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Effect of the Pregnant+ smartphone application in women with gestational diabetes mellitus: a randomised controlled trial in Norway

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ABSTRACT

Objective To assess the effect of the Pregnant+ app on the 2-hour glucose level of the routine postpartum oral glucose tolerance test (OGTT) among women with gestational diabetes mellitus (GDM). The Pregnant+ app was designed to provide information about GDM, and promote physical activity and a healthy diet.

Design A multicentre, non-blinded randomised controlled trial.

Setting Five diabetes outpatient clinics in the Oslo region.

Participants Women ≥18 years old with a 2-hour OGTT blood glucose level ≥9 mmol/L who owned a smartphone; understood Norwegian, Urdu or Somali; and were <33 weeks pregnant. A total of 238 women were randomised; 158 women completed the OGTT post partum.

Intervention The Pregnant+ app and usual care, the control group received usual care.

Primary and secondary outcomes The primary outcome was the 2-hour blood glucose level of the routine postpartum OGTT. Secondary outcomes reported were mode of delivery, induction of labour, Apgar score, birth weight, transfer to the neonatal intensive care unit and breast feeding practice. Blood glucose levels during pregnancy, knowledge of diabetes, diet and physical activity are not reported.

Results No difference was found for the 2-hour blood glucose level of the postpartum OGTT, with 6.7 mmol/L (95% CI 6.2 to 7.1) in the intervention group and 6.0 mmol/L (95% CI 5.6 to 6.3) in the control group. The significant difference in the proportion of emergency caesarean sections between the intervention group, 10 (8.8%) and the usual care group, 27 (22.1%), disappeared when adjusted for parity. There were no differences in birth weight, breast feeding practice, obstetric complications or transfer to the intensive neonatal care unit. No adverse events were registered.

Conclusion The Pregnant+ app had no effect on 2-hour glucose level at routine postpartum OGTT. After controlling for parity, the difference in emergency caesarean section was not statistically significant.

Trial registration number NCT02588729.

Strengths and limitations of this study

- This is a large randomised controlled trial among women with gestational diabetes mellitus.
- This study included a high number of women with multiethnic backgrounds.
- Almost all of the included non-native Norwegians had a good command of Norwegian.
- Loss to follow-up restricts the value and interpretation of the findings.
- The study had insufficient power to perform subgroup analyses.

INTRODUCTION

Gestational diabetes mellitus (GDM) is glucose intolerance with initial onset or recognition during pregnancy.[1] The prevalence of women with GDM is increasing globally, ranging from 5.8% to 12.9% depending on the screening procedure and population characteristics.[2] In Norway, the prevalence of GDM was 5.1% in 2017.[3] Similar to international studies, ethnic differences in the prevalence of GDM were also found in a suburb in Oslo, with an overall prevalence of 13%, 11% in women of Western European origin and 15% in ethnic minorities.[4] Particularly women of South Asian origin have a high risk of developing GDM.[5] Other risk factors include advanced maternal age, obesity, family history of diabetes, previous GDM and polycystic ovarian syndrome.[6–8]

GDM influences health outcomes for the mother and child in the short and the long term. Women with GDM have an increased risk of caesarean section (CS) and developing type 2 diabetes mellitus (T2DM) later in life.[9–11] A child born to a mother with GDM has an increased risk of prematurity, macrosomia and T2DM in adult life.[12–14]

The successful management of GDM involves tight glycaemic control, preventing adverse health consequences for mothers and their children.[15 16] For the majority of women diagnosed with GDM, lifestyle changes may be

sufficient to obtain optimal glycaemic control.[17] However, having diabetes during pregnancy is challenging, and women need information about how to maintain a healthy lifestyle and monitor their blood glucose levels. Women with GDM should be informed about the advantages of breast feeding for both mother and child,[18–20] as breast feeding has been reported to reduce the risk of T2DM later in life.[21]

Even though pregnant women may be highly motivated to optimise their health, studies indicate difficulties to understand advice from health professionals, especially among women with immigrant backgrounds.[22 23] Mobile health may offer cost-effective and personalised tools to manage GDM.[24] In particular, smartphone applications (apps) have shown a positive impact on the self-management of T2DM.[25–28] Health information via an app may be convenient and serve as a supplement to oral information during consultation with health professionals.[29]

Thus, this study developed the Pregnant+ app for women with GDM. It contains the possibility to automatically transfer and record blood glucose levels from a glucometer to the mobile phone and provides tailored information on diet, physical activity, breast feeding and GDM.[30] The app is available in Norwegian, Urdu and Somali—nutrition advice was culturally adapted for these three language groups.

There is a limited body of research on the effect of apps in the management of GDM.[24 28] Despite GDM being more prevalent in certain ethnic groups, we did not find any studies where a high number of women with multiethnic background were included. The main aim of the present study was to investigate the effect of the Pregnant+ app on the 2-hour blood glucose level of the routine postpartum oral glucose tolerance test (OGTT) in a multiethnic population.

METHOD

Study design

We conducted a randomised controlled trial (RCT) at five diabetes outpatient clinics in the Oslo region, recruiting from October 2015 to April 2017, with final follow-up data collection in November 2017. We compared the effect of the Pregnant+ app and usual care to usual care only on the 2-hour blood glucose level of the routine postpartum OGTT.

