p-GDM: A qualitative study of pregnant women's attitudes and willingness to engage with interventions to prevent gestational diabetes

Short title: p-GDm: Prevention of gestational diabetes

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Abbreviations

BMI	Body mass index
BRC	Biomedical research centre
DASH	Dietary approaches to stop hypertension
GDM	Gestational diabetes
GI	Glycaemic index
GWG	Gestational weight gain
IOM	Institute of Medicine

LGA	Large for gestational age
OGTT	Oral glucose tolerance test
PIS	Participant information sheet
RCOG	Royal College of Obstetricians and Gynaecologists
RCT	Randomised controlled trial
RR	Risk ratio
SGA	Small for gestational age
SMBG	Self-monitoring of blood glucose

BACKGROUND

Gestational diabetes (GDM) is a common pregnancy-related condition characterised by hyperglycaemia, and which increases the risk of adverse outcomes for both mother and child [1,2]. Risk factors for the development of GDM include obesity (BMI >30kg/m^2), previous diagnosis of GDM or a large baby (birth weight >4.5kg), a first-degree relative with diabetes, and belonging to a high-risk ethnic group (South Asian, Chinese, Afro-Caribbean or Middle Eastern) [3]. The global prevalence of GDM increased by 30% from 2005-2015 [4], meaning that one in seven births was affected by GDM [5]. This increase reflected not only changes in diagnostic thresholds and screening criteria, but also an increase in the proportion of women living with obesity and in those from higher-risk ethnic groups [4]. It is challenging to assess the prevalence of GDM in the UK, but past studies have reported that 6.5-16.8% of pregnant woman developed GDM [6], and the Royal College of Obstetricians and Gynaecologists (RCOG) has estimated an overall prevalence rate of 16% [7].

GDM is commonly diagnosed at 24-28 weeks gestation, and both prevention and earlier diagnosis and treatment have been suggested in order to improve outcomes [8,9]. In terms of prevention, modifiable risk factors include elevated blood glucose levels, pre-pregnancy obesity, excessive gestational weight gain, physical activity, and dietary factors including poor diet quality, low dietary fibre intake, high glycaemic index (GI) diet, and greater intake of sugar-sweetened beverages [10]. Studies designed to evaluate behavioural interventions (diet and physical activity) for GDM prevention have had disappointing results, partly explained by the fact that the interventions were introduced later in pregnancy, usually between 16-20 weeks gestation, and there is a lack of evidence for efficacy of earlier interventions [8]. The effects of early diagnosis and treatment of GDM, and the association between early pregnancy and glycaemia has been identified as a research gap [9].

Modifiable risk factors for gestational diabetes

1. **Hyperglycaemia in early pregnancy and blood glucose monitoring**

Observational and case-control studies have reported an association between glycaemic status in early pregnancy and development of GDM, with positive associations for HbA1c [11] and fasting plasma glucose [12], although only between 16-50% of women with fasting hyperglycaemia in early pregnancy go on to develop GDM [13,14]. There is a lack of randomised controlled trials (RCT) investigating the potential benefit or harm of early treatment of pregnant women with hyperglycaemia, although an underpowered RCT which was stopped early, reported that dietary and physical activity interventions started before 15 weeks gestation were not associated with neonatal benefits [15]. In addition, self-monitoring of blood glucose (SMBG) is an important component of the assessment of early hyperglycaemia, and the acceptability of SMBG in early pregnancy has not been evaluated in women at risk of GDM.

In Oxford, a remote monitoring digital application called GDm-Health has been developed to support management of GDM [16]. GDm-Health comprises a smart phone application that interfaces with a standard blood glucose meter via Bluetooth and automatically transmits blood glucose measurements to a secure web site, which is accessed and monitored by health professionals. The system allows for annotations about lifestyle behaviour and medication and has a built-in capability for communication between healthcare professionals and women with GDM via text messaging. This system is clinically reliable, highly satisfactory to women with GDM and has been shown to improve adherence with blood glucose monitoring in women with GDM [17]. This system has only been proven in women in later pregnancy with a confirmed diagnosis of gestational diabetes, and the efficacy and acceptability of this technology applied earlier in pregnancy for prevention of GDM is unknown.

2. Pre-pregnancy overweight, obesity and excessive gestational weight gain

Data from observational studies have shown that pre-pregnancy BMI is associated with GDM risk [18,19], with the prevalence of GDM reportedly increasing by 0.92% for each 1 kg/m^2 increase in BMI [19]. Maternal obesity is widely regarded as a modifiable risk factor, but intensive weight loss interventions are not recommended during pregnancy as a minimum weight gain (~5kg) is advocated to prevent fetal

undernutrition [8]. One meta-analysis reported that that weight loss during pregnancy in women with BMI >25 kg/m^2 was not associated with GDM, and that although it reduced the risk of large-for-gestational-age (LGA) babies, macrosomia and caesarean section, it also increased the risk of small-for-gestational-age babies (SGA) and low birth weight [20].

