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Faculteit Geneeskunde en Levenswetenschappen *School voor Levenswetenschappen*

master in de biomedische wetenschappen

Masterthesis

Feasibility of Telemonitoring in Gestational Diabetes Mellitus Care: Expectations and Satisfaction of Healthcare Providers and Patients

Anouk Bollen

Scriptie ingediend tot het behalen van de graad van master in de biomedische wetenschappen, afstudeerrichting klinische biomedische wetenschappen

PROMOTOR :

dr. Dorien LANSSENS

De transnationale Universiteit Limburg is een uniek samenwerkingsverband van twee universiteiten in twee landen: de Universiteit Hasselt en Maastricht University.



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2023
2024



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Feasibility of Telemonitoring in Gestational Diabetes Mellitus Care: Expectations and Satisfaction of Healthcare Providers and Patients*

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*Running title: *TEGEDIM study*

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Keywords: gestational diabetes mellitus, telemonitoring, iHealth Gluco-Smart application, gestational outcomes, user-experience

ABSTRACT

Pregnant women with gestational diabetes mellitus (GDM) require dietary adjustments and blood glucose monitoring to maintain normoglycemia. Inconsistent reporting can lead to ineffective follow-up, higher complication risks, and increased healthcare workload. Telemonitoring (TM) can address this limitation by promoting therapy adherence and reducing complication risks.

In this study, we evaluated the expectations and satisfaction of pregnant women and healthcare providers regarding the integration of TM into GDM care, and investigated its impact on gestational outcomes. Pregnant women were divided into the standard care (SC) or TM group. Expectations and satisfaction of pregnant women and healthcare providers were assessed by start- and end-of-study questionnaires. Gestational outcomes were collected from the patient's electronic health records.

The expectations about TM were high in both the TM and SC groups. Post-study, the TM group expressed higher satisfaction ($P = 0.037$) with their care compared to the SC group, although care preferences did not significantly differ. Comparing the start-and end-of-study questionnaires of the healthcare providers revealed good expectations and satisfaction with TM. Healthcare providers expected TM to improve GDM follow-up ($P = 0.043$) and decrease administrative tasks ($P = 0.025$), but their experiences did not align with their

expectations. No significant differences were observed in healthcare workload or gestational outcomes between the SC and TM groups.

In conclusion, TM shows the potential to enhance patient satisfaction with GDM monitoring. However, further optimization of the TM program is required to reduce healthcare workload, and more comprehensive studies are needed to assess the impact on gestational outcomes.

INTRODUCTION

Background – Gestational diabetes mellitus (GDM) is characterized by the onset of spontaneous hyperglycemia, typically diagnosed in the second or third trimester of gestation (1, 2). The diagnosis of GDM is based on the International Association of Diabetes and Pregnancy Study Groups (IADPSG) criteria, defined as a fasting blood glucose level above 5.1 mmol/l and/or a two-hour blood glucose level of 8.5 mmol/l during a 75-gram oral glucose tolerance test (3). Globally, GDM affects 14.7% of pregnant women, with a prevalence of almost 10% in Flanders (4, 5). The prevalence of GDM is increasing, attributable to an increase in obesity and maternal age (6).

During an uncomplicated pregnancy, the temporary insulin response may be reduced. This reduction is due to increased levels of diabetogenic hormones, including cortisol, progesterone, and estrogen, and hormones and adipokines secreted from the placenta, including tumor necrosis factor α , human

placental lactogen, and growth hormone (7, 8). Normally, this decrease in insulin levels is compensated by augmented insulin production from the pancreatic β cells (9). However, in pregnant women complicated with GDM, insulin resistance arises due to impaired function of the pancreatic β -cells, resulting in persistently elevated blood glucose levels (1, 9). Consequently, these elevated blood glucose levels can result in neonates with macrosomia which can complicate delivery, necessitating a cesarean section (10). Other complications may encompass preterm birth, maternal hypertension, and a high risk of developing type 2 diabetes for both the mother and neonate later in life (10, 11). To protect both the pregnant woman and the neonate from these potential complications, a proper follow-up, including blood glucose monitoring, is crucial (Figure 1). Although the standard care of GDM incorporates a prenatal follow-up methodology, it lacks efficacy and, therefore, is in need of improvement.

Standard care and prenatal follow-up of GDM – The principal measures for blood glucose level regulation in GDM involve lifestyle modifications, comprising dietary adjustments, supplemented as necessary by intermittent insulin therapy (1, 8, 12). Insulin therapy is initiated if maternal blood glucose levels persistently exceed target levels despite dietary adjustments (8, 12). To sustain normoglycemia throughout the day, carbohydrate consumption should be restricted to 35-45% of the total caloric intake, distributed

among three main meals and two to four snacks daily. This adjustment serves to mitigate the postprandial glucose peaks, thereby ensuring the attainment of normoglycemic values (8).

Together with these lifestyle modifications and/or insulin therapy, pregnant women need to self-monitor their blood glucose levels at home. Hereafter, the data obtained in the patient's home environment will be sent to the healthcare providers in the hospital. This medical information allows the endocrinologist to make treatment adjustments (low sugar diet or insulin therapy) when necessary, potentially preventing the development of GDM-associated complications (8).

However, a limitation of this prenatal follow-up method lies in the potential oversight by pregnant women in monitoring and reporting their blood glucose values to the endocrinology department. Unfortunately, delayed detection of abnormal blood glucose values can result in less effective follow-up, increasing the risk of developing GDM-related complications and healthcare costs, particularly in situations where hospitalization is required (13). Additionally, it imposes an increased workload on the dietitians and nurses, as they are required to contact these patients on each occasion.

Telemonitoring of GDM – Incorporating telemonitoring (TM) into the standard care of GDM offers a viable solution to mitigate the limitations described above. TM can be defined as the use of telecommunication technologies to assist the transmission of medical information between the patient and the healthcare provider

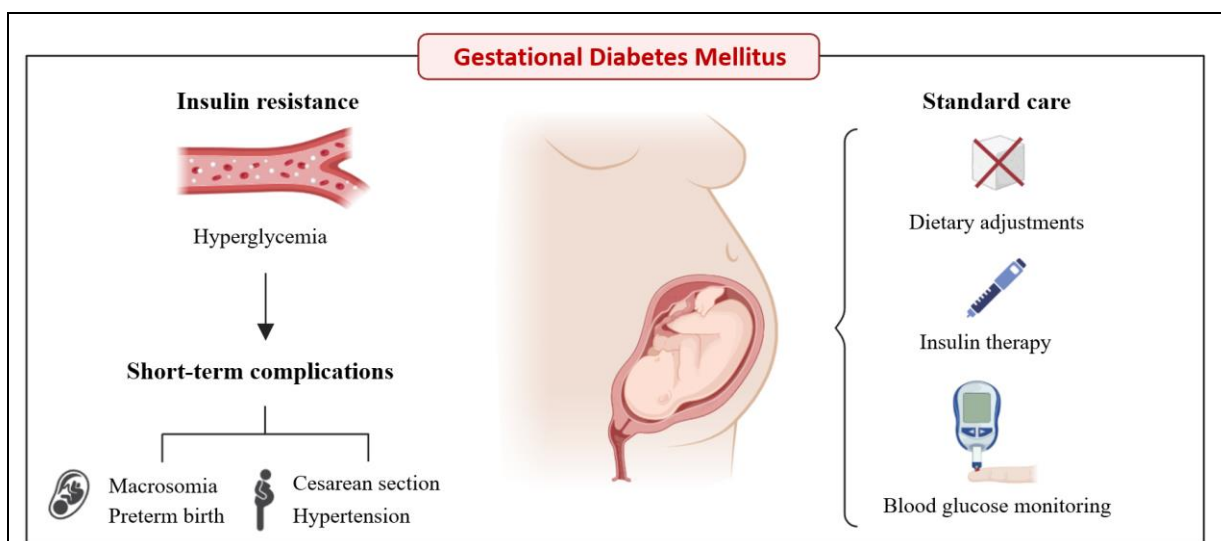


Fig. 1 – Pathophysiology and potential short-term complications for both the mother and neonate which can be mitigated with the current standard care for pregnant women with GDM. GDM, gestational diabetes mellitus.

and has already proven its efficacy in other domains, including cardiovascular diseases, pulmonary conditions, and diabetes (14, 15, 16).

