



Effectiveness of a comprehensive telemedicine intervention replacing standard care in gestational diabetes: a randomized controlled trial

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Abstract

Aims Telemedicine improves glycemic and perinatal outcomes when used as an adjunct to standard care in gestational diabetes (GDM). Little is known about its effectiveness when used instead of standard care. We aimed to compare the outcomes of telemedicine care and the standard care in women with GDM.

Methods In a single-center, parallel, randomized controlled trial, women were randomized to: (1) a telemedicine group, sending glucose readings via an application installed on a smartphone and monthly individual video calls replacing on-site visits or (2) standard care group with routine monthly on-site visits. The primary outcome was the effectiveness of glycemic control. The secondary outcomes were gestational weight gain (GWG) and perinatal data, including birth weight, gestational age, the incidence of the offspring large for gestational age, preterm birth, preeclampsia and cesarean section.

Results A total of 106 women were randomized to the telemedicine ($n=54$) and the standard care group ($n=52$). The telemedicine group demonstrated less postprandial measurements above the glycemic target (10.4% [3.9–17.9] vs. 14.6% [6.5–27.1]; $p=0.015$), together with lower average postprandial glucose (5.6 ± 0.3 vs. 5.9 ± 0.4 ; $p=0.004$). Percentage of cesarean section was lower in the telemedicine group (9 (17.3%) vs. 18 (35.3%); $p=0.038$).

Conclusions Telemedicine offers an effective alternative to delivering care to women with GDM.

Trial registration NCT05521893, ClinicalTrials.gov Identifier URL: <https://www.clinicaltrials.gov/ct2/show/NCT05521893?term=NCT05521893&draw=2&rank=1>

Keywords Telemedicine · Gestational diabetes · LGA (large for gestational age) · Cesarean section · Standard care

Introduction

Gestational diabetes (GDM) is one of the most common complications of pregnancy. If untreated, it is associated with many adverse maternal and fetal outcomes [1]. Many telemedicine tools were already tested with the aim to achieve swift glycemic control and optimal perinatal results [2]. Although available evidence suggests that telemedicine

tools can be useful in GDM in general [3] and can give comparable or favorable outcomes regarding glycemic control or some adverse perinatal outcomes [4–9], the tools used are very diverse, applied in different clinical settings and within different organizations of care. Altogether, they seem useful [3, 10, 11]. However, in a subgroup analysis [10], more comprehensive patterns of telemedicine interventions, e.g., real-time monitoring + feedback + healthcare education + question answering, were more effective than the simple telemedicine interventions, e.g., real-time monitoring and feedback. Importantly, in the majority of studies, telemedicine tools served as a complement to the standard care and not as a replacement for standard care. Thus, it is still unknown whether care delivered solely through telemedicine tools is as effective as the standard care in GDM.

Therefore, we aimed to study whether telemedicine care can replace the standard in-person care in a typical sample of women, newly diagnosed with GDM, by focusing on, glycemic control indicators and, secondly, on perinatal outcomes.

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Methods

This was a single-center parallel randomized controlled trial initiated by the University Medical Centre Ljubljana, Slovenia, and conducted between March 2020 and October 2021. Screening for GDM in Slovenia is universal, and diagnosis is made according to the IADPSG criteria [12]. The GDM diagnosis was verified by diabetologists. In Slovenia, women with GDM are treated for their diabetes at diabetes outpatient clinics.

