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# Assessing Telemedicine in Gestational Diabetes Mellitus: Study Protocol for a Randomized Controlled Trial on Clinical, Economic, and Patient-Centered Outcomes

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## ABSTRACT

Managing blood glucose levels is essential to reduce perinatal complications in gestational diabetes mellitus (GDM). Insulin therapy often necessitates frequent hospital visits for dose adjustment, which can be inconvenient for pregnant patients. Telemedicine offers a potential approach to minimize these visits, with prior studies indicating its safety in GDM care. This study aims to investigate the effectiveness of telemedicine in GDM management, focusing on patient satisfaction and economic outcomes. This randomized, open-label, parallel-group trial will be conducted at a single center, Keio University School of Medicine, Japan. Pregnant patients diagnosed with GDM via oral glucose tolerance test (OGTT) before 30 weeks of gestation, requiring self-monitoring of blood glucose and insulin therapy, are eligible. Participants will be randomly assigned to either the telemedicine intervention group using the MeDaCa system (Medical Data Card, Inc., Tokyo, Japan) or a control group receiving routine in-person visits every 2–3 weeks. Primary outcomes include patient satisfaction and health economic measures, assessed through a cost-consequence framework. Secondary outcomes encompass glycemic control and perinatal results. Participant enrollment is ongoing and will continue until the target sample size is achieved, aiming to provide evidence for the clinical and economic benefits of telemedicine in GDM care.

**Keywords:** Gestational diabetes mellitus, Telemedicine, Patient satisfaction, Health economics

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## Introduction

Effective management of diabetes requires daily monitoring of glycemic patterns (including HbA1c control) and addressing comorbidities such as hypertension, dyslipidemia, and obesity to prevent long-term vascular and neurological complications. In recent years, advances in information and cloud-based technologies have transformed diabetes care, with self-monitoring and continuous glucose monitoring representing key innovations [1].

Gestational diabetes mellitus (GDM), characterized by abnormal glucose metabolism during pregnancy, is associated with an elevated risk of adverse perinatal outcomes, including cesarean delivery, labor induction, large-for-gestational-age infants, macrosomia, shoulder dystocia, preterm birth, neonatal hypoglycemia, and preeclampsia [2]. Findings from the HAPO study demonstrated that even maternal glucose levels previously considered non-diabetic were linked to poor perinatal outcomes [3], prompting stricter diagnostic criteria for GDM [4]. Combined with trends toward delayed childbearing, this has led to an increasing prevalence of GDM worldwide [5]. Achieving tight glycemic control is crucial in GDM to minimize these risks, making daily glucose monitoring more critical than in other forms of diabetes. However, as pregnancy progresses, frequent hospital visits can impose significant physical and psychological burdens on expectant mothers. This challenge has been further exacerbated during the COVID-19 pandemic due to concerns over infection exposure.

Telemedicine has emerged as a promising tool to alleviate healthcare burdens. Evidence from chronic disease management—such as in hypertension, type 2 diabetes, heart failure, chronic obstructive pulmonary disease

(COPD), and dermatological conditions—supports its safety and demonstrates reductions in both psychological and economic burdens [6–11]. Given that GDM consultations primarily focus on dietary and exercise guidance and insulin dose adjustments based on self-monitored blood glucose records, telemedicine may provide an efficient alternative to frequent in-person visits.

Despite growing interest, research on telemedicine specifically for GDM remains limited. Rasekaba *et al*. reported that telemedicine did not alter maternal or neonatal outcomes or the frequency of hospital visits but enabled faster optimization of glycemic control compared with standard care [12]. Similarly, a UK study found no significant differences in glycemic outcomes, but telemedicine improved patient satisfaction as measured by the Oxford maternity DTSQ score, without impacting direct healthcare costs [13, 14]. Conversely, a non-randomized Canadian study reported a 16% reduction in direct healthcare costs with telemedicine [15]. These variations may be attributable to differences in telemedicine systems and country-specific healthcare cost structures.

Meta-analyses and previous studies consistently indicate that telemedicine achieves comparable glycemic control and perinatal outcomes to traditional face-to-face care, while reducing hospital visit burdens [16, 17]. However, most studies have focused on direct healthcare costs, and there is limited evidence regarding indirect and non-healthcare costs, such as transportation, or comprehensive assessments of patient satisfaction and psychological well-being [14, 18].