Various studies have examined the impact of TM on the compliance rate in managing blood glucose levels, showing significant improvements in both non-pregnant diabetic and GDM populations compared to standard care (17, 18, 19, 20). However, limited is known about the feasibility of adding TM to the standard care of GDM. Although certain studies have indicated pregnant women's satisfaction with TM in prenatal care, these findings were not the primary focus of the study, necessitating further exploration (18, 21, 22). To our knowledge, no other articles are investigating the expectations of pregnant women and healthcare providers of adding TM to the standard care of GDM. Therefore, the primary focus of this study is on further investigating the feasibility of integrating TM into the standard care of GDM by examining the expectations and satisfaction of both pregnant women and healthcare providers regarding the use of TM. These data can validate previous findings and examine whether TM can improve the prenatal follow-up for pregnant women with GDM while alleviating the workload of the healthcare providers.

While the effect of TM on gestational outcomes has been extensively studied in other gestational disorders, its effect in GDM-complicated pregnancies remains less investigated. In 2015, Lanssens *et al.* initiated the PRenancy REmote MONitoring (PREMOM) I study, focusing on pregnant women with gestational hypertensive disorders (GHD). In the PREMOM I study, TM was integrated into the standard prenatal care to monitor their blood pressure at home. Interestingly, the results indicated that TM leads to fewer prenatal hospitalizations and fewer inductions compared to standard care (14). Next, a study by Miremberg *et al.* has indicated positive trends of TM on gestational outcomes in GDM, including a lower birth weight, a lower rate of cesarean delivery, and a lower rate of adverse neonatal outcomes compared to standard care. Nevertheless, there was not enough power to confirm these results (18). A recently published systematic review has also demonstrated a reduction in neonatal intensive care (NIC) unit admissions when integrating a smartphone-based intervention system

compared to those receiving standard care of GDM. However, Wang *et al.* noted that further research is needed to investigate the effects of TM on gestational outcomes (23). Hence, the secondary focus of this study is to address this gap by further investigating the impact of TM on maternal and neonatal outcomes during GDM. Given the increased risk of GDM complications in the absence of proper blood glucose monitoring, it is important to investigate whether the addition of TM can reduce these complications in comparison to the standard follow-up method (17).

EXPERIMENTAL PROCEDURES

Study design – This monocentric, prospective, interventional, research-initiated, randomized controlled feasibility study was performed at the secondary hospital Ziekenhuis Oost-Limburg (ZOL) in Genk between November 27, 2023, and June 06, 2024. Ethical approval was obtained by the ethics committee of the University of Hasselt and the local ethics committee of ZOL on March 21, 2023 (European Union Drug Regulating Authorities Clinical Trials (EudraCT) number: B3712023000003). This study was conducted in accordance with the Declaration of Helsinki and is registered on ClinicalTrials.gov (NCT06251466). In total, 16 pregnant women participated in this study. Study participation started upon the diagnosis of GDM and concluded with the postpartum discharge of the pregnant women and their neonates from the hospital.

Study population – Pregnant women with GDM were recruited and screened by the attended endocrinologist of ZOL, Genk. Eligible participants were pregnant women of ≥ 18 years old, who were able to understand oral and written information in Dutch, with a diagnosis of GDM from 20 weeks gestation. Pregnant women were excluded if: (1) any congenital malformation was detected (2) diabetes type 1 or 2 was diagnosed (3) they had multiple pregnancy (4) or they did not own a smartphone. If the pregnant women met all the eligibility criteria, they were invited to the nurses and the dieticians who gave oral information regarding the use of the glucose meter and treatment options, including dietary adjustments and insulin therapy. Hereafter, the pregnant women were referred to the investigator, who gave oral and written information about the study, including: the aim

of the study, risks, benefits, confidentiality, and anonymity of information. Finally, eligible pregnant women were included after signing the informed consent.

Randomization – Participants were randomized into one of the two study groups, including the standard care (SC) group or the TM group in a 1:1 ratio. Randomization was performed using the electronic case report form (eCRF) (Castor EDC, New York, United States).

SC group – Pregnant women in the SC group were provided with a glucose meter for blood glucose monitoring at home. These women adhered to the standard procedure for follow-up during GDM, meaning that they needed to measure their blood glucose levels weekly at four different time points, including: (1) fasting before breakfast (2) two hours after breakfast (3) two hours after lunch (4) and two hours after dinner. Hereafter, they needed to call their blood glucose levels weekly to the endocrinology department of the hospital. Participants measuring abnormal blood glucose levels at one of the four time points were requested to measure their blood glucose levels again on the following day. If the blood glucose levels remained abnormal for several measurement days, pregnant women were requested to go to the endocrinologist to start insulin therapy. Whereas pregnant women only receiving dietary adjustments needed to measure their blood glucose levels once a week, women receiving insulin treatment needed to measure daily at four different time points, including: (1) fasting before breakfast (2) two hours after breakfast (3) two hours after lunch (4) and two hours after dinner, and two days a week at seven different time points, including:

(1) fasting before breakfast (2) two hours after breakfast (3) before lunch (4) two hours after lunch (5) before dinner (6) two hours after dinner (7) and before they are going to sleep.

TM group – Pregnant women in the TM group also adhered to the standard procedure for follow-up during GDM. However, the difference between the groups lay in how they transmit their blood glucose measurements to the hospital. After each measurement, the participants in the TM group needed to register these blood glucose levels in a smartphone application (iHealth Gluco-Smart, California, United States). This data was sent, via Bluetooth and Wi-Fi, to an online digital health platform (Dharma, Hasselt, Belgium) for review by the investigators of the Mobile Health Unit of ZOL, Genk (24). Participants measuring abnormal blood glucose levels at one of the four time points were requested to measure their blood glucose levels again on the following day. The investigator contacted the endocrinology department if any abnormal blood glucose values were detected. Interventions, including insulin treatment, were performed by the endocrinologist when necessary (Figure 2).

Primary outcome – The primary outcome measures included the pregnant women's and healthcare providers' expectations and satisfaction regarding TM, measured through questionnaires. After inclusion and randomization, pregnant women were asked to complete a questionnaire assessing their expectations regarding the addition of TM to GDM care (Supplementary 1). This questionnaire included the following aspects: familiarity with TM, expectations regarding the addition of TM (positive/negative), impact of TM on gestational outcomes, user experience of

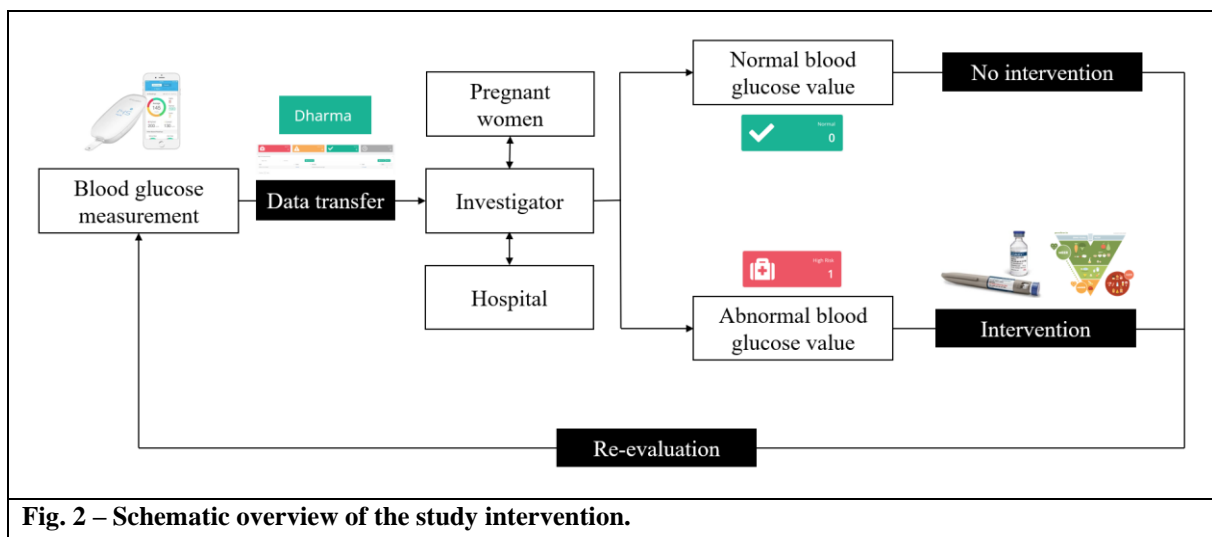


Fig. 2 – Schematic overview of the study intervention.