In order to be invited into the study, the following inclusion criteria should be fulfilled: (1) less than 30 weeks of gestation, (2) confirmed GDM diagnosis, (3) at least moderate Slovenian language skills and (4) willingness to participate. The exclusion criteria were as follows: (1) 30 weeks of pregnancy or more, (2) overt diabetes or fasting glucose > 6.9 mmol/l at diagnosis, (3) multiple pregnancy, (4) poor Slovene language skills, (5) history of bariatric surgery or other surgeries that induce malabsorption, (6) use of systemic steroids prior to enrollment and (7) presence of concomitant disease that could affect glucose control or self-management. Women that met the inclusion criteria and who gave informed consent were then randomly allocated (allocation ratio was 1:1) into one of the two groups: the telemedicine or the standard care group by the use of simple randomization. At the randomization visit, all women attended group education regarding diet and exercise, and self-monitoring of blood glucose (SMBG). The lifestyle education, treatment goals and proposed GDM self-care were the same for the telemedicine and standard care group. Women were asked to perform the four-point home blood glucose profile monitoring daily with the target capillary fasting glucose concentration < 5.3 mmol/l and postprandial capillary glucose < 6.7 mmol/l. Insulin therapy was initiated if described targets were not achieved at least within 14 days of lifestyle intervention. Insulin treatment education was performed in person in both groups. However, in the telemedicine group, follow-up visits were performed via telemedicine, whereas in the standard care group, they were performed in-person.

In the standard care group, visits were scheduled at the diabetes outpatient clinic once monthly; however, healthcare professionals (HCPs) could increase appointment frequency of visits if the patients did not achieve treatment targets. At the on-site visits, glucose readings were analyzed from the glucose meter, ketone presence and body weight were assessed, data from the gynecological examinations were discussed, and the treatment plan was reviewed. Outside the scheduled visits, women received a phone number and an email address for contacting the diabetes center when in need. On the other hand, in the

telemedicine group, the appointments were performed online via scheduled videoconferences, also on a monthly basis, with a similar structure to the on-site visit (evaluation of SMBG, ketone presence, body weight and data from the gynecologist's examination). For that purpose, we used the telehealth service of the Telemedicine Center of the University Medical Centre Ljubljana. All women in the telemedicine group received a smartphone with the installed application that enabled a transfer of the measured capillary glucose concentration at the same instant it was performed. A nurse from the Telemedicine Center, specifically assigned to our study, reviewed glucose data weekly. If the measurements were not sent regularly, or if they were above the target range, the Telemedicine Center contacted those women and tried to understand whether there were some understanding issues, technical issues or motivational issues and addressed them first. If the issues were resolved, no additional measure was undertaken. However, if the issues persisted, one of the nurse educators or a diabetologist from the diabetes center called the woman or arranged an additional videoconference and tried to find a solution to the problem. Moreover, women were able to ask questions or share any concerns on a daily basis with the Telemedicine Center.

In the telemedicine group, no on-site visits were performed, except for the randomization visit, and the visit for the final HbA_{1c} control before the estimated date of delivery.

Variables and outcomes

Participants' baseline characteristics, together with data on GDM diagnosis and management, were collected from patients' medical charts. Excessive GWG was defined according to the Institute of Medicine (IOM) guidelines [13]. Data on pregnancy outcomes were gathered from hospital discharge letters provided by participants themselves or obtained from the National Perinatal Registry.

The primary outcome was the achieved level of glycaemic control. We described it with (1) the average fasting glucose concentration; (2) the average postprandial glucose concentration; (3) the percentage of glucose readings in the target range; (4) baseline and the last visit HbA_{1c}; (5) compliance with SMBG, which was defined as the number of actual glucose measurements performed divided by the number of recommended glucose measurements*100; and (6) the percentage of individuals needing insulin treatment. The secondary outcome consisted of perinatal data, based on the core outcome set for trials evaluating interventions of GDM [14]. It included birth weight, gestational age, the incidence of large for gestational age (LGA) and small for gestational age (SGA), preterm birth (< 37 weeks of gestation), birth trauma, the incidence of neonatal hypoglycemia, neonatal jaundice, neonatal death and stillbirth. LGA

was defined as birthweight > 90th percentile and SGA was defined as birthweight < 10th percentile, both using locally derived standardized centiles, adjusted for the infant's sex and gestational age. Rare perinatal outcomes (birth trauma, neonatal hypoglycemia, neonatal jaundice, neonatal death and stillbirth) were included in the composite outcome of child adverse outcomes.

Perception of telemedicine care was assessed using the Service User Technology Acceptability Questionnaire (SUTAQ) [15]. The questionnaire consists of 22 items divided into six subscales: Perceived benefit, Privacy and discomfort, Care personnel concerns, Satisfaction and Kit as a substitution. Two subscales (Privacy discomfort and Care personnel concerns) are inverted; therefore, a low value reflects a positive perception of telemedicine. In other subscales, higher results represent more positive telemedicine perception.

