



BMJ Open Comprehensive self-tracking of blood glucose and lifestyle with a mobile application in the management of gestational diabetes: a study protocol for a randomised controlled trial (eMOM GDM study)

Mikko Kytö ^{1,2}, Lisa Torsdatter Markussen ^{1,3}, Pekka Marttinen,⁴ Giulio Jacucci,² Sari Niinistö,⁵ Suvi M Virtanen,^{6,7} Tuuli E Korhonen,⁵ Harri Sievänen,⁸ Henri Vähä-Ypyä,⁸ Ilkka Korhonen,⁹ Seppo Heinonen,¹⁰ Salla B Koivusalo^{10,11}

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For numbered affiliations see end of article.

Correspondence to

Dr Mikko Kytö;
mikko.kyto@hus.fi

ABSTRACT

Introduction Gestational diabetes (GDM) causes various adverse short-term and long-term consequences for the mother and child, and its incidence is increasing globally. So far, the most promising digital health interventions for GDM management have involved healthcare professionals to provide guidance and feedback. The principal aim of this study is to evaluate the effects of comprehensive and real-time self-tracking with eMOM GDM mobile application (app) on glucose levels in women with GDM, and more broadly, on different other maternal and neonatal outcomes.

Methods and analysis This randomised controlled trial is carried out in Helsinki metropolitan area. We randomise 200 pregnant women with GDM into the intervention and the control group at gestational week (GW) 24–28 (baseline, BL). The intervention group receives standard antenatal care and the eMOM GDM app, while the control group will receive only standard care. Participants in the intervention group use the eMOM GDM app with continuous glucose metre (CGM) and activity bracelet for 1 week every month until delivery and an electronic 3-day food record every month until delivery. The follow-up visit after intervention takes place 3 months post partum for both groups. Data are collected by laboratory blood tests, clinical measurements, capillary glucose measures, wearable sensors, air displacement plethysmography and digital questionnaires. The primary outcome is fasting plasma glucose change from BL to GW 35–37. Secondary outcomes include, for example, self-tracked capillary fasting and postprandial glucose measures, change in gestational weight gain, change in nutrition quality, change in physical activity, medication use due to GDM, birth weight and fat percentage of the child.

Ethics and dissemination The study has been approved by Ethics Committee of the Helsinki and Uusimaa Hospital District. The results will be presented in peer-reviewed journals and at conferences.

Trial registration number NCT04714762.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ A mobile app for self-management of gestational diabetes (GDM) that combines lifestyle (eg, nutrition, physical activity and sleep) with continuous glucose levels in a real time and without support from healthcare personnel is evaluated in randomised controlled trial.
- ⇒ Maternal outcomes and neonatal outcomes are compared between the intervention and the control group with different measurements, including physical activity sensors and neonatal air displacement plethysmography.
- ⇒ Usage logs enable investigations of the effect of compliance with the eMOM GDM app on the outcomes.
- ⇒ As a limitation, we cannot fully isolate or mitigate the effect of sensors' own apps on the outcomes.

INTRODUCTION

Digital health holds a promise for more efficient and improved healthcare with minor additional human resources. Gestational diabetes (GDM) is a type of diabetes that develops during pregnancy.¹ Today, the burden of GDM on healthcare system and economy is remarkable since the incidence of GDM is increasing together with obesity globally,² and it is associated with a range of adverse short-term and long-term consequences for both the mother and child.^{3–7} The primary treatment for GDM and glycaemic control is through adjustments toward healthier lifestyle, especially changing the diet and increasing exercising.^{8,9} It is critical that women with GDM are supported in this behaviour change.¹⁰ The lifestyle interventions for the treatment of women with GDM have been shown to reduce the incidence of large-for-gestational-age

(LGA)^{8 11} and post partum weight retention.¹² For this support different digital health interventions have been tested in women with GDM and a recent meta-analysis shows that interventions where participants receive weekly or more frequent guidance and feedback from healthcare personnel have shown the potential to improve glycaemic control.¹³ For example, in a study by Miremberg *et al*¹⁴ women with GDM received dietary tips for optimising off-target measurements and reassuring and positive messages every evening via email. However, mobile app interventions without such substantial input from healthcare professionals are limited and lack effectiveness.^{15–17} Recently, Yew *et al*¹⁸ found improvements in mean glucose and in proportion of off-target preprandial and 2-hour postprandial measurements. However, their app included a chat feature with healthcare team, which use and effect on the results remained unclear.¹⁹ In this study, we evaluate if the effectiveness can be increased with the eMOM GDM mobile app, which visualises continuous glucose data together with lifestyle data in a single view in a real time without involvement of healthcare personnel. Comprehensive self-tracking with wearable sensors has been identified as a desirable feature for increasing competence to self-manage GDM,^{20 21} but has not been clinically evaluated before.