Patient and public involvement

Pregnant women of different ethnic backgrounds with GDM were involved in a qualitative user involvement study during app development.[30] Functionality was tested by asking women to perform given tasks and speak aloud while doing so. A multidisciplinary research team developed the app and designed the study and developed the questionnaires. The questionnaires were pilot tested among women of different ethnic backgrounds. During the RCT, individual interviews with participants and healthcare providers were conducted to gain knowledge on their experiences with the intervention.[31 32]

Participants

Pregnant women with a 2-hour OGTT blood glucose level of ≥9 mmol/L who owned a smartphone; understood Norwegian, Urdu or Somali; were <33 weeks pregnant; and were a minimum of 18 years old were eligible to participate. The exclusion criteria were having diabetes type 1 or 2, twin pregnancy and lactose/gluten intolerance. In total, 774 women were assessed for eligibility and 238 participated (figure 1).

Recruitment

Health professionals at the Diabetes Outpatient Clinics identified pregnant women with GDM, checked their eligibility and gave them an information booklet about the study. Women who agreed to participate signed a consent form. Those who declined to participate were given the opportunity to offer their reasons, such as too time consuming, or no interest in the study or other reasons. Once written consent was obtained, the women filled out questionnaire 1 (Q1) on an electronic tablet (average time: 30–45 min). Health professionals completed a recruitment form for all the participating women.

Safety

Ethical approval was applied for from the Norwegian Regional Committees for Medical Health Research Ethics South East (REK, ID number: 2014/5068) but was deemed unnecessary. The Norwegian Social Science Data Services (ID number: 2014/38942) approved the study. Besides obtaining informed consent the Pregnant+ app was considered safe to use. In addition, all participants were under close medical observation and monitored for adverse events.

Randomisation and blinding

Randomisation was performed on a 1:1 basis with allocated blocks of 4. After completing Q1, a computer-based programme randomised and allocated the women to either the Pregnant+ app and usual care or usual care only. Participants and the health professionals at the diabetes outpatient clinic were not blinded to the allocation. The staff analysing the OGTT samples were blinded. Health professionals providing care during labour were most likely blinded. The statistician was blinded to the allocation of the participants until the primary outcome analysis was completed.

The intervention (the Pregnant+ app and usual care)

The intervention consisted of the Pregnant+ app in addition to usual care. Women allocated to the app could download the app at the hospital or at home. We relied on women's own capability to download and start using the app. The app was designed to support pregnant women's management of GDM by adapting a healthy diet, being physically active and receiving feedback on their blood glucose levels.[30] It contains four main icons:

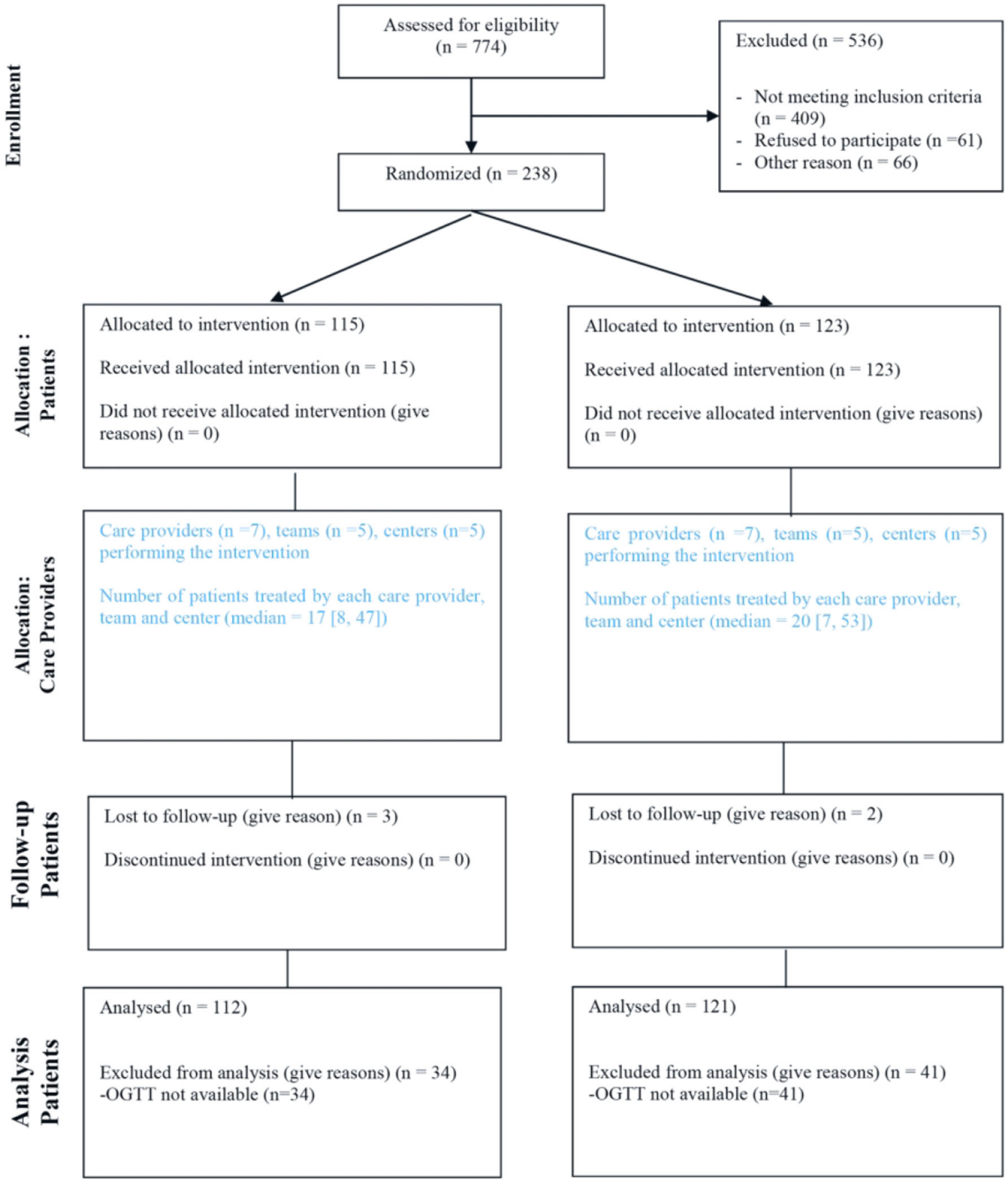

Figure 1 Modified Consolidated Standards of Reporting Trials (CONSORT) flow diagram for individual randomised controlled trials of non-pharmacological treatments. max, maximum; min, minimum; OGTT, oral glucose tolerance test.

'Blood glucose', 'Physical activity', 'Food and beverages' and 'Diabetes information' (figure 2).

Choosing the blood glucose icon, women had their real-time glucose values appear, visualised in a table or a graph. A green smiley face indicated a normal value and a red smiley face indicated a high level. The blood glucose values from the glucometer were either recorded manually or transferred automatically via the Bluetooth Low Energy function. Women could print out their blood glucose values to facilitate communication with their health professionals.

The icon 'Physical activity' gave women written examples, illustrated by images, of how to perform some of activities such as swimming, stretching and strength training adapted for pregnant women. Moreover, women had the opportunity to write down personal goals and read about the advantages of being physically active during pregnancy.

The icon 'Food and beverages' gave culturally adapted information about a healthy diet and recommendations for healthy drinks (figure 3). Women could select one of three different food cultures identified by language: Norwegian, Urdu or Somali. In addition to the culturally adapted food items illustrated in the app by images, a link to the Norwegian Diabetes Foundation was provided. This link gave the women access to recipes and suitable information when pregnant.

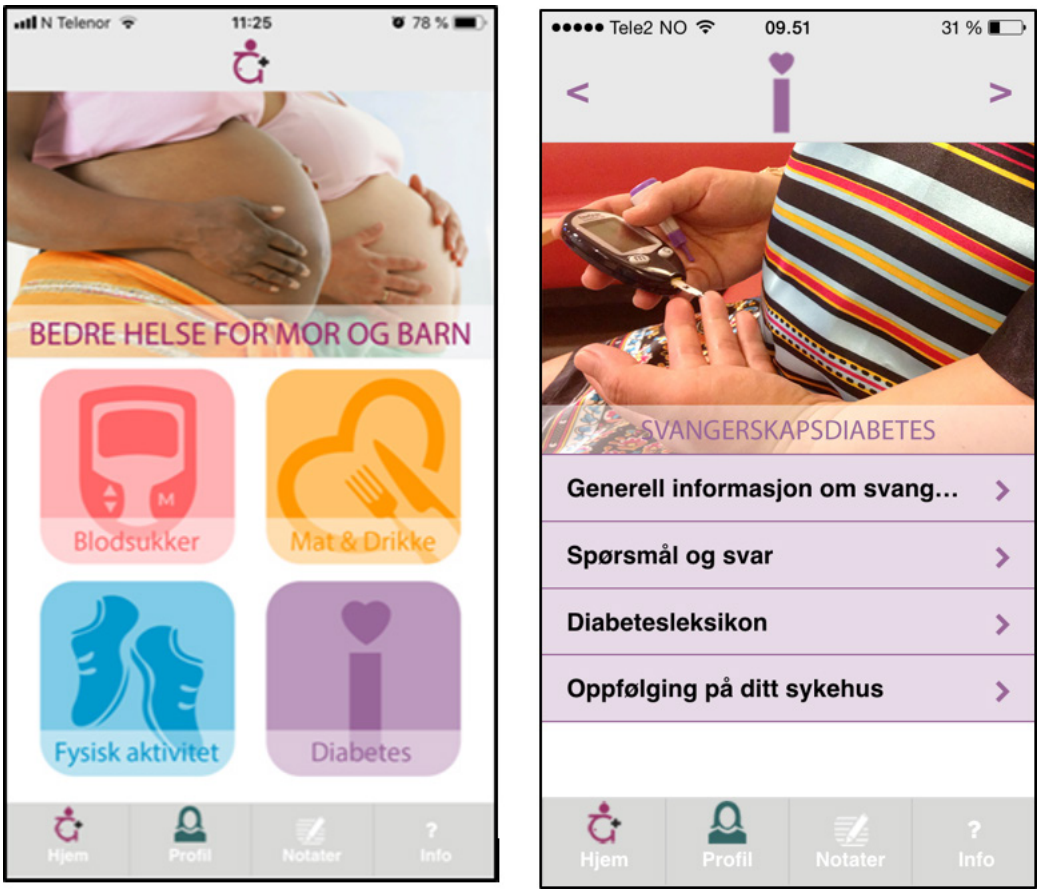

Figure 2 The start-up screen and home menu of the blood glucose section.

