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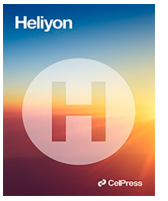

Efficacy and safety of a telemedicine system in subjects with gestational diabetes mellitus (TELEGLAM): Study protocol for a randomized controlled trial

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ABSTRACT

Background: Strict glycemic control is important to prevent perinatal complications in patients with gestational diabetes mellitus (GDM). Patients often require insulin injection, and frequent hospital visits are necessary to adjust the dose of insulin, which is considered burdensome for pregnant patients. Telemedicine may reduce the burden of hospital visits, and previous studies have reported its safety in GDM patients. This study aimed to evaluate the efficacy of telemedicine in GDM patients, focusing on patient satisfaction and health economic indicators.

Methods: This is a single-center, two-arm, randomized, open-label parallel-group study. Subjects will be selected from the patient population attending the Department of Endocrinology, Metabolism, and Nephrology, Keio University School of Medicine, Japan. Patients diagnosed with GDM by an oral glucose tolerance test (OGTT) by 29 weeks and 6 days of gestation who have undergone self-monitoring of blood glucose (SMBG) and insulin injection are eligible for inclusion. In the intervention group, telemedicine will be administered using the MeDaCa telemedicine system developed by the Medical Data Card, Inc., Tokyo, Japan. Subjects in the control group will be examined face-to-face every 2–3 weeks, as usual. We set health economic indicators and patient satisfaction as the primary endpoints, and will perform a cost-consequence analysis. Glycemic control indicators and perinatal outcomes will be evaluated as secondary endpoints.

Conclusions: Eligible patients are currently being recruited. Recruitment will be completed when the expected number of patients are enrolled.

Trial registration

This study was registered in the University Hospital Medical Information Network Clinical Trials Registry in Japan (number:

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1. Background

In the treatment of diabetes, it is important to prevent chronic vascular and neurological complications by implementing daily glycemic pattern management (i.e., glycemic/HbA1c control) and managing comorbidities such as blood pressure, lipids, and obesity. In recent years, information and cloud technologies have revolutionized diabetes care, with self-monitoring and continuous glucose monitoring being representative breakthroughs [1]. Abnormal glucose metabolism during pregnancy in patients with gestational diabetes mellitus (GDM) is associated with an increased risk of adverse perinatal outcomes, such as cesarean section, induction of labor, large for gestational age, macrosomia, shoulder dystocia, preterm delivery, neonatal hypoglycemia, and preeclampsia [2]. The HAPO study showed significant associations between adverse perinatal outcomes and higher levels of maternal glucose within what was considered the non-diabetic range at that time [3], and the diagnostic criteria for GDM were changed to be more stringent according to the results [4]. Because of the strict diagnostic criteria and delayed childbearing years, more patients are diagnosed with GDM than ever before [5], and this trend is expected to continue in the future. In patients with GDM, strict glycemic control goals are required to reduce the risk of perinatal complications, making daily glycemic pattern management more important than in other types of diabetes mellitus. However, frequent visits to the hospital can become a physical and emotional burden for pregnant women as gestational age progresses. Especially in the era of the COVID-19 pandemic, the burden is expected to increase further owing to concerns about the risk of infection.

In recent years, telemedicine has been increasingly applied. In particular, there have been many reports on its efficacy and economic efficiency in chronic diseases, such as hypertension, type 2 diabetes, heart failure, chronic obstructive pulmonary disease (COPD), and skin diseases. All of these studies suggest its safety, reduced psychological burden, and reduced economic burden [6–11]. As mentioned above, hospital visits can be a burden for patients with GDM. Considering that the main content of the consultation is guidance on diet/exercise therapy and adjustment of insulin dosage based on records of self-monitoring of blood glucose, telemedicine can be an effective method to reduce this burden.