Statistical analysis

Differences between the two models of care were performed according to the intention-to-treat analysis. (Per-protocol analysis is found in Supplementary Material.)

Data analysis was carried out using SPSS Statistics, version 21 (IBM, Armonk, NY, USA). Continuous data are presented as mean with the corresponding standard deviation or median with interquartile range regarding fitting a normal distribution. Glucose concentration values at the oral glucose tolerance test (OGTT) were standardized (*z*-score). Student's *t*-test or Mann–Whitney U test was used for normally or non-normally distributed variables, respectively. For calculating differences between groups in categorical data, Chi-square test was used. Cohen's *d* was used for calculating the effect size and Spearman's rho for correlations. One-way ANCOVA was conducted to determine differences between the groups, controlling for covariates. The overall percentage of missing data was 5.1%, which is just above recommended percentage (< 5.0%) of missing values for complete case analysis [16]. However, there is no precise consensus on how to deal with missing data [17], and since the majority of randomized controlled trials did not decide for data imputation [18], we decided for complete case analysis.

The a-priori sample size calculation was based on the findings of Mirembert and colleagues (6), who showed that the effect size of the difference between groups in mean blood glucose was 0.9. With an alpha of 0.05 and power of 0.8, the required sample size should be 32 women in each group.

Ethical approval

The study has been conducted in accordance with the guidelines of the Declaration of Helsinki. It received

ethical approval from Slovenian Ethics Committee, number 0120–301/2020–4.

Results

A total of 106 consecutive women with GDM were randomized to the telemedicine group ($n = 54$) or standard care group ($n = 52$) (Fig. 1). One participant from the telemedicine group was excluded from the analysis due to pregnancy termination because of a fetal anomaly that was not related to GDM and occurred after the first medical check-up. The secondary outcomes, i.e., perinatal data, could not be reached for one participant per every group.

Seven participants, six of whom were from the telemedicine group, were lost to follow-up (Fig. 1). Two women decided to discontinue telemedicine care soon after their enrollment due to technical problems and dissatisfaction with the telemedicine experience. Others were lost to follow-up toward the end of pregnancy for unspecified reasons.

At baseline, no significant differences were found between the groups (Table 1). However, the GDM diagnosis was set earlier in the telemedicine group (15.3 [10.4–24.6] than in the standard care group (23.9 [11.2–25.3], $p = 0.119$). The majority of women were diagnosed with GDM based on the increased fasting glucose concentration (74.5% in the telemedicine group and 64.7% in the standard care group).

24.0% of women in the telemedicine group and 34.0% of women in the standard care group gained more weight than recommended; however, the difference was not statistically significant (Table 2).

HbA_{1c} at the last visit was significantly higher in the telemedicine group; however, after controlling for gestational age at the last visit, the difference was no significant ($F(1,81) = 1.17$, $p = 0.283$). The number of visits/contacts with HCPs was significantly higher in the telemedicine group ($p < 0.001$).

The percentage of women, who needed insulin treatment in the standard care group, was almost double the one of the telemedicine group, but not statistically significant.

Ninety-two women provided complete glucose data from the glucose meters. Post hoc analysis to assess actually achieved power was performed. The power achieved was 0.88, 0.77 and 0.84 for postprandial glucose concentration, total compliance and postprandial measurements above the glycemic target, respectively. The standard care group of women had on average higher postprandial glucose concentrations at SMBG. Also, a higher percentage of glucose concentration above the target in the standard care group was found (Table 3). All differences in glycemic parameters were statistically significant, even after controlling for the number of contacts/visits (postprandial glucose concentration: $F(1,91) = 14.232$, $p < 0.001$; postprandial glucose