TM, time-saving part of TM, cost-effectiveness of TM, effectiveness of follow-up with TM, added value of TM to GDM care, and violation of privacy when integrating TM. After gestation, they were asked to fill in a questionnaire to assess the satisfaction with the care they received (Supplementary 2, 3). This questionnaire included the following aspects: feeling about TM after study participation (positive/negative), satisfaction with the care received, clarity of the instructions about reporting the blood glucose measurements, satisfaction about the communication with healthcare providers, user experience, time-consumption of reporting blood glucose measurements, feeling about monitoring their health by healthcare providers, preference of care (standard phone call or TM). The questions were scored on a 10-point scale from zero (disagree/not satisfied) to ten (agree/satisfied), with five being neutral.

At the start of the study, the healthcare providers, including the endocrinologists, dieticians, and nurses, were also asked to complete a questionnaire assessing their expectations about TM (Supplementary 4). At the end of the study period, a similar questionnaire was administered to assess any changes in these expectations (Supplementary 5). The following aspects were evaluated: (1) demographics, including function within the endocrinology department, years of experience, education, gender, and age (2) familiarity with TM, satisfaction with standard care of GDM,

the time needed to perform standard follow-up, expectations regarding the addition of TM, the usefulness of TM in the context of their work, the impact of TM on the quality of GDM care, the time-saving part of TM, and the impact of TM on making administrative mistakes. The questions were scored on a 10-point scale from zero (disagree/not satisfied) to ten (agree/satisfied), with five being neutral.

Secondary outcomes – The secondary outcome measures were: (1) demographical data of the pregnant women with GDM, including age, body mass index (BMI), primipara pregnancy, genesis of pregnancy, and familial history of GDM (2) gestational data, including the number of gestational weeks, mode of delivery (vaginal delivery or cesarean section), and spontaneous or induced delivery (3) neonatal data, including neonatal height, neonatal weight, head size, admission to the neonatal intensive care unit (NIC), and the Apgar-score (4) prenatal data, including number of consultations with endocrinologist and gynaecologist, number of hospitalizations, and number of reminders send to call or register measurements. An overview of the study process is given in Figure 3.

Data collection – The answers to the questionnaires of both the pregnant women and healthcare providers were registered in Qualtrics (Provo, Utah, United States). All data according to the secondary outcomes were collected from the patient's electronic health records (HiX, Chipsoft, Amsterdam, The

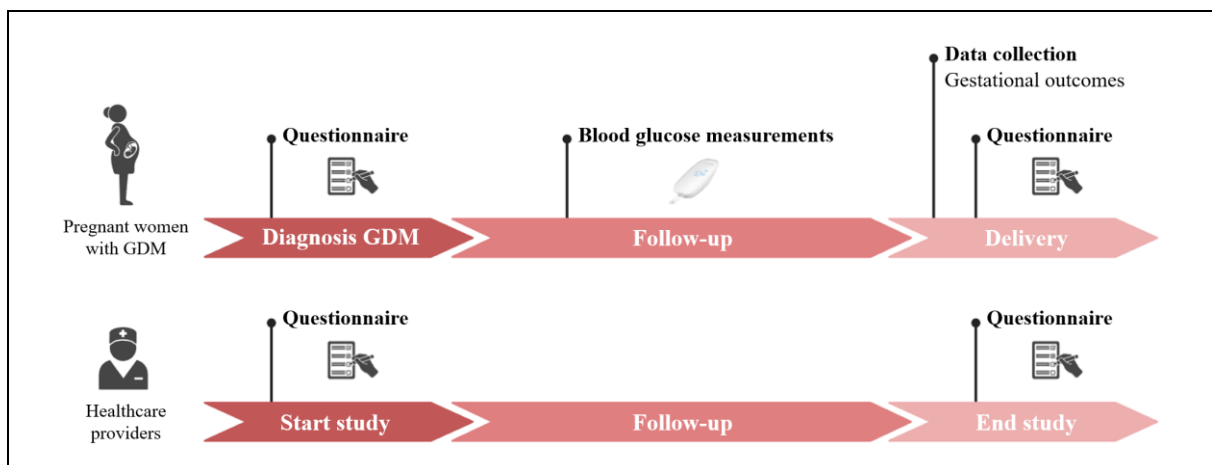


Fig. 3 – Schematic overview of the study process. For both groups, the study started from the diagnosis of GDM and ended after giving birth. During this period, the pregnant women received follow-up either via telephone (SC group) or TM (TM group). Before and after study participation, pregnant women completed a questionnaire regarding their expectations of TM and their experience with the care received (SC or TM). Gestational data was collected from both the SC and TM groups at the end of study participation. Additionally, the healthcare providers completed a questionnaire regarding their expectations and experience with the implementation of TM into the SC at the start and end of the study. *GDM*, gestational diabetes mellitus. *SC*, standard care. *TM*, telemonitoring.

Netherlands) and stored in the eCRF. The blood glucose measurements inserted in the iHealth Gluco-Smart application were stored on Dharma.

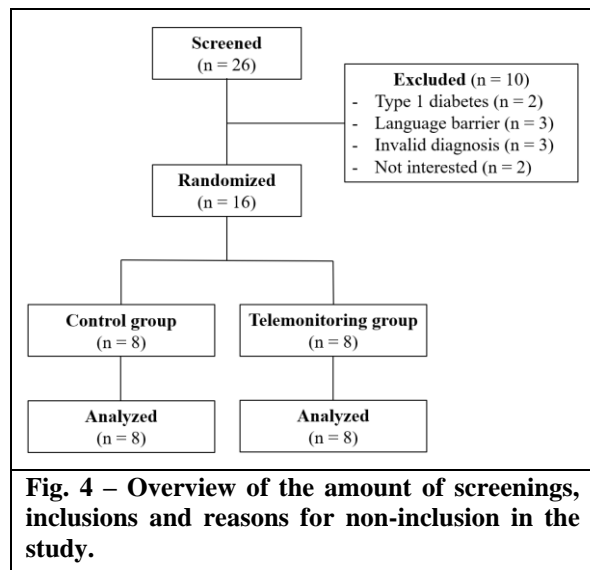
Statistical analysis – All data was statistically analyzed using IBM SPSS version 28.0 (Chicago, United States) to answer the research objectives. Data was presented as mean \pm standard deviation (SD) and median with interquartile ranges (IQR) for parametric and non-parametric data, respectively. In order to perform parametric tests, the data was assessed for normality using the Shapiro-Wilk test. If the data was not normally distributed, the non-parametric variant was used. For unpaired data, continuous variables were compared using the Independent Samples T-test for parametric data or the Mann-Whitney U-test for non-parametric data. Categorical variables were compared using the Fisher's Exact test. For paired data, continuous variables were compared using the Paired T-test for parametric data and the Wilcoxon Signed Rank test for non-parametric data. For categorical data, the Wilcoxon Signed Rank test and McNemar test were used. A two-sided *P*-value <0.05 was considered statistically significant.

