Study protocol:

Reducing the risk of Type 2 diabetes after gestational diabetes: Exploring women's views on health behaviour change interventions incorporating mobile technology.

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Part 1

Project summary

Rationale: The study aims to explore how to reduce the risk of women diagnosed with Gestational Diabetes (GD) going on to develop Type 2 Diabetes Mellitus (T2DM).

Objectives: The overall aim is to inform the design of an intervention study aimed at reducing the risk of women diagnosed with GD progressing to T2DM. Objectives subsumed within this are; 1) Postnatally, to explore the views of women diagnosed with GD regarding the antenatal health behaviour change intervention they received in secondary care, 2) To identify the barriers and facilitators to maintaining a healthy weight, engaging in regular exercise, and eating a healthy diet, 3) To ascertain women's views on how mobile technology could be used to help support the adoption and maintenance of these health behaviours, and 4) To incorporate findings into a future bid for funding for a primary care based health behaviour change intervention aimed at reducing the risk of progression from GD to T2DM.

Methods: The study will recruit 20-25 women (or until data saturation is reached) previously diagnosed with GD. These women will receive information about the study and an invitation to take part by post. Those wishing to participate will return a signed consent form with their contact details. Women will be contacted, and the time and location for a 45 minute audio recorded interview arranged. Interviews will be transcribed and analysed using Framework Analysis methodology.

Time frame: Recruitment and interviewing will run in parallel between February and May 2016. Transcription and analysis will start during this period and analysis and write up will be completed by December 2016. Dissemination of findings will continue into 2017.

Expected outcomes: Findings will inform future applications for a pilot primary care based intervention aimed at reducing the risk of women who have had GD going on to develop T2DM.

Rationale & background information

Gestational diabetes (GD) is defined as glucose intolerance with its onset during pregnancy[1]. In the UK, 4.4% of pregnant women develop GD and prevalence is increasing[2]. A diagnosis of GD doubles the risk of being diagnosed with Type 2 Diabetes Mellitus (T2DM) in the 4 months after giving birth[3], and women with gestational diabetes are 7.4 times more likely to develop T2DM than women with a normo-glycaemic pregnancy[4]. The health consequences of T2DM are well documented and include a reduction of life expectancy by 10 years on average[5]. Being born to a mother with GD increases the child's subsequent risks of developing T2DM, obesity, and cardiovascular disease[6]. Women with GD receive intensive antenatal specialist care in order to minimise risks of adverse materno-foetal outcomes, including an antenatal Behaviour Change Intervention (BCI) to promote increased activity levels and modify diet. Antenatally, NICE guidance to support women with GD is generally well adhered to in secondary care[7], however, primary care provisions post-natally are less satisfactory. For example, one national retrospective primary care cohort study in England revealed annual rates of long term follow up for GD in primary care of around 20% per year[8]. We are therefore missing a critical window of opportunity in the post-natal stage to continue the work commenced in secondary care that could reduce the risk of progression from GD to T2DM.

Although there have been a number of interventions trialled to reduce the risk of T2DM amongst women with a previous diagnosis of GD, only two full-scale RCTs have shown a significant impact on the development of T2DM, and these were intensive interventions that could not be easily delivered in primary care[9,10]. We propose that a self-management behaviour change intervention, based on current guidelines[11,12], and supported by a healthcare assistant (HCA) trained in motivational interviewing techniques[13] may provide a novel solution to providing continuing care to at-risk women post-natally. Smartphones and peripheral devices have the potential to improve public health (mHealth promotion)[14] and have shown some success in health behaviour change interventions[15]. These new technologies could shift the need for intensive, face to face interventions towards an interactive, self-directed, personalised lifestyle intervention for mothers following a diagnosis of GD.