In addition, excessive gestational weight gain (GWG) increases the risk of GDM [21], but there is some controversy about early excessive GWG (0-28 weeks gestation, or before a formal diagnosis of GDM) with some observational studies suggesting no significant association with GDM or adverse pregnancy outcomes [22,23], and others confirming the relationship [24]. There are challenges for implementing weight management interventions in pregnant women living with overweight and obesity and who are at risk of GDM, including a lack of evidence for effective strategies and that there is no consensus about targets for weight gain during pregnancy, although the Institute of Medicine (IOM) has recommended targets of 7-11kg for women with BMI 25-29.9 kg/m^2 and 5-9kg for women with BMI >30 kg/m^2 [25].

3. Physical activity

Data from observational studies have consistently reported a significant association between higher levels of physical activity and reduced GDM risk [26,27]. However, intervention trials investigating the effect of physical activity for GDM prevention in pregnant women have reported conflicting results. One meta-analysis published in 2018 stated that exercise-only interventions reduced the risk of developing GDM by 38% [28], but a more recent Cochrane review concluded that the evidence was of low quality and there was unknown harm or benefit for antenatal exercise interventions on the risk of GDM: risk ratio (RR) 1.10, 95% CI 0.66 to 1.84 [29].

4. Dietary factors

Reports based on observational and prospective cohort studies suggest that total fat intake, higher intakes of red meat, refined grains and added sugars were associated with increased risk of GDM, and that a Mediterranean-style diet was protective [30]. However, many of these studies did not correct for BMI and it is challenging to draw

conclusions for the role of specific nutrients, food and dietary patterns in the development of GDM. Intervention studies have assessed the effects of carbohydrate restriction, low glycaemic index (GI) diets, Mediterranean-style diets, dietary approaches to stop hypertension (DASH) diets and total energy restriction [8], but results have been largely disappointing and the Cochrane review stated that dietary interventions were of very low quality evidence and there was unknown benefit or harm of dietary advice versus standard care on the risk of GDM: RR 0.60, 95% CI 0.35 to 1.04 [29].

Although individual dietary and physical activity intervention trials have not shown efficacy for GDM prevention, multicomponent behavioural trials including both dietary and physical activity strategies have demonstrated some effect, with an assessment from the recent Cochrane review stating they had possible benefit and that the evidence was of moderate quality: RR 0.85, 95% CI 0.71 to 1.01 [29].

Summary

Despite strong evidence from observational and case-control studies reporting the association between obesity, diet, physical activity and the risk of GDM, intervention studies in at-risk women have largely failed show an effect on the development of GDM. The quality of evidence for behavioural interventions to prevent GDM is generally low, although there is moderate evidence of benefit for interventions including both physical activity and dietary strategies [29]. In addition, a workshop that explored the effect of early diagnosis and treatment of GDM concluded that more information was needed about the association between early pregnancy glycaemia and pregnancy outcomes, and this was identified as a research gap [31]. As little is known about the effects of early intervention in at-risk women and whether this can affect prevention of GDM or improve outcomes, further high quality evidence is needed. Criticisms of published studies have identified heterogeneity as an issue, including characteristics of trial participants, GDM screening and diagnostic criteria, types and intensity of interventions and lack of engagement among trial participants [8,29]. In addition, most trials did not introduce an intervention until 16-20 week gestation. Retention of participants and adherence

have also been identified as challenges in many behavioural interventions, and this is also true of GDM prevention studies [32]. Women at risk of GDM appear reluctant to take part in interventions while pregnant and are frequently unable to adhere to specific interventions once randomised [8]. As pregnant women who volunteer for studies are often highly motivated, the translation of evidence from GDM prevention studies to the general population must be questioned.

The Oxford Biomedical Research Centre (BRC) funds a group with a particular interest in GDM, and over the past couple of years the focus has shifted from the management of diagnosed GDM to prevention of GDM. At present, one study is underway investigating the efficacy of a reduced carbohydrate diet for GDM prevention, and more studies are planned. An important aspect of research is that of patient engagement, which can be defined as the involvement of patients in the planning, conduct and dissemination of research [33]. Patient engagement in research is now widely recommended and studies have shown that involving participants in study development has the potential to improve study design and delivery, shape interventions, and increase participant recruitment, engagement and retention [34]. A systematic review reported that patient engagement increased study enrolment rates and aided researchers in securing funding, designing study protocols and choosing relevant outcomes [35]. This study was designed to engage pregnant women at risk of GDM and explore their attitudes to early interventions to prevent GDM.