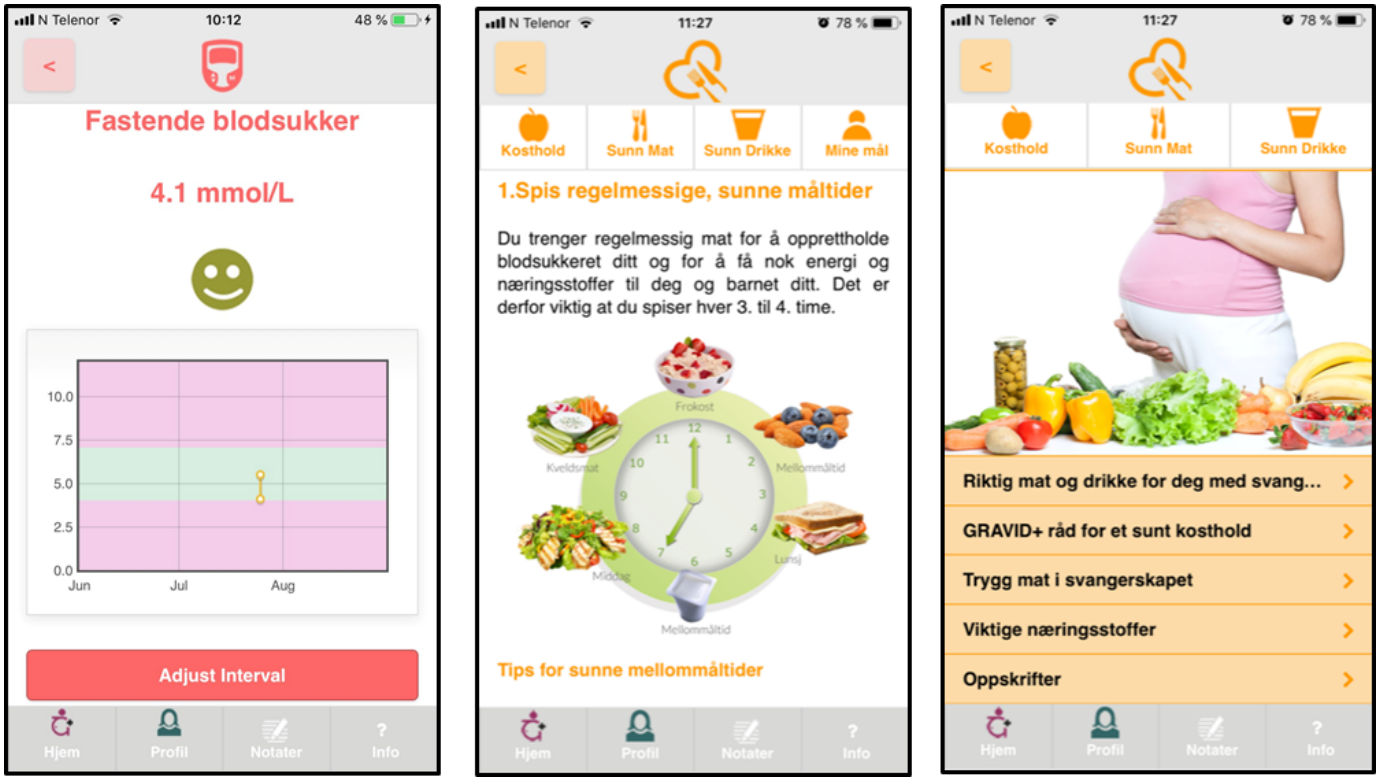

Figure 3 The graphic presentation of blood glucose values page, an example of advice on diet and the home menu of the food and beverage section.

The icon 'Diabetes information' consisted of general information about GDM. Women received specific information about their follow-up, both during pregnancy and post partum. The app described the advantages of breast feeding, such as maintaining stable blood glucose in the newborn baby. A frequently asked question section answered questions like: 'Is GDM dangerous for me and my baby?', 'Can I have a normal delivery?' and 'Can I breastfeed?'. A small glossary intended to help women to understand terms commonly used.

Usual care

All participants received usual care consisting of information about a healthy diet, which encouraged limited intake of sugar-rich products, increased intake of whole grains and vegetables and frequent small meals. Midwives and/or diabetes nurses gave usual care during consultations, every second week. Pregnant women with GDM were recommended regular physical activity and to adjust their activity in accordance to the stage of pregnancy. Part of usual care was teaching women how and when to measure blood glucose levels. In addition, women in the usual care group were taught to record their blood glucose levels either on a single sheet of paper or in a diary and asked to take this record to their consultations. If women in the usual care group, without the assistance of staff and on their own initiative, downloaded the Pregnant+ app, their access was restricted to a single page with a link to the website of the Norwegian Directorate of Health with generic health information for women with GDM and a link to the Norwegian Federation of Diabetes. Women in the usual care group were not able to access any Pregnant+ app intervention content. Regular ultrasound and cardiotocography was part of usual care for women with GDM in Norway. All participants received glucometer and lancets from the study administrators.