METHODS

Study design

Participants are randomised 1:1 into the intervention and the control group. The intervention group receives standard antenatal care and the eMOM GDM app, while the control group will receive only standard care. Participants in the intervention group are instructed to use the eMOM GDM app with continuous glucose metre (CGM)

and activity bracelet 1 week/month until delivery. During the same week when participants have the CGM installed, participants are instructed to keep an electronic food diary for 3 days. After keeping the food diary, the nutrition entries are checked and corrected in a call by a nutritionist. In addition to this instructed use, participants can use the eMOM GDM app with activity bracelet and food-tracker freely. Participants in both groups are invited to the follow-up visit at 3 months post partum.

We follow the Standard Protocol Items: Recommendations for Interventional Trials checklist²² in the study design and reporting. Study design and data collection is depicted in [figure 1](#), please see details for laboratory tests, measurements and questionnaires in the Measurements section.

Participants

Inclusion and exclusion criteria are given in [table 1](#). Women with GDM are randomised into the intervention and the control group using stratification at gestational week (GW) 24–28. Strata are GW of GDM diagnose (early: < 24 GW or late: 24–28 GW), parity (primiparous or multiparous) and body mass index (BMI) (< or ≥30 kg/m²). Three strata resulted in eight blocks. The Finnish Current Care Guidelines provide the thresholds for diagnosing GDM based on 2-hour 75 g oral glucose tolerance test (OGTT): 0 hour >5.3 mmol/L, 1 hour >10.0 mmol/L and 2 hours >8.6 mmol/L.²³ Participants are voluntary and they are allowed to withdraw any point without any reason, and they have also right to cancel the consent. If a participant withdraws, the research data collected in the study will be stored and included in the analysis. If a participant cancels the consent, all the data which are not processed as research results, will be deleted according

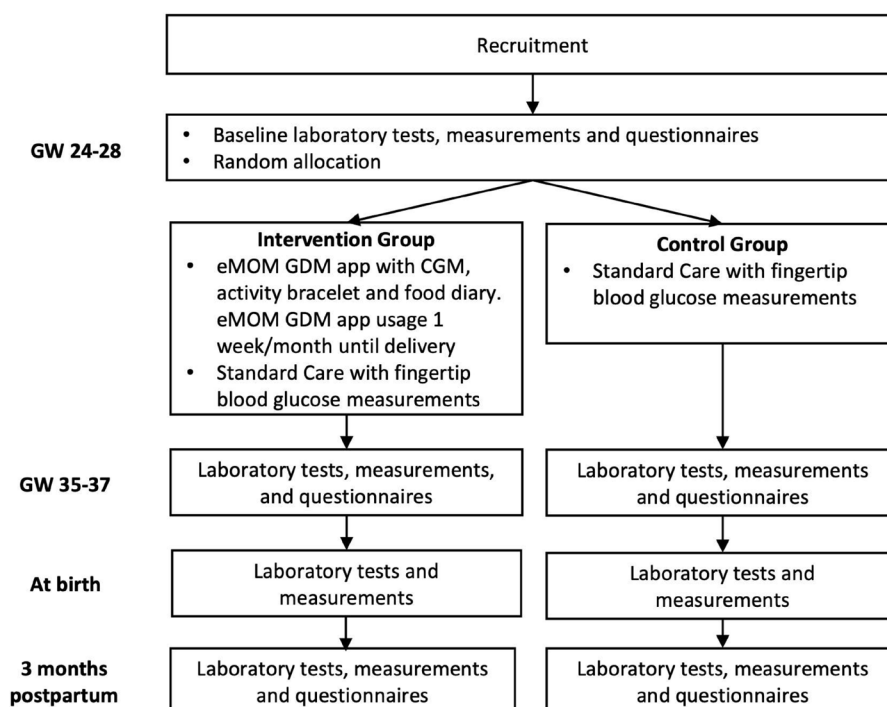


Figure 1 Design of the randomised controlled trial.

Table 1 Inclusion and exclusion criteria

Inclusion criteria:	Exclusion criteria:
<ul style="list-style-type: none"> ▶ 18–45 years ▶ GDM diagnosis at GW 24–28 	<ul style="list-style-type: none"> ▶ Type 1 or type 2 diabetes. ▶ Use of medication that influences glucose metabolism (such as continuous therapy with oral corticosteroids or metformin). ▶ Multiple pregnancy. ▶ Physical disability. ▶ Current substance abuse. ▶ Severe psychiatric disorder (that complicates participation to the study). ▶ Significant difficulty in cooperating (eg, inadequate Finnish language skills).
GDM, gestational diabetes mellitus; GW, gestational week.	

to General Data Protection Regulation (GDPR) (<https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32016R0679&from=EN#d1e2001-1-1>) of European Union. If medication is started, the participant will drop out from the study and the data collected until the decision to start medication will be collected.