Aims and objectives

The aims of this study were to assess the willingness of women at risk of GDM to:

- Engage with using GDm-Health technology to monitor blood glucose levels for the purpose of identifying hyperglycaemia before the current clinical practice of an oral glucose tolerance test (OGTT) at 24-28 weeks gestation
- Adopt behavioural strategies to reduce the risk of GDM in early pregnancy

Objectives

The secondary objectives of this study were to assess women's views about:

1. Acceptability of:

    - Being informed they are a high risk of GDM
    - Testing blood glucose levels before a formal diagnosis of GDM
    - Different interventions to reduce the risk of GDM
2. Use of technology:
    - Blood glucose meters
    - App
3. Feedback:
    - Blood glucose levels
    - Text messages

METHODS

Study design

This qualitative study used semi-structured telephone interviews to elicit the views of women at risk of GDM. Individual interviews, rather than focus groups, were selected as they allow for in-depth analysis, have a higher potential for insights, less bias and can be coded thematically and then analysed by themes.

Participants

Eligible participants included women in the first trimester of pregnancy who had been identified as at risk of GDM.

Inclusion criteria:

- Participant is willing and able to give informed consent for participation in the study.
- Female, aged 18 years or above
- First trimester of pregnancy
- At risk of GDM, assessed by one of the following:
    - Pre-pregnancy obesity (BMI>30kg/m^2) or
    - Previous diagnosis of GDM or
    - Previous large baby (birth weight >4.5kg) or
    - A first-degree relative with diabetes or
    - Belonging to a high-risk ethnic group (South Asian, Chinese, Afro-Caribbean or Middle Eastern)

Exclusion criteria

Women were excluded from the study if any of the following applied:

- Severe congenital anomaly found on ultrasound

- Planned termination
- Significant pre-pregnancy comorbidity including renal failure, severe liver disease, organ transplant, cardiac failure, psychiatric conditions requiring in-patient admission, history of eating disorder
- Diagnosed diabetes or gestational diabetes
- Hyperemesis gravidarum
- Unable to understand English

Sampling strategy and recruitment

This study utilised volunteer, convenience sampling in women attending their routine 12-week nuchal scan or specialist antenatal clinic. Women were screened by a sonographer or consultant obstetrician, and eligible women were given a participant information sheet (PIS) with details of the study. Women were given the opportunity to discuss the study with family, friends or the research team and if they wished to take part were invited to contact the researcher. Those that agreed to participate gave informed consent over the telephone and the interview took place by telephone at a mutually convenient time.

Sample size

Calculating sample sizes for qualitative studies is challenging as there are no computations or power analyses that can be performed to determine *a priori* a minimum number [36]. Experts in the field of social science recommend a range of 12-101 participants, with a mean of 30-40 [37], with some guidelines recommending 10-50 for participant generated text [38], as was the case here. Sufficient participants were required to fulfil exhaustive saturation i.e. when the researcher no longer receives new information to add to the theory that has been developed. This was achieved by completing thematic analysis after each individual interview. After discussion with an experienced qualitative researcher, a pragmatic approach based on the above information was taken and the sample size was calculated as 40 participants. If saturation was reached before 40 participants had been interviewed, recruitment was halted.

Interviews

Once women had agreed to take part in the study, they were sent a short vignette by e-mail describing the interventions that would be explored in a semi-structured interview (see Appendix 1). A topic guide with suggestions for questions and topics to be covered was written and used to guide the interview (see Appendix 2). Interviews were recorded on a digital recording device and immediately downloaded onto a computer. Once the interviews have been downloaded from the recording device, they were deleted from that device. Interviews were encrypted and sent for transcription by an experienced audio typist who had signed a confidentiality agreement. The interviews lasted between 20-35 minutes.

Data analysis

The thematic analysis was conducted according to the framework described by Braun and Clarke [39]. Thematic analysis is a method for identifying, analysing and reporting patterns within data and is usually applied using 6 clearly defined steps:

1. Familiarisation with the data (listening to the taped interviews and reading the transcripts)
2. Generating initial codes (manually highlighting data under separate headings e.g. positive/negative feelings)
3. Searching for themes (sorting all codes into themes)
4. Reviewing themes (formulating a thematic map incorporating all identified themes)
5. Defining and naming themes
6. Final analysis and report writing

Themes were identified for each topic based on the objectives of the study, and included acceptability of blood glucose testing, use of technology and acceptability of behavioural interventions. Using this approach established confirmability by means of a clear audit trail which set out each step in the analysis of data and provided a rationale for the decisions made. This provided evidence that the study's findings accurately portrayed the participants' responses, and did not reflect any personal bias or beliefs of the researcher. Credibility and transferability was established by ensuring that interviews were conducted until saturation was reached, or until 40 participants have been interviewed. Saturation ensured that an exhaustive exploration of the

various themes has taken place. The data used for analysis was based on identified themes from the original interview transcripts from the participants.

