'Mediterranean-style diet' will be undertaken using established methods. We will use a short-term time horizon (the feasibility study period) that will inform the full trial. Costs will be assessed from the perspective of the NHS and personal social services. Cost components included in the analysis will be: the cost of the intervention (this will include the cost of the health coach, the visits, the Mediterranean-style diet and its administration); the cost of the application and the phone calls; the cost of routine and additional laboratory tests; cost of further investigations, clinic visits; cost of hospital admissions (length of stay); cost to treat side effects or adverse events. Resource use data will be prospectively collected at patient level using clinical records. Unit costs will be taken from standard sources. The effectiveness of the intervention will be measured in terms of changes in HbA1c levels and side effects. QALYs will be calculated based on the health-related quality of life collected during the study using EQ-5D-5L questionnaires. The QALYs (Quality-Adjusted Life-Year) experienced from baseline to end of trial will be calculated as the area underneath this profile.

Trial oversight and data management

The trial will be overseen by the Trial Management Group consisting of the lead investigators, research midwives and the project team at Barts Research Centre for Women's Health. This group will meet regularly throughout the trial to review progress and resolve issues. Central and site self-monitoring will be performed according to a study monitoring plan in accordance with the sponsor's

risk assessment. All participant data will be pseudoanonymised and stored securely. Only delegated members of the study team will enter data to the trial database. Data will be monitored centrally for consistency, viability and quality by the co-ordinating centre. The sponsor retains the right to audit the study, including any study site or central facility.

The PSC will meet twice per year and provide independent supervision for the trial, providing advice to the chief and coinvestigators and the sponsor on all aspects of the study and ensure that it is being conducted according to the protocol, good clinical practice and relevant regulations. Given the low risk of the study intervention and that it is non-blinded, no separate data safety monitoring committee will be established.

Progression criteria

Clear indicators to progress to a full-scale trial will be: a consent rate of 25% or above out of eligible women, a follow-up rate of 80% by 1 year post delivery, a minimum of 6 interactions per year with the health coach (defined as engagement through the phone or the App), and a minimum two points difference from baseline on the Mediterranean-style diet adherence (measured using the ESTEEM diet questionnaire). A consent rate of less than 10%, a follow-up rate of less than 50% by 1 year post delivery, engagement with the health coach of less than 3 times in a year, and 0 points difference from baseline in the ESTEEM diet questionnaire[18] will require full re-evaluation of the trial processes taking into account the qualitative findings prior to progression to a full-scale trial. Any results between the criteria mentioned above will require re-evaluation of the trial processes and minimal to moderate changes before the progression to a full-scale trial.

Ethics and dissemination

Ethical approval was granted by the South Central—Berkshire Research Ethics Committee (19/SC/0064, 25 January 2019). All subjects participating in the trial will provide written informed consent. Summary findings will be available via the ISRCTN (International Standard Randomised Controlled Trial Number) registry website. The findings will be disseminated to peers and experts through presentations in relevant specialty conferences and published in a peer-reviewed journal. Authorship will be assigned in compliance with International Committee of Medical Journal Editors guidelines. Newsletters will be made available to participants, healthcare professionals and members of Katie's Team to disseminate findings.

DISCUSSION

Women with gestational diabetes in pregnancy are not only at risk of type 2 diabetes later on in life but are also at risk of cardiovascular disease, weight gain and obesity.[8 25] The Mediterranean-style diet has been shown to reduce the aforementioned risks.[26] The postnatal period offers an optimal opportunity to introduce a healthier diet to women and subsequently their families. A small number of studies have investigated usefulness of the Mediterranean-style diet for diabetes prevention in the postnatal period in women with gestational diabetes in pregnancy.[10 27] These trials are not powered to detect significant differences, are based on small samples and vary in terms of intervention content.[28] The Nurses Health Study Cohort II[10] did not introduce an intervention to the participants but rather assessed the adherence to the Mediterranean-style diet by questionnaires. The study by Pérez-Ferre *et al*[27] included both an intervention based on the Mediterranean diet and a physical activity programme and participants received support as part of the follow-up visits. The participants of this study were accustomed to this type of diet.[27] Our study will aim to recruit participants from multiethnic backgrounds which represent the London NHS Trust population. In the MERIT study women will be introduced to the Mediterranean-style diet and will be supported and encouraged by a health coach to achieve their goals and change their dietary habits. Queries about the diet and support will be given on an individual basis. This will allow us to see if the personalised care that women will receive from their health coach will play a role in increasing adherence and the way they adapt to the intervention.