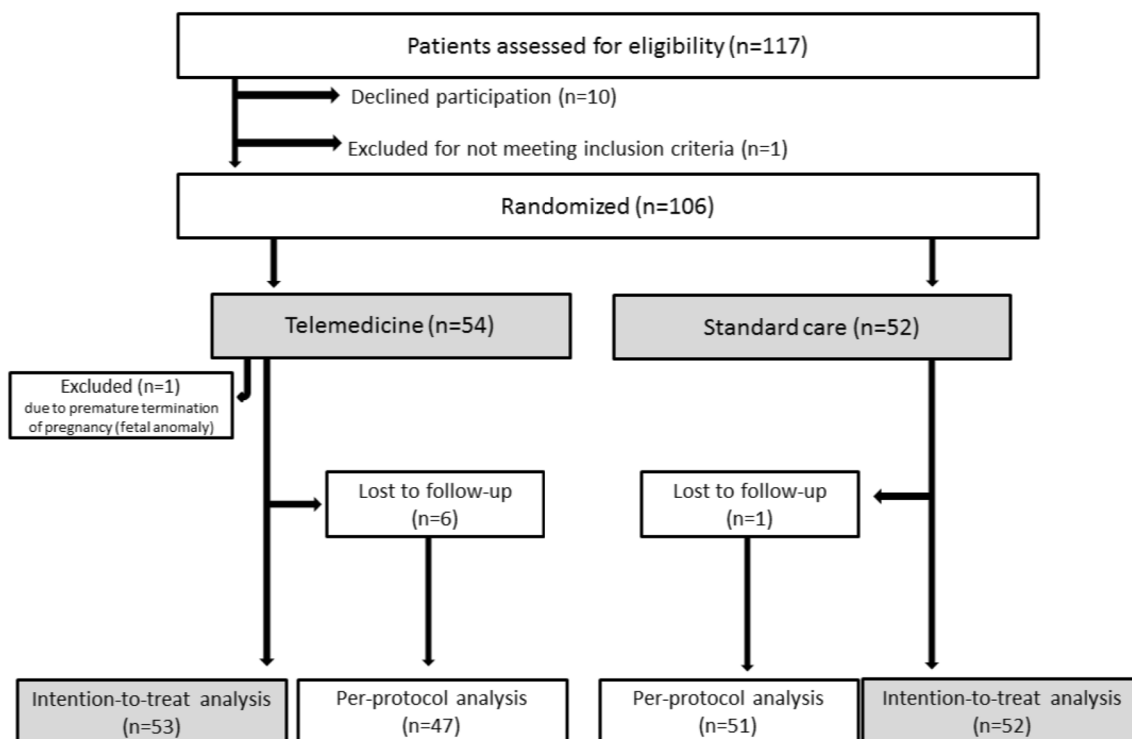


Fig. 1 Flowchart of the study

Table 1 Baseline characteristics of participants and glyceemic parameters at the time of GDM diagnosis

	Telemedicine care group (N= 53)	Standard care group (N= 52)	p value
Age (years)	32.8 [28.1–34.9]	32.0 [29.6–34.6]	0.977
Height (cm)	166.5 ± 6.0	167.5 ± 5.6	0.396
Pre-conception BMI (kg/m ²)	23.3 [21.8–28.5]	24.6 [21.8–28.4]	0.661
Parity			0.759
0, n (%)	29 (54.7)	30 (57.7)	
1 or more, n (%)	24 (45.3)	22 (42.3)	
Gestational age at GDM diagnosis (weeks)	15.1 [10.4–24.6]	23.9 [11.2–25.3]	0.119
Fasting glucose at GDM diagnosis (mmol/l)	5.1 [5.1–5.4]	5.1 [4.7–5.2]	0.150
Standardized (z) value of glucose measurement at GDM diagnosis	0.30 [0.09–0.90]	0.30 [0.09–0.55]	0.327

Data are presented as mean ± standard deviation for normally distributed variables, median [interquartile range] for non-normally distributed data or number (%) for categorical data

BMI—body mass index

* $p < 0.05$; ** $p < 0.01$; *** $p < 0.001$

concentration above the target: $F(1,91) = 11.785$, $p = 0.001$). Nevertheless, compliance with the postprandial self-monitoring of blood glucose and the total number of glucose measurements was smaller in the telemedicine group.

