A Randomized Controlled Trial to Evaluate the Effects of a Smartphone Application–Based Lifestyle Coaching Program on Gestational Weight Gain, Glycemic Control, and Maternal and Neonatal Outcomes in Women With Gestational Diabetes Mellitus: The SMART-GDM Study

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OBJECTIVE

SMART-GDM examined whether Habits-GDM, a smartphone application (app) coaching program, can prevent excessive gestational weight gain (EGWG) and improve glycemic control and maternal and neonatal outcomes in gestational diabetes mellitus (GDM).

RESEARCH DESIGN AND METHODS

In this randomized controlled trial, women diagnosed with GDM between 12 and 30 weeks were randomly assigned to usual care (control) or to additional support from Habits-GDM that integrated dietary, physical activity, weight, and glucose monitoring (intervention). The primary outcome was the proportion of participants with EGWG. Secondary outcomes included absolute gestational weight gain (GWG), glycemic control, and maternal, delivery, and neonatal outcomes.

RESULTS

In total, 340 women were randomized (170 intervention, 170 control; mean ± SD age 32.0 ± 4.2 years; mean BMI 25.6 ± 5.6 kg/m^2). There were no statistically significant differences in the proportions of women with EGWG, absolute GWG, or maternal and delivery outcomes between experimental groups. Average glucose readings were lower in the intervention group (mean difference −0.15 mmol/L [95% CI −0.26; −0.03], $P = 0.011$) as were the proportions of glucose above targets (premeal: 17.9% vs. 23.3%, odds ratio 0.68 [95% CI 0.53; 0.87], $P = 0.003$; 2-h postmeal: 19.9% vs. 50%, 0.54 [0.42; 0.70], $P < 0.001$). When regarded as a composite (although not prespecified), the overall neonatal complications (including birth trauma, neonatal hypoglycemia, hyperbilirubinemia, respiratory distress, neonatal intensive care unit admission, and perinatal death) were significantly lower in the intervention group (38.1% vs. 53.7%, 0.53 [0.34; 0.84], $P = 0.006$).

CONCLUSIONS

When added to usual care, Habits-GDM resulted in better maternal glycemic control and composite neonatal outcomes (nonprespecified) but did not reduce EGWG among women with GDM.

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Gestational diabetes mellitus (GDM) affects 20–30% of pregnancies in Singapore (1,2). It is associated with increased cesarean section (CS) and the risk of preeclampsia, preterm labor, macrosomia, and neonatal hypoglycemia (3). Good glycemic control has been shown to reduce complications (4).

Besides glycemic control, avoiding excessive gestational weight gain (EGWG) may be an important goal. EGWG is associated with a higher risk of hypertensive diseases in pregnancy, CS (5), and large-for-gestational-age infants independently of GDM (6). It is also a strong predictor of postpartum weight retention (7), which in turn predicts future development of type 2 diabetes (8). However, evidence on the effectiveness of lifestyle interventions in reducing EGWG is mixed, with some trials showing improvement and others showing no significant benefit (9–11).

In Singapore, as in many countries, women with GDM are supported to carry out self-care through face-to-face consultations and lifestyle intervention programs. These activities are resource intensive, do not allow for learning to be spaced over time to facilitate better encoding and information retention, or do not allow patients to revisit information at their preferred time. Additionally, patient support and feedback typically occur only during consultations and may not be delivered in a timely manner. The use of mobile technologies could fill these gaps and has been demonstrated to improve glycemic control, adherence, blood pressure, depression, and self-management among nonpregnant patients with diabetes (12,13). The widespread use of smartphones worldwide provides a promising opportunity to harness technology to improve diabetes care and self-management (14,15).

GDM may provide an ideal clinical scenario for the use of smartphone technologies to improve outcomes. First, studies (including our own interviews of women with GDM) have found that women of childbearing age prefer and accept web-based and smartphone application (app)-based support for diabetes management (16–19). Second, they are generally highly motivated, driven by concern for the well-being of their babies. Additionally, the short-lived and finite intervention period (from the diagnosis of GDM until delivery) reduces the likelihood of technology fatigue. While there have been several studies examining the use of technologies such as websites, phone calls, short message service (SMS), e-mails, and telemonitoring to reduce gestational weight gain (GWG) or HbA_{1c} with largely positive findings (20,21), these technologies are not so relevant today. There are only a handful of smartphone apps designed specifically for GDM (16,22–25), and most still involve a significant amount of manual feedback by health care professionals, which is resource intensive.

In this randomized controlled trial (RCT), we sought to examine the effectiveness of Habits-GDM, a largely automated smartphone app-based lifestyle coaching program designed for women with GDM, aimed at preventing EGWG. As secondary aims, we assessed its efficacy on glycemic control and prevention of GDM-related maternal and perinatal complications.

RESEARCH DESIGN AND METHODS

The Web/Smartphone-Based Lifestyle Coaching Program in Pregnant Women With Gestational Diabetes (SMART-GDM) was a single-center RCT conducted at National University Hospital (NUH), a tertiary care hospital in Singapore. This study was approved by the National Healthcare Group Domain Specific Review Board and was prospectively registered as a clinical trial. All participants provided written informed consent before commencement of study procedures.