The intervention is underpinned by key principles from social cognitive theory (SCT), which addresses the sociostructural determinants of health as well as the personal determinants. SCT has been widely used in health promotion given the emphasis on the individual and the environment. Central in SCT is self-efficacy, a person's confidence in one's ability to successfully perform a behaviour. Self-efficacy is influenced by a person's specific capabilities and other individual factors, as well as by environmental factors (barriers and facilitators).[13] In the postnatal period, there are many barriers that can hinder the establishment of an intervention, such as the demands of caring for a newborn, lack of time and lack of support.[11 12] These demands of motherhood lead us to deliver part of the intervention remotely in order to address these barriers. Likewise, the intervention will start at 6–13 weeks postnatally, as this will allow women to adjust to living with and taking care of their newborn. A limitation of the study is that we will only interview women and no other family members, but our interview schedule will include questions regarding the reaction of their families to the new diet, and challenges to incorporating the intervention into their daily lives.

Interventions based on SCT tend to increase self-efficacy though supporting goal-setting and self-monitoring and providing rewards and prompts/cues to support behaviour change.[14] A review of health Apps highlighted that those Apps which most matched principles from SCT were more likely to lead to successful behaviour change.[14] However, most studies of healthcare Apps tend to be descriptive[15] with most Apps theory-deficient.[16] Future research is needed on the behaviour change

techniques and intervention efficacy of health Apps.[17] A qualitative study which has explored the opinion of 27 postnatal women with GDM has shown that technology could be used as an additional means for type 2 diabetes prevention, by providing extra information, enabling self-management and promoting social support.[29] As part of the MERIT study, the health coach will support women to engage with the intervention, will promote the use of the group chat function in the App and support women with setting and meeting their goals.

This is a non-randomised study as we aim to learn about the acceptability of the intervention and the intervention group is an exact replication. Prior to running a full-scale trial, a feasibility study will allow us to improve a future large-scale study by reviewing the trial processes. If the findings are positive, this will be a proof that the study can run based on the preliminary work and if the results are negative, it will mean that the study will have to change to overcome the problems faced. A recent study has shown that feasibility studies judged as not feasible saved approximately £20 million of further funding.[30]

The trial processes, clinical outcomes, health economic data and qualitative findings will be used to inform a large-scale trial. The qualitative interviews will explore the acceptability of the intervention to women, their perceived risk of type 2 diabetes, the acceptability of the App and of the material used to deliver the intervention, the influence of the support strategies on adherence and the suggestions of women and healthcare professionals on the intervention and the trial processes.

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Contributors AB: wrote the first draft and final version of the manuscript, developed the protocol and will collect and analyse the qualitative data. DL, ZD, JD, AT, JH: contributed to the methodology, will coordinate the study, reviewed the manuscript draft, and approved the final version of the manuscript. AM, AH: reviewed the manuscript draft, developed and will lead the qualitative evaluation, contributed to the methodology, and reviewed the manuscript draft. EP: developed and will conduct the economic evaluation and approved the final version of the manuscript. TP, MdCPL, FJGC: developed and will lead the statistical evaluation, contributed to methodology, and reviewed the manuscript. AS, MSBH, GH, FA: provided clinical oversight, reviewed the manuscript draft and approved final version of manuscript. ST: designed the trial and developed the protocol, reviewed the manuscript and has approved the final version.

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REFERENCES

1 Bellamy L, Casas J-P, Hingorani AD, *et al*. Type 2 diabetes mellitus after gestational diabetes: a systematic review and meta-analysis. *Lancet* 2009;373:1773–9.
2 Rayanagoudar G, Hashi AA, Zamora J, *et al*. Quantification of the type 2 diabetes risk in women with gestational diabetes: a systematic review and meta-analysis of 95,750 women. *Diabetologia* 2016;59:1403–11.
3 National Institute for Clinical Excellence. Diabetes in pregnancy; management from preconception to postnatal period. NICE guideline NG3 2015.
4 McGovern A, Butler L, Jones S, *et al*. Diabetes screening after gestational diabetes in England: a quantitative retrospective cohort study. *Br J Gen Pract* 2014;64:e17–23.
5 Hex N, Bartlett C, Wright D, *et al*. Estimating the current and future costs of type 1 and type 2 diabetes in the UK, including direct health costs and indirect societal and productivity costs. *Diabet Med* 2012;29:855–62.
6 Kim C, Berger DK, Chamany S. Recurrence of gestational diabetes mellitus: a systematic review. *Diabetes Care* 2007;30:1314–9.
7 Getahun D, Fassett MJ, Jacobsen SJ. Gestational diabetes: risk of recurrence in subsequent pregnancies. *Am J Obstet Gynecol* 2010;203:467.e1–467.e6.
8 Estruch R, Ros E, Salas-Salvadó J, *et al*. Primary prevention of cardiovascular disease with a Mediterranean diet. *N Engl J Med* 2013;368:1279–90.
9 Karamanos B, Thanopoulou A, Anastasiou E, *et al*. Relation of the Mediterranean diet with the incidence of gestational diabetes. *Eur J Clin Nutr* 2014;68:8–13.