Background variables

The questionnaires for baseline and follow-up data collection were developed using standard ways of measuring background variables and validated instruments to measure well-being (health-related quality of life, EQ-5D-SL), diet (Fit for Delivery food frequency questionnaire), physical activity (Pregnancy Physical Activity Questionnaire), symptoms of depression (Edinburgh Postnatal Depression Scale Short version with 5 questions, EDS-5) and knowledge of diabetes.[33–37] The baseline questionnaire measured age, level of education, country of birth, employment status and Norwegian language skills. Perceived health was measured on a scale of 0–100, which is part of the 5-level EQ-5D version.[33] A score of 100 indicates highest perceived health. Pre-pregnancy body mass index was calculated using self-reported pre-pregnancy weight and height. Gestational age in weeks and 2-hour OGTT blood glucose levels at inclusion were collected from the recruitment form.

Outcomes

The primary outcome was the 2-hour blood glucose level of routine postpartum OGTT. The OGTT consists of a fasting blood glucose sample followed by drinking a beverage containing 75 g of glucose and a second blood glucose sample measured 2 hours later. The OGTT measurement was performed at the hospital or at the general practitioner's office. OGTT was reported as a mean with a 95% CI. A change from baseline to 3 months post partum was reported in mmol/L.

The secondary outcomes were collected from the medical records and a questionnaire (Q3) approximately 3 months post partum. They included induction of labour, mode of delivery, transfer of the baby to the neonatal intensive care unit (NICU), Apgar score <7 after 5 min, birth weight, infant feeding in the first week of life and cessation of breast feeding. Engagement in health was measured with our own non-validated question, 'Apps make me more engaged in my health', with the response options: strongly agree, agree, slightly agree, slightly disagree, disagree and strongly disagree. Blood glucose levels during pregnancy, diet, physical activity and knowledge of GDM are not reported in this paper.

Changes to planned protocol

In the published protocol, we expressed the intention to measure glycated haemoglobin (HbA1c) as well as the 2-hour blood glucose levels from routine postpartum OGTT.[38] To add a non-routinely performed blood test proved too difficult for the study team. Our study had insufficient power to perform the intended subanalyses for ethnicity.

Statistical analyses

The data were collected using self-reported questionnaires, a recruitment form and hospital records, and analysed according to the intention-to-treat principle. Unfortunately, we did not collect analytical data on usage to protect women's privacy.

The sample size calculation was based on a power of 80%, a significance level of 5% and an attrition rate of 25%. A total of 230 participants, 115 participants per group, were required to detect a 10% difference in the 2-hour OGTT blood glucose level 3 months post partum between the intervention and the usual care group. This was based on the assumption that the intervention group had a 2-hour glucose level at 3 months post partum of 7.5 mmol/L (SD of 1.8 mmol/L). The estimates used for the power calculation were based on other studies investigating the effect of lifestyle changes.[39–41]

Descriptive statistics were used to present the characteristics of the intervention and usual care group, providing frequencies (counts) and proportions (percentages) for categorical variables. Continuous variables were presented with means and SDs. The main outcomes are presented as point estimates with 95% CIs. The missing data in the present study were not imputed.

The crude differences between the intervention group and the usual care group were assessed using a χ^2 test for categorical data. Continuous data were analysed using the t-test when the data were normally distributed or the Mann-Whitney-Wilcoxon test when the distributions were skewed. The analyses were stratified by selected clinically relevant variables such as parity, childbirth and emergency CS. A sensitivity analysis was performed to evaluate the effect of the 2-hour OGTT blood glucose level at inclusion. All the tests were two sided, and p values<0.05 were considered to be statistically significant.

Analyses were performed using SPSS statistics V.24.0 and V.25.0 (IBM SPSS Statistics for Windows, IBM).

RESULTS

The modified Consolidated Standards of Reporting Trials diagram presents the flow chart (figure 1). At baseline, there were no differences between the groups except for their self-reported perceived health (p=0.01) (table 1).

There were no differences between the groups for medical and obstetric characteristics except for a higher number of primipara in the usual care group (51.2%) versus the intervention group (40.9%) (p=0.11) (table 2).

Women in the intervention group were less likely to have an emergency CS compared with the usual care group: 8.8% vs 22.1%, respectively (table 3). However, when the women were stratified by parity, this difference was no longer statistically significant: p=0.21 for primipara and p=0.55 for multipara (data not in tables). Breast feeding was the most common method of infant nutrition during the first week, and no difference was observed between the two groups (table 3). The proportion of babies receiving breast milk varied according to the mothers' country of birth (data not in tables). 44.8% African, 58.9% Asian, 61.9 Eastern European, 92.9% Western European and North American, and 84.3% Norwegian babies received breast milk during the first week. A higher number of women reported that apps made them more engaged with their health: 84.4% in the intervention group and 63.5% in the usual care group (p<0.01) (table 3).