Compliance with SMBG was not associated with maternal age (Spearman $R = 0.217$, $p = 0.054$ in the telemedicine group and 0.066 , $p = 0.684$ in the standard care group),

nor with GWG or average fasting (Spearman $R = 0.151$, $p = 0.154$) or postprandial glucose concentration (Spearman $R = 0.043$; $p = 0.689$).

Perinatal outcomes were similar in both groups (Table 4) with the exception of the cesarean section, which occurred more frequently in the standard care group. Likewise, the per-protocol analysis pointed to the same conclusion,

Table 2 Maternal outcomes of the telemedicine and the standard care treatment

	Telemedicine care group (N=53)	Standard care group (N=52)	p value
GWG (kg)	10.7±4.5	11.3±5.6	0.551
Excessive GWG ^a , n (%)	12 (24.0)	17 (34.0)	0.271
<i>HbA1c first visit</i>			
%	4.9 [4.7–5.2]	4.9 [4.8–5.0]	0.507
mmol/mol	30.1 [27.9–33.3]	30.1 [29.0–31.1]	
<i>HbA1c last visit</i>			
%	5.2±0.31	5.1±0.27	0.016*
mmol/mol	33.7±3.4	32.0±2.9	
Gestational age at last visit (weeks)	36.7±1.16	35.3±1.80	<0.001***
Difference in HbA1c (last visit–first visit)	0.30±0.26	0.22±0.24	0.121
Number of visits/contacts	7 [5.0–10.0]	4 [3.0–6.5]	<0.001***
Insulin treatment, n (%)	7 (13.2)	13 (25.0)	0.124
Insulin initiation (weeks)	22.1±8.0	28.0±7.3	0.111
Long acting insulin n, %	5 (9.4)	9 (17.3)	0.235
Long acting insulin–final dose (IU)	20.0±13.9	12.9±7.6	0.234
Short acting insulin n, %	2 (3.8)	7 (13.5)	0.076
Short acting insulin–final dose (IU)	18.0 [12.0–24.0]	8 [6.0–28.5]	0.889

Data are presented as mean ± standard deviation for normally distributed variables, median [interquartile range] for non-normally distributed data or number (%) for categorical data

GWG—gestational weight gain

HbA1c—glycated hemoglobin

IU—international units

^aAccording to the IOM guidelines (14)

* $p < 0.05$; ** $p < 0.01$; *** $p < 0.001$

Table 3 Self-measurement of blood glucose analysis

	Telemedicine care group (N=51)	Standard care group (N=41)	p value
FG average (mmol/l)	4.8±0.4	4.8±0.3	0.853
PPG average (mmol/l)	5.6±0.3	5.9±0.4	0.004**
FG compliance (%)	84.4 [62.5–96.8]	93.8 [78.1–100.0]	0.063
PPG compliance (%)	66.7 [38.1–88.2]	88.5 [66.7–96.8]	0.013*
Total compliance (%)	75.0 [49.5–93.2]	90.4 [69.8–97.1]	0.022*
FG % above target	6.3 [0.0–17.4]	6.3 [0.0–16.7]	0.717
PPG % above target	10.4 [3.9–17.9]	14.6 [6.5–27.1]	0.015*
CV	0.15±0.03	0.16±0.05	0.164

Data are presented as mean ± standard deviation for normally distributed variables, median [interquartile range] for non-normally distributed data or number (%) for categorical data

FG—fasting glucose concentration

PPG—postprandial glucose concentration

CV—coefficient of variation

* $p < 0.05$; ** $p < 0.01$; *** $p < 0.001$

although it was underpowered to detect significant differences between the groups (Supplementary Table 4).

Forty-six women from the telemedicine group responded to the SUTAQ questionnaire, and five of those prematurely discontinued telemedicine treatment.