While there have been an increasing number of reports on telemedicine, reports on telemedicine for patients with GDM are limited. Rasekaba et al. reported that, although there were no differences in the number of hospital visits or maternal or neonatal outcomes, telemedicine for GDM allowed optimization of glycemic control more quickly than usual care [12]. A study in the UK showed no significant differences in glycemic control and improved patient satisfaction as assessed by the Oxford maternity DTSQ score in the telemedicine group for GDM compared to usual care, with no significant differences in direct healthcare costs [13,14]. In contrast, a non-randomized trial in Canada reported a 16 % reduction in direct healthcare costs in the telemedicine group for GDM [15]. The differences between these studies may be caused by differences in the telemedicine systems used and in healthcare costs by country.

In summary, the results of the aforementioned studies and meta-analyses on telemedicine in GDM [16,17] have consistently shown that glycemic control and perinatal complications in telemedicine are similar to those in face-to-face consultations. However, the major benefit of telemedicine is the reduction of the burden of hospital visits. We think that it is necessary to consider not only direct healthcare costs but also indirect costs and direct non-healthcare costs, which include transportation costs, because there have been few randomized studies showing improvements in patient satisfaction or overall economic indicators. In addition, it has been reported

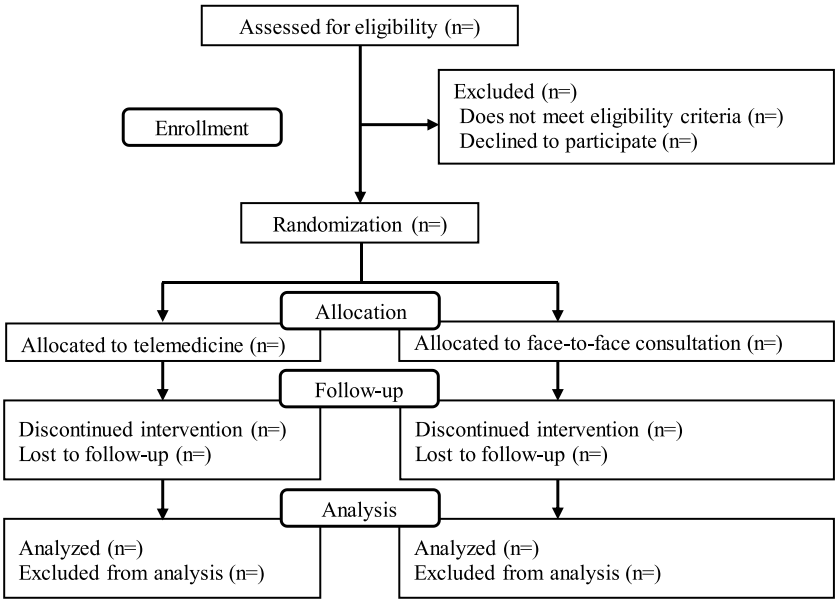

Fig. 1. Flow diagram of the study.

that telemedicine for patients with GDM improves satisfaction scores and psychosocial self-efficacy [14,18], but we consider it necessary to assess psychological burden using another measure to evaluate the benefit of reduced hospital visits.

Therefore, we plan to conduct a prospective randomized controlled trial to evaluate the efficacy of a telemedicine system in patients with GDM, particularly in terms of patient satisfaction and health economic indicators which have not been examined in previous studies.

2. Methods

2.1. Study design

This is a single-center, two-arm, randomized, open-label, parallel-group study to evaluate the efficacy and safety of a telemedicine system in patients with GDM. In this study, research subjects will be selected from the patient population attending the Department of Endocrinology, Metabolism, and Nephrology, Keio University School of Medicine, Japan. A flow diagram of the study is shown in Fig. 1. Informed written consent will be obtained from each subject who meets the criteria below and who agrees to participate in the study. As baseline information, we will record the comorbidities, date, and results of the oral glucose tolerance test (OGTT), pre-pregnancy weight, gravidity, parity, history of GDM, nationality, number of fetuses (singleton or twins or higher), drug information, height, and weight. During this study, all participants may withdraw at any time without providing a reason. GDM will be diagnosed by the International Association of Diabetes Pregnancy Study Groups Consensus Panel [4]: FPG (Fasting Plasma Glucose) $\geq$ 5.1 mmol/L (92 mg/dL), and/or 1-h plasma glucose $\geq$10.0 mmol/L (180 mg/dL), and/or 2-h plasma glucose $\geq$8.5 mmol/L (153 mg/dL). This study was initiated on March 1, 2022, and will be completed on March 31, 2024.