Recruitment and consent

Participants are recruited from antenatal clinics from the Helsinki metropolitan area at GW 24–28. Local nurses at the municipal maternal clinics in Helsinki, Espoo and Vantaa inform about the possibility to participate in the eMOM GDM study in peer-support groups and share flyers in one-to-one meetings. We started the recruitment in March 2021 and we plan to continue until January 2023. Women who agree to participate sign two consent forms, one copy for themselves and one for the study nurse.

Blinding

For each block (see the Participants section), envelopes consisting of equal number of intervention and control cases were created for blinding. Based on the participant's status, a study nurse opens a sealed envelope from the respective block. The content of the envelope determines whether the participant is assigned to the intervention or to the control group. This approach balances the allocation of subgroups of participants to intervention and control groups in a blinded manner.

Description of the eMOM GDM app and its wearable sensors

The eMOM GDM app and its integration to the medical personnel user interface (UI) was developed in 2020. The eMOM GDM app visualises lifestyle data (physical activity, sleep and nutrition) together with tissue glucose data in a single view (see [figure 2A,B](#)). For displaying the data, the eMOM GDM app has two views, a week view (see [figure 2](#)) and a day view (see [figure 2B](#)). The information from the sensors and food tracker are updated each 10 min to the eMOM GDM app. We included an information section regarding pregnancy and GDM (see [figure 2C](#)). Based on recent studies^{20 21} providing reliable information about how to manage GDM (particularly what to eat and how

the fetus is developing) should be integrated in the GDM apps, so that no separate app for this is needed.

Medtronic Guardian Connect CGM with Enlite sensor (Medtronic, Dublin, Ireland; see [figure 3](#)) continuously measures tissue glucose. A flexible filament is inserted just under the skin to measure glucose levels in interstitial fluid approximately every 5 min. The eMOM GDM app shows these detailed glucose values when tapping the glucose curve on the screen (see [figure 2D](#)). Glucose values are sent to the mobile phone via Bluetooth. Medtronic requires calibration of the sensor by capillary blood glucose measurements two times a day.

Garmin Vivosmart 3 (Garmin International, Kansas, USA; see [figure 3](#)) is a wrist-worn optical heart rate and activity tracker which measures activity, sleep and heart rate continuously based on its optical heart rate sensor, and 3D acceleration. Garmin Vivosmart 3 has been found to be feasible among pregnant women with good ratings on user experience²⁴ and measures steps well at slow walking speeds.²⁵ The tracked parameters include steps, estimated energy expenditure in calories (based on motion and heart rate), stairs, walking and running distance, all-day heart rate and stress. It connects automatically to a mobile app (Garmin Connect) and data are stored automatically to the cloud, where it can be accessed via application programming interfaces (APIs).

A dedicated food-tracker was developed by Helsinki University Hospital to make the food intake data collection easier for pregnant women. A user enters the time of each meal, food items consumed and portion sizes to the food-tracker. The food-tracker fetches the food items and their nutrient contents from Fineli food composition database (Finnish National Institute for Health and Welfare, <http://www.fineli.fi>), calculates nutrient intake and shows the amounts of the energy yielding nutrients and fibre to the user. This data is transferred to the eMOM GDM app where the energy intake from each energy yielding nutrient is visualised as stacked bars (see [figure 2B](#)). More detailed information (recorded food items, nutrient intake in grams) can be accessed (see [figure 2E](#)) by tapping the stacked bar (see [figure 2B](#)). In addition, participants were asked to add their weight to the eMOM GDM app once a week.

Standard care for both groups

All participants in the study receive standard care, in addition to the study protocol. The public healthcare system in Finland offers all pregnant women antenatal healthcare on a regular basis in municipal maternity clinics at primary healthcare centres. A doctor and a nurse are following the pregnancy in collaboration. Sessions are divided into periodic audits (basic visits) and discretionary additional visits. The periodic health check includes a minimum number (9–10) of visits with a nurse, and two doctor examinations designed for normal, low risk pregnancies. The first medical check-up is during GW 8–10. Maternity clinics and hospitals have provided detailed instructions on