One investigator (PAD) conducted the interviews, undertook close reading of the transcripts, generated codes and clustered these into categories. These categories were then integrated into themes. Once the themes were identified they were named, defined, described and synthesised. This was followed by a process of illustrating each theme with relevant excerpts from the transcripts.

Findings

Eighteen pregnant women identified as at risk of GDM agreed to take part in the study, and although saturation was reached relatively early (after recruiting 12 women), recruitment continued to ensure that exhaustive saturation had been fully achieved. As this study was anonymous, women who took part were not asked any questions that would identify them, but the majority volunteered information about themselves. All were in the first or early second trimester of pregnancy and had been identified at their booking clinic as at risk of GDM. Eight (45%) had had previous pregnancies and the remaining ten were primigravidae. The majority were aware of their personal risk factors for GDM and they included a previous diagnosis of GDM (1 participant), living with overweight or obesity (9 participants), ethnic background (4 participants) and family history (7 participants). Five participants had two or more risk factors and only 2 participants stated that they knew little about GDM generally and were unaware of their risk factors.

Knowledge of GDM

Fifteen women (83%) were aware that GDM was diabetes that developed during pregnancy, and that it usually resolved after birth:

It's diabetes bought on by the condition of pregnancy #002

You get diabetes for the period you are carrying the baby. It will go away once the baby is born, but there is some risk to the baby if it's not managed or controlled #005

I guess it's all about getting diabetes when you're pregnant and then it sort of goes away once your baby's born #013

The remaining 3 participants stated that they did not know much about GDM, although all were aware that it was *'something you get when you're pregnant' #011*

Ten women (57%) were aware of the link between blood glucose and/or insulin and GDM:

It's bought on by pregnancy and it's similar to other diabetes, insulin and sugar levels in your blood #006

So I know that in pregnancy it's a risk, your body's not producing enough insulin whilst your pregnant with your extra needs #007

…and gestational diabetes, I think it's just like other types of diabetes so it means high sugar levels and they build up in your blood #018

Responses to being informed of risk of GDM

Women's responses to being informed that they were at high risk of GDM were variable. Eleven women (61%) stated that they weren't surprised, one as she had had GDM diagnosed in a previous pregnancy and seven (39%) as they had a family history of diabetes:

Not very surprised because my father-in-law and grandmother both had type 2 #005

Not, to be honest, completely surprised because I knew my mum had it so the risk was there #009

Four women (22%) stated that their ethnic background increased the risk of GDM, but the most frequently reported risk factor was living with overweight or obesity and this was mentioned by nine of the fourteen women (78%) living with overweight and obesity. The nine women reporting overweight or obesity as a risk factor also had a second risk factor:

Just another thing to add to the list as my pregnancies are quite high risk #006

I did kind of think that maybe my height, my weight, my age and everything else would put me at higher risk #010

However, four (22%) women did mention that they thought the issue of overweight and obesity could have been more tactfully managed by the health professionals that they came into contact with:

To be honest, I think for me and I probably think for many women, well, most women have issues with their weight and the way it was phrased was maybe not the most sensitive way #007

So, I am classified as obese in my BMI, just like, just in the bracket, which I mean isn't great to hear #012

Yes, I think they said that my weight put me in the obese level, which was upsetting because you know I've been overweight for as long as I can remember and I try to be careful about what I eat #013

Although eleven women stated that they were not surprised by being informed they were at risk of GDM, of the remaining seven one was unaware of her personal risk, and six (33%) mentioned that they were anxious or nervous:

Nervous, to be honest, my first question was what can I do to prevent that from happening? #012

I just suppose, I just feel a bit anxious about it, you know. This is my first pregnancy and I want everything to go well and I suppose this is another thing for me to worry about #013

Well, I have to say I was really worried the first time it was mentioned because I'm the kind of person who gets quite worked up about things #015

The majority of women (78%), including those that were not surprised by being told they were at risk of GDM, did express some concern about the possibility of developing GDM, and nine (50%) of them expressed their desire to change their behaviours to reduce the risk:

If it had to happen, it will happen, but hopefully none of my food consumptions would lead me to have GDM #005

….but I want to do everything the doctor recommends to avoid and also like to control if I do get the gestational diabetes #008

I was like, my instant thought was I wanna do what I can to stop this from happening #012

Five women (28%) appeared more sanguine about the risk of GDM, and appeared to accept that if they could do little to reduce the risk, but would be prepared to mange the condition once diagnosed:

I'm not really worried as I'm a scientist by profession and trust in the medical profession #002

I know all about it because I'm a doctor #004

All right, it's one of them things, it's a bit like pre-eclampsia isn't it really? #016

Summary: The majority of women (83%) were aware of GDM, and although eleven (61%) were not surprised when informed that they were at risk, fourteen women (78%) expressed their concern. The most common modifiable risk factor for GDM was overweight or obesity, with 78% of the participants stating they were living with overweight or obesity.