2.2. Ethics

The protocol for this study was approved by the Keio University School of Medicine Ethics Committee on February 7th, 2022 (approval number:20211125), and registered in the University Hospital Medical Information Network Clinical Trials Registry in Japan (number: UMIN000047009). This study was designed in accordance with the principles of the Declaration of Helsinki and Japan's 'Ethical Guidelines for Medical and Health Research Involving Human Subjects'.

2.3. Inclusion/exclusion criteria

In Japan, only insulin is covered by insurance for GDM, and a diabetologist is in charge of blood glucose control and chooses the treatment at his/her discretion. The general consensus is that the management goals for gestational diabetes are pre-prandial blood glucose less than 100 mg/dL and 2-h postprandial blood glucose less than 120 mg/dL, and that insulin therapy should be initiated at the discretion of the specialist when blood glucose levels exceed these criteria on multiple occasions.

The inclusion and exclusion criteria are presented in Table 1. Participants will be considered eligible for this study if they fulfill the inclusion criteria: (1) patients diagnosed with GDM by OGTT by 29 weeks and 6 days of gestation who have undergone self-monitoring of blood glucose (SMBG) and insulin injection by diabetologist; (2) patients provided written consent to participate in the study after receiving sufficient explanation and understanding of the study; and (3) patients who can understand and operate the telemedicine system.

The exclusion criteria are as follows: (1) diagnosed with GDM after 30 weeks and 0 days of gestation; (2) diagnosed with overt diabetes in pregnancy; (3) patients with type 2 diabetes; (4) patients with type 1 diabetes; (5) patients with serious uncontrolled complications; (6) patients with pacemakers or other implantable medical devices; (7) requested not to participate in the study; (8)

Table 1
Inclusion and exclusion criteria.

Inclusion criteria
1. Patients diagnosed with GDM by OGTT by 29 weeks and 6 days of gestation who have undergone self-monitoring of blood glucose (SMBG) and insulin injection by diabetologist
2. Patients provided written consent to participate in the study after receiving sufficient explanation and understanding of the study
3. Patients who can understand and operate the telemedicine system
Exclusion criteria
1. Diagnosed with GDM after 30 weeks and 0 days of gestation
2. Diagnosed with overt diabetes in pregnancy
3. Patients with type 2 diabetes
4. Patients with type 1 diabetes
5. Patients with serious uncontrolled complications
6. Patients with pacemakers or other implantable medical devices
7. Requested not to participate in the study
8. Judged inappropriate to participate in the study by the physicians (e.g. difficulty in understanding Japanese and responding to questionnaires, refusal to treat GDM, difficulty in making regular visits to the hospital)
9. Patients who do not have the necessary internet environment for online consultation
10. Patients who do not use a smart phone

judged inappropriate to participate in the study by the physicians (e.g. difficulty in understanding Japanese and responding to questionnaires, refusal to treat GDM, difficulty in making regular visits to the hospital); (9) patients who do not have the necessary internet environment for online consultation; and (10) patients who do not use a smart phone.

2.4. Randomization

After informed consent is obtained, randomization will be performed in an approximately 1:1 ratio by a blinded, independent third-party system using a modified minimization method with a biased-coin assignment balancing maternal age (under 39 years old vs. over 40 years old), pre-pregnancy obesity, history of GDM, number of fetuses (singleton vs. twins or higher order pregnancy), and ethnicity. The University Hospital Medical Information Network Internet Data and Information System for Clinical and Epidemiological Research (Cloud version) will be used for randomization. An allocation registration form was created by a physician unrelated to the study. Subjects and physicians will not be blinded to the treatment allocation.