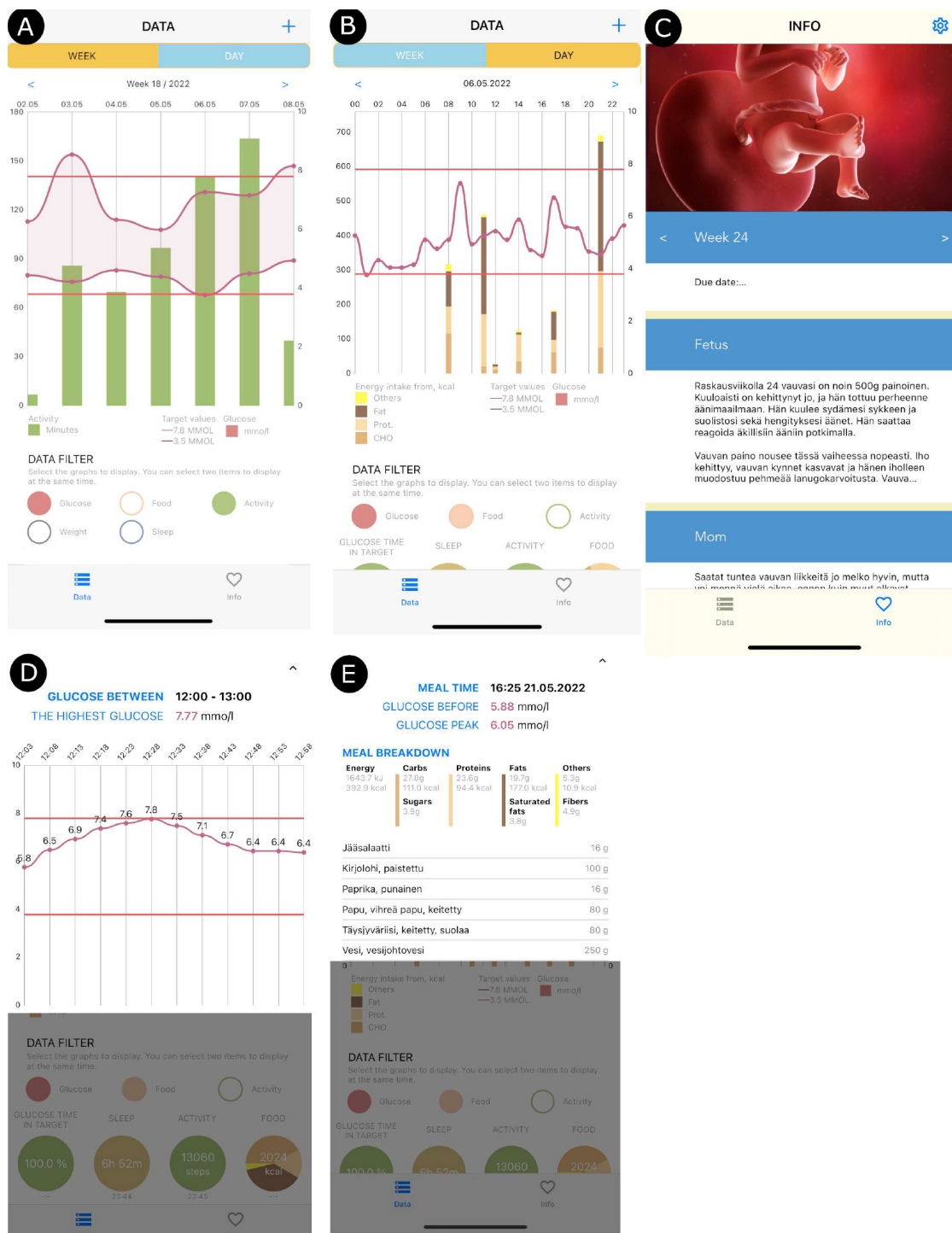


Figure 2 Screenshots of main views in the eMOM GDM APP. (A) A week view for self-tracking data (Copyright: Fujitsu Finland), (B) a day view for self-tracking data (Copyright: Fujitsu Finland), (C) pregnancy and GDM related information (Copyright: Helsinki university hospital), (D) detailed glucose view (Copyright: Fujitsu Finland) and (E) detailed nutrition view (Copyright: Fujitsu Finland). GDM, gestational diabetes.

when the mother should be sent to the hospital for further examinations and follow-up.²⁶

A 2h-OGTT is performed normally at GW 24–28, but if the risk of GDM is considered high (BMI >35 kg/m², previous GDM, glycosuria in early pregnancy, incidence of type 2 diabetes in grandparents, parents or siblings, oral corticosteroid therapy, polycystic ovary

syndrome), OGTT is performed already at GW 12–16. After a GDM diagnosis, the women receive guidance on diet, physical activity and self-monitoring of blood glucose with electronic capillary glucose meters.²³ In case of repeated fasting capillary glucose of ≥ 5.5 mmol/L or a 1-hour postprandial value of ≥ 7.8 mmol/L, the maternity clinic refer the woman to

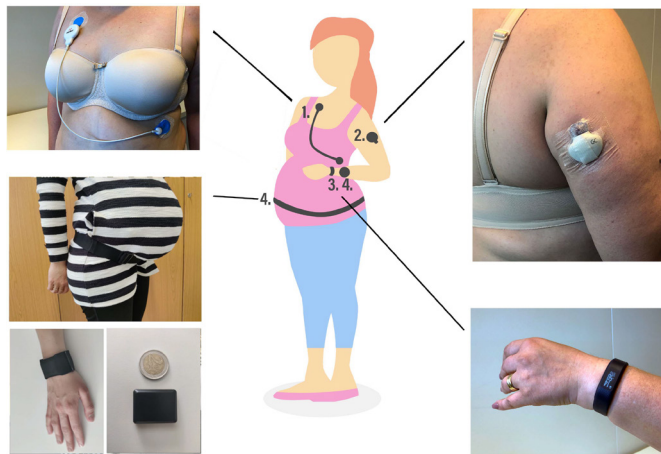


Figure 3 The sensors used in the study. The sensors on the left (1. HRV sensor and 4. movement sensor) are worn by both control and intervention group. The movement sensor is a small box, which is attached either to a belt or to a bracelet. Sensors on the right (2. CGM and 3. activity bracelet) are part of the intervention.