To address these gaps, we propose a prospective randomized controlled trial to evaluate the effectiveness of a telemedicine system in GDM patients, with a primary focus on patient satisfaction and economic outcomes, including both direct and indirect costs, which have not been thoroughly examined in prior research.

## Materials and Methods

*Study design*

This trial is a single-center, open-label, randomized, parallel-group study aimed at evaluating both the effectiveness and safety of a telemedicine platform in managing gestational diabetes mellitus (GDM). Participants will be enrolled from patients receiving care at the Department of Endocrinology, Metabolism, and Nephrology, Keio University School of Medicine, Japan. An overview of the study workflow is illustrated in **Figure 1**.

Eligible participants will provide written informed consent before enrollment. Baseline characteristics to be recorded include pre-pregnancy weight, body mass index, gestational history (gravidity and parity), previous GDM history, OGTT results, comorbidities, medications, nationality, and the number of fetuses. Participants may withdraw from the study at any stage without the need to justify their decision.

The diagnosis of GDM will follow the criteria set by the International Association of Diabetes and Pregnancy Study Groups (IADPSG) [4], defined as fasting plasma glucose ≥5.1 mmol/L (92 mg/dL), 1-hour plasma glucose ≥10.0 mmol/L (180 mg/dL), or 2-hour plasma glucose ≥8.5 mmol/L (153 mg/dL). The study began on March 1, 2022, with an anticipated completion date of March 31, 2024.

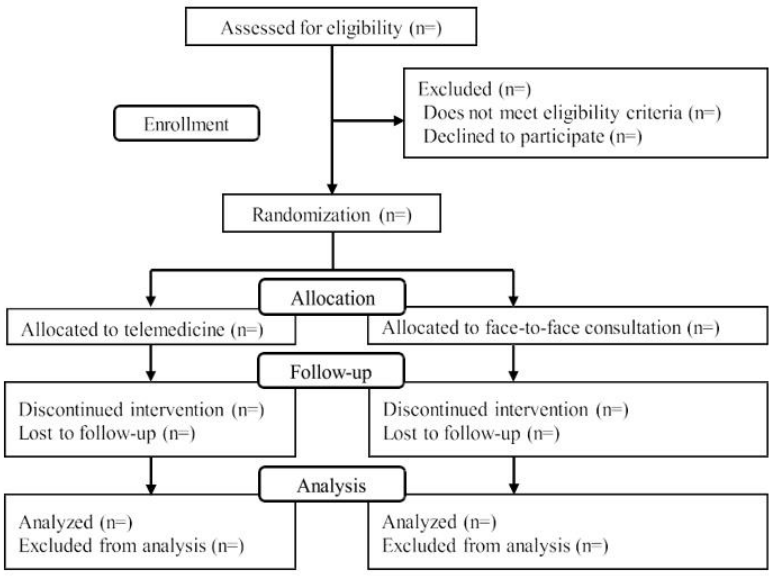


**Figure 1.** Flow diagram of the study.

*Ethical approval*

The study protocol received approval from the Keio University School of Medicine Ethics Committee on February 7, 2022 (approval number: 20211125) and was registered with the University Hospital Medical Information Network Clinical Trials Registry in Japan (UMIN000047009). All procedures were conducted in accordance with the Declaration of Helsinki and Japan's "Ethical Guidelines for Medical and Health Research Involving Human Subjects."

*Eligibility criteria*

In Japan, insulin remains the only therapy covered by insurance for GDM management, with treatment decisions guided by a diabetologist based on individual glycemic profiles. The standard management targets include pre-prandial blood glucose <100 mg/dL and 2-hour postprandial glucose <120 mg/dL, with initiation of insulin therapy when these thresholds are exceeded consistently.

*Inclusion criteria*

Participants eligible for this study must meet all of the following requirements:

1. Diagnosis of GDM by OGTT before 29 weeks and 6 days of gestation, with ongoing self-monitoring of blood glucose (SMBG) and insulin therapy under specialist supervision.
2. Provision of informed written consent after receiving a comprehensive explanation of the study objectives and procedures.
3. Ability to understand and operate the telemedicine platform independently.

*Exclusion criteria*

Patients will be excluded from participation if they meet any of the following conditions:

1. Diagnosis of GDM after 30 weeks of gestation.
2. Diagnosis of pre-existing or overt diabetes during pregnancy.
3. Type 1 or type 2 diabetes.
4. Presence of severe, uncontrolled comorbidities.
5. Presence of pacemakers or other implantable medical devices.
6. Refusal or inability to provide consent.
7. Language barriers or cognitive limitations that prevent understanding of study procedures or completion of questionnaires.
8. Lack of necessary internet access or inability to use a smartphone for telemedicine consultations.
9. Considered unsuitable for participation by the treating physician for any other clinical reason.