2.5. Intervention/control

Telemedicine will be administered to the intervention group using the MeDaCa telemedicine system developed by Medical Data Card, Inc., Tokyo, Japan. MeDaCa is a system that connects a medical institution's computer to a patient's smartphone, tablet, or computer using the Internet, to enable real-time video calls comparable to face-to-face consultations. MeDaCa has already been introduced and used at Keio University School of Medicine, and is utilized by almost all pregnant women attending the Department of Obstetrics & Gynecology. At Keio University, One Touch Reveal®, a smartphone application for the glucose meter One Touch Verio Reflect® (LifeScan, Inc., Malvern, PA, USA), is linked to MeDaCa in the cloud, and data from blood glucose measurements can be automatically imported into MeDaCa. Therefore, MeDaCa is also used in the control group to confirm the blood glucose measurement data, but examinations are performed face-to-face. The study design is illustrated in Fig. 2. The first outpatient visit after the introduction of the insulin injection and self-monitoring of blood glucose will be set the start date of the intervention period, and the end date will be set at 10 (±2) weeks later. In the intervention group, face-to-face consultations will be conducted at the beginning and end of the intervention, and online consultations will be conducted every 2–3 weeks in the interim period. Face-to-face consultations can be conducted at any time if the physician deems it necessary or if the subject desires it. In the control group, the subjects will be examined face-to-face at 2–3 weeks, as usual. After the intervention, both online and face-to-face consultations will be selected until delivery, according to the wishes of the subjects in both the intervention and control groups. During this study, unscheduled visits will be available at any time in both groups and nurses provided telephone support as needed.

2.6. Outcomes

2.6.1. Primary outcomes

In this study, we will perform a cost-consequence analysis (CCA), which is defined as "a form of health economic evaluation study in which all direct and indirect costs and a catalogue of different outcomes of all alternatives are listed separately." [19] Thus, two primary endpoints–health economic indicators and patient satisfaction–will be set for evaluation. The following health economic indicators will also be evaluated: (1) direct healthcare costs, (2) direct non-healthcare costs, and (3) indirect costs. For direct healthcare costs, the actual healthcare costs incurred by medical examinations will be evaluated using the claims data of the subjects. Direct non-health-care costs include transportation costs and will be calculated by obtaining the home or work addresses of the subjects through questionnaires and using Google Maps (Google, Inc., Mountain View, CA, USA). In this study, calculations will be performed assuming that all the subjects use public transportation. Indirect costs are defined losses due to the inability of subjects to work as a

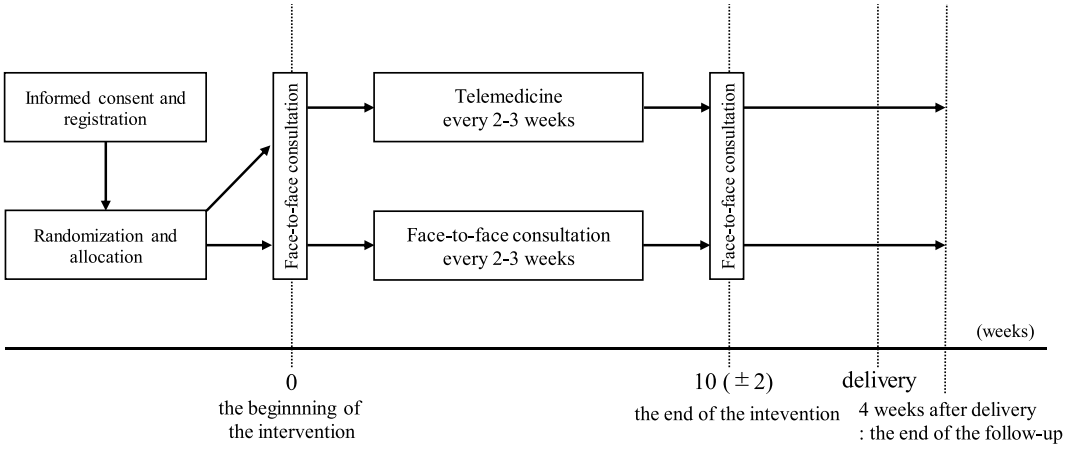

Fig. 2. Study design.