a maternity hospital for further assessment regarding need of medication.²³

Objectives and hypotheses

The principal aim of the study is to evaluate the effect of the eMOM GDM application on maternal glucose levels by comparing intervention and control groups. We also study the effects of the application on different other maternal and neonatal outcomes (please see the specific objectives below). The follow-up visit after the delivery and intervention takes place 3 months post partum.

The specific objectives of the intervention study are to compare between the intervention and the control groups:

1. Differences in maternal glucose levels during pregnancy.
2. Differences in physical activity and stress levels during pregnancy.
3. Differences in total diet during pregnancy.
4. Difference in the need for medication due to GDM.
5. Difference in gestational weight gain (GWG).
6. Birth weight, incidence of large-for-gestational-age (LGA) and macrosomic (birth weight >4000 g) newborns, and infant's body composition.
7. Differences in motivation during the pregnancy.
8. Differences in physical activity, total diet, weight retention and glucose values 3 months post partum.

Main hypothesis: Fasting plasma glucose, between baseline (BL) and GW 35–37, will decrease more in the intervention than in the control group.

Outcomes

Primary outcome is the change in fasting plasma (fP)-glucose from BL (GW 24–28) to GW 35–37. The main secondary outcomes are given in [box 1](#).

Box 1 The main secondary outcomes

1. Difference in capillary fasting glucose and 1-hour postprandial glucose values during pregnancy.
2. Difference in capillary glucose area under the curve during pregnancy.
3. Change in Homeostatic Model Assessment for Insulin Resistance during pregnancy and 3 months post partum.
4. Difference in physical activity level during pregnancy and 3 months post partum.
5. Difference in total diet during pregnancy and 3 months post partum.
6. Difference in medication use due to gestational diabetes mellitus (GDM) (insulin, metformin).
7. Difference in gestational weight gain and postpartum weight retention.
8. Difference in birth weight (SD) of child.
9. Difference in large-for-gestational-age of child and macrosomia.
10. Difference in infant's body composition.
11. Difference in neonatal hypoglycaemia (<2.6 mmol/L) incidence within a week from birth.
12. Difference in motivation to manage GDM during pregnancy.
13. Difference in fP-glucose and 2-hour blood glucose levels measured with oral glucose tolerance test (75 g) at 3 months post partum.

Measurements

We take measurements with multiple techniques and sensors. All the measurements, except measurements specific to the eMOM GDM app intervention are taken from both groups (see a summary in [table 2](#)).

Background information

Age, BMI, parity and previous GDM status are collected from hospital registries, and socioeconomic status (eg, education, occupation), alcohol use, possible special diet, and experience with self-tracking from a background questionnaire.

Maternal glucose levels

Maternal glucose levels are collected in the intervention and the control groups with three measurement types: (1) 2-hour OGTT at GW 12–16 (early) or GW 24–28 (late) as well as 3 months post partum, (2) capillary glucose measures (eg, fasting glucose, postprandial glucose, area under the curve (AUC)) (Contour Next One, Ascensia Diabetes Care, Basel, Switzerland) from BL until delivery and (3) laboratory fP-glucose, glycated hemoglobin (HbA1c), fP-insulin at study visits at BL, GW 35–37 and 3 months post partum. In addition in the intervention group, glucose levels are collected with a CGM (Medtronic Guardian Connect) 1 week/month from BL to delivery.

Maternal physical activity

Maternal physical activity is extracted from both groups at BL, GW 35–37 and 3 months post partum with two 'blind' sensors: UKK RM 42 and Firstbeat Bodyguard 2 (see [figure 3](#)).

Movement is measured with UKK RM42 (UKK Institute, Tampere, Finland). It is a triaxial accelerometer that measures the device movement located either at the

**Table 2** Measurements for intervention and control groups

Measurements for intervention and control groups	Baseline GW 24–28	III trim GW 35–37	Birth	Post partum (3 months)
o Background questionnaire	•			
o OGTT	•			•
o Capillary glucose measurements	•	•		
o Laboratory blood samples	•	•		•
o Questionnaires*	•	•		•
o Physical activity (UKK RM42 accelerometer)	•	•		•
o Heart rate variability (Firstbeat Bodyguard 2) (analyses shown to participants only after postpartum visit)	•	•		•
o Cord blood			•	
o Placental weight			•	
o Infant's anthropometry (Pea Pod)			•	
Measurements only for intervention group:				
▶ Data from sensors and apps: the eMOM GDM app, Garmin Vivosmart, Medtronic CGM, food tracker	One app week +3 normal care weeks repeatedly until delivery			
▶ Technology acceptance questionnaire (UTAUT-technology)				
o Usability questionnaire	•			
o Semi-structured interview†		•		

*Questionnaires=Food Frequency Questionnaire (FFQ), depression, motivation and quality of life. At the postpartum study visit (3 months) FFQ and depression questionnaire.