Eligibility Criteria

Universal screening for GDM was adopted at NUH in January 2017. Women who were diagnosed with GDM between 12 and 30 weeks of gestation and had completed face-to-face GDM education sessions as part of usual care were eligible for the trial. GDM was diagnosed if there was at least one abnormal plasma glucose ($\geq$5.1, 10.0, and 8.5 mmol/L for fasting, 60 min, and 120 min, respectively) after a 75-g oral glucose tolerance test (OGTT), using the World Health Organization 2013 criteria (26). Other inclusion criteria were age $\geq$21 years, singleton pregnancy, possession of a smartphone, ability to navigate an app, proficiency in English, a plan to deliver the baby at NUH, and ability to provide informed consent. Exclusion criteria were preexisting diabetes of any type before the current pregnancy, unavailability of first trimester ($\leq$12 weeks gestation) weight, need for insulin therapy at the start of GDM diagnosis, heart failure, chronic kidney disease, feeding and eating disorders, history of bariatric surgery, use of long-term systemic corticosteroids, impaired mobility, and concomitant participation in other phase I–III clinical trials of investigational medicinal products.

Randomization

Participants were randomly allocated to either intervention or control in a 1:1 fashion on the basis of random permuted blocks with varying sizes of four and six, assuming equal allocation between treatment arms. Randomization was stratified according to ethnicity (Chinese or non-Chinese) and prepregnancy BMI ($<$25 or $\geq$25 kg/m^2). The randomized sequence was generated using the ralloc command of Stata statistical software. Allocation was concealed, as the assignment of intervention was made through a central call center.

Treatment

This study was designed specifically to isolate the effect of introducing the app into the existing care pathway; hence, participants in both arms received the same usual care at NUH. Usual care included one face-to-face education session 1–2 weeks from diagnosis conducted jointly by a diabetes nurse educator and dietitian. This is a group (four to six patients) teaching session that lasts 1–1.5 h. A 1-h-long, individual session was provided for those with plasma glucose at 120 min of $>$11.1 mmol/L on OGTT. The sessions covered pathophysiology and complications of GDM, healthy eating, carbohydrate exchange, and future risk of diabetes but not GWG. Self-monitoring of blood glucose (SMBG) using the Aina or Aina Mini glucometer was initiated, typically seven times a day for 2–3 days a week.

Subsequent care was provided by attending obstetricians. Further advice on diet and lifestyle modification and initiation of insulin and/or metformin was individualized on the basis of SMBG results. In general, insulin was initiated when two or more readings within a 7-point capillary glucose profile on any 2 days of a week exceeded 5.5 mmol/L (premeal) or 6.6 mmol/L (2 h postmeal). Once insulin was initiated, SMBG frequency

was increased to seven times daily. Patients were referred to the endocrinology service if their 120-min plasma glucose on OGTT was ≥11.1 mmol/L or when insulin exceeded 20 units/day. The clinicians were not blinded to the group allocation. The frequency of clinic visits was typically two to four weekly until 32 weeks, then two weekly until 36 weeks, and weekly until delivery, but it could be increased on the basis of individual situations.

In addition to usual care, participants in the intervention group downloaded the Habits-GDM app and were given a Bluetooth weighing scale. The app was passcode protected throughout the study period such that access was restricted to only participants in the intervention group. Habits-GDM was codeveloped with Jana Care, the creators of the Habits program, a smartphone app for diabetes management among nonpregnant individuals (https://www.habitsprogram.com). It targets behavior change to achieve optimal weight and glycemia by providing education, easy monitoring, timely feedback, and cues to empower patients to make lifestyle changes. Preliminary studies examining the Habits program on weight changes, caloric intake, and physical activity have shown promising results (27). The components of its design fit the key constructs of the Health Belief Model, including perceived threat, barriers, benefits, self-efficacy, and cues to action (28). Incorporating behavior change theories into the program design is important for improving program adherence and success, and the Health Belief Model has been considered relevant for pregnant women (19,29).

Habits-GDM is a modification of the original Habits program designed to equip women with GDM with the means to independently manage and monitor their own condition. It also takes into consideration the nutritional requirements and exercise restrictions during pregnancy as well as the need to prevent EGWG as opposed to weight loss, which is the aim of the original program.

The program comprises 12 interactive lessons; diet, SMBG, physical activity, and weight tracking tools; and a messaging platform with health care professionals. The content was codeveloped by endocrinologists, obstetricians, diabetes educators, and dietitians at NUH. The lesson content was similar to the in-person education provided to both study arms, with additional modules on GWG and more detailed dietary and physical activity guidance. Provided in "bite-sized" modules, participants could go through the lessons at their own pace and revisit them whenever they wished.

Participants in the control group manually recorded their SMBG readings on a paper diary, which is usual care at NUH. For the intervention group, the readings were automatically captured into Habits-GDM that interfaces with the Aina or Aina Mini glucometer. The app would prompt participants to capture a 7-point capillary glucose profile on any 2 days of the week (increased to daily if on insulin). SMBG reports were generated weekly for them to monitor progress, which were reviewed by their health care teams as in the control group.