10 Tobias DK, Hu FB, Chavarro J, *et al*. Healthful dietary patterns and type 2 diabetes mellitus risk among women with a history of gestational diabetes mellitus. *Arch Intern Med* 2012;172:1566–72.
11 Lie MLS, Hayes L, Lewis-Barned NJ, *et al*. Preventing type 2 diabetes after gestational diabetes: women's experiences and implications for diabetes prevention interventions. *Diabet Med* 2013;30:986–93.
12 Lim S, Dunbar JA, Versace VL, *et al*. Comparing a telephone- and a group-delivered diabetes prevention program: characteristics of engaged and non-engaged postpartum mothers with a history of gestational diabetes. *Diabetes Res Clin Pract* 2017;126:254–62.
13 Bandura A. Health promotion from the perspective of social cognitive theory. *Psychol Health* 1998;13:623–49.
14 Lyons EJ, Lewis ZH, Mayrsohn BG, *et al*. Behavior change techniques implemented in electronic lifestyle activity monitors: a systematic content analysis. *J Med Internet Res* 2014;16:e192.
15 Payne HE, Lister C, West JH, *et al*. Behavioral functionality of mobile apps in health interventions: a systematic review of the literature. *JMIR Mhealth Uhealth* 2015;3:e20.
16 West JH, Hall PC, Hanson CL, *et al*. There's an app for that: content analysis of paid health and fitness apps. *J Med Internet Res* 2012;14:e72.
17 Schoeppe S, Alley S, Van Lippevelde W, *et al*. Efficacy of interventions that use apps to improve diet, physical activity and sedentary behaviour: a systematic review. *Int J Behav Nutr Phys Act* 2016;13:127.
18 Al Wattar BH, Dodds J, Placzek A, *et al*. Effect of simple, targeted diet in pregnant women with metabolic risk factors on maternal and fetal outcomes (ESTEEM): study protocol for a pragmatic multicentre randomised trial. *BMJ Open* 2016;6:e013495.
19 Julious SA. Sample size of 12 per group rule of thumb for a pilot study. *Pharm Stat* 2005;4:287–91.
20 Sim J, Lewis M. The size of a pilot study for a clinical trial should be calculated in relation to considerations of precision and efficiency. *J Clin Epidemiol* 2012;65:301–8.
21 Teare MD, Dimairo M, Shephard N, *et al*. Sample size requirements to estimate key design parameters from external pilot randomised controlled trials: a simulation study. *Trials* 2014;15:264.
22 Stallard N. Optimal sample sizes for phase II clinical trials and pilot studies. *Stat Med* 2012;31:1031–42.
23 Cocks K, Torgerson DJ. Sample size calculations for pilot randomized trials: a confidence interval approach. *J Clin Epidemiol* 2013;66:197–201.
24 NIHR. Feasibility and pilot studies. Available: https://wwwnihracuk/funding-and-support/documents/funding-for-research-studies/research-programmes/PGfAR/CCF-PGfAR-Feasibility-and-Pilot-studiespdf
25 Järvelä IY, Juutinen J, Koskela P, *et al*. Gestational diabetes identifies women at risk for permanent type 1 and type 2 diabetes in fertile age: predictive role of autoantibodies. *Diabetes Care* 2006;29:607–12.
26 Sánchez E, Betriu Àngels, Salas-Salvadó J, *et al*. Mediterranean diet, physical activity and subcutaneous advanced glycation end-products' accumulation: a cross-sectional analysis in the ILERVAS project. *Eur J Nutr* 2020;59:1233–42.
27 Pérez-Ferre N, Del Valle L, Torrejón MJ, *et al*. Diabetes mellitus and abnormal glucose tolerance development after gestational diabetes: a three-year, prospective, randomized, clinical-based, Mediterranean lifestyle interventional study with parallel groups. *Clin Nutr* 2015;34:579–85.
28 D'Arcy E, Rayner J, Hodge A, *et al*. The role of diet in the prevention of diabetes among women with prior gestational diabetes: a systematic review of intervention and observational studies. *J Acad Nutr Diet* 2020;120:69–85.
29 McMillan B, Easton K, Goyder E, *et al*. Reducing risk of type 2 diabetes after gestational diabetes: a qualitative study to explore the potential of technology in primary care. *Br J Gen Pract* 2018;68:e260–7.
30 Morgan B, Hejdenberg J, Hinrichs-Krapels S, *et al*. Do feasibility studies contribute to, or avoid, waste in research? *PLoS One* 2018;13:e0195951.
31 Kris-Etherton P, Eckel RH, Howard BV, *et al*. AHA science Advisory: Lyon diet heart study. benefits of a Mediterranean-style, National cholesterol education Program/American heart association step I dietary pattern on cardiovascular disease. *Circulation* 2001;103:1823–5.