†Twenty participants will conduct the semi-structured interview about the user experience with the eMOM GDM app

CGM, continuous glucose metre; GDM, gestational diabetes mellitus; GW, gestational week; OGTT, oral glucose tolerance test; UTAUT, Unified Theory of Acceptance and Use of Technology.

hip during waking hours and at the wrist during the time in bed for sleeping (see sensor 4 in figure 3). The data analysis is based on validated MAD-APE algorithms.^{27 28} The amount of daily physical activity is described in durations and intensity in METs, the amount of sedentary behaviour (lying, sitting and standing) in durations, and sleep as movement categories. These analyses have been employed in population-based studies of Finnish adults.^{29 30}

Heart rate variability (HRV) is measured with Firstbeat Bodyguard 2 sensor (Firstbeat Technologies, Jyväskylä, Finland), which is a chest worn wearable device which measures beat-to-beat HRV and activity (3D acceleration) continuously for 3 days. The device is attached to the chest with two disposable clinical grade ECG electrodes (see sensor 1 in figure 3). The device is able to continuously measure beat-to-beat HRV with <3 ms error and >99.9% detection rate as compared with clinical grade ECG.³¹ Proprietary analytics software (Firstbeat Lifestyle Assessment, Firstbeat Technologies, Jyväskylä, Finland) is used to transform the recorded beat-to-beat and motion data into continuous assessment of energy expenditure, VO₂, physical activity, stress and recovery. These measurement methods have been validated widely in several studies.^{32 33}

Physical activity measures are also collected in the intervention group with activity bracelet Garmin Vivosmart 3 1 week/month from BL until delivery (see sensor 3 in figure 3 and Description of the eMOM GDM app section and its wearable sensors).

Maternal nutrition

We measure maternal total diet including food consumption and nutrient intake among intervention and control women during the preceding month with a digital semi-quantitative 142-item Food Frequency Questionnaire (FFQ) (updated from³⁴) at BL, GW 35–37 and 3 months post partum. FFQ is used for intervention effect estimation. Nutritional outcomes include, for example, intake of fruits and vegetables, wholegrain cereals, sugar, protein, carbohydrates, fibre, unsaturated and saturated fat, vitamins and minerals. In addition, participants in the intervention group are instructed to keep an electronic food diary for 3 days/month while they are wearing the CGM.

Maternal gestational weight gain and weight retention 3 months post partum

Weights (in kg) are extracted from the maternity card and at study visits at BL and GW 35–37, within 2 days after birth, and 3 months post partum.

Neonatal outcomes

Neonatal anthropometric measures at birth are extracted from hospital registry; birth weight (SD), birth length, incidence of LGA/macrosomic newborn (>+2 SD/>4000 g), and newborn body composition (body fat%, lean body mass%) by Pea Pod (COSMED, Italy, Rome) air-displacement plethysmography,^{35–37} within 2 days after birth. Also, Apgar scores, neonatal hypoglycaemia (<2.6 mmol/L), transfer to intensive care and intravenous glucose infusion of newborn are collected.

Psychological factors, motivation and health-related quality of life

Maternal depression and health-related quality of life are collected with the digital questionnaires at BL, GW 35–37 and 3 months post partum. Motivation is collected with the digital questionnaires at BL and GW 35–37. Depression is measured with Edinburgh Depression Postnatal Depression Scale,³⁸ which is also used during pregnancy (eg,³⁹), health-related quality of life with 15D questionnaire⁴⁰ and motivation with Treatment Self-Regulation Questionnaire⁴¹ and Perceived Competence for Diabetes Scale (PCDS).⁴¹

Measures about the intervention

We measure the app usage by logging the time and type of every interaction with the eMOM GDM app. Human factors relating to app use are measured with Unified Theory of Acceptance and Use of Technology questionnaire,⁴² Software Usability Measurement Inventory⁴³ and with a semistructured interview on user experience with the eMOM GDM app with randomly selected 20 participants.