A database of common foods in Singapore was incorporated into Habits-GDM. To avoid overloading the users with information, only two variables (total calories and carbohydrates) relevant to blood glucose and weight management were provided for each food. Drawing from principles of ecological momentary interventions (30,31), the use of the food database was specifically designed to get participants to reflect and learn from the exercise rather than to capture dietary intake accurately. Rather than collecting comprehensive dietary information in the form of a food diary, participants were cued through automated messages to record their diet in the preceding 2–4 h when their 2-h postmeal glucose readings were >6.6 mmol/L, maximizing ecological circumstances for real-time reflections and learning.

To assist them with weight management, participants were provided with a Bluetooth weighing scale, which links directly to the app. Participants were prompted by automated messages to weigh themselves weekly. Weight gain was assumed to be linear over the course of pregnancy. Optimal GWG was defined as per the 2009 Institute of Medicine guidelines (32). We superimposed a range of weights that was considered optimal on the basis of the mother's prepregnancy BMI on the recorded weight-by-time graph on their app. The frequency of prompts to weigh themselves increased to daily once GWG exceeded the optimal range.

Habits-GDM also has a manual chat function where participants could pose questions and the health care team would respond within 24 h. The health care team did not reach out proactively through this function because most of the coaching was designed to be automated as described above. More detailed description on Habits-GDM, including screen shots of the interface, are provided in Supplementary Information 2.

Outcome Evaluation

All participants were followed up at 35–37 weeks of gestation for face-to-face administration of questionnaires on depression and anxiety. Information on maternal and neonatal outcomes were collected from delivery medical records. Additional data, including SMBG and frequency of interactive lessons accessed and weight tracking, were extracted from electronic and paper medical records as well as from the Habits-GDM app as required.

Sample Size Calculation

The sample size was estimated on the basis of EGWG as the primary end point of interest. It was postulated that 30% of the control group would experience EGWG (on the basis of 6-month retrospective data of clinic patients) and that a reduction to 15% with EGWG in the intervention group was considered to be clinically important. A sample size of 170 participants per arm on the basis of a two-sided significance level of 5% would provide a power of at least 85% to detect this difference, after accounting for an anticipated attrition rate of 10%.

Primary Outcome

The primary outcome was the proportion of participants who had EGWG. GWG was calculated by subtracting the first recorded weight in pregnancy at or before 12 weeks gestation from the most recent weight taken in the hospital clinics or wards before delivery. The clinical staff taking the weight were not aware of whether the patient was enrolled in a study or in which arm. The weighing scales (Avamech B1000 or seca 703) were standardized monthly using standard weights of 20, 40, and 60 kg. EGWG was defined as GWG exceeding the recommended GWG for each prepregnancy BMI category by gestational age at delivery on the basis of the 2009 Institute of Medicine guidelines (32).

Secondary Outcomes

Secondary outcomes included absolute GWG, adherence to SMBG (frequency of SMBG performed), glycemic control (average blood glucose readings and the proportion of glucose above targets [premeal >5.5 mmol/L, 2-h postmeal >6.6 mmol/L]), the proportion of participants requiring insulin therapy, maternal and delivery outcomes, and neonatal complications. Maternal outcomes included hypertensive disorders of pregnancy (nonproteinuric pregnancy-induced hypertension, preeclampsia, eclampsia), depression (measured using the Edinburgh Postnatal Depression Scale) (33), and anxiety (measured using the State-Trait Anxiety Inventory) (34). Delivery outcomes included mode of delivery, preterm delivery before 37 weeks of gestation, Apgar score at 1 and 5 min, birth weight, and macrosomia (birth weight >4 kg). Neonatal complications included birth trauma (shoulder dystocia and soft tissue, bone, nerve, and intra-abdominal injuries), neonatal hypoglycemia (capillary blood glucose <2.6 mmol/L within 24 h of birth), hyperbilirubinemia (according to diagnosis by attending pediatricians), respiratory distress, neonatal intensive care unit (NICU) admission within 24 h of birth, and perinatal death. A composite measure of neonatal complications defined by the presence of any one of these conditions is also presented. The trial data were collected on printed forms and entered into a REDCap web database by the study team.

Statistical Analysis

Difference in proportion of participants with EGWG, participants requiring insulin therapy, mode of delivery, hypertensive disorders, preterm delivery, Apgar score of <7 at 1 and 5 min, and neonatal complications were compared between groups using the Fisher exact test. The effect estimates are presented as odds ratios (ORs) with 95% CIs. Covariates such as insulin treatment of GDM and the presence of baseline EGWG for gestation at enrollment into the study were accounted for using logistic regression analysis as appropriate.

For secondary outcomes, which are continuous variables such as absolute GWG, frequency of SMBG, average glucose readings, depression and anxiety scores, and birth weight, the mean differences between interventions were compared using the Student *t* test, with adjustment for insulin treatment of GDM and presence of baseline EGWG in multiple linear regression as appropriate. Prespecified subgroup analyses stratified by whether a participant already showed EGWG for the gestational weeks at recruitment were also performed for the primary outcome and absolute GWG. All statistical analyses were generated using Stata 16 software and performed according to the intention-to-treat principle. Statistical significance was taken at $P < 0.05$. To assess for safety because of concerns that frequent reminder app messages may cause increased anxiety and to examine the adequacy of the sample size, a preplanned interim analysis was conducted on 30 July 2018 when 167 participants had been accrued, with 136 individuals completing follow-up and contributing information. The report was presented to a data and safety monitoring committee comprising a multidisciplinary panel (an endocrinologist, an obstetrician, and a statistician) independent from the study team so that the study operational team remained blinded to the results.