Women who discontinued telemedicine treatment achieved higher score on subscales privacy and discomfort (16.0 [13.0–18.0] vs. 8.0 [5.0–12.0]; $p = 0.003$) and care personnel concern (12.0 [12.0–13.0] vs. 6.0 [3.0–9.0];

Table 4 Perinatal outcomes of telemedicine and standard care groups

	Telemedicine care group (N=52)	Standard care group (N=51)	p value
Gestational age at birth (weeks)	39.3 [38.6–40.0]	39.4 [38.7–40.0]	0.581
Preterm birth (< 37 weeks)	6 (11.5%)	3 (5.9%)	0.309
Cesarean section (%)	9 (17.3%)	18 (35.3%)	0.038*
Birth weight (g)	3366 ± 437	3400 ± 429	0.685
LGA	7 (13.5%)	5 (9.8%)	0.563
SGA	4 (7.7%)	1 (2.0%)	0.176
Child composite adverse outcomes †	7 (13.5%)	6 (11.8%)	0.795

Data are presented as mean ± standard deviation for normally distributed variables, median [interquartile range] for non-normally distributed data or number (%) for categorical data

LGA—large for gestational age

SGA—small for gestational age

†Child composite adverse outcome includes hyperbilirubinemia, hypoglycemia, birth trauma, stillbirth, neonatal death

* $p < 0.05$; ** $p < 0.01$; *** $p < 0.001$

$p = 0.001$), indicating lower satisfaction with those aspects of telemedicine.

Discussion

This randomized controlled trial indicates that monitoring women with GDM using telemedicine as a replacement approach leads to at least comparable glycemic and perinatal results compared to standard care. GDM women in the telemedicine group demonstrated better glycemic control. In addition, cesarean sections were less frequent in the telemedicine group.

In the telemedicine group, we found a lower average postprandial glucose and a lower percentage of postprandial measurements above the target, which was also confirmed in previous studies [3, 5, 10, 19]. However, it needs to be emphasized that in those studies, telemedicine tools were used as a complement and not as a replacement for standard care. Some studies also detected, however, a decrease in fasting glucose, which was not seen in our study. It may be that via telemedicine tools, larger postprandial glucose excursions could be detected earlier and acted upon by implementing individualized lifestyle advice, whereas fasting glucose concentration is more related to pre-pregnancy BMI and overall metabolic health.

Moreover, overall compliance with glucose measurements was lower in our telemedicine group (75%), contrast with the results of Miremberg and colleagues (84%), where participants received additional daily feedback on their compliance and glycemic control [6]. Nevertheless, we do not know what the target compliance rate for women with GDM is and whether all women need daily feedback to remain/become compliant. In addition, the number of visits /contacts with the HCPs was higher in the telemedicine group,

which may indeed increase the burden of the HCPs. Our study was not powered to determine whether the number of contacts affects the treatment; however, it is important to design future studies with the aim to optimize the protocol for telemedicine care and the structure of telemedicine contacts in a way that would be feasible to implement into everyday clinical practice. We hypothesize that timely interventions, more than the number of contacts, are the key to better glycemic results.

In our study, HbA_{1c} was higher at the end of follow-up in the telemedicine group. It should be noted that women in the telemedicine group had HbA_{1c} determination at a later gestational age than women from the standard care group which may result in higher HbA_{1c}. It may be due to anemia due to progressive iron deficit and related changes in erythrocyte turnover rate. Indeed, after we controlled the difference in HbA_{1c} between the groups for gestational age, the difference was no longer significant [20]. The reason for performing the last visit in the telemedicine group at, on average, a 1.4-week later gestational age than in the standard care group may be in the higher motivation of the telemedicine group to perform this visit on site, since they did not have on-site visits during follow-up and could organize themselves for this last visit more easily. In the standard group, on the contrary, women had to organize many on-site visits during follow-up and some of them might be less motivated to come to the clinic also at this late time in pregnancy.

In our study, the difference in GWG between groups was not statistically significant, which was also found in other studies [21]. Similarly, there was a numerically lower need for insulin treatment in the telemedicine group. We hypothesize that the main reason is providing timely contacts initiated by when glycemic targets were not achieved, with an additional personalized diet and physical activity advice given. In contrast, although the standard care group had

the opportunity for additional contacts with the HCPs, they were not initiated by the HCPs. The other reason for lower insulin initiation rate may be also a greater feeling of safety of HCPs, having actual “real-time” access to participants’ glucose data, and knowing insulin can be initiated in a few days’ time if needed [22].