Blood glucose monitoring in early pregnancy

Thirteen women (72%) gave a very positive response to the idea of measuring blood glucose levels early in pregnancy (defined as from 12 weeks gestation), pointing out that it would increase their sense of control, give useful information and was important to reduce any risk to their baby:

There is the sense of not being in control, if I'm allowed to test earlier I would like to do that #005

I would be 100% up for it #012

I don't think that would be a problem for me cos I'm the kind of person who would need to know what was happening, and so that would be OK for me #015

Three women (17%) stated that they would be unwilling to monitor before a formal diagnosis of GDM, one of whom had had GDM diagnosed in a previous pregnancy. Their reasons included that they disliked needles, thought it would be painful and could be frustrating if they were unable to control any raised glucose levels:

Probably not, I'd be like, no, I don't want to do it #001

I wouldn't, I'd rather have the (OGTT) test first #003

I think it would be frustrating #004

The remaining two women expressed ambivalence about monitoring in early pregnancy:

I wouldn't necessarily be happy about it, and I'd kind of wish that I didn't have to do it, but at the same time I'd do it because I know it's important for the safety of myself and the baby #003

Well, I don't really like needles so that would be a big thing for me. I mean I really wouldn't like it and of course I'd wish I didn't have to do it. But, well, I suppose I would have to do it #013

Women were asked about any concerns that they may have had about the process of blood glucose monitoring. Although a fear of needles was mentioned by five women (28%), pain and sore fingers by four (22%), disliking the sight of blood by four (22%), and a risk of infection by one women, all women agreed that if it was necessary then they would be prepared to monitor their blood glucose levels:

I mean I would, as someone who had a bit more knowledge about it, I think I would be OK with that. But doing that four times in a day even for two days a week can make your fingers quite sore #007

I don't think it's an enjoyable experience, but I kind of feel like a risk benefit analysis is that I'd probably benefit more from the information than the slight inconvenience of doing it #012

If I'm told I need to do something and this would be something for the good of the baby, then I think I'd just get on with it. Yes, I'd definitely just get on with it even if it did hurt a bit #015

Women were asked to consider how they would feel if they continued to monitor blood glucose levels and the results remained in the normal range, and if there was no indication that they were rising over time. Under these circumstances, they were asked if they would continue to monitor or if they would discontinue. Thirteen women (72%) stated that they would continue to monitor as there was no certainty that blood glucose levels would remain stable during the entire pregnancy, and that it would be reassuring to know that levels were maintained within the normal range.

I think I'd still be very motivated because things can change in the flick of an eyelid can't they? #010

I think that I'd carry on because….you don't know when they would go up and I think I'd rather keep an eye on it cos you just don't know #014

It would make me feel better to keep testing because it would be really reassuring if the blood sugar didn't go up, you know that would mean I was OK and I didn't have gestational diabetes #015

Summary: Despite concerns about needles, blood and pain, thirteen women (72%) indicated that they would welcome the opportunity to monitor blood glucose levels from early pregnancy, and that they would continue monitoring even if levels were maintained within the normal range.

Using GDm-Heath technology

All women stated that they would have no issue using a blood glucose meter, although three mentioned that they would need to be shown how to use the technology. There was a strong positive response to using the app and no-one mentioned any issues with the data security using this system, in fact the increased use of telemedicine during the COVID pandemic was mentioned by five women (28%) as positive proof that technology was a useful and safe strategy for medical management:

Fine, absolutely brilliant! #004

I think that sounds like a really good idea, it's nice to know that someone is keeping an eye on things #014

That's alright, I have, I get quite a lot of my stuff through on text message anyway, or e-mail #016

All women welcomed the idea of feedback through this system, and were happy to receive advice and support by text, although seven (39%) mentioned that if there was any indication of an abnormal result, they would prefer a phone call rather than a text to give them the opportunity to ask questions and discuss the results fully:

I think that would be better than collecting the readings when you see the doctor or the team every two weeks or a month, someone giving you reassurance #005

I think it's a brilliant idea…..if the midwife looks at the, you know, results of the glucose monitoring and sends us a text, that I think is absolutely amazing #008

Actually that sounds really good. You know, if I'm having to test my blood then it's nice to know that someone is looking at them and then letting me know. I would be happy with a text if everything was OK, but if there was something wrong then I'd like a phone call so we could discuss it properly #013

Summary: All women gave positive responses to using GDm-Health technology in early pregnancy, including the blood glucose meter and the app and welcomed the idea of feedback, although seven women (39%) mentioned that a phone call rather than a text message would be preferable if there were any abnormal readings.