RESULTS

A total of 340 eligible women (170 intervention, 170 control) were enrolled between September 2017 and November 2018. Two intervention and four control participants were lost to follow-up because they returned to their home country for delivery (Supplementary Fig. 1). There was a further control participant who delivered in another local hospital and did not provide information on the delivery outcomes. However, her depression and anxiety scores were collected before delivery. One participant in each arm withdrew from the trial but, nevertheless, contributed information to the delivery outcomes. Thus, in total, 333 participants contributed to the analysis for the primary outcome and delivery outcomes. All participants, except for one in the control group who withdrew very shortly after recruitment, contributed outcome information for frequency of SMBG and blood glucose readings. Thirteen women (nine intervention, four control) delivered before the scheduled 35–37-week gestational follow-up and did not have their depression and anxiety scores recorded. As such, only 319 participants were included in the analysis of the depression and anxiety outcomes. Eighty-four (49.4%) participants in the intervention group accessed the educational lessons. Mean ± SD number of weight values logged per week was 1.85 ± 1.60, with 116 (68%) participants logging weight at least once every week.

Participant Characteristics

Table 1 shows that the demographic characteristics of participants in the two study arms were comparable, with similar distributions for age, BMI, ethnic mix, and OGTT glycemia. The mean prepregnancy BMI was 25.6 ± 5.6 kg/m^2, and 47.7% were overweight or obese with a BMI ≥25 kg/m^2. The proportion with EGWG at recruitment was also similar between groups, as were the proportions with a history of previous GDM and mean HbA_{1c} at GDM diagnosis.

Primary and Other Maternal Outcomes

The effect of intervention on the proportion with EGWG (OR 1.55 [95% CI 0.84; 2.87], $P = 0.152$), absolute GWG (mean difference 0.58 kg [95% CI −0.32; 1.49], $P = 0.207$), hypertensive disorders of pregnancy, or insulin use was not statistically significant (Table 2). Adjustment for insulin use or baseline EGWG did not materially affect these outcomes (Supplementary Table 3). However, the average glucose readings were lower in the intervention group than in the control group (mean difference −0.15 mmol/L [−0.26; −0.03], $P = 0.011$), with no differences in the frequency of SMBG. The proportions of glucose above targets were also significantly lower in the intervention than in the control group (premeal: 17.9% vs. 23.3%, OR 0.68 [0.53; 0.87], $P = 0.003$; 2-h postmeal: 19.9% vs. 50%, 0.54 [0.42; 0.70], $P < 0.001$). The intervention did not increase anxiety or depression. Furthermore, in the prespecified subgroup analyses according to EGWG at recruitment, there was no difference between study arms with respect to proportion with EGWG and absolute GWG by the end of pregnancy (Supplementary Table 4).

Delivery Outcomes

There were 98 (58%) and 85 (52%) male babies in the intervention and control groups, respectively. There was no difference between groups with respect to mode of delivery, preterm delivery, Apgar score <7 at 1 and 5 min, and mean

Table 1—Patient characteristics by experimental group

	Intervention (n = 170)	Control (n = 170)	Total (n = 340)
Age (years)	31.7 ± 4.0	32.2 ± 4.4	32.0 ± 4.2
Ethnicity			
Chinese	75 (44.1)	74 (43.5)	149 (43.8)
Non-Chinese*	95 (55.9)	96 (56.5)	191 (56.2)
Prepregnancy BMI (kg/m^2)	25.5 ± 5.5	25.6 ± 5.7	25.6 ± 5.6
Nulliparous	82 (48.2)	83 (48.8)	165 (48.5)
Gestation at recruitment (weeks)	27.0 ± 3.2	26.7 ± 3.7	26.9 ± 3.5
Gestation at delivery (weeks)	38.5 ± 1.9	38.7 ± 1.1	38.6 ± 1.6
Plasma glucose on OGTT (mmol/L)			
0 min	4.7 ± 0.5	4.6 ± 0.5	4.7 ± 0.5
60 min†	10.3 ± 1.4	10.2 ± 1.2	10.3 ± 1.3
120 min	8.6 ± 1.4	8.6 ± 1.3	8.6 ± 1.3
Preexisting hypertension	6 (3.5)	0 (0)	6 (1.8)
Prenatal smoking	4 (2.4)	2 (1.2)	6 (1.8)
Prenatal alcohol consumption	23 (13.5)	23 (13.5)	46 (13.5)
History of previous GDM‡	19 (11.3)	21 (12.7)	40 (12.0)
Family history of diabetes§	69 (42.3)	79 (47.3)	148 (44.8)
HbA_{1c} at recruitment			
%‖	5.3 ± 0.4	5.3 ± 0.4	5.3 ± 0.4
mmol/mol‖	34.4 ± 4.7	34.2 ± 4.5	34.4 ± 4.6
EGWG at recruitment	38 (22.4)	34 (20.0)	72 (21.2)

Data are mean ± SD or n (%). *Non-Chinese included Malays, Indians, and other minority ethnic groups such as Burmese, Filipino, Pakistani, Sikh, Sri Lankan, Thai, and Vietnamese. †Two with missing data. ‡Seven with history of GDM unknown. §Ten with family history of diabetes unknown. ‖One missing HbA_{1c} in each arm.

birth weight of babies. There were only two cases of macrosomia in the control group but none in the intervention group.