RESULTS

Demographics of the pregnant women – A total of 26 pregnant women complicated with GDM were screened to ensure they met the predefined eligibility criteria. Among them, 16 (61.54%) pregnant women met the eligibility criteria and were willing to participate in the study. Subsequently, these 16 pregnant women were randomized into the SC group or TM group in a 1:1 ratio. Ten (38.46%) pregnant women with GDM were excluded from the study due to a diagnosis of type 1 diabetes (20%), a language barrier (30%), an invalid diagnosis of GDM (30%) or they were not willing to participate in the study (20%) (Figure 4).

An overview of the demographic data of the two groups is presented in Table 1. No significant differences were observed in the demographics between the SC group and the TM group.

Expectations and satisfaction of the pregnant women – All participants that were included in the study completed the questionnaire at the beginning of their study participation. Almost nobody (15/16, 93.75%) had heard from TM before study participation.



When asked about their feelings toward TM, the majority (15/16, 93.75%) experienced a positive feeling. Written comments supported the scores given. These comments included: “We are adapting to the era of digitalization.” “Today, everything is sent online.” “It is effective and easy, and there is a better follow-up with the use of TM.”

A comparison of the expectations about TM between the SC and TM groups is given in Figure 5. The mean scores of responses to the majority of the survey questions exceed the midpoint of the scale, indicating generally favorable expectations about TM. No significant differences are observed between the two groups regarding the expectations of TM. When asked if TM could improve gestational outcomes, the majority (12/16, 75.00%) agreed with this statement with three (18.75%) participants being neutral (scored 5) and one (6.25%) participant giving a negative score (scored 0). Overall, most of the participants (10/16, 62.50%) thought TM could be easy to use, with one (6.25%) being neutral and five (31.25%) giving a negative score (scored 0-4). The time-saving aspect of TM received notably high ratings (15/16, 93.75%), with only one (6.25%) participant giving a neutral score. Expectations regarding the cost-effectiveness of TM were positive overall (9/16, 56.25%), with four (25.00%) neutral scores and three (18.75%) instances of disagreement. Unanimous agreement (100.00%) was reached on the ability of healthcare providers to effectively monitor their health via TM, as well as its potential to be an added value to the standard care of GDM. Most (10/16, 62.50%)

Table 1. Demographics of pregnant women with gestational diabetes mellitus.

		Total (n = 16)	SC group (n = 8)	TM group (n = 8)	P-value (0.05)
Age (years)		32.94 ± 3.75	32.63 ± 4.78	33.25 ± 2.66	0.752
BMI (kg/m²)		31.43 ± 6.16	33.36 ± 3.36	29.51 ± 7.84	0.232
Parity	Primipara	7 (43.75%)	2 (25.00%)	5 (62.50%)	0.313
	Multipara	8 (50.00%)	6 (75.00%)	3 (37.50%)	
Pregnancy genesis	Natural	15 (93.75%)	8 (100.00%)	7 (87.50%)	1.000
	IVF	1 (6.25%)	0	1 (12.50%)	
Familial history GDM	Yes	5 (31.25%)	1 (12.50%)	4 (50.00%)	0.281
	No	11 (68.75%)	7 (87.50%)	4 (50.00%)	

Values are presented as mean ± SD or percentages. Statistical analysis was performed using the Independent Samples T-test for continuous data and the Fisher's Exact test for categorical data with a significance level of $P < 0.05$. BMI, body mass index. GDM, gestational diabetes mellitus. IVF, in vitro fertilization. SC, standard care. SD, standard deviation. TM, telemonitoring.

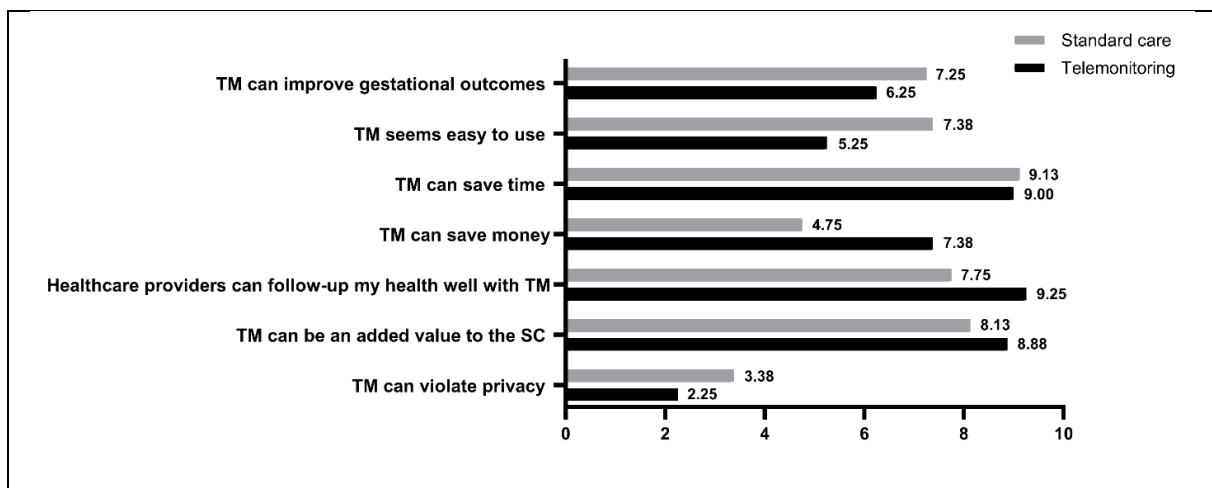


Fig. 5 – Responses of the pregnant women with GDM to the questionnaire at the start of study participation. Pregnant women with GDM were asked to fill in a questionnaire documenting the expectations of TM at the start of study participation. The grey bars represent the mean answers of the participants in the SC group. The black bars represent the mean answers of the participants in the TM group. A score of zero indicates strongly disagreement and a score of ten indicates strongly agreement. Statistical analysis was performed using the Mann-Whitney U test with a significance level of $P < 0.05$. GDM, gestational diabetes mellitus. SC, standard care. TM, telemonitoring.

participants exhibited minimal concerns regarding privacy violations associated with TM, with five (31.25%) participants being neutral and one (6.25%) participant agreed with this statement (scored 6).

After gestation, both the SC and TM groups filled in a questionnaire about their satisfaction with the care received. All (100.00%) participants completed the questionnaire. When asked about their feelings towards TM, the majority (14/16, 87.50%) experienced a positive feeling, with two (14.29%) participants experiencing a negative feeling. Written comments highlighted the negative feedback: “I didn't get to use the

application because I was assigned to the SC group.” “The study is explained to you but afterward, you can't use the application because you are assigned to the SC group.” No significant differences were observed between the two groups in terms of their preference of care after study participation (keep standard care or standard care in addition to TM).

A comparison of the satisfaction with the care received between the SC and TM groups is given in Figure 6. The mean scores for all survey questions were above the midpoint of the scale, indicating overall satisfaction with the care received. All participants agreed that they were satisfied with the follow-up method they