consequence of the disease. If the subject is employed, the amount of time she takes as leave will be collected in both the intervention and control groups, and the production loss will be calculated from the hours of sick leave and the average wage in Japan. In addition, indirect costs associated with childcare will be also considered, such as leaving a child with a babysitter for a hospital visit or a spouse taking leave. To evaluate patient satisfaction, the Problem Areas in Diabetes Survey (PAID) [20] and Diabetes Therapy-Related QOL (DTR-QOL) questionnaire [21], which are used as methods to assess burden and satisfaction in diabetes treatment, will be used to compare scores between groups before and 10 weeks after the intervention. The subjects will be informed in advance that both questionnaires are designed for patients with diabetes.

In addition, stratified analysis by type of insulin injection (basal insulin only or multiple injection) will also be performed for all primary outcomes.

2.6.2. Secondary outcomes

We will evaluate glycemic control indicators and perinatal outcomes as secondary endpoints (Table 2) for the evaluation schedule of each indicator. Fasting and postprandial blood glucose levels from self-monitoring records, frequency of hypoglycemia and hyperglycemia, insulin dose, HbA1c, and glycated albumin will be evaluated as glycemic control indicators. Maternal hypoglycemia is defined using the definition for Level 2 and/or 3 of the American Diabetes Association (ADA) guidelines as follows: glucose <54 mg/dL (3.0 mmol/L) and/or a severe event characterized by altered mental and/or physical status requiring assistance for treatment of hypoglycemia [22]. Subjects will measure their blood glucose 6 times a day (just before each meal and 2 h after each meal) from the start of self-monitoring of blood glucose to the first outpatient visit, and for one week before the end of the intervention. For other periods, blood glucose measurement can be reduced to twice a day through the 'staggered' testing, in which three patterns of blood glucose measurement are repeated daily in sequence: (1) immediately before/2-h after breakfast, (2) immediately before/2-h after lunch, (3) immediately before/2-h after dinner [23]. If necessary, the number of measurements should be increased at the discretion of the attending physician. The insulin dose should be adjusted with the goal of achieving pre-prandial blood glucose less than 100 mg/dL and 2-h postprandial blood glucose less than 120 mg/dL. We will evaluate the following perinatal outcomes: gestational age, fetal growth status, mode of delivery, maternal weight, obstetric complications that occur during the perinatal period, such as premature rupture of the membrane and postpartum hemorrhage, maternal complications such as gestational hypertension, fetal indexes (sex, height, weight, neonatal hypoglycemia, Apgar score, large for gestational age, small for gestational age, and shoulder dystocia), umbilical artery pH, incidence of congenital diseases, and admission to the neonatal intensive care unit (NICU). Neonatal hypoglycemia is defined as less than 40 mg/dL, and blood glucose should be measured using point-of-care testing (POCT) equipment. An intervention criterion of <50 mg/dL is used. As an exploratory evaluation item, the degree of psychological burden on the medical staff in conducting online consultations will be assessed using a questionnaire for outpatient physicians at the end of the intervention. Furthermore, we will measure the time spent in consultation and outpatient waiting times based on the questionnaires and medical records in both intervention and control groups.

In addition, stratified analysis by type of insulin injection (basal insulin only or multiple injection) will also be performed for all secondary outcomes.

2.7. Sample size

No prior study has used the endpoints evaluated in this study for telemedicine in GDM, which made it difficult to assess the number of cases needed. Of the primary endpoints in this study, PAID was considered the least likely to change with intervention. Based on the results of past studies using PAID and questionnaires that we conducted in advance, we estimated that the PAID score after the intervention would be approximately 30 points in the intervention group and approximately 40 points in the control group [24,25]. Therefore, the sample size required to achieve a significance of 0.05 from a two-sided test with a statistical power of 80 % was estimated to be 32 subjects. Assuming a 20 % dropout rate during the study, the target number of subjects was set to 40 total.