Qualitative work examining women's experiences after a diagnosis of GD has highlighted many important issues for future BCIs with this group[16]. While women diagnosed with GD are aware of their increased risk of T2DM, they do not always act on this knowledge, and although pregnancy motivates health behaviour change, this is often not maintained post-natally. Barriers to health behaviour change include fatigue, the demands of family and childcare, and facilitators to change include weaning and provision of long term support for self-management[16]. One study noted that "women in the post-natal period require flexible, longer term approaches that accommodate their family and work commitments, and new information technologies may have potential to support this"[16] (p991) but did not go on to consider how these new information technologies could be incorporated into BCIs. The proposed study would provide further insight into how this might be achieved. Other qualitative studies have examined the experiences of those using mobile technologies to aid health behaviour change. One such study utilised focus groups to explore the views of healthy young adults towards mobile health apps and found concerns with accuracy, legitimacy, security, effort required, and immediate effects on mood[17]. Positive themes that emerged included the ability to track and record goals and behaviour, and immediate access to advice and information. While there have been a number of studies published examining the role of mHealth in diabetes management[18], only two have examined the use of mobile technology in this specific population[19,20], and both these focussed on self-monitoring of blood glucose levels.

A theoretically informed, affordable BCI that is acceptable and accessible to women from the early post-natal period, in order to enable a sustained change in diet and exercise over a minimum of 12 months (and preferably longer) is urgently needed in the UK[2]. We have not identified any studies

to date which have used novel mobile technology to both monitor lifestyle change and provide ongoing tailored feedback to women to prompt and maintain lifestyle change post-natally. Qualitative work is needed to elicit the views of those recently diagnosed with GD and ascertain how the secondary care management of GD can best be extended into primary care. This study would fill the evidence gap regarding how mHealth interventions can be applied to maximise patient engagement and improve outcomes in terms of reducing progression of GD to T2DM.

Study goals and objectives

1) In the post-natal period, to explore the recollection, understanding and views of women diagnosed with GD regarding the antenatal health behaviour change intervention they received in secondary care.
2) To elicit the barriers and facilitators in the post-natal period to physical activity and dietary modification amongst women with a previous diagnosis of GD.
3) To ascertain the views of women previously diagnosed with GD on the utility of mobile health technology in health behaviour change interventions.
4) To incorporate our findings into a future bid for funding for a primary care based health behaviour change intervention aimed at reducing the risk of progression from GD to T2DM.

Study Design

This will be a qualitative study consisting of one in depth semi-structured interview per participant. Participants will be women aged over 16 years who are fluent in English and have diagnosed with gestational diabetes in the preceding six months. Participants will be recruited between February and May 2016, and will be free to withdraw from the study at any time.

Methodology

Women with a diagnosis of GD are identified from hospital records as part of their routine antenatal care. All pregnant women with a diagnosis of GD are sent a letter inviting them to attend for a postnatal oral glucose tolerance test. Women will be recruited into the study via an information leaflet sent along with this appointment letter (Appendix A). This information leaflet explains that participation is entirely voluntary, that they are free to withdraw at any time, and that a £20 shopping voucher will be given to thank those who take part. The information leaflet also contains contact details for the chief investigator, should potential participants require any further information about the study. Those wishing to take part will be advised to complete and return a written consent form, supplying their contact details (Appendix B). With the exception of those who have suffered a miscarriage or stillbirth (who will be excluded), those returning consent forms will be contacted to arrange a suitable time and location for an interview. Interviews will be audio recorded and transcribed.

Safety Considerations

As a qualitative study involving interviews no potential adverse effects to participants are anticipated apart from the inconvenience of taking time to undertake the interviews. Although the risks of the project causing distress to any participant is small, researchers will make every effort to ensure no pressure to participate is applied to patients through the process of informed consent and explaining every participant's right to withdraw and the fact that the right to withdraw can be exercised at any point during the study without having to give reasons. The written information for patients clearly states that withdrawal from the study will in no way affect the clinical care that they receive. If participants have more to share with the researcher outside the time constraints of the interview, they will be offered an opportunity to speak with the researcher again to ensure everyone has the opportunity to contribute as they wish. If patients raise concern about their medical care, they will be directed through the normal general practice dispute resolution procedures. The researchers will at no time comment on the quality of care received by the patient, nor will they advise the patient on management of the condition.

The risks in carrying out interviews in participants own homes is minimal but appropriate precautions will be taken to ensure that other members of the research team are aware of the interviewers location.