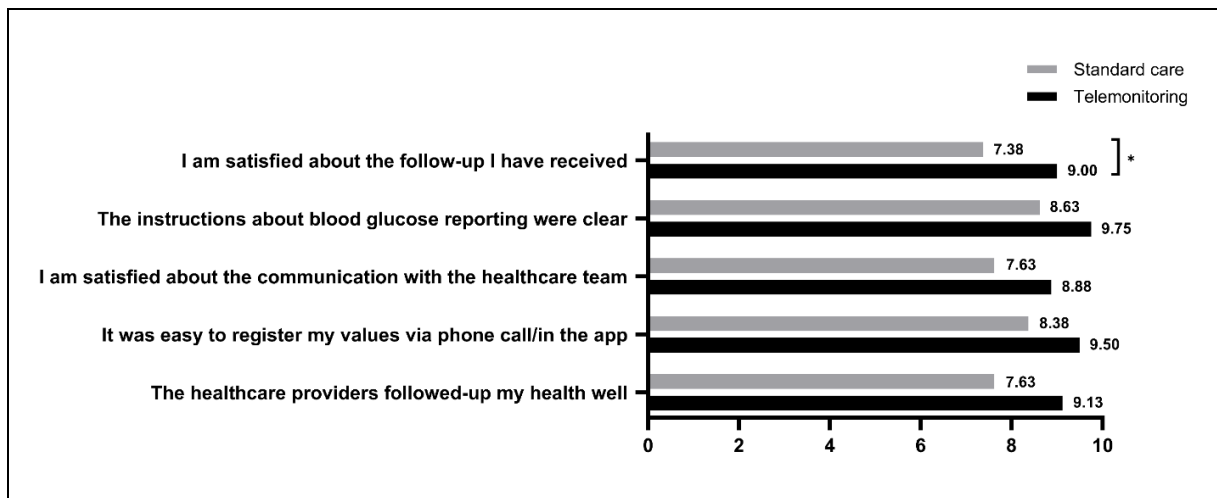


Fig. 6 – Responses of the pregnant women with GDM to the questionnaire at the end of study participation. Pregnant women with GDM were asked to fill in a questionnaire documenting the experiences of TM at the end of study participation. The grey bars represent the mean answers of the participants in the SC group. The black bars represent the mean answers of the participants in the TM group. A score of zero indicates strongly disagreement and a score of ten indicates strongly agreement. Statistical analysis was performed using the Independent Samples T-test or Mann-Whitney U test with a significance level of $P < 0.05$. * $p < 0.05$. GDM, gestational diabetes mellitus. SC, standard care. TM, telemonitoring.

received, that the instructions about blood glucose reporting were clear, and that it was easy to register their blood glucose values via phone call (SC group) or in the application (TM group). Most (15/16, 93.75%) participants were satisfied with the communication with the healthcare providers, with one (6.25%) participant being neutral. Additionally, most (15/16, 93.75%) participants felt that their health was well-monitored by the healthcare providers, except for one (6.25%) participant who disagreed. Regarding the time spent on reporting blood glucose values, the responses were divided: five of 16 (31.25%) scored < 5 minutes/week, seven of 16 (43.75%) scored 5-10 minutes/week, two of 16 (12.50%) scored 10-15 minutes/week, and two of 16 (12.50%) scored > 20 minutes/week. No significant differences were observed between the responses of the SC and TM groups, except for the satisfaction with the care received. The TM group reported significantly higher satisfaction with the care received compared to the SC group (SC: 7.38 ± 0.60 vs. TM: 9.00 ± 0.38 ($P = 0.037$)).

Demographics of the healthcare providers – The healthcare providers that completed the questionnaires consisted of seven people with specific disciplines, including one (14.29%) endocrinologist, three (42.86%) dieticians, and three (42.86%) nurses. The total number of healthcare providers that work at the endocrinology department is 18, so the survey

was completed by seven of 18 (38.89%) of all healthcare providers within the endocrinology department. Demographic data of these healthcare providers is presented in Table 2.

Expectations and satisfaction of the healthcare providers – The answers on the expectations and satisfaction of healthcare providers on the integration of TM into the prenatal follow-up of GDM are shown in Figure 7.

Before the start of the study, the healthcare providers were asked to fill in a questionnaire about their satisfaction with the standard care process and their expectations about the integration of TM into the prenatal follow-up of GDM. When asked about their satisfaction with the current standard follow-up process of GDM, the scores were evenly divided: three of seven (42.85%) were not satisfied (scored < 5), one of seven (14.29%) was neutral (scored 5), and three of seven (42.85%) were satisfied (scored > 5). For the time needed for the follow-up of pregnant women with GDM, the scores were divided: two of seven (28.57%) scored < 2 hours/week, two of seven (28.57%) scored 2-4 hours/week, two of seven (28.57%) scored 4-8 hours/week, and one of seven (14.29%) scored > 8 hours/week. Regarding the expectations about TM, all (100.00%) healthcare providers agreed that TM can be useful in the context of their work, that it can improve the care for GDM, and that it can fasten their administrative tasks. Written comments supported these

Table 2. Demographics of the healthcare providers.

		Response frequency (n = 7)
Years of experience (years)	< 5	1 (14.29%)
	5-10	2 (28.57%)
	11-20	3 (42.86%)
	> 20	1 (14.29%)
Graduation	Bachelor diploma	5 (71.43%)
	Master diploma	3 (42.86%)
Gender	Male	1 (14.29%)
	Female	6 (85.71%)
	Other	0
Age (years)	25-35	2 (28.57%)
	36-45	3 (42.86%)
	46-55	2 (28.57%)

Values are presented as percentages.

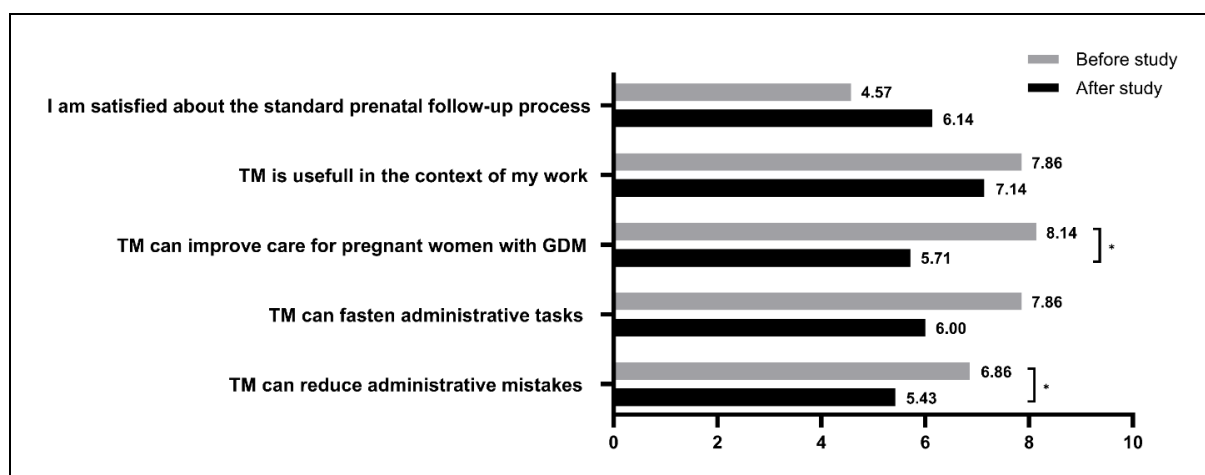


Fig. 7 – Responses of the healthcare providers to the start- and end-of-study questionnaires. Healthcare providers of the endocrinology department of ZOL were asked to fill in a questionnaire documenting the expectations and the experience of TM at the start and end of the study, respectively. The black bars represent the mean answers on the expectations of TM. The grey bars represent the mean answers on the experience of TM. A score of zero indicates strongly disagreement and a score of ten indicates strongly agreement. Statistical analysis was performed using the Wilcoxon signed-rank test with a significance level of $P < 0.05$. * $p < 0.05$. GDM, gestational diabetes mellitus. TM, telemonitoring. ZOL, ziekenhuis Oost-Limburg.

positive expectations toward TM. These comments included: “TM can be more efficient for both the healthcare providers and the patients.” “TM can reduce the workload for healthcare providers.” “TM can provide easier communication between the healthcare provider and the patient.” The majority (6/7, 85.71%) of the healthcare providers agreed that TM can reduce administrative mistakes, with one (14.28%) person being neutral.

After the study, the healthcare providers were asked to fill in a similar questionnaire to assess their satisfaction with the integration of TM into the prenatal follow-up process of

GDM. When asked about their satisfaction with the current standard follow-up process of GDM, the scores were evenly divided: two of seven (28.57%) were not satisfied (scored < 5), one of seven (14.29%) was neutral (scored 5), and four of seven (57.14%) were satisfied (scored > 5). For the time needed for the follow-up of pregnant women with GDM, the scores were divided: two of seven (28.57%) scored < 2 hours/week, two of seven (28.57%) scored 2-4 hours/week, two of seven (28.57%) scored 4-8 hours/week, and one of seven (14.29%) scored > 8 hours/week. These scores did not differ from the answers given on the start-of-study

questionnaire. The majority (5/7, 71.43%) agreed that TM can be useful in the context of their work, with two of seven (28.57%) healthcare providers that did not agree with this statement. For the statements 'TM can improve care for pregnant women with GDM' and 'TM can fasten administrative tasks': four of seven (57.14%) agreed, one of seven (14.29%) stated neutral, and two of seven (28.75%) did not agree with this statement. When asked if TM can reduce administrative mistakes, most (4/7, 57.14%) of the healthcare providers agreed, with one (14.29%) being neutral and three (42.86%) not agreeing.