There was no difference between the groups regarding 2-hour OGTT at 3 months post partum. The mean 2-hour blood glucose level at OGTT in the intervention group was 6.7 mmol/L (6.0 mmol/L in the usual care group). The change in this value from baseline to approximately 3 months post partum in the intervention group was 3.2 mmol/L vs 3.9 mmol/L in the usual care group (reported as means; p=0.25) (table 4). A sensitivity analysis on the baseline 2-hour OGTT blood glucose level test was performed, with the sample stratified using an OGTT cut-off at 13 mmol/L (there were differences between the intervention group and the usual care group). OGTT was categorised as presented in table 2. Due to small numbers of individuals in categories >12.99, these categories were merged. To investigate how sensitive our analyses were in relation to this chosen cut-off and to further investigate if our intervention had any effect on extreme cases (OGTT>13), we used cut-off=13 in these analyses.

In total, 158 women completed the OGTT 3 months post partum. No adverse events were reported.

DISCUSSION

Summary of the main results

There were no differences between the groups regarding their 2-hour blood glucose levels measured at routine postpartum OGTT. No effect of the intervention was seen on birth weight, breast feeding practice, obstetric complications and transfer to the NICU. The proportion of emergency CS was lower in the intervention group compared with the usual care group, but lost its significance when adjusted for parity. No adverse events were reported.

The effect of the Pregnant+ app

The Pregnant+ app had no effect on the main outcome. This result is in line with a recent RCT that tested the efficacy of a mobile phone-based real-time blood glucose management system among women with GDM.[28] The study found no difference in the rate of change of blood glucose. A possible explanation why our study did not find effects on the main outcome might be that we did not account for dropouts and did not adjust the estimates from the power calculation. Fewer women than were required completed the routine postpartum OGTT. Undergoing an OGTT is an unpleasant experience—haphazard and varied follow-up post partum and lack of motivation by women affected the number of women who completed the OGTT. In addition, new national guidelines were implemented early in 2017 that replaced the routine postpartum OGTT with an HbA1c 4 months post partum.[42 43] Health professionals were very positive to this change, resulting in a rapid implementation and in some cases even before the new guidelines were officially implemented. The reason why postpartum outcome was originally chosen was to test whether the app would encourage lifestyle changes visible on blood glucose levels post partum. However, most women's blood glucose levels will have returned to normal 2–3 days post partum. After discharge from hospital, blood glucose monitoring is no longer needed, which might have reduced the women's motivation to continue using the Pregnant+ app and following its lifestyle advice. Furthermore, the first months post partum can be quite chaotic for mothers, and this is possibly not the best time to test for a lasting effect. The limited time of having GDM during a pregnancy (3–4 months) may also explain the lack of lasting results. There might have been some effect of the intervention on the blood glucose levels during pregnancy, as Mackillop *et al* found.[28] To respect the women's privacy, no app-related data were collected. Methods of monitoring blood glucose levels varied considerably among the five diabetes outpatient clinics, complicating comparison. Knowing about the Pregnant+ app may have

Table 1 Sociodemographic characteristics at baseline in the Pregnantcy+ study, n=238

Variable	Total n=238 n (%)	The intervention group n=115 n (%)	The usual care group n=123 n (%)	P value
Age				0.12
≤29	57 (23.9)	30 (26.1)	27 (22.0)	
30–37	128 (53.8)	66 (57.4)	62 (50.4)	
≥38	53 (22.3)	19 (16.5)	34 (27.6)	
Education				0.12
Primary school/no education	23 (9.7)	10 (8.7)	13 (10.6)	
High school	57 (23.9)	20 (17.4)	37 (30.1)	
College or university <4 years	59 (24.8)	32 (27.8)	27 (22.0)	
College or university ≥4 years	99 (41.6)	53 (46.1)	46 (37.4)	
Marital status				0.93
Married/cohabiting	222 (93.3)	108 (93.9)	114 (92.7)	
Single	9 (3.8)	4 (3.5)	5 (4.1)	
Other	7 (2.9)	3 (2.6)	4 (3.3)	
Country of birth				0.32
Norway	111 (46.8)	50 (43.5)	61 (49.6)	
Western Europe+USA	14 (5.9)	4 (3.5)	10 (8.1)	
Eastern Europe	21 (8.9)	10 (8.7)	11 (8.9)	
Asia	56 (23.6)	33 (29.6)	23 (18.7)	
Africa	30 (12.7)	14 (12.2)	16 (13.0)	
South America	5 (2.1)	3 (2.6)	2 (1.6)	
Employment status				0.07
Employed or self-employed	180 (75.6)	93 (80.9)	87 (70.7)	
Not employed or not self-employed	58 (24.4)	22 (19.1)	36 (29.3)	
Joined income				0.97
≤Kr599.000	79 (33.2)	39 (33.9)	40 (32.5)	
Kr600.000 to ≥Kr1.0000.000	119 (50.0)	57 (49.6)	62 (50.4)	
I don't know	40 (16.8)	19 (16.5)	21 (17.1)	
Norwegian skills (self-reported)				0.11
Native Norwegian	109 (45.8)	45 (39.1)	64 (52.0)	
Very good/good	110 (46.2)	61 (53.0)	49 (39.8)	
Very poor/poor	19 (8.0)	9 (7.8)	10 (8.1)	
Use of apps on the smartphone				0.38
Never/seldom	48 (26.8)	19 (22.9)	29 (30.2)	
Sometimes	31 (17.3)	18 (21.7)	13 (13.5)	
Often	34 (19.0)	14 (16.9)	20 (20.8)	
All the time	66 (36.9)	32 (38.6)	34 (35.4)	
Perceived health score 0–100				<0.01
Mean (SD)	71.1 (19.6)	66.7 (18.5)	74.8 (19.8)	
Smoking or wet tobacco				0.61
Yes	15 (8.4)	6 (7.2)	9 (9.4)	
No	164 (91.6)	77 (92.8)	87 (90.6)	
Recruitment site				0.96
Site 1	99 (41.6)	46 (40.0)	53 (43.1)	
Site 2	15 (6.3)	8 (7.0)	7 (5.7)	
Site 3	38 (16.0)	18 (15.7)	20 (16.3)	