Neonatal Complications

A total of 152 infants (64 intervention, 88 control) experienced at least one of the specified neonatal complications. Although there were fewer events of neonatal hypoglycemia, hyperbilirubinemia, respiratory distress, and NICU admission in the intervention versus control group, these differences did not reach statistical significance individually. When regarded as a composite (although not prespecified), the overall neonatal complications were significantly lower in the intervention group (38.1%) than in the control group (53.7%; OR 0.53 [95% CI 0.34; 0.84], P = 0.006) (Table 3). The proportion experiencing birth trauma was similar in both groups (4%), and there was one perinatal death in the control group because of hemolysis, elevated liver enzymes, and low platelet count syndrome associated with stillbirth at 37 weeks of gestation.

CONCLUSIONS

SMART-GDM showed that the use of a smartphone app-based lifestyle coaching program designed specifically for women with GDM did not substantially reduce the odds of EGWG compared with usual care. However, women in the intervention group demonstrated better glycemic control, and this was associated with fewer composite adverse neonatal outcomes, mainly as a consequence of reduced neonatal hypoglycemia.

A systematic review and meta-analysis on the use of telemedicine for diabetes in pregnancy found insufficient evidence of superiority over usual care, but the trials included were small and displayed potential methodological bias and the technologies were not smartphone apps (21). To our knowledge, there are only four published RCTs that evaluated a smartphone app-based solution for the management of GDM (16,22–24). Improved GWG was reported in two such trials (22,24), and improved glycemia (mean SMBG, proportion of off-target pre- and postprandial glucose) and compliance with SMBG were also reported in two

Table 2—Primary and other maternal outcomes by experimental group

	Intervention (n = 170)	Control (n = 170)	Effect estimate (95% CI)	P value
Primary outcome				
EGWG by end of pregnancy*	35 (20.8)	24 (14.6)	6.29 (−1.88; 14.45)	0.152
Secondary outcomes				
Absolute GWG (kg)*	9.03 ± 4.49	8.44 ± 3.88	0.58 (−0.32; 1.49)	0.207
Frequency of SMBG per week†	12 ± 5	12 ± 6	0 (−1; 1)	0.745
Blood glucose readings (mmol/L)†	5.40 ± 0.53	5.54 ± 0.53	−0.15 (−0.26; −0.03)	0.011
Proportion of glucose above target†‡				
Premeal >5.5 mmol/L	30 (17.9)	39 (23.2)	0.68 (0.53; 0.87)	0.003
2-h postmeal >6.6 mmol/L	34 (19.9)	50 (29.4)	0.54 (0.42; 0.70)	<0.001
Insulin treatment*	17 (10.1)	27 (16.4)	−6.24 (−13.50; 1.01)	0.106
Hypertensive disorder of pregnancy*	8 (4.8)	4 (2.4)	2.34 (−1.64; 6.32)	0.489
EPDS§	5.1 ± 4.1	5.3 ± 4.3	−0.25 (−1.17; 0.67)	0.589
STAI state score§	33.50 ± 9.50	33.52 ± 9.57	−0.02 (−2.12; 2.09)	0.988
STAI trait score§	32.71 ± 8.14	33.42 ± 8.63	−0.71 (−2.56; 1.13)	0.448

Data are mean ± SD or n (%) unless otherwise indicated. Effect estimate for comparison of means and proportions refers to mean difference and difference in proportions, respectively, except for proportion of glucose above targets, which are in terms of ORs. EPDS, Edinburgh Postnatal Depression Scale; STAI, State-Trait Anxiety Inventory. *Seven with missing observations (two intervention, five control). †One missing observation in the control group because of study withdrawal. ‡Analyzed through mixed-effects logistic regression to take into account possible intracorrelation in measurements taken at the various time points and assuming random effects of individuals and weeks of gestation nested within individuals. An interaction between intervention and meal type (pre- or postmeal) was also included in this model. §Twenty-one missing observations (12 intervention, 9 control).