When comparing the start- and end-of-study questionnaire responses, the healthcare providers scored statistically lower on the statements 'TM can improve care for pregnant women with GDM' (start: 8.14 ± 0.69 vs. end: 5.71 ± 2.43 ($P = 0.043$)) and 'TM can reduce administrative tasks' (start: 6.86 ± 1.57 vs. end: 5.43 ± 2.44 ($P = 0.025$)) after the study. There is a trend indicating lower scores after the study for the statement 'TM can fasten administrative tasks' (start: 7.86 ± 0.69 vs. end: 6.00 ± 2.65 ($P = 0.095$)). No significant differences were

observed in responses to the remaining questions before and after the study.

Gestational outcomes – To investigate the impact of integrating a TM follow-up program into the standard care of GDM, the gestational outcomes were compared between the SC group and the TM group. The gestational outcomes are shown in Table 3. During the prenatal follow-up period, the number of hospitalizations and consultations with the endocrinology and gynaecology department were not significantly different between the TM and the SC groups. Despite the non-significant differences in the consultations and hospitalizations, the number of reminders (SC: 3.25 ± 1.00 vs. TM: 0.38 ± 0.26 ($P = 0.004$)) sent to the mothers during the prenatal follow-up period is significantly higher in the SC group compared to the TM group. Regarding neonatal outcomes, there are no statistically significant differences in neonatal weight, height, head size, NIC admissions, or Apgar scores between both groups. Additionally, there are no significant differences in the number of cesarean sections, induction rates, or gestational weeks at delivery between the SC and TM groups.

Table 3. Comparison of the maternal and neonatal outcomes between the SC group and the TM group.

		Total (n = 16)	SC group (n = 8)	TM group (n = 8)	P-value (0.05)
Mode of delivery	Vaginal delivery	13 (81.25%)	6 (75.00%)	7 (87.50%)	1.000
	Cesarean section	3 (18.75%)	2 (25.00%)	1 (12.50%)	
Induced delivery	Spontaneous	8 (50.00%)	5 (62.50%)	3 (37.50%)	0.619
	Induced	8 (50.00%)	3 (37.50%)	5 (62.50%)	
Gestational weeks		39.01 ± 1.26	39.25 ± 0.93	38.77 ± 1.55	0.462
Hospitalizations		0	0	0	NA
Consultations	Gynaecology	6.06 ± 1.98	6.25 ± 1.75	5.88 ± 2.30	0.719
	Endocrinology	1.00 ± 1.00	1.50 ± 1.00	1.00 ± 1.00	0.626
Reminders		1.81 ± 2.48	3.25 ± 1.00	0.38 ± 0.26	0.004
Neonatal weight (kg)		3.51 ± 0.52	3.46 ± 0.36	3.56 ± 0.66	0.714
Neonatal height (cm)		49.94 ± 2.49	49.56 ± 2.29	50.31 ± 2.78	0.565
Head size (cm)		34.31 ± 1.46	33.75 ± 0.93	34.96 ± 1.75	0.112
NIC admission	Yes	2 (12.50%)	0	2 (25.00%)	0.467
	No	14 (87.50%)	8 (100.00%)	6 (75.00%)	
Apgar score	1 minute	8.00 ± 1.00	8.00 ± 1.00	8.00 ± 2.50	0.563
	5 minutes	9.00 ± 1.00	9.00 ± 1.00	9.00 ± 1.00	0.765

Values are presented as mean \pm SD, median \pm IQR, or percentages. Statistical analysis was performed using the Independent Samples T-test or Mann-Whitney U test for continuous data and Fisher's Exact test for categorical data with a significance level of $P < 0.05$. IQR, interquartile range. NIC, neonatal intensive care. SC, standard care. SD, standard deviation. TM, telemonitoring.

DISCUSSION

Various studies have examined the impact of a prenatal TM program on the compliance rate of blood glucose management during GDM. However, limited is known about the feasibility of incorporating TM for both mothers and healthcare providers within the standard care of GDM (17, 18, 19, 20). Given the promising results of TM in managing other chronic diseases and pregnancy-related complications, the aim of this study was to investigate the expectations and satisfaction of both pregnant women and healthcare providers associated with integrating TM into the standard care of GDM and examine the effect of TM on gestational outcomes (14, 15, 16).

Expectations and satisfaction of the pregnant women – In order to encourage patient involvement with a novel follow-up method, it is important that they experience a safe and positive feeling. Although most pregnant women had not heard from TM before study participation, almost everyone felt positive about it. No significant differences were observed between the SC and TM groups regarding their expectations of TM. Participants in both groups expressed positive expectations toward TM based on all survey questions, indicating overall acceptance of integrating TM into the standard care of GDM. These findings align with prior research, which indicated pregnant women's willingness to integrate a TM program within their prenatal care as they perceived many benefits from it, including early detection and prompt treatment of pregnancy complications, convenience, cost-effectiveness, increased sense of empowerment in their own health care, and improved care continuity (25). These findings were in line with the feedback of pregnant women provided in response to our questions, which included perceptions of safety with the TM system, improved follow-up, and ease of use. Overall, our findings highlight the expected convenience of using a smartphone application compared to standard care.

Interestingly, pregnant women in the TM group were more satisfied with the care they received compared to the SC group. Our findings align with prior research, indicating a high level of satisfaction with TM systems compared to traditional care methods (18, 26, 27). However, no significant differences were observed between the two groups regarding their preference for either standard care alone or standard care in addition to TM. On the

contrary, a study by Mackillop *et al.* showed that pregnant women preferred a TM-based model over standard care (28). This contradiction could be explained by the fact that most pregnant women (6/8, 75.00%) in the SC group were experiencing their first pregnancy and, therefore, lacked a basis for comparison between standard care and alternative follow-up models such as TM. Future studies could focus on the satisfaction of TM on multipara pregnancies complicated with GDM, particularly those previously diagnosed with GDM. This alternative may provide a clearer understanding of the preference for TM over standard care in managing GDM.

Expectations and satisfaction of the healthcare providers – Our study provides a novel insight into the expectations of healthcare providers on the implementation of TM into GDM care, which has been limited in previous research. Given the mean scores of the healthcare providers on the start-and end-of-study questionnaires, we can conclude that the healthcare providers had overall good expectations and satisfaction with the implementation of TM into the standard prenatal follow-up of GDM. These findings align with previous research on MobiGuide, a TM system that continuously monitors the blood glucose levels of GDM patients using a sensor and smartphone application, which also demonstrated increased satisfaction among healthcare providers compared to the standard method (29). However, our results showed that healthcare providers had significantly higher expectations on the ability of TM to improve follow-up care and reduce administrative tasks compared to their experiences after implementing TM. One possible explanation for these lower scores is reflected in a comment from a healthcare provider: “We didn't notice that much of a difference due to the low number of participants in the study. Also, the fact that the values of patients with insulin therapy were still forwarded to us by the investigator because of routine follow-up made that we still had to enter blood glucose values into the electronic health record of the patient.” As a result, administrative errors can still occur, which contributes to the perceived gap between expectations and experiences. A feasibility study by Given *et al.* noted that healthcare providers perceived TM as providing a greater positive impact for their patients than for their

own practice, which can confirm our findings (26).