Physical activity

Women were asked about their present levels of physical activity and 4 women described their jobs as physically active (1 hairdresser, 1 nurse, 1 nursery assistant and 1 woman working with horses). These women stated that they undertook very little extra activity in their leisure time as their work was so physically demanding. Two women admitted that they had low levels of physical activity:

They are not what they should be. I know I should be doing 150 minutes moderate activity, I think with it being winter and work being very busy, not being able to do it in the daylight and I don't, I don't want to do it alone in the dark #009

I don't much. My job is office-based and so I'm sitting down all day and during COVID I was working at home so I probably haven't taken as much exercise as I should, you know with no commuting to work #015

The remaining twelve women (67%) described themselves as moderately active and stated that walking was their main form of physical activity. The majority reported that they walked for between 20-45 minutes on at least 5 days a week, with one mentioning swimming once a week and one attended Pilates once a week. Barriers to physical activity were discussed and two women mentioned that increasing physical activity during the winter, when it was cold and dark, was a factor. One woman stated that she had developed shortness of breath since becoming pregnant, one woman said she had been advised to increase her activity in early pregnancy but was prevented by morning sickness and one women said she avoided the gym because she was living with obesity and thought other users were judging her.

Some recent studies have suggested that walking after meals reduces postprandial glucose excursions in women with diagnosed GDM [40,41], and the acceptability of this intervention for women at risk of GDM was investigated. Thirteen women (72%) stated that they were already walking after two meals a day. Six women (33%)

stated that they walked after breakfast when they either went to work or took their children to school. A further six women (33%) reported that breakfast was the most challenging meal as they went straight to work by car. Five women (28%) explained that finding time to walk after lunch was also demanding as they were at work, and another five were reluctant to walk in the evening during winter as it was cold and dark:

….so I've been trying to time my walks at work after lunch, but then I don't really go for a walk after breakfast because I drive to work…..and you're like, oh, I don't wanna do that at the end of the day, you're tired and it's dark #012

After breakfast I drive straight to work, then I grab lunch when I can, you know, between appointments, so that's out really. Then the only one I could do is after dinner but then I'm tired and anyway it's dark #013

Summary: Most participants (89%) felt that they were moderately physically active, either because they had a physically demanding job, or because they walked in their leisure time. The majority preferred walking to other forms of physical activity, and were prepared to increase their physical activity by walking after meals.

Dietary intake

Women were asked about the relationship between diet and GDM. Most women were aware of the relationship between carbohydrate and blood glucose and twelve women (67%) specifically mentioned carbohydrates, with the remainder identifying sugary foods as having the most impact on blood glucose:

So like sugary things and too many carbs are the main things, but even then that's my sort of knowledge on that is quite limited to be honest #007

I imagine foods such as…..chocolate and kind of sugar based pastries and stuff would cause spikes in blood glucose #009

Obviously I found out mostly about carbs #012

Five women (28%) reported that they believed that fatty and fried foods also had a role in increasing the risk of GDM. When women were asked about any changes to their diet that they had made to reduce the risk of GDM, most reported that they had already attempted to reduce the amount of sugary foods that they ate:

…and I'm avoiding refined sugar like cakes and chocolate #006

Sweets and also some fruit, like there's some fruit that also contains glucose so that might (um) and lots of chocolates and sweets #008

Women were asked about their attitudes to reducing the amount of starchy foods that they ate, and about the type of starchy carbohydrate. Women were more likely to have made changes to the type of starchy foods, rather than the amount. Eight women (45%) mentioned that they had made changes to starchy food intake including avoiding refined carbohydrates such as white bread, white pasta, white pasta and potatoes and eating oats, porridge and wholegrain versions of bread, pasta and rice. One woman reported that she was not aware that starchy foods increased blood glucose levels and had made no change, and another had been on a course in Northampton and had been recommended a low GI diet. A second woman had obtained information about low GI diets from the internet. A number of barriers to changing the type of carbohydrate eaten were mentioned, including a preference for white bread, pasta and rice:

…our diet is quite heavy on carbohydrates because sometimes we eat the boiled white rice three times a day….maybe I could eat brown rice with vegetables and curries #008

I do use pasta, rice and potatoes as kind of staples and I tend to prefer the white. I have, like, had the brown in the past and you know, if it was necessary, would switch over, except bread #009

…which is quite devastating because I do love a good carb, and so I've been trying to kind of not limit that but be mindful of what I'm eating, so I have swapped for wholegrain bread and pasta and things #012

There appeared to be some confusion about fruit, with five women (28%) reporting that fruit was high in glucose and should be avoided:

I probably wouldn't like that (cutting down on fruit) because I am vegetarian so my diet is quite high in fruit so I probably wouldn't like that #011

Yeah, so I try to be mindful of fruit, because I know it's high in natural sugars #012

Summary: All women were aware of the effect of sugar and sugary foods on blood glucose levels, and twelve women (67%) mentioned carbohydrate. Most women had

already attempted to reduce the amount of sugar they ate, and eight women (45%) stated they had substituted wholegrain for refined carbohydrates.