Table 3—Delivery and neonatal outcomes by experimental group

	Total (n = 333)	Intervention (n = 168)	Control (n = 165)	P value
Delivery outcomes				
Mode of delivery				0.769
Normal vaginal	201 (60.4)	104 (61.9)	97 (58.8)	
Assisted vaginal*	16 (4.8)	7 (4.2)	9 (5.5)	
CS	116 (34.8)	57 (33.9)	59 (35.8)	
Elective	56 (16.8)	30 (17.9)	26 (15.8)	
Emergency	60 (18.0)	27 (16.1)	33 (20.0)	
Preterm	24 (7.2)	14 (8.3)	10 (6.1)	0.526
Apgar score <7 at 1 min	10 (3.0)	6 (3.6)	4 (2.4)	0.750
Apgar score <7 at 5 min	1 (0.3)	0 (0.0)	1 (0.6)	0.494
Birth weight (g)	3,060.1 ± 452.5	3,055.5 ± 414.9	3,064.8 ± 489.0	0.853
Macrosomia >4 kg	2 (0.6)	0 (0)	2 (1.2)	0.245
Neonatal outcomes				
Composite neonatal complications†	152 (45.8)	64 (38.1)	88 (53.7)	0.006
Birth trauma	13 (3.9)	7 (4.2)	6 (3.6)	1.000
Neonatal hypoglycemia	61 (18.3)	24 (14.3)	37 (22.4)	0.065
Hyperbilirubinemia	60 (18.0)	27 (16.1)	33 (20.0)	0.355
Respiratory distress	53 (15.9)	24 (14.3)	29 (17.6)	0.455
NICU admission	33 (9.9)	12 (7.1)	21 (12.7)	0.100
Perinatal death	1 (0.3)	0 (0.0)	1 (0.6)	0.495

Data are n (%) or mean ± SD. *Five vacuum and two forceps delivery in the intervention group and six vacuum and three forceps delivery in the control group. †Not prespecified.

studies (16,22). No studies showed differences in maternal and neonatal outcomes, except for a lower rate of CS in one (23). SMART-GDM is the largest RCT to date, adding to the literature reinforcing the effectiveness of the use of mobile technologies for supporting the management of glycemia in GDM. It is the first to demonstrate an associated reduction in adverse neonatal outcomes.

There are several possible reasons for the intervention to show better glycemic control but not the primary outcome of EGWG. First is the intensity of intervention. While the interventions in these RCTs used smartphone apps, all of them included proactive manual feedback by health care professionals, which was resource intensive. These included individualized daily manual feedback (up to 2 h daily, including weekends) and immediate answers to questions posed through the app (16,22), proactive review of SMBG readings one to three times weekly and sending of feedback manually (23,24), alerts sent to the health care team when there was an abnormal SMBG reading (22–24), and proactive communication using a conversation map (24). In contrast, Habits-GDM provided largely automated interactive coaching to promote self-awareness of specific lifestyle choices at momentary periods in daily lives, minimizing the need of intensive human resources, and this may have had an impact on the magnitude of effect. The temporal connection between lifestyle habits and weight changes is more removed compared with blood glucose levels, making the link between diet or physical activity and GWG less salient than that for blood glucose. Five of the 12 education modules had little direct bearing on weight management but covered other aspects of GDM, and the total duration of these modules may have been insufficient to have effects on GWG.

Second, the time for intervention from recruitment (27 weeks) to delivery (38 weeks) may be enough to show a difference in glycemia but too short to have an impact on GWG. A study with mean gestation at recruitment of 25 weeks showed improved glycemia and GWG (22), while another with mean gestation of 31 weeks showed no effect on glycemia and GWG (23). Third, only 21% of participants had EGWG at recruitment, and the likelihood of a substantial number of participants developing EGWG after a GDM diagnosis when they were more aware of lifestyle modification and after being able to maintain optimal GWG for two trimesters before recruitment was low. This would reduce the power to detect a difference in EGWG. Fourth, mean baseline BMI of our study population was relatively low (25.6 kg/m^2), and in studies not limited to GDM, mobile technologies appeared to have greater efficacy in preventing EGWG among women who were overweight or obese before pregnancy (20,35) and less effective in those with lower baseline BMI (36). Findings were more varied in GDM: In two studies where baseline BMI was >30 kg/m^2 (24) and >25 kg/m^2 (22), both saw GWG reductions, but in another with mean baseline BMI of 31.3 kg/m^2, there was no GWG reduction (23).

Our study shows that improved glycemic control in GDM is associated with improved neonatal outcomes, even when EGWG is not affected. This discordance in the effects of our intervention on GWG and glycemic control, while inadvertent, provides an opportunity to make inferences about the differential impact of targeting EGWG as opposed to glycemia in women with GDM. These are hard to tease apart. Previous RCTs involving interventions that decreased GWG did not affect perinatal outcomes (37) and were not performed in the context of GDM. It is difficult to conduct interventional studies in GDM where a difference in EGWG is reached while maintaining similar glycemic control. RCTs have shown that lowering glycemia improves perinatal outcomes in GDM (4), but all except for two did not collect data on GWG. Both of the studies that collected GWG data saw improved glycemia but similar GWG, with one showing a reduction in large-for-gestational-age infants (38) but the other showing no difference in neonatal outcomes (39). Perhaps EGWG should be the focus early in pregnancy, and it may

be more relevant to the prevention of GDM (40), allowing more time to have an impact at a point when it is more relevant. After the diagnosis of GDM, the focus should be on glycemia.