Although Caballero-Ruiz *et al.* showed a reduction in workload when implementing TM, this is not in line with our findings (22). The start- and end-of-study questionnaires revealed no significant differences in the workload of healthcare providers, as measured by the number of hours per week spent on GDM follow-up. A possible explanation could be the small sample size. The healthcare providers have around 57 follow-up patients with GDM each week in ZOL, Genk. Hence, it was not possible to observe an effect on eight patients in follow-up. Another study mentioned that TM can save time on certain patient follow-ups, enabling healthcare providers to spend more time with patients requiring additional contact (26). This may also explain the non-significant differences in workload observed before and after the implementation of TM. In the future, it would be beneficial to look at a larger sample size and to implement a system where blood glucose measurements can be directly transferred to the patient's electronic health record. This approach can eliminate the need for healthcare providers to manually enter blood glucose values into patients' records, thereby reducing administrative errors and workload. In addition, incorporating quantitative measurements could validate previous findings and enhance the power of the study.

Gestational outcomes – Given the importance of blood glucose monitoring during GDM in preventing pregnancy complications, we expected better gestational outcomes in the TM group compared to the SC group. However, no significant differences were observed in gestational outcomes between both groups. Our study results are consistent with the findings of a study of Rasekaba *et al.*, indicating no significant differences between the TM system and the usual care in rates of cesarean sections, neonatal weight, and NIC admissions (30). Other studies also showed no differences in gestational outcomes between the TM and the usual care (18, 31). Contrastingly, previous studies indicated lower cesarean section rates, decreased incidences of macrosomia, and reduced NIC admissions in the SC group compared to the TM group (23, 32, 33). A possible explanation could be the variations in the frequency of blood glucose monitoring across the different studies. In the study conducted by Dalfrà *et al.*, participants in the

TM group were instructed to report their blood glucose levels weekly, while those in the SC group underwent medical examinations every two weeks (32). In contrast, our study ensured uniformity in monitoring frequency for both the TM and SC groups, thereby maintaining consistency in the care received. Another reason could be that the sample size was too small to see any effect on the gestational outcomes.

A previous study reported that pregnant women with GDM experienced the use of a smartphone application as an important tool for keeping motivation and self-awareness (34). Interestingly, these findings are in line with our results, in which pregnant women in the TM group were more compliant with self-monitoring their blood glucose levels compared to the SC group. Compared to the SC group, the frequency of phone calls from healthcare providers reminding pregnant women to monitor their blood glucose levels every week was significantly lower. Previous studies assessing the compliance rate when implementing TM into the prenatal follow-up program confirmed our findings (18, 23).

Strengths and limitations – The strengths of this project are the high completion rate of the questionnaires (pregnant women: 100%) and the implementation of TM under the standard operations of the multidisciplinary diabetes team of ZOL, Genk. However, this research is not without limitations. First, this study included only pregnant women who own a smartphone, and are compliant to understand the Dutch language. Analysis of screening procedures and exclusion criteria indicates that 30% of patients diagnosed with GDM lack proficiency in Dutch. A study of Kim *et al.* indicated an increased risk of developing GDM in the Asian, black, American Indian, and Hispanic women population (35). Therefore, these inclusion criteria probably under-represent a high-risk population that does not meet these criteria. Second, the study encountered a small sample size due to unexpected circumstances, meaning that there were fewer pregnant women with GDM presenting for consultation than initially anticipated. Consequently, the number of interviews was limited. To generalize our findings, it is necessary to conduct more interviews with both pregnant women and healthcare providers. Additionally, a larger sample size is essential to validate our findings on the impact of TM on gestational outcomes.

CONCLUSION

In this study, the focus was on investigating the feasibility of integrating TM into the standard care of GDM by examining the expectations and satisfaction of pregnant women and healthcare providers, and investigating the impact of TM on gestational outcomes. Our findings show high expectations and satisfaction with TM among pregnant women and healthcare providers, along with a significant increase in therapy compliance compared to the SC group. However, TM did not significantly reduce the workload of healthcare providers, and no significant differences were observed in gestational

outcomes. Therefore, future studies should incorporate direct integration of blood glucose data into patient electronic health records to minimize administrative tasks and reduce the workload of healthcare providers. Additionally, including more participants will be crucial to further assess the added value of TM and the impact of TM on gestational outcomes. Acknowledging the limitations of this study, we conclude that a prenatal TM-based follow-up program is feasible and should remain an alternative to the standard follow-up method of GDM, and that further studies are needed to confirm our findings.

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Acknowledgments – I would like to express my gratitude to Dorien Lanssens, my principal supervisor, for her patient guidance, encouragement, and helpful critiques of this research project. Furthermore, I would like to thank the principal investigator of this study, Dr. Ine Lowyck, for entrusting me with this opportunity. I acknowledge gratitude to the endocrinologists, dieticians, and nurses of the Department of Endocrinology at the ZOL hospital for their good collaboration. Additionally, The ICT service of ZOL is thanked for facilitating access to the electronic health records of the participants. Lastly, I would thank my friends and family who supported me during this senior internship.

Author contributions – The research was designed by DL and AB. The experiments were performed by AB and the endocrinologists, dieticians, and nurses of the Department of Endocrinology at ZOL. AB wrote the paper, and DL was involved in critiquing the results and improving the paper.

SUPPLEMENTARY

Supplementary 1: Questionnaire start study – pregnant women

Question 1: What is your study number?

Question 2: Do you own a smartphone?

☐ Yes

☐ No

Question 3: *Telemonitoring entails remotely monitoring patients, typically from the comfort of their homes. This process includes bringing home the necessary measuring devices (glucose meter). The data collected at home is then securely transmitted via the internet (iHealth Gluco-Smart application) to the healthcare provider at the hospital.* Have you heard of telemonitoring elsewhere?

☐ Yes, where?

☐ No

Question 4: How do you feel when you think about telemonitoring?

☐ Positive, because

☐ Negative, because

Question 5: Telemonitoring can improve the health of me and my baby.

0 1 2 3 4 5 6 7 8 9 10
0 = disagree, 10 = agree

Question 6: Telemonitoring seems easy to use.

0 1 2 3 4 5 6 7 8 9 10
0 = disagree, 10 = agree

Question 7: Telemonitoring can save time.

0 1 2 3 4 5 6 7 8 9 10
0 = disagree, 10 = agree

Question 8: Telemonitoring can be cost-effective.

0 1 2 3 4 5 6 7 8 9 10
0 = disagree, 10 = agree

Question 9: With the use of telemonitoring, healthcare providers can follow-up my health well.

0 1 2 3 4 5 6 7 8 9 10
0 = disagree, 10 = agree

Question 10: Telemonitoring can be an added value to the standard care of gestational diabetes mellitus.

0 1 2 3 4 5 6 7 8 9 10
0 = disagree, 10 = agree

Question 11: Telemonitoring can violate my privacy.

0 1 2 3 4 5 6 7 8 9 10
0 = disagree, 10 = agree

Supplementary 2: Questionnaire end study – pregnant women (telemonitoring)

Question 1: What is your study number?

Question 2: *Telemonitoring entails remotely monitoring patients, typically from the comfort of their homes. This process includes bringing home the necessary measuring devices (glucose meter). The data collected at home is then securely transmitted via the internet (iHealth Gluco-Smart application) to the healthcare provider at the hospital.* How do you feel about telemonitoring after study participation?

- ☐ Positive, because
☐ Negative, because

Question 3: How would you rate your satisfaction with monitoring your blood sugar levels through telemonitoring?

0 1 2 3 4 5 6 7 8 9 10
 0 = unsatisfied, 10 = satisfied

Question 4: Were the instructions for reporting your blood glucose values via telemonitoring clear to you?

0 1 2 3 4 5 6 7 8 9 10
 0 = not clear, 10 = clear

Question 5: How would you rate the communication with the healthcare providers when using telemonitoring?

0 1 2 3 4 5 6 7 8 9 10
 0 = unsatisfied, 10 = satisfied

Question 6: How difficult/easy have you experienced using telemonitoring to report your blood sugar values to healthcare providers?

0 1 2 3 4 5 6 7 8 9 10
 0 = difficult, 10 = easy

Question 7: How much time did you spend reporting your blood glucose values when using telemonitoring?

- ☐ < 5 minutes
☐ 5-10 minutes
☐ 10-15 minutes
☐ 15-20 minutes
☐ > 20 minutes

Question 8: Did you feel that healthcare providers were effectively able to monitor your health well through telemonitoring?