Data analysis

We will analyse the data using RStudio (V.1.1.456, RStudio, Boston, USA) and perform the analyses according to intention-to-treat principle. Missing data will not be replaced. For comparing maternal outcomes and neonatal outcomes between intervention and control group we will use classical statistical tests (such as t-test, χ^2 test and analysis of covariance (ANCOVA)) depending on type of the variable and its distribution (ie, normality and homogeneity). The comparisons of changes between the control and the intervention group will be performed using either analysis of variance of change from BL or ANCOVA, having the BL measurements as covariate.⁴⁴ The selection depends on the possible differences at BL.⁴⁴ Other maternal covariates will be maternal socioeconomic situation (education, occupation), age at childbirth, BMI, parity and smoking during pregnancy. The birthweights will be adjusted according to Sankilampi *et al.*⁴⁵ Regarding the eMOM GDM app use, we will investigate correlations between usage patterns of the eMOM GDM app and outcomes (maternal and neonatal). We will conduct a cluster analysis for the usage patterns to identify effective usage strategies of the eMOM GDM app similar to apps designed for type 2 diabetes management.⁴⁶

For the CGM data, we will conduct time series analysis using standard techniques,⁴⁷ such as AUC and incremental AUC^{48 49} and mean amplitude of glycaemic excursions.⁵⁰ Interim data analysis will be performed by data analysis team (MK, LTM and PM) when the research data from a half of the participants (N=100) is collected. Study nurses will remain blinded to the interim results, and we will blind the statistical analyses by asking an external person to recode the participants before conducting final analyses. The final dataset is accessed by data analysis

team (MK, LTM and PM). The final decision to terminate the trial will be made by the principal investigator (SBK).

Sample size

To detect at least a 0.32 mmol/L between-group mean difference in the fP-glucose (primary outcome) response to the intervention ($\alpha < 0.05$, power=95%, an assumed drop-out rate of 40%), a sample of 200 women (100 in each intervention arm) is needed for the intervention study. This anticipated difference of 0.32 mmol/L between the intervention group and control group corresponds to 0.7 SD of variation in fP-glucose change observed previously in similar women and stage of pregnancy (SD needed for power calculation has been calculated from the Finnish Gestational Diabetes Prevention Study-population; SD for change in fP-glucose value between II and III trimesters in women who got GDM diagnoses at II trimester).⁵¹

eMOM GDM system implementation and data maintenance

The system implementation was designed to support wider employment of eMOM GDM service concept as a part of future digital healthcare path for women with GDM in Helsinki metropolitan area. Technical implementation of the eMOM GDM app as well as browser-based UI for healthcare professionals were conducted by Fujitsu Finland Oy. The data transfer to the eMOM GDM app and professional UI is implemented in the cloud so that eMOM app's back-end server fetches data from a data integration server. Data integration server (implemented by Elisa Corp.) gathers data from sensors' and food tracker's cloud services. The data from eMOM GDM service's back-end server are further transferred to secure HUS Data Lake environment (Microsoft HDInsight Hadoop cluster).

Feasibility study

Before this randomised controlled trial, we conducted feasibility studies of the eMOM GDM app, wearable sensors and food-tracker involving women with GDM (data not published yet). The digital food-tracker used in this study was originally speech-enabled, but in the feasibility study we noticed that a large majority of participants preferred typing to speech. Thus, we discontinued the support for speech recognition.

Ethics and dissemination

The eMOM GDM study is in accordance with the Declaration of Helsinki (www.wma.net). All the participants sign informed consent forms, and they are instructed that they can withdraw at any point during the study. Data during any processes or analyses is pseudonymised, and it does not contain personal information that could be directly linked to any individual. For example, a participant of the intervention group gets a pseudonym (ID based) email address, which the participant uses when she logs in to the eMOM GDM app and the sensor-associated apps. We have ethical approval from ethical committee of HUS, and study permissions from three cities (Helsinki, Espoo and Vantaa) in the Helsinki Metropolitan area to recruit participants.



As a part of quality assurance, the study is being monitored by an external institution, Helsinki University Central Hospital's Study Monitor of Clinical Research Institute (<https://hyksinstituutti.fi/clinical-research-institute-huch/?lang=en>), according to legislation, official guidance and Good Clinical Practice (<https://hyksinstituutti.fi/clinical-research-institute-huch/?lang=en>). The auditing visits are conducted every 6 months during the trial, and the auditing process is independent of investigators and the sponsor.

Important protocol modifications will be communicated with research group, Ethical committee of Helsinki University Hospital and ClinicalTrials.gov.

Sponsor provides facilities for the trial and funder partly funds the trial, but they do not have a role in study design. There are monthly technical steering group meetings by project partners, in which the progress of the trial is followed. However, the ultimate authority to make decisions regarding the clinical trial is the principal investigator (SBK).

The results of the eMOM GDM study will be published in peer-reviewed journals and at national and international scientific conferences. We promote open science by blogs and interact actively with the media, including social media (eg, Twitter and LinkedIn), to gain visibility to our findings among journalists and among non-research community as well.