Follow-Up

A lay summary of the findings of the research will be sent to participants in the study.

Data Management and Statistical Analysis

Interviews will be audio recorded and identified by a unique research number only. Thus when tapes are transcribed and checked the recording will be deleted. All transcribed and electronic data will be held on a password protected University computer. Identifiable forms such as consent forms will be held in the Academic Unit of Primary Medical Care under lock and key.

All data will be treated in accordance with the Data Protection Act (1998). All physical data will be stored securely in a locked filing cabinet; all electronic data will be held on a password protected computer. All data will only be accessible to members of the research team. All data will be anonymised and not attributed to any individual participant. Audiotapes will be coded with a participant code number and interview date. Where names are mentioned during the interview, these will be removed during the transcription process. Audiotapes and consent forms will be stored separately and securely. Access to the data will be restricted to Dr Brian McMillan who will be interviewing and analysing data, the research secretary who will be transcribing the interviews, Dr Katherine Easton who will carry out independent verification of themes, and Dr Caroline Mitchell who is the academic supervisor of this project.

The data generated from this study will be analysed at the Academic Unit of Primary Medical Care by McMillan, Dr Katherine Easton, and Dr Caroline Mitchell. Date will be analysed using NVivo software by systematically coding the data into categories and subcategories to identify emerging concepts and themes using Framework Analysis methodology. Independent verification of themes will be undertaken by two experienced post-doc qualitative researchers (CM, KE) to triangulate data interpretation. Initial analyses will allow modification of questions for the next interview in an iterative process. Analysis meetings will subject the identified themes to interpretive challenge, grounded within the body of existing qualitative work.

Quality Assurance

The study has been reviewed and funded by the RCGP Scientific Foundation Board.

Expected Outcomes of the Study

It is expected that the study will provide insights into the experiences of women diagnosed with GD regarding the antenatal health behaviour change intervention they received in secondary care. We also expect to elucidate perceived barriers and facilitators in the post-natal period to physical activity and maintaining a healthy BMI. The study will ascertain the views of women on the potential utility of mobile health technology in health behaviour change interventions. We expect to incorporate our findings into a future bid for funding for a primary care based health behaviour change intervention aimed at reducing the risk of progression from GD to T2DM.

Dissemination of Results and Publication Policy

In addition to disseminating our findings through publications in scientific peer-reviewed journals and at scientific conferences, we will also involve our PPI group to best ascertain how to disseminate findings to the public. This may involve the use of social media such as discussion forums, facebook groups, twitter, and e-mail.

Duration of the Project

We expect recruitment to last from February to May 2016. During this time transcription and data analysis will also be ongoing. By December we hope to have completed analysis of the data, along with verification of the themes identified. Dissemination will commence in 2017, along with preparation of grant proposals for the next stages of the research, a pilot intervention study.

Problems Anticipated

We do not anticipate any major problems with recruitment, conducting the study, or analysing the data.

Project Management

Recruitment and data collection will be completed by Dr Brian McMillan. Transcription will be completed by the project secretary (yet to be recruited). Analysis of the data will be completed by Dr Brian McMillan, Dr Caroline Mitchell, and Dr Katherine Easton, who will be aided in writing up the results by Dr Priya Madhuvrata and Dr Helen Baston.

Ethics

Ethical approval will be sought from the Clinical Research Office at Sheffield Teaching Hospitals NHS Foundation Trust.

The chief investigator has considered if his interests as a researcher will conflict his duties as a health care professional. There may be situations during the interview when he is tempted to offer medical advice to participants on issues such as weight loss, exercise, or healthy eating. If participants describe symptoms during the interview that are strongly suggestive of diabetes mellitus, his duty as a health care professional would come into play. While he will ensure the interviews are used entirely for the purpose of gathering qualitative data, participants with symptoms suggestive of diabetes will be strongly advised to see their own GP.

Informed Consent Forms

A copy of the informed consent form can be found in Appendix B.