**Table 1.** Inclusion and Exclusion Criteria for the Telemedicine Study in Gestational Diabetes Mellitus (GDM)

| **Inclusion Criteria** |
|---|
| 1. Diagnosed with GDM by 75-g oral glucose tolerance test (OGTT) at ≤ 29 weeks and 6 days of gestation |
| 2. Currently performing self-monitoring of blood glucose (SMBG) and receiving insulin therapy prescribed by a diabetologist |
| 3. Provided written informed consent after receiving full explanation and demonstrating adequate understanding of the study |
| 4. Able to understand, operate, and actively use the telemedicine platform |
| **Exclusion Criteria** |
| 1. Diagnosis of GDM made at ≥ 30 weeks and 0 days of gestation |
| 2. Overt diabetes in pregnancy |
| 3. Pre-existing type 1 diabetes mellitus |
| 4. Pre-existing type 2 diabetes mellitus |
| 5. Presence of severe, uncontrolled complications of diabetes or pregnancy |
| 6. Implanted electronic medical devices (e.g., pacemaker, implantable cardioverter-defibrillator) |
| 7. Patient declines participation in the study |
| 8. Judged unsuitable by the attending physician (examples: inability to understand Japanese or complete questionnaires, refusal of GDM treatment, inability to attend regular hospital visits, psychiatric issues, etc.) |
| 9. No stable internet environment required for telemedicine consultations |

10. Does not own or use a smartphone

*Randomization*

Once participants provide informed consent, they will be randomly assigned in a roughly 1:1 ratio using a blinded, independent third-party system. A modified minimization approach with a biased-coin design will be employed to ensure balance across key stratification factors, including maternal age (<40 vs. ≥40 years), pre-pregnancy obesity status, history of GDM, number of fetuses (singleton vs. multiple gestations), and ethnicity. Randomization will be performed through the University Hospital Medical Information Network Internet Data and Information System for Clinical and Epidemiological Research (cloud-based version). Allocation will be managed using a registration form prepared by a physician not involved in the study. Both participants and treating physicians will be aware of the assigned intervention, as the study is open-label.

*Intervention and control procedures*

Participants assigned to the intervention arm will receive telemedicine-based care via the MeDaCa system (Medical Data Card, Inc., Tokyo, Japan). MeDaCa enables real-time video consultations between the medical facility and the patient's device (smartphone, tablet, or computer), providing an experience comparable to in-person visits. This platform is already widely implemented at Keio University School of Medicine and is routinely used by pregnant patients in the Department of Obstetrics & Gynecology.

Integration with the One Touch Reveal® application (linked to the One Touch Verio Reflect® glucose meter; LifeScan, Inc., Malvern, PA, USA) allows automatic upload of blood glucose measurements to MeDaCa. In the control group, MeDaCa is similarly used to review glucose readings, but consultations are conducted in person.

The intervention period begins with the first outpatient visit following the initiation of insulin therapy and SMBG and continues for approximately 10 weeks (±2 weeks). In the telemedicine group, initial and final consultations will be conducted in person, while interim consultations occur online every 2–3 weeks. Additional face-to-face consultations may be scheduled at the discretion of the physician or upon patient request. In the control group, standard in-person visits occur every 2–3 weeks. After the formal intervention period, participants in both groups may choose between online or in-person consultations until delivery. Unscheduled visits are available at any time for all participants, with telephone support provided by nursing staff as needed.

