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# Impact of Bluetooth-enabled versus traditional glucometers on glycaemic control in adults with insulin-treated diabetes integrated with telehealth in personalized diabetes management: a randomized controlled trial

**Submission date**
10/12/2024

**Recruitment status**
No longer recruiting

**Registration date**
16/12/2024

**Overall study status**
Completed

**Last Edited**
07/01/2026

**Condition category**
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

## Plain English summary of protocol

Background and study aims
People with diabetes mellitus (DM) managing newly initiated insulin or requiring intensification of insulin therapy require frequent glucose monitoring and timely insulin adjustments. This study explores whether an integrated telehealth program using Bluetooth-enabled glucometers can enhance glycaemic control and reduce diabetes-related distress compared to traditional glucometers.

Who can participate?
People aged between 21 and 70 years with DM who were on newly initiated insulin or experiencing intensification of insulin therapy for diabetes management from a tertiary hospital.

What does the study involve?
Participants will be randomly allocated to either the intervention group (using a Bluetooth-enabled glucometer and mobile phone app) or the control group (using a manual logbook). They answer questionnaires relating to quality of life and distress from diabetes. In total, about 11 ml of blood will be collected for clinical tests, HbA1c and cholesterol levels (lipid panel) requested by the diabetes doctor as part of participants' routine follow-up. Participation in the study will last 22 to 28 weeks. Participants will be expected to perform structured self-monitoring of blood glucose based on their insulin regime throughout the study period. Participants will need to visit the doctor’s office two times in the course of the study and will receive phone consultations every 2 weeks for 3 sessions.

What are the possible benefits and risks of participating?
Benefits include having closer monitoring and analysis of self-monitoring blood glucose (SMBG) by a diabetes nurse, and closer titration of insulin therapy to achieve targets. Possible risks include technical error, where SMBG readings are not transferred to the mobile phone app (for

participants in the intervention group). Participants in the intervention group will be using a free, commercially available mobile phone app, which they have to agree to the terms and conditions of the designers of the mobile phone app. There is a risk of privacy breach since participants' information will be stored by the mobile App on an external server. However, there will be no sharing of information between the mobile App company and the hospital.

Where is the study run from?
Tan Tock Seng Hospital (Singapore)

When is the study starting and how long is it expected to run for?
December 2020 to December 2023

Who is funding the study?
Ng Teng Fong Health Innovation Programme (Singapore)

Who is the main contact?
Ms Lian Xia, lian_xia@ttsh.com.sg

# Contact information

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Public, Principal investigator

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# Additional identifiers

### Protocol serial number
NTF-SIP_WoW_P1

# Study information

### Scientific Title
Effectiveness of a Bluetooth-enabled glucometer which automatically syncs blood glucose readings to a mobile app, on adults with diabetes mellitus for glycaemic control (HbA1c), diabetes-related distress, satisfaction and cardiometabolic parameters, as compared to using a traditional glucometer

### Acronym
IT-PDM

### Study objectives
Bluetooth-enabled glucometers improve glycaemic control in adults with diabetes mellitus as compared to traditional glucometers.

### Ethics approval required
Ethics approval required

### Ethics approval(s)
Approved 15/10/2021, National Healthcare Group Domain Specific Review Board (NHG DSRB) (3 Fusionopolis Link #03-08 Nexus@one-north, Singapore, 138543, Singapore; +65 (0)64966600; OHRPP@nhg.com.sg), ref: 2021/00644

### Primary study design
Interventional

### Study design
Single-centre two-armed open-labelled parallel randomized controlled trial

### Study type(s)
Treatment

### Health condition(s) or problem(s) studied
Type 2 diabetes mellitus

### Interventions
This interventional study was a 6-month, single-centre, two-armed, open-labelled parallel randomized controlled trial, where participants with diabetes mellitus newly started on insulin or requiring intensification of insulin therapy were assigned to either the intervention group or control group via a 2:2 ratio using a computer-generated randomization sequence with variable block sizes of 4, overseen by a statistician who was independent of the clinical team to maintain allocation concealment

The intervention group used a Bluetooth-enabled glucometer (ACCU-CHECK Instant) that automatically syncs blood glucose readings to a mobile app (MySugr), while the control group used a standard glucometer (ACCU-CHECK Performa) and manually logged blood glucose readings in a physical logbook.

### Intervention Type
Device

### Phase
Not Applicable

### Drug/device/biological/vaccine name(s)
ACCU-CHECK Instant Meter, ACCU-CHECK Performa

### Primary outcome(s)
Glycaemic control is measured via glycosylated Haemoglobin (HbA1c) at baseline, week 12 and week 24

### Key secondary outcome(s)
1. Cardiometabolic parameters measured via Low-Density Lipoprotein (Measured) (LDL-M), weight, Body Mass Index (BMI), and blood pressure at baseline, week 12 and week 24
2. Satisfaction measured using the Glucose Monitoring Satisfaction Survey (GMSS) at baseline and week 24
3. Diabetes-related distress measured using the Problem Area In Diabetes (PAID) scale at baseline and week 24

### Completion date
29/12/2023

## Eligibility

### Key inclusion criteria
1. Patients with diabetes mellitus and on insulin treatment, which is being newly-initiated or require significant dose adjustment
2. Patients of a tertiary hospital in Singapore (Tan Tock Seng Hospital) during their inpatient stay or routine outpatient clinic visits for diabetes management
3. Patients aged between 21 and 70 years old

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Mixed

### Lower age limit
21 Years

**Upper age limit**
70 Years

**Sex**
All

**Total final enrolment**
120

**Key exclusion criteria**
1. Severe comorbid conditions
2. Pregnancy
3. Cognitive impairments
4. Unable to comply with the study procedures or provide informed consent

**Date of first enrolment**
21/02/2022

**Date of final enrolment**
16/06/2023

# Locations

**Countries of recruitment**
Singapore

**Study participating centre**
**Tan Tock Seng Hospital**
11 Jalan Tan Tock Seng, Clinic 4B and B2B
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# Sponsor information

**Organisation**
Tan Tock Seng Hospital

**ROR**
https://ror.org/032d59j24

# Funder(s)

**Funder type**
Hospital/treatment centre

**Funder Name**
Ng Teng Fong Healthcare Innovation Programme

# Results and Publications

### Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be published as a supplement to the results publication. Datasets include analyses of participants' cardiometabolic parameters, distress (PAID) and satisfaction measures (GMSS) using an intention-to-treat approach. Data will be analysed by paired t-test results for within-group changes, mixed-effects models for effects over time, and simple linear regression for effects across subgroups.

### IPD sharing plan summary
Published as a supplement to the results publication

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | | 16/12/2025 | 07/01/2026 | Yes | No |
| Participant information sheet | version 7 | 11/03/2022 | 16/12/2024 | No | Yes |