Patient and public involvement statement

Both women with GDM and registered nurses from the Helsinki Metropolitan Area were involved in the design process of the eMOM GDM service concept. Based on the feedback from the use of the first version of the eMOM GDM app, it was modified into the version, which is used in the eMOM GDM clinical trial. The user-centred design process involved women with GDM (N=21) who did not participate in the clinical trial and the results will be published in a separate article. The local nurses gave insights into the design of the professional UI.

Adverse events

All participants will be under standard care, and thus will be in close medical observation. In the case of adverse or harmful events, study nurses will report to principal investigator (SBK) and the appropriate response to these will be discussed within the research group. All participants are insured with the patient injury insurance by Helsinki University Hospital.

DISCUSSION

Our approach differentiates from existing GDM app interventions in three main aspects. First, we have wearable sensors integrated with the eMOM GDM app. This enables viewing self-tracking data in one place. Objectively and automatically measured, and constantly available data through wearable sensors data can be expected to support learning. However, learning through self-tracking requires active agency from women with GDM, as

associations between lifestyle and nutrition are complex and difficult to identify, especially within first weeks after the GDM diagnosis.⁵² Thus, it remains to be seen if this type of feedback, being quite different from what women with GDM receive in standard care, is effective enough for improving maternal glycaemic levels and neonatal outcomes. Second, our intervention differentiates from other app-based interventions in timewise. Our intervention has clearly defined instructions when participants should use the app (1 week per month) and keep food diary (3 days per month). These time periods were chosen based on the validity (3-day food diary have shown to provide equally valid results with 9-day food diary⁵³), decrease of engagement with mHealth over time,⁵⁴ practicality (battery of CGM lasts approx. a week) and costs (the price of the sensors; we were able to rotate them among participants). The effects of this type of periodical intervention remain unclear, and we will collect experiences on this with interviews with the participants. Third, the system does not consist of an app only, as there is UI for professionals to view the data from the CGM, activity bracelet and food diary from each participant in the intervention group. In this study, the professional UI is used only for remote monitoring of the technical data flow from the participants in a real time. In the future, the professional UI is planned to be used as a resource for monitoring and giving guidance for women with GDM. Together with the eMOM GDM app, the professional UI forms a novel service concept, which can be employed as future digital healthcare path for women with GDM.

The comprehensive self-tracking approach also poses challenges. As we are using multiple sensors and they have their own apps, it is difficult to identify how much the eMOM GDM app and other apps (CGM's app and activity bracelet's app) influence the learning. Especially, the CGM solely has been identified to facilitate self-discovery, that is, finding associations between lifestyle (eg, nutrition) and glucose levels.^{55 56} In order to evaluate the eMOM GDM app's role, we will log the interactions with the app, and we will interview a subgroup of participants about the user experience with the app. By doing so, we are able to evaluate the compliance and engagement with the app, which has been identified as a shortcoming in studies evaluating the effectiveness of GDM apps.¹⁹ The other challenges emerge from technical implementation and maintenance. The sensors' apps need to be installed in compatible mobile phones and the data is fetched to the eMOM GDM app through APIs in the cloud services. This requires active monitoring for the updates regarding compatibility issues between phones and sensors and their APIs.

Author affiliations

¹Department of IT Management, Helsinki University Hospital, Helsinki, Finland

²Department of Computer Science, University of Helsinki, Helsinki, Finland

³Department of Food and Nutrition, University of Helsinki, Helsinki, Finland

⁴Department of Computer Science, Aalto University, Aalto, Finland

⁵Department of Public Health, Welfare Finnish Institute for Health and Welfare, Helsinki, Finland

- ⁶Department of Public Health and Welfare, The National Institute for Health and Welfare, Helsinki, Finland
- ⁷Faculty of Social Sciences, Unit of Health Sciences, University of Tampere, Tampere, Finland
- ⁸UKK Institute for Health Promotion Research, Tampere, Finland
- ⁹Faculty of Medicine and Health Technology, Tampere University, Tampere, Finland
- ¹⁰Department of Obstetrics and Gynaecology, Helsinki University Central Hospital, Helsinki, Finland
- ¹¹Department of Obstetrics and Gynecology, Turku University Hospital, Turku, Finland

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Contributors SBK, SH, MK, PM and GJ planned the design of the study. MK, LTM, PM and SBK planned the analysis of the data and performed the power calculation. SN, SMV and TEK were responsible of methods of dietary data collection and calculations. HS, HV-Y and IK designed the collection of physical activity data. MK and SBK wrote the draft and all authors MK, SBK, LTM, PM, GJ, SN, SMV, HS, HV-Y, IK, TEK and SH have reviewed and approved the final manuscript.

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Competing interests IK is a shareholder of Firstbeat Technologies and products of Firstbeat Technologies are used in the present study. These are sold on commercial basis to researchers. Firstbeat does not fund or supervise the study as an organization.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

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ORCID iDs

Mikko Kytö <http://orcid.org/0000-0002-4936-3502>

Lisa Torsdatter Markussen <http://orcid.org/0000-0002-9337-1198>

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