Continued

Table 1 Continued

Variable	Total n=238 n (%)	The intervention group n=115 n (%)	The usual care group n=123 n (%)	P value
Site 4	32 (13.4)	15 (13.0)	17 (13.8)	
Site 5	54 (22.7)	28 (24.3)	26 (21.1)	

encouraged women in the control group to download the app. However, their access was restricted to just one link to the Norwegian Federation of Diabetes and the Norwegian Directorate of Health. Finally, usual care is of very good quality and may explain some of the lack of impact of the app post partum.

In line with the recently published RCT already mentioned,[28] our study found no significant differences between the intervention group and the usual care group concerning induction of labour, birth weight, admission to the NICU or Apgar score. Most of the transfers to the NICU were the result of a routine procedure to transfer all babies born to women who received insulin during pregnancy. The lower rate of emergency CS in the intervention group was an interesting finding; however, stratified analysis explained this effect to be confounded with parity. Diabetic pregnancies have a higher risk of obstructed labour and emergency CS; this is associated with blood

Table 2 Medical and obstetric characteristics at baseline in the Pregnant+ study, n=238

Variable	Total n=238 n (%)	The intervention group n=115 n (%)	The usual care group n=123 n (%)	P value
Gestational age at diagnosis (weeks)				0.98
≤17	18 (7.6)	9 (7.8)	9 (7.3)	
18–24	38 (16.0)	18 (15.7)	20 (16.3)	
25–32	182 (76.5)	88 (76.5)	94 (76.4)	
BMI (kg/m^2)				0.78
17–24	82 (35.3)	43 (37.4)	39 (33.3)	
25–30	74 (36.1)	28 (34.1)	46 (48.0)	
31–40	39 (16.4)	17 (14.8)	22 (17.9)	
≥41	3 (1.3)	2 (1.7)	1 (0.8)	
Parity				0.11
Primiparous	110 (46.2)	47 (40.9)	63 (51.2)	
Multiparous	128 (53.8)	68 (59.1)	60 (48.8)	
Previous GDM among multipara (n=128)				0.80
Yes	42 (32.8)	23 (33.8)	19 (31.7)	
No	86 (67.2)	45 (66.2)	41 (68.3)	
2-hour OGTT blood glucose level at inclusion*				0.54
9–9.99	139 (58.4)	64 (55.7)	75 (61.0)	
10–10.99	64 (26.9)	33 (28.7)	31 (25.2)	
11–11.99	20 (8.4)	10 (8.7)	10 (8.1)	
12–12.99	7 (2.9)	2 (1.7)	5 (4.1)	
13–13.99	5 (2.1)	4 (3.5)	1 (0.8)	
≥14	3 (1.3)	2 (1.7)	1 (0.8)	
Close family member with diabetes				0.67
Yes	105 (44.1)	53 (46.1)	52 (42.3)	
No	127 (53.4)	60 (52.2)	67 (54.5)	
I don't know	6 (2.5)	2 (1.7)	4 (3.3)	

*Categories ≥12 were merged to fulfil assumptions of the χ^2 test.
BMI, body mass index; GDM, gestational diabetes mellitus; OGTT, oral glucose tolerance test.

Table 3 Pregnancy outcomes in the Pregnant+ study, n=233

Variable	Total n=233 n (%)	The intervention group n=112 n (%)	The usual care group n=121 n (%)	P value
Use of medication for GDM				0.50
Metformin (M)	25 (10.7)	10 (8.9)	15 (12.4)	
Insulin (I)	45 (19.3)	21 (18.8)	24 (19.8)	
Both (M and I)	12 (5.2)	8 (7.1)	4 (3.3)	
No medication	151 (64.8)	73 (65.2)	78 (64.5)	
Induction of labour				0.33
Yes	120 (51.5)	54 (48.2)	66 (54.5)	
No	113 (48.5)	58 (51.8)	55 (45.5)	
Mode of delivery				0.03
Spontaneous vaginal delivery	156 (66.4)	81 (71.7)	75 (61.5)	
Operative vaginal delivery	20 (8.5)	9 (8.0)	11 (9.0)	
Planned caesarean section	20 (8.5)	12 (10.6)	8 (6.6)	
Emergency caesarean section	37 (15.7)	10 (8.8)	27 (22.1)	
Apgar score after 5 min				1.0
<7	3 (1.3)	1 (0.9)	2 (1.7)	
≥7	230 (98.7)	111 (99.1)	119 (98.3)	
Weight of the baby (g)				0.69
≤4000	206 (88.4)	100 (89.3)	106 (87.6)	
>4000	27 (11.6)	12 (10.7)	15 (12.4)	
Transfer to neonatal intensive care unit				0.38
Yes	34 (14.6)	14 (12.5)	20 (16.5)	
No	199 (85.4)	98 (87.5)	101 (83.5)	
Infant nutrition in the first week				
Breast milk				0.42
Yes	168 (72.1)	78 (69.6)	90 (74.4)	
No	65 (27.9)	34 (30.4)	31 (25.6)	
Formula				0.57
Yes	83 (35.6)	42 (37.5)	41 (33.9)	
No	150 (64.4)	70 (62.5)	80 (66.1)	
Cessation of breast feeding*				0.21
<1 month	8 (4.8)	6 (7.7)	2 (2.2)	
1–2 months	6 (3.6)	2 (2.6)	4 (4.4)	
≥3 months and still breast feeding	154 (91.7)	70 (89.7)	84 (93.3)	
Apps make me more engaged in my health				<0.01
Agree	119 (73.5)	65 (84.4)	54 (63.5)	
Disagree	43 (26.5)	12 (15.6)	31 (36.5)	
Perceived health 3 months post partum score 0–100				
Mean (SD)	74.9 (17.9)	76.5 (14.9)	73.6 (20.1)	0.21†