References

1. World Health Organization. *Diagnostic Criteria and Classification of Hyperglycaemia First Detected in Pregnancy.* Geneva: WHO, 2013. http://www.who.int/diabetes/publications/Hyperglycaemia_In_Pregnancy/en/ [Accessed May 23, 2017].

2. National Institute for Health and Care Excellence. *Diabetes in pregnancy: management from preconception to the postnatal period. NG3.* London: NICE, 2015. https://www.nice.org.uk/guidance/ng3 [Accessed May 23, 2017].

3. Ratner RE. Prevention of type 2 diabetes in women with previous gestational diabetes. *Diabetes Care* 2007; **30(S2):** 242–245.

4. Bellamy L, Casas P, Hingorani AD, Williams D. Type 2 diabetes mellitus after gestational diabetes: a systematic review and meta-analysis. *Lancet* 2009;**373(9677):** 1773-1779.

5. Department of Health. National service framework for diabetes: standards. London: Department of Health, 2001. https://www.gov.uk/government/publications/national-service-framework-diabetes [Accessed May 23, 2017].

6. Dabelea D. The predisposition to obesity and diabetes in offspring of diabetic mothers. *Diabetes Care* 2007; **30(S2):** 167–174.

7. Sukumaran S, Madhuvrata P, Bustani R, *et al.* Screening, diagnosis and management of gestational diabetes mellitus: A national survey. *Obstetric Medicine* 2014; **7(3):** 111–115.

8. McGovern A, Butler L, Jones J, *et al.* Diabetes screening after gestational diabetes in England: a quantitative retrospective cohort study. *Br J Gen Pract* 2014; **64(618):** e17-e23.

9. Ratner RE, Christophi C, Metzger BE, et al. Prevention of diabetes in women with a history of gestational diabetes: effects of metformin and lifestyle interventions. J Clin Endocrinol Metab 2008; 93(12): 4774–4779.

10. Wein P, Beischer N, Harris C, Permezel M. A trial of simple versus intensified dietary modification for prevention of progression to diabetes mellitus in women with impaired glucose tolerance. Aust N Z J Obstet Gynaecol 1999; 39(2): 162–166.

11. NICE (2014). Behaviour Change: individual approaches. NICE: London.

12. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. (2008). Developing and evaluating complex interventions: the new Medical Research Council Guidance. British Medical Journal, 337, 979-983.

13. Rollnick S, Butler CC, Kinnersley P, Gregory J, Mash B. (2010). Motivational interviewing. British Medical Journal, 340, 1242-1245.

14. WHO. (2011) mHealth: New Horizons for Health through Mobile Technologies. Geneva: WHO.

15. Free C, Phillips G, Galli L, Watson L, Felix L, Edwards P, Patel V, Haines A. (2013). The Effectiveness of Mobile-Health Technology-Based Health Behaviour Change or Disease Management Interventions for Health Care Consumers: A Systematic Review, PLoS Medicine, 10, 1-45.

16. 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. *Diabetic Medicine* 2013; **30:** 986–993.

17. Dennison L, Morrison L, Conway G, Yardley L. (2013). Opportunities and Challenges for Smartphone Applications in Supporting Health Behavior Change: Qualitative Study. Journal of Medical Internet Research, 15(4), e86. doi:10.2196/jmir.2583

18. Arnold M, Quade M, Kirch W. (2014). Mobile applications for diabetics: A systematic review and expert-based usability evaluation considering the special requirements of diabetes patients age 50 years or older. Journal of International Medical Research, 16(4), e104. doi: 10.2196/jmir.2968.

19. Garnweidner-Holme LM, Borgen I, Garitano I, Noll J, Lukasse M. (2015). Designing and Developing a Mobile Smartphone Application for Women with Gestational Diabetes Mellitus Followed-Up at Diabetes Outpatient Clinics in Norway. Healthcare, 3, 310-323.

20. Mackillop L, Loerup L, Bartlett K, Farmer A, Gibson OJ, Hirst JE, Kenworthy Y, Kevat DA, Levy JC, Tarassenko L. (2014). Development of a real-time smartphone solution for the management of women with or at high risk of gestational diabetes. Journal of Diabetes Science and Technology, 8, 1105–1114.