Weight management

Women appeared open to discussing their weight and fourteen (78%) stated that they were living with overweight or obesity. Three women stated that their weight was in the normal range and one women did not comment on her weight status. Those women living with overweight and obesity were aware that this would increase their risk of GDM, and five women (28%) stated that before they became pregnant, they had attempted to lose weight:

My weight has kind of yo-yoed over the years, I went up to sixteen and half stone and I was down to twelve before I fell pregnant #009

I'm overweight, I know that, and that's something I was tackling prior to getting pregnant #011

I've been overweight as long as I can remember and I try to be careful about what I eat #013

The remainder appeared to be more accepting of their weight status:

So, I am classified as obese…..but it hasn't affected me too much #012

I'm definitely overweight and I thought it might stop me getting pregnant, but actually that was OK #014

Yeah, I don't know how much I weigh, but I know I'm overweight #016

Women were asked for their views on weight gain during pregnancy, and whether they would be willing to adopt any interventions to manage weight gain during pregnancy. Five women (28%) stated that they were unsure of the amount of weight they would be advised to gain during pregnancy, and did not recall any discussion about this with their healthcare team:

No I didn't get told, but I haven't really gained any I don't think #016

Seven women (38%) stated that they thought total weight gain during pregnancy should be between 6-12kg (1-2 stones):

..the total pregnancy, I think it's something like 28lbs, or something like that, with most of it coming in the second half, I believe #010

Well, I think that most women should gain about, I don't know, one and a half to two stone? But for me, probably it's less, but I'm not sure how much less #013

The remaining women either did not volunteer information about their views on weight gain (1 women), felt that their weight was within the normal range and weight gain was not an issue (2 women) or guessed either a kilogram or a pound a week (2 women).

When asked about interventions to limit weight gain in pregnancy, six women (33%) stated that they had already made some changes to their diet:

I've been trying for eighteen months, so I had already reduced my carb portions and introduced portion control, but I relaxed the carb restriction once I became pregnant #003

Yes, not as much sweet stuff and also looking at the fat content of the meals that I eat and reducing where I can the fat content. So, lean meats and white meats, that kind of thing #010

Five women (28%) pointed out that active weight loss during pregnancy may affect fetal growth and development, with one stating that she had been advised to discontinue with her weight loss plan:

Now that I'm pregnant, I've been advised not to continue losing that weight. They just said I haven't gained any weight yet and I should have, but no-one's told me how much, how to, or I haven't been told anything really #011

Summary: Fourteen women (78%) reported living with overweight or obesity and five of these had attempted weight loss before pregnancy. The majority recognised obesity was a risk factor for GDM, but reported that they had received little or no advice about targets for weight gain in pregnancy.

Conclusions

Most of the participants in this qualitative study were concerned about the risk of developing GDM, and were open to interventions in early pregnancy to reduce the risk. The majority of women reported that they felt positive about blood glucose monitoring, and the idea of using GDm-Health technology was well-received.

In terms of behavioural interventions, all but two participants stated that they were already moderately active, but were open to increasing their physical activity. The most common activity was walking. Women reported awareness of both sugar and starchy carbohydrates on blood glucose levels and were willing to reduce the amount of sugar they ate and to substitute refined carbohydrates with wholegrain versions.

Participant's responses to weight management during pregnancy were more inconsistent. Although fourteen women (78%) reported living with overweight and obesity, only nine identified this as risk factor for GDM, and four mentioned that they felt that this issue could have been handled more sensitively by the health professionals that they came into contact with. Five women reported that they had not been informed of target weight gains during pregnancy and only two mentioned that they had received advice about weight gain from a health professional, with the remainder getting information from the internet. In terms of the actions that women were willing to make to limit weight gain and reduce the risk of GDM, most had adopted a somewhat glucocentric approach by restricting sugar and sugary foods, and only one mentioned reducing portion size.

In summary, it appears that women at risk of GDM are open to early interventions in pregnancy to reduce their risk, including blood glucose monitoring, adopting GDm-Health technology, increasing activity and making some dietary changes. The issue of weight management appears more complex, and further qualitative research is required to identify specific issues and develop appropriate interventions.