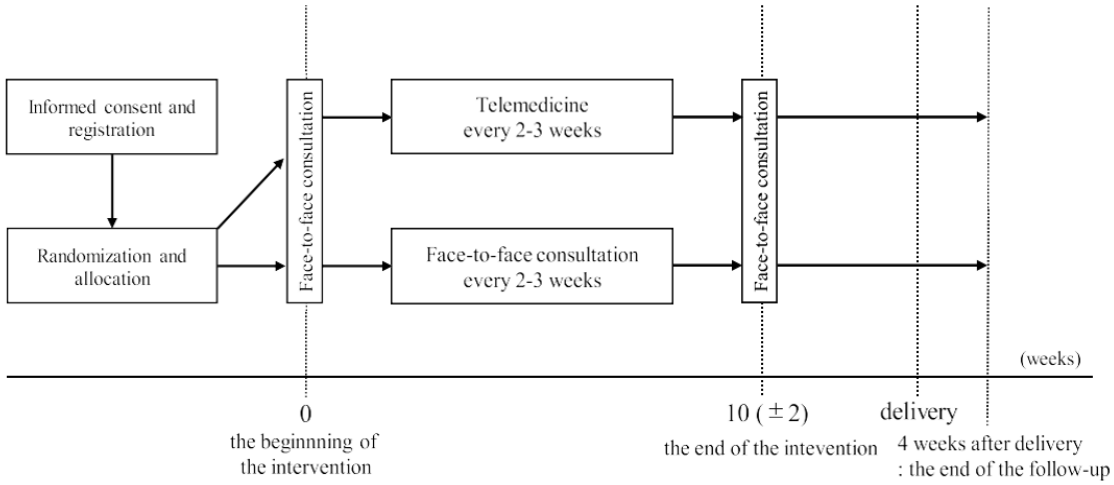


**Figure 2.** Study design.

including childcare or spouse leave for hospital visits, will also be considered. Patient satisfaction will be measured using the Problem Areas in Diabetes (PAID) survey and the Diabetes Therapy-Related Quality of Life (DTR-QOL) questionnaire, comparing scores between baseline and 10 weeks after the intervention. Both instruments are validated tools for assessing treatment burden and satisfaction in patients with diabetes. Stratified analysis will also be conducted according to the type of insulin regimen, whether basal-only or multiple injections. Secondary outcomes will include glycemic control parameters and perinatal outcomes. Glycemic control will be evaluated using fasting and postprandial blood glucose levels obtained from SMBG records, the frequency of hypoglycemia and hyperglycemia, total insulin dose, HbA1c, and glycated albumin. Maternal hypoglycemia will

be defined according to the American Diabetes Association Level 2 and 3 criteria as glucose <54 mg/dL (3.0 mmol/L) or severe events requiring external assistance for treatment. Participants will measure blood glucose six times daily, before and two hours after each meal, from the start of SMBG to the first outpatient visit, and for one week before the end of the intervention. During other periods, blood glucose monitoring can follow a staggered schedule, with three repeating patterns each day, and measurement frequency may be increased at the discretion of the attending physician. Insulin doses will be adjusted to maintain preprandial glucose below 100 mg/dL and postprandial glucose below 120 mg/dL. Perinatal outcomes will include gestational age, fetal growth, mode of delivery, maternal weight, obstetric complications such as premature rupture of membranes and postpartum hemorrhage, maternal complications including gestational hypertension, neonatal parameters such as sex, height, weight, hypoglycemia, Apgar scores, large or small for gestational age, shoulder dystocia, umbilical artery pH, congenital anomalies, and NICU admissions. Neonatal hypoglycemia will be defined as a blood glucose level below 40 mg/dL, measured using point-of-care testing, with intervention considered at <50 mg/dL. Exploratory outcomes will include the psychological burden on medical staff conducting online consultations, measured through questionnaires. Time spent in consultations and outpatient waiting periods will also be recorded. All secondary outcomes will be stratified by the type of insulin regimen, basal-only or multiple injections.

**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.

*Sample size*

Because no previous studies have evaluated telemedicine for GDM using the endpoints selected in this trial, estimating the required number of participants was challenging. Among the primary outcomes, the Problem Areas in Diabetes (PAID) score was expected to exhibit the smallest change following intervention. Based on prior studies utilizing PAID and preliminary questionnaires conducted by the research team, it was anticipated that the post-intervention PAID score would average approximately 30 points in the telemedicine group and 40 points in the control group [19, 20]. With these assumptions, a sample size of 32 participants was calculated to achieve a two-sided significance level of 0.05 with 80% statistical power. Accounting for a potential dropout rate of 20%, the target enrollment was set at 40 participants in total.

*Data collection and management*

Data for the primary outcomes will be collected from participants' responses to the questionnaires administered at the start and end of the intervention. Investigators will review completed questionnaires for missing or inconsistent data and, when necessary, confirm responses directly with the participants. For participants hospitalized near the end of the intervention, such as due to preterm delivery, questionnaires will be administered at an appropriate time that does not interfere with medical care. Secondary outcomes collected via questionnaires will follow the same process as primary outcomes. Maternal and neonatal clinical data will be extracted from medical records, and self-monitoring blood glucose (SMBG) data will be synchronized with the MeDaCa system and smartphone application through Bluetooth.