Table 2
Observation items and study schedule.

Items	Enrollment	Before intervention	While intervention	After intervention	Postpartum
Informed consent	○				
Baseline Characteristics[a]	○				
Height	○				
Weight	○	○		○	
Blood pressure	○	○		○	
Blood test		○		○	
Urine test		○		○	
Questionnaire for primary outcomes		○		○	
Blood glucose by self-monitoring record		○	○	○	
Perinatal outcomes		○	○	○	○
Adverse event		○	○	○	○
Questionnaire for outpatient physicians				○	
Waiting time records		○		○	

[a] Baseline characteristics included comorbidities, date and results of OGTT, pre-pregnancy weight, gravidity, parity, history of GDM, nationality, number of fetuses (singleton or twins or higher), and drug information.

2.8. Data collection and management

Results for the primary endpoints in this study will be obtained from the study participants' responses to questionnaires at the beginning and end of the intervention. The physicians who collect the questionnaires will check for missing data and, if necessary, confirm with the study subject individually. In patients hospitalized at the end of the intervention for reasons such as preterm delivery, the questionnaire will be administered at a time that does not affect delivery. The secondary endpoints related to the questionnaire are the same as those for the primary endpoints. Maternal and infant data will be collected from medical records. Self-monitoring of blood glucose data can be synchronized with the smartphone application and MeDaCa using Bluetooth.

Physicians participating in this study will complete the case report form (CRF) using the research subject's ID as soon as possible after obtaining the research subject's information and delete all or part of a description containing a personal identification code that would allow a specific individual to be identified. If data on research subjects are transferred electronically, they must be encrypted. Physicians confirm that the data of the research subjects recorded in the CRF are complete, and if the data need to be corrected, the correction details on the CRF and the correction date and reason for correction will be recorded. The physician will verify that all data, including the corrected data, are accurate and complete before entering the database. For cases in which the study are discontinued, the data up to the point of discontinuation will be entered into the database.

Anonymized data will be handled when analyzing the obtained information, and we will pay close attention to data management to prevent data leakage. Data and correspondence tables for anonymization will be managed and stored by the personal information manager. In accordance with the ethical guidelines, the data provided and the correspondence table will be stored for at least five years from the date of the report on the completion of the research or three years from the date of the final report on the research results, whichever is later. After this storage period, all data will be irretrievably destroyed. If any patients withdraw consent for participation, data will be discarded individually.

2.9. Statistical analysis

Analyses of the primary and secondary outcomes will be performed in the full analysis set (FAS), which will include all patients who completed at least two online consultations during the study period, did not present any serious violation of the study protocol, such as the inappropriate procurement of consent or a breach of the inclusion and exclusion criteria, and whose data were collected after treatment. For the baseline characteristics, summary statistics will be comprised of frequencies and proportions for categorical variables, and means and standard deviations for continuous variables. Patient characteristics will be compared using a chi-square test for categorical variables and a *t*-test or Wilcoxon rank-sum test for continuous variables. For the primary endpoints, representative values, such as the number of subjects, mean, standard deviation, minimum, median, and maximum, will be calculated for each measurement point, and an analysis of covariance will be conducted using the following variables: maternal age, pre-pregnancy obesity, history of GDM, and number of fetuses. The secondary analysis will be performed in the same manner as the primary analysis. All comparisons will be planned, and all p-values will be two sided. Statistical significance will be set at $P < 0.05$. Analyses will be conducted using IBM SPSS Statistics software for Windows version 28.0.0.0 (IBM Corp, Armonk, NY, USA).

3. Discussion

Previous studies have shown that glycemic control and perinatal outcomes in telemedicine are similar to those at face-to-face consultations [12–14]. Based on these results, the aim of this study was to determine whether telemedicine for patients with GDM can contribute to improved patient satisfaction and healthcare costs.