0 1 2 3 4 5 6 7 8 9 10
 0 = disagree, 10 = agree

Question 9: If given the option, would you prefer reporting your blood glucose levels via telemonitoring or would you opt to maintain the weekly telephone follow-up?

- ☐ Telemonitoring
☐ Maintain weekly telephone follow-up

Question 10: Would you be willing to participate in this study again during your next pregnancy?

☐ Yes, because

☐ No, because

Question 11: Do you have any comments or suggestions for the investigators?

Supplementary 3: Questionnaire end study – pregnant women (standard care)

Question 1: What is your study number?

Question 2: *Telemonitoring entails remotely monitoring patients, typically from the comfort of their homes. This process includes bringing home the necessary measuring devices (glucose meter). The data collected at home is then securely transmitted via the internet (iHealth Gluco-Smart application) to the healthcare provider at the hospital.* How do you feel about telemonitoring after study participation?

☐ Positive, because

☐ Negative, because

Question 3: How would you rate your satisfaction with monitoring your blood sugar levels through weekly phone calls?

0 1 2 3 4 5 6 7 8 9 10
0 = unsatisfied, 10 = satisfied

Question 4: Were the instructions for reporting your blood glucose values through weekly phone calls clear to you?

0 1 2 3 4 5 6 7 8 9 10
0 = unclear, 10 = clear

Question 5: How would you rate the communication with the healthcare providers during the weekly phone calls?

0 1 2 3 4 5 6 7 8 9 10
0 = unsatisfied, 10 = satisfied

Question 6: How difficult/easy have you experienced the weekly phone calls to report your blood sugar values to healthcare providers?

0 1 2 3 4 5 6 7 8 9 10
0 = difficult, 10 = easy

Question 7: How much time did you spend reporting your blood glucose values via weekly phone calls?

☐ < 5 minutes

☐ 5-10 minutes

☐ 10-15 minutes


☐ 15-20 minutes

☐ > 20 minutes

Question 8: Did you feel that healthcare providers were effectively able to monitor your health well via weekly phone calls?

0 1 2 3 4 5 6 7 8 9 10

0 = disagree, 10 = agree



Question 9: If given the option, would you prefer reporting your blood glucose levels via weekly telephone follow-up or would you prefer another option of monitoring?

- ☐ Maintain weekly telephone follow-up
- ☐ Another option of monitoring, such as telemonitoring

Question 10: Would you be willing to participate in this study again during your next pregnancy?

- ☐ Yes, because
- ☐ No, because

Question 11: Do you have any comments or suggestions for the investigators?

Supplementary 4: Questionnaire start study – healthcare providers

Demographics

Question 1: What is your function within the endocrinology department?

- ☐ Endocrinologist
- ☐ Nurse
- ☐ Dietician
- ☐ Other:

Question 2: How many years of expertise do you have in this field?

- ☐ <5 years
- ☐ 5-10 years
- ☐ 11-20 years
- ☐ >20 years

Question 3: Do you possess a bachelor's and/or master's degree?

- ☐ Bachelor's degree
- ☐ Master's degree
- ☐ Neither of them

Question 4: What is your gender?

- ☐ Male
- ☐ Female
- ☐ Other

Question 5: What is your age?

Telemonitoring

Question 1: *Telemonitoring entails remotely monitoring patients, typically from the comfort of their homes. This process includes bringing home the necessary measuring devices (glucose meter). The data collected at home is then securely transmitted via the internet (iHealth Gluco-Smart application) to the healthcare provider at the hospital.* Have you heard of telemonitoring elsewhere?

☐ Yes, where?

☐ No

Question 2: How satisfied are you with the standard follow-up method (weekly calls) for pregnant women with gestational diabetes mellitus?

0 = unsatisfied, 10 = satisfied

0	1	2	3	4	5	6	7	8	9	10
---	---	---	---	---	---	---	---	---	---	----

Question 3: How many hours per week do you spend on the follow-up of pregnant women with gestational diabetes mellitus?

- ☐ <2 hours
☐ 2-4 hours
☐ 4-8 hours
☐ >8 hours

Question 4: What are your expectations regarding the integration of telemonitoring into the standard care of gestational diabetes mellitus?

Question 5: The use of telemonitoring would be beneficial in the context of my work.

0 = disagree, 10 = agree

0	1	2	3	4	5	6	7	8	9	10
---	---	---	---	---	---	---	---	---	---	----

Question 6: The use of telemonitoring could improve the quality of care for pregnant women with gestational diabetes mellitus.

0 = disagree, 10 = agree

0	1	2	3	4	5	6	7	8	9	10
---	---	---	---	---	---	---	---	---	---	----

Question 7: The use of telemonitoring could enable me to complete my administrative tasks more efficiently.

0 = disagree, 10 = agree

0	1	2	3	4	5	6	7	8	9	10
---	---	---	---	---	---	---	---	---	---	----

Question 8: The use of telemonitoring could ensure that I make fewer administrative errors.

0 = disagree, 10 = agree

0	1	2	3	4	5	6	7	8	9	10
---	---	---	---	---	---	---	---	---	---	----

Supplementary 5: Questionnaire end study – healthcare providers

Demographics

Question 1: What is your function within the endocrinology department?

- ☐ Endocrinologist
- ☐ Nurse
- ☐ Dietician
- ☐ Other:

Question 2: How many years of expertise do you have in this field?

- ☐ <5 years
- ☐ 5-10 years
- ☐ 11-20 years
- ☐ >20 years

Question 3: Do you possess a bachelor's and/or master's degree?

- ☐ Bachelor's degree, specify
- ☐ Master's degree
- ☐ Neither of them

Question 4: What is your gender?

- ☐ Male
- ☐ Female
- ☐ Other

Question 5: What is your age?

Questionnaire telemonitoring

Question 1: How satisfied are you with the standard follow-up method (weekly calls) for patients with gestational diabetes mellitus?

0 1 2 3 4 5 6 7 8 9 10	0 = unsatisfied, 10 = satisfied

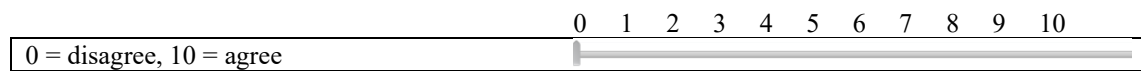
Question 2: How many hours per week have you spent on the follow-up of pregnant women with gestational diabetes mellitus?

- ☐ <2 hours
- ☐ 2-4 hours
- ☐ 4-8 hours
- ☐ >8 hours

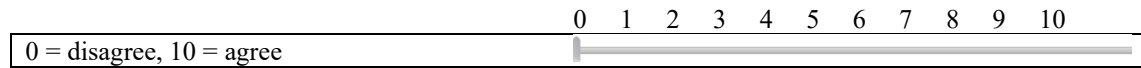
Question 3: Did the expectations regarding the use of telemonitoring in the follow-up of gestational diabetes align with your expectations before the study started?

- ☐ Yes, clarify
- ☐ No, clarify

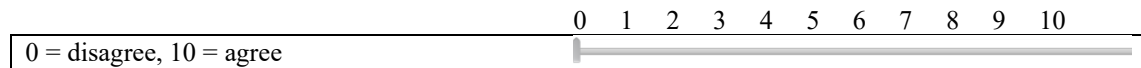
Question 4: The use of telemonitoring was beneficial in the context of my work.



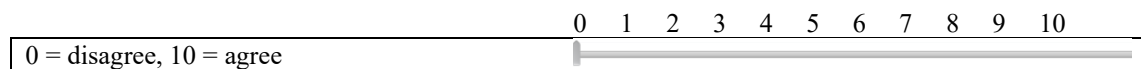
Question 5: The use of telemonitoring has improved the quality of care for pregnant women with gestational diabetes mellitus.



Question 6: The use of telemonitoring has enabled me to complete my administrative tasks more efficiently.



Question 7: The use of telemonitoring has ensured that I make fewer administrative errors.



Question 8: Do you have any comments or suggestions for the investigators?