Investigators will complete case report forms (CRFs) using participants' study IDs as soon as possible after obtaining the information, removing any identifiable personal information. When electronic data transfer is necessary, all data will be encrypted. Investigators are responsible for verifying that CRFs are complete and accurate; any corrections will be documented with the date, reason for change, and details of the correction. Data for participants who discontinue the study will be recorded up to the point of discontinuation.

All data will be anonymized for analysis, with strict measures in place to prevent data leakage. The correspondence table linking study IDs to participant identities will be managed by the personal information manager and securely stored. In compliance with ethical guidelines, collected data and the correspondence table will be retained for at least five years after study completion or three years after the final report, whichever is later. After this period, all records will be permanently destroyed. Any participant who withdraws consent will have their data discarded individually.

*Statistical analysis*

Primary and secondary outcomes will be analyzed using the full analysis set (FAS). The FAS will include all participants who completed at least two online consultations during the study, had no major protocol violations—such as improper consent procedures or failure to meet inclusion/exclusion criteria—and had post-treatment data available. Baseline characteristics will be summarized using frequencies and percentages for categorical variables and means with standard deviations for continuous variables. Comparisons of patient characteristics will be conducted using chi-square tests for categorical variables and either t-tests or Wilcoxon rank-sum tests for continuous variables.

For the primary endpoints, descriptive statistics—including sample size, mean, standard deviation, minimum, median, and maximum—will be generated for each measurement point. An analysis of covariance (ANCOVA) will be performed, adjusting for maternal age, pre-pregnancy obesity, history of gestational diabetes, and number of fetuses. Secondary outcomes will be analyzed using the same approach as the primary outcomes. All comparisons will follow a pre-specified plan, and p-values will be two-sided. Statistical significance will be defined as $P < 0.05$. Analyses will be conducted using IBM SPSS Statistics for Windows, version 28.0.0.0 (IBM Corp., Armonk, NY, USA).

**Results and Discussion**

Previous research has demonstrated that glycemic control and perinatal outcomes achieved through telemedicine are comparable to those obtained through in-person care [12–14]. Building on these findings, the present study aims to evaluate whether telemedicine for patients with gestational diabetes mellitus (GDM) can improve patient satisfaction and reduce healthcare costs.

This study offers several strengths. First, it is the first investigation focused specifically on insulin-treated GDM patients to assess how telemedicine affects psychological burden. For example, in the study by Mackillop *et al*., although patient satisfaction slightly improved in the telemedicine group, individuals who required immediate insulin therapy at enrollment were excluded [14]. While dietary and exercise interventions are central to GDM treatment, many patients ultimately require insulin to maintain glycemic control. Given the narrow target glucose range and substantial fluctuation during pregnancy, patients often need frequent medical visits—an especially significant psychological burden for those on insulin therapy. Understanding this burden is therefore essential.

Second, the MeDaCa system supports not only the sharing of blood glucose and blood pressure data but also allows for video-based consultations that can closely resemble face-to-face care. Earlier telemedicine platforms largely focused on cloud-based glucose logging and SMS communication. As technology advances, systems such as MeDaCa may yield improved outcomes, including greater patient satisfaction.

Third, this study will assess not only direct healthcare costs but also direct and indirect non-healthcare costs. To date, no telemedicine studies in GDM have reported these broader economic impacts. Reducing clinic visits and work disruptions may positively influence society by supporting women's continued participation in the workforce. Additionally, since blood glucose measurements are automatically transmitted via Bluetooth, patients do not need to manually input values—reducing the risk of data entry errors, as noted by Donsa *et al*. [21], and improving data accuracy.

Nevertheless, the study has several limitations. Blinding is not feasible, which may introduce clinical bias. The relatively small sample size limits the ability to detect rare complications. Because physicians are not randomized, variations in communication style may influence patient satisfaction. The study is conducted at a Japanese medical

institution, meaning most participants will likely be Asian; thus, findings may not generalize across racial or ethnic groups. Furthermore, differences in access to healthcare and psychological burden may exist between urban and suburban settings, which could affect the applicability of the results.
Despite these limitations, we anticipate that the study will provide valuable evidence regarding the effectiveness of telemedicine for GDM and help support broader implementation in the future.

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**Conflict of Interest:** None

**Financial Support:** None

**Ethics Statement:** 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.

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