This study has several strengths. First, it is the first study on GDM patients to evaluate the impact of telemedicine on psychological burden when restricted to a population of insulin users only. In a study by Mackillop et al., patient satisfaction was mildly improved in the telemedicine group, but patients who needed insulin therapy immediately at recruitment were excluded from the study [14]. Although diet and exercise therapy are fundamental in the treatment of GDM, a certain number of patients cannot control their blood glucose with diet and exercise and use insulin. Patients with GDM require frequent medical examinations because the target range of blood glucose is narrow, and blood glucose fluctuates widely during pregnancy. However, in patients who use insulin, a high frequency of hospital visits during pregnancy is considered particularly psychologically burdensome. Therefore, it is important to evaluate the psychological burden on insulin users. Second, the use of MeDaCa not only enables blood glucose and blood pressure data sharing, but also makes it possible to provide medical care that is comparable to face-to-face consultations using only video calls. In fact, systems used in previous studies have mainly focused on sharing blood glucose records in the cloud and communicating with patients via short message services (SMS). Thus, advances in technology may improve outcomes, including patient satisfaction, compared with previous studies. Third, this study will evaluate not only direct healthcare costs, but also direct and indirect non-healthcare costs. No studies have yet reported these indicators in the field of telemedicine in GDM. We believe that reducing the frequency of hospital visits and the impact on work will have a positive impact on the social economy and help encourage women to play an active role in society. Furthermore, the measurement data of blood glucose are automatically shared through Bluetooth; therefore, there is no need for the patients themselves to enter numerical values. Thus, as Donsa et al. noted [26], input errors are likely to be prevented, allowing more accurate data to be obtained.

This study has several limitations. First, owing to the nature of this study, clinical bias remains because blinding is not possible. Next, the sample size in this study was set to be small, which will reduce the power to detect infrequent complications. As outpatient physicians are not randomized, differences in communication styles between physicians may affect patient satisfaction. In addition,

because this study will be conducted at a Japanese medical institution, it is expected that nearly all subjects will be Asian, and the effect of racial differences on the results cannot be discussed. Finally, because there are many hospitals in Japan's urban areas, there may be differences in economic indicators and psychological burdens compared to if this study is conducted in suburban areas.

Despite the several limitations mentioned above, we hope that this study will demonstrate the efficacy of telemedicine in GDM and provide evidence for the further widespread use of telemedicine in the future.

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Ethics declarations

This study was reviewed and approved by the Keio University School of Medicine Ethics Committee on February 7th, 2022, with the approval number: 20211125, and registered in the University Hospital Medical Information Network Clinical Trials Registry in Japan (number: UMIN000047009). After the approvement and registration, we have started execution of this study on February 7th, 2022. All participants/patients will provide informed consent to participate in the study.

Data availability statement

Data associated with our study has not been deposited into a publicly available repository. Derived data supporting the findings of this study will be made available from the corresponding author on request because it includes residency and other privacy sensitive information.

CRediT authorship contribution statement

Kazuki Aoyama: Writing – original draft, Investigation, Formal analysis, Conceptualization. **Yuya Nakajima:** Writing – review & editing, Methodology, Investigation, Conceptualization. **Shu Meguro:** Writing – review & editing, Project administration, Methodology, Investigation, Conceptualization. **Yasunori Sato:** Writing – review & editing, Methodology, Formal analysis, Conceptualization. **Rei Goto:** Writing – review & editing, Methodology, Formal analysis, Conceptualization. **Mariko Hida:** Writing – review & editing, Methodology, Conceptualization. **Takeshi Arimitsu:** Writing – review & editing, Methodology, Conceptualization. **Yoshifumi Kasuga:** Writing – review & editing, Methodology, Conceptualization. **Mamoru Tanaka:** Supervision, Methodology, Conceptualization. **Hiroshi Itoh:** Writing – review & editing, Supervision, Project administration, Methodology, Conceptualization.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Abbreviations

GDM, gestational diabetes mellitus; OGTT, oral glucose tolerance test; SMBG, self-monitoring of blood glucose; COPD, chronic obstructive pulmonary disease; CCA, cost-consequence analysis; CRF, case report form; FAS, full analysis set.

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