The strengths of SMART-GDM include its methodical design and randomization, a large sample size, and the real-life clinical setting where it was conducted as well as its consideration of a comprehensive range of outcomes. However, our trial design did not allow for the exploration of longer-term maternal and neonatal outcomes postpartum. Additionally, we did not collect data that would have allowed us to evaluate the mechanisms by which our digital intervention differentially affected GWG and glycemic control. This limits the ability to inform the development of similar digital applications for GDM in other cultural contexts. Our trial did not evaluate the digital intervention in place of usual care. Nonetheless, we believed that the demonstration of efficacy when added to usual care was an appropriate first step before attempting a noninferiority trial comparing a digital intervention with usual care. Clinicians initiating treatment were not blinded to intervention assignment and could have potentially introduced bias, but the nature of the study did not allow clinician blinding. Adherence to the lesson modules was relatively low but satisfactory in weight measurements. Other components of intervention were more complex, and adherence was difficult to define or measure.

In conclusion, we developed a smartphone app-based lifestyle coaching program that integrates with SMBG and a Bluetooth weighing scale designed to prevent EGWG and optimize glycemic control in women with GDM. When added to usual care, the use of the app lowered maternal blood glucose and was associated with fewer neonatal complications but did not reduce EGWG. Further studies are required to better understand which components of the app gave rise to these findings and to determine whether it can replace some components of usual care.

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References

1. Chong YS, Cai S, Lin H, et al.; GUSTO study group. Ethnic differences translate to inadequacy of high-risk screening for gestational diabetes mellitus in an Asian population: a cohort study. BMC Pregnancy Childbirth 2014;14:345
2. Yew TW, Khoo CM, Thai AC, Kale AS, Yong EL, Tai ES. The prevalence of gestational diabetes mellitus among Asian females is lower using the new 2013 World Health Organization diagnostic criteria. Endocr Pract 2014;20:1064–1069
3. Perkins JM, Dunn JP, Jagasia SM. Perspectives in gestational diabetes mellitus: a review of screening, diagnosis, and treatment. Clin Diabetes 2007;25:57–62
4. Horvath K, Koch K, Jeitler K, et al. Effects of treatment in women with gestational diabetes mellitus: systematic review and meta-analysis. BMJ 2010;340:c1395
5. Kominiarek MA, Saade G, Mele L, et al.; Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) Maternal-Fetal Medicine Units (MFMU) Network. Association between gestational weight gain and perinatal outcomes. Obstet Gynecol 2018;132:875–881
6. Kim SY, Sharma AJ, Sappenfield W, Wilson HG, Salihu HM. Association of maternal body mass index, excessive weight gain, and gestational diabetes mellitus with large-for-gestational-age births. Obstet Gynecol 2014;123:737–744
7. Margerison Zilko CE, Rehkopf D, Abrams B. Association of maternal gestational weight gain with short- and long-term maternal and child health outcomes. Am J Obstet Gynecol 2010;202:574.e1–574.e8
8. Al Mamun A, Mannan M, O'Callaghan MJ, Williams GM, Najman JM, Callaway LK. Association between gestational weight gain and postpartum diabetes: evidence from a community based large cohort study. PLoS One 2013;8:e75679
9. Bogaerts AFL, Devlieger R, Nuyts E, Witters I, Gyselaers W, Van den Bergh BRH. Effects of lifestyle intervention in obese pregnant women on gestational weight gain and mental health: a randomized controlled trial. Int J Obes 2013;37:814–821
10. Hui AL, Back L, Ludwig S, et al. Effects of lifestyle intervention on dietary intake, physical activity level, and gestational weight gain in pregnant women with different pre-pregnancy Body Mass Index in a randomized control trial. BMC Pregnancy Childbirth 2014;14:331
11. Ronnberg AK, Ostlund I, Fadl H, Gottvall T, Nilsson K. Intervention during pregnancy to reduce excessive gestational weight gain—a randomised controlled trial. BJOG 2015;122:537–544
12. Garabedian LF, Ross-Degnan D, Wharam JF. Mobile phone and smartphone technologies for diabetes care and self-management. Curr Diab Rep 2015;15:109
13. Wu X, Guo X, Zhang Z. The efficacy of mobile phone apps for lifestyle modification in diabetes: systematic review and meta-analysis. JMIR Mhealth Uhealth 2019;7:e12297
14. Tufano JT, Karras BT. Mobile eHealth interventions for obesity: a timely opportunity to leverage convergence trends. J Med Internet Res 2005;7:e58
15. Wigginton C, Curran M, Brodeur C, Curran M, Brodeur C. *Global Mobile Consumer Trends*. 2nd ed. New York, Deloitte Touche Tohmatsu Ltd., 2017
16. Miremberg H, Ben-Ari T, Betzer T, et al. The impact of a daily smartphone-based feedback system among women with gestational diabetes on compliance, glycemic control, satisfaction, and pregnancy outcome: a randomized controlled trial. Am J Obstet Gynecol 2018;218:453.e1–453.e7
17. Hirst JE, Mackillop L, Loerup L, et al. Acceptability and user satisfaction of a smartphone-based, interactive blood glucose management system in women with gestational diabetes mellitus. J Diabetes Sci Technol 2015;9:111–115
18. Skar JB, Garnweidner-Holme LM, Lukasse M, Terragni L. Women's experiences with using a smartphone app (the Pregnant+ app) to manage gestational diabetes mellitus in a randomised controlled trial. Midwifery 2018;58:102–108
19. Garnweidner-Holme LM, Borgen I, Garitano I, Noll J, Lukasse M. Designing and developing a mobile smartphone application for women with gestational diabetes mellitus followed-up at diabetes outpatient clinics in Norway. Healthcare (Basel) 2015;3:310–323
20. Lau Y, Klainin-Yobas P, Htun TP, et al. Electronic-based lifestyle interventions in overweight or obese perinatal women: a systematic review and meta-analysis. Obes Rev 2017;18:1071–1087
21. Ming W-K, Mackillop LH, Farmer AJ, et al. Telemedicine technologies for diabetes in pregnancy: a systematic review and meta-analysis. J Med Internet Res 2016;18:e290
22. Guo H, Zhang Y, Li P, Zhou P, Chen L-M, Li S-Y. Evaluating the effects of mobile health intervention on weight management, glycemic control and pregnancy outcomes in patients with