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Appendix 1

p-GDm: prevention of gestational diabetes

Vignette

Please read the following carefully and we will ask your opinions about what you think once you have finished

Becky was delighted when she missed a period and found out that she was pregnant. She visited her GP and was booked in for a routine 12-week scan at the local hospital. Her scan went well, but she was upset when the midwife she saw told her that her weight meant that she was at increased risk of gestational diabetes. The midwife explained that this meant that she would have a test at about 24 weeks of pregnancy where she would have a glucose drink and some blood tests to see if she had developed gestational diabetes. If she had developed gestational diabetes, this meant that she and her baby were at risk and she would have to monitor her blood glucose levels, watch what she ate and take more physical activity. She was also told that she may need to take some medication.

Becky was scared to hear all this, but the midwife went on to explain that she was involved in a study looking to see if measuring and monitoring blood glucose levels early on in pregnancy would help women avoid developing gestational diabetes and asked Becky if she would take part. Becky agreed to join the study. First of all, the midwife downloaded a special app onto Becky's smartphone and gave her a blood glucose monitor that was connected by Bluetooth to the app. She taught Becky how to use the blood glucose monitor and the app and explained that every time she tested her blood, the results would be automatically transmitted by a secure process to a computer in the hospital, where a specialist midwife could look at them and send Becky text messages.

On her return from her appointment, Becky had to measure her blood glucose levels four times a day on two days each week. Each time she did a test, she had to open the app on her phone and then wash her hands and put a test strip into her blood glucose meter. Then she used a special pricking device, which she thought felt a bit like a bee-sting, on the side of her finger to get a drop of blood. She touched and held the edge of the test strip to the drop of blood, then waited a few seconds for the result to be shown on the front of the meter. She then disposed of the test strip and the result was automatically sent to the hospital through the app on her phone. It usually took Becky 30 seconds to do this.

Once she got the hang of blood testing, she found it relatively easy to do, although she did get a bit bored of seeing similar results each time. However, she noticed that when she did a test after breakfast, her results seemed much higher and she was concerned about that. She began to receive some text messages from the midwife giving her advice about these higher levels and they suggested that she should try taking a thirty minute walk after breakfast or eat smaller portions of carbohydrate (starchy and sugary foods) at breakfast in order to control her blood glucose levels.

Appendix 2

p-GDm: Prevention of gestational diabetes

Interview guide

Introduction

This interview guide is designed to elicit the views of women in early pregnancy who have been identified as at risk of developing gestational diabetes. There are three main topic areas:

1. Acceptability of:
    - Being informed they are a high risk of GDM
    - Testing blood glucose levels before a formal diagnosis of GDM
    - Different interventions to reduce the risk of GDM
2. Use of technology:
    - Blood glucose meters
    - App
3. Feedback:
    - Blood glucose levels
    - Text message

Topic guide

Script

Thank you so much for agreeing to take part in this interview. I'd like to talk to you today about your views on a study that we are thinking of running in women who are at risk of developing gestational diabetes.

This will help us understand more about what we might do earlier in pregnancy to prevent gestational diabetes.

The interview should take no more than 30 minutes.

I just want to let you know that everything you say is private and confidential and won't affect any of the care you receive during your pregnancy. Please feel free to tell me exactly what you think. Just to help me recall what we've discussed, I would like to record our conversation. Is this OK?

Can I start by asking if you have received and read the vignette about Becky?

I hope that story was clear - do you have any questions about what you have just read?

Can we move on to some questions about what you think of this idea of testing blood glucose levels before receiving a formal diagnosis of gestational diabetes?

Sample questions

1. You can see that this story was all about the risk of gestational diabetes and what may be done to prevent it. What does gestational diabetes mean to you?

2. How about the phrase blood glucose? What does that mean to you?

3. Could you tell me how you feel about being told that you are at high risk of gestational diabetes?

4. Thinking about the piece you have just read – can I ask you some questions about your opinions of the things that were described?

   – If you were told that you would be pricking your finger and testing your blood glucose levels four times a day on two days each week, starting tomorrow, how would you feel about doing that?

5. Becky was told that she might have to increase her physical activity to help control her blood glucose levels. What do you think about that?

   – Would you be willing to do this?

6. Becky was also told that she may have to change what she eats and reduce her portion size. How would you feel about this?

7. Now I'd like you to think about using the technology described. What do you think about using a blood glucose meter?

8. What do you think about the fact that once blood glucose has been tested, the results are automatically sent to a secure site at the hospital via an app on your phone?

9. Can we move on to thinking about the feedback that you may get from this system? What are your views on finding out about your blood glucose level before a diagnosis of gestational diabetes?

10. What do you think about receiving feedback on your blood glucose levels from a specialist midwife?