The overall incidence of adverse neonatal outcomes was small. Nevertheless, the proportion of cesarean section was significantly lower in the telemedicine group, which is in line with previous studies [5, 10]. This may be due to a lower weight gain and improved lifestyle. Also, since fewer women were treated with insulin, they might be perceived at a lower risk of complications by their obstetricians, and therefore, fewer cesarean sections were performed.

The greatest advantage of our study is that it is, according to the best of our knowledge, the first randomized trial, studying the effect of Web-based telemedicine care compared to standard care and not merely as an adjunct to standard care in a broad group of women with GDM. This is even more important in the setting of the COVID-19 pandemic, where safe and effective alternatives to in-patient care are needed and were recognized as especially suitable for diabetes [23]. Another advantage is the analysis of participant satisfaction with the use of telemedicine tools, since very few trials reported those, while these measures are being increasingly recognized as important outcomes that impact health [24]. The participants of both groups established a relationship with the HCPs for the first time. If and how telemedicine affects woman-HCP relationships was out of the scope of our study. Our study represents a step toward the introduction of artificial intelligence in the treatment of women with GDM. But, before we leave it to artificial intelligence, it is necessary to study to whom telemedicine care suits best, e.g., according to personality, attachment styles, etc.

One of the main limitations of our study was a small sample size to detect differences in perinatal results. Another limitation refers to incomplete SMBG data in the standard care group since not all participants agreed to bring their glucometers to the clinic (they only brought the paper self-written diaries). This could be an important source of bias; however, adding the results of those women to the standard care group would probably even emphasize the worse glycemic control in the standard care group. Also, the difference in glycemic outcomes may have been related to more frequent interactions with the HCPs in the telemedicine group in women not achieving treatment targets, rather than to the mode of care delivery itself. However, the number of visits/contacts with the HCPs did not show as crucial. Nevertheless, care delivered through telemedicine has a large potential to become more optimized, further lowering the number of contacts with the healthcare professionals in those who do not need so much support and rather offering more contacts to those who would benefit from them. Another limitation is

a relatively high drop-out from the telemedicine group and therefore loss of follow-up data. Also, telemedicine group was diagnosed with GDM at an earlier gestational age, which could lead to lower GWG and better glycemic control due to longer treatment time frame. In addition, in this group insulin was initiated earlier compared to the standard care group (22nd vs. 28th gestational week), although the difference was not statistically significant, possibly due to the overall low number of participants. The analysis of patient satisfaction with the telemedicine service showed that those were the women who felt their privacy is at risk and were also more concerned about the skills and continuity of the personnel looking after them. On the other hand, many women found the possibility of not attending in-person office follow-up examinations as a great advantage. Therefore, comprehensive analyses of satisfaction and maybe also technical skills are needed to gain the most benefit from telemedicine care. Another limitation of our study is that we did not consider what effect the level of education could have on our results. Namely, the level of education might play an important role in the compliance of participants, so it is an important variable that should be included in further studies. Unfortunately, no continuous glucose monitoring (CGM) data were obtained; however, in future studies, using CGM would be crucial to get more accurate insight into women’s glycemic control. Although the statistical sample size has been largely achieved, a replication of the result in a larger cohort, with a different geographical context and with the acknowledgment of education level is needed in order to generalize our results.

Our study showed that telemedicine treatment may be efficient and safe when used instead of the standard in-person care in GDM. Indeed, GDM women in the telemedicine group demonstrated lower average postprandial glucose concentration and lower cesarean section rate. The beneficial effect on GWG and less insulin treatment was also indicated but should be confirmed on a larger sample. Nevertheless, telemedicine interventions offer an exciting venue to pursue in future, enabling a more personalized way of delivering care.

Supplementary Information The online version contains supplementary material available at <https://doi.org/10.1007/s00592-023-02099-8>.

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Data availability DPB is the guarantor of this work and, as such, had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. The dataset generated during the current study is available from the corresponding author upon reasonable request.

Declarations

Conflict of interest The authors declare that there is no conflict of interest.

Informed consent All participants gave their informed consent prior to their inclusion.

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