gestational diabetes mellitus. J Endocrinol Invest 2019;42:709–714
23. Mackillop L, Hirst JE, Bartlett KJ, et al. Comparing the efficacy of a mobile phone-based blood glucose management system with standard clinic care in women with gestational diabetes: randomized controlled trial. JMIR Mhealth Uhealth 2018;6:e71
24. Al-Ofi EA, Mosli HH, Ghamri KA, Ghazali SM. Management of postprandial hyperglycaemia and weight gain in women with gestational diabetes mellitus using a novel telemonitoring system. J Int Med Res 2019;47:754–764
25. Borgen I, Garnweidner-Holme LM, Jacobsen AF, et al. Smartphone application for women with gestational diabetes mellitus: a study protocol for a multicentre randomised controlled trial. BMJ Open 2017;7:e013117
26. World Health Organization. Diagnostic criteria and classification of hyperglycaemia first detected in pregnancy. Geneva, Switzerland, World Health Organization, 2013. Accessed 27 April 2020. Available from https://www.who.int/diabetes/publications/Hyperglycaemia_In_Pregnancy/en/
27. Jena S, Ranjani H, Anjana RM, Mohan V. Reality-TV based diabetes prevention for millions of people in India. Abstract presented at the 41st Annual Conference of the Research Society for the Study of Diabetes, New Delhi, India, 8–10 November 2013
28. Carpenter CJ. A meta-analysis of the effectiveness of health belief model variables in predicting behavior. Health Commun 2010;25:661–669
29. Pearce EE, Evenson KR, Downs DS, Steckler A. Strategies to promote physical activity during pregnancy: a systematic review of intervention evidence. Am J Lifestyle Med 2013;7:38–50
30. Carter BL, Day SX, Cinciripini PM. Momentary health interventions: where are we and where are we going? In *The Science of Real-Time Data Capture: Self-Reports in Health Research*. Stone AA, Ed. Oxford, Oxford University Press, 2007, pp. 289–307
31. Runyan JD, Steenbergh TA, Bainbridge C, Daugherty DA, Oke L, Fry BN. A smartphone ecological momentary assessment/intervention "app" for collecting real-time data and promoting self-awareness. PLoS One 2013;8:e71325
32. Institute of Medicine, National Research Council. Weight gain during pregnancy: reexamining the guidelines. Washington, DC, The National Academies Press, 2009. Accessed 27 April 2020. Available from https://www.nap.edu/catalog/12584/weight-gain-during-pregnancy-reexamining-the-guidelines
33. Cox JL, Holden JM, Sagovsky R. Detection of postnatal depression. Development of the 10-item Edinburgh Postnatal Depression Scale. Br J Psychiatry 1987;150:782–786
34. Spielberger CD, Gorsuch RL, Lushene R, Vagg PR, Jacobs GA. *Manual for the State-Trait Anxiety Inventory*. Palo Alto, CA, Consulting Psychologists Press, 1983
35. Willcox JC, Wilkinson SA, Lappas M, et al. A mobile health intervention promoting healthy gestational weight gain for women entering pregnancy at a high body mass index: the txt4two pilot randomised controlled trial. BJOG 2017;124:1718–1728
36. Olson CM, Groth SW, Graham ML, Reschke JE, Strawderman MS, Fernandez ID. The effectiveness of an online intervention in preventing excessive gestational weight gain: the e-moms roc randomized controlled trial. BMC Pregnancy Childbirth 2018;18:148
37. Champion ML, Harper LM. Gestational weight gain: update on outcomes and interventions. Curr Diab Rep 2020;20:11
38. Bonomo M, Corica D, Mion E, et al. Evaluating the therapeutic approach in pregnancies complicated by borderline glucose intolerance: a randomized clinical trial. Diabet Med 2005;22:1536–1541
39. Garner P, Okun N, Keely E, et al. A randomized controlled trial of strict glycemic control and tertiary level obstetric care versus routine obstetric care in the management of gestational diabetes: a pilot study. Am J Obstet Gynecol 1997;177:190–195
40. Shepherd E, Gomersall JC, Tieu J, Han S, Crowther CA, Middleton P. Combined diet and exercise interventions for preventing gestational diabetes mellitus. Cochrane Database Syst Rev 2017;11:CD010443