*Adjusted for baseline values of those who received breast milk during the first week.
†Adjusted for baseline values.
GDM, gestational diabetes mellitus.

glucose regulation.[44 45] Blood glucose regulation during pregnancy may have been better in the intervention group. The women with the Pregnant+ app potentially had a continuous overview of their blood glucose values, and this might have motivated them to optimise their glycaemia during pregnancy. The Hyperglycemia and Adverse Pregnancy Outcomes study found an enhanced risk of maternal and infant outcomes with increasing levels of hyperglycaemia.[45] Efforts to optimise blood glucose levels during pregnancy are important, given

Table 4 Effect on blood glucose levels in the Pregnant+ study, n=233

Variable	Total n=233 n (%)	The intervention group n=112 n (%)	The usual care group n=121 n (%)	P value
2-hour OGTT 3 months post partum				0.22
Mean, mmol/L (CI)		6.7 (6.2–7.1)	6.0 (5.6–6.3)	
Missing	75	34	41	
2-hour OGTT change from baseline to 3 months post partum				0.25
Mean, mmol/L (CI)		3.2 (2.7–3.8)	3.9 (3.6–4.4)	
Missing	75	34	41	
Number of days (SD) postpartum OGTT was performed		99.9 (26.4)	99.0 (23.6)	0.75

OGTT, oral glucose tolerance test.

the consequences of GDM for both the mother and the infant. Mobile apps in the self-management of T2DM were found to improve blood glucose levels among individuals with T2DM.[27] A scoping review concluded that apps on a mobile phone might be time effective and cost-effective, and they may offer a tailored intervention in GDM.[24] Similarly, app technology has been found to potentially improve HbA1c and pre-pregnancy planning—important aspects in women with a history of GDM.[46] The majority of women with previous GDM recover from the condition after they give birth; however, women with GDM have a sevenfold risk of developing T2DM.[11] The intervention group reported apps increased their engagement in their own health more than in the control group, but we used a single self-constructed non-validated question to measure this and it was not specific to the intervention app. Thus, this result needs to be considered with caution.

While the majority of babies in the study received breast milk during the first week, the proportion was less than in the general population in Norway.[47] Studies do report differences in breast feeding initiation by maternal diabetes status and race.[48 49] In addition, the breast feeding pattern in many South Asian and Middle East countries is characterised by late initiation of breast feeding and non-exclusive breast feeding.[50 51] While our app promotes breast feeding and we did not collect information on app usage, it is likely that the app was used only during pregnancy, and that information about breast feeding after delivery was mediated through other communication channels.

Strengths and limitations

The strengths of the study included the RCT design, the large sample size and the high number of non-native Norwegian speakers. Thus, the sample appears to reflect the population of pregnant women with GDM.[5 37 42] The present study had many limitations. While we recruited a large number of women with an immigrant background, we were not able to perform subgroup analyses among Somali and Pakistani women as intended, due to small sample sizes in these particular groups. While providing the app and the questionnaire in Urdu and Somali may have enhanced participation in the study by women from these groups, few women filled out the questionnaire in these languages. A major weakness of our study is the fact that only two-thirds of the women completed the primary outcome (postpartum OGTT); despite this proportion being higher than what is routinely collected (~30%), the number of completers was still smaller than needed to reveal statistical significance. We overestimated women's commitment to the study and did not account for the low rates of OGTT completion post partum in our power calculations. In addition, app usage data were not available. The results may be generalised to women from urban areas in Norway and hospitals with pregnant women with different ethnical backgrounds.

Implications for practice and research

The Pregnant+ app was designed for women with GDM in addition to usual care to provide information and stimulate a change in lifestyle. While we have not shown an effect on clinical outcomes we still think it might be a useful tool for managing GDM. Policymakers should support innovative methods to enhance the management of GDM among pregnant women. Future research should investigate which specific features of smartphone apps enhance GDM management.

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Contributors ML, AFJ, LMGH, JN, SF, MCS and IB planned and designed the study. MCS and IB performed the analysis. ML, AFJ and IB interpreted the results. IB wrote the draft. ML, MCS, LMGH, AFJ and SF contributed to writing the manuscript. All the authors (IB, ML, JN, SF, LMGH, AFJ, MCS and SF) reviewed and approved the final manuscript.

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