

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	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 16/12/2024	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 16/12/2024	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data
		<input checked="" type="checkbox"/> Record updated in last year

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

Type(s)

Public, Principal Investigator

Contact name

Ms Xia Lian

ORCID ID

<http://orcid.org/0009-0004-4819-7444>

Contact details

11 Jalan Tan Tock Seng

Singapore

Singapore

308433

+65 (0)63571000

lian_xia@ttsh.com.sg

Type(s)

Scientific

Contact name

Mr Isaac Tan

ORCID ID

<http://orcid.org/0000-0003-2997-5760>

Contact details

11 Jalan Tan Tock Seng

Singapore

Singapore

308433

+65 (0)6256 6011
isaac_jun_song_tan@ttsh.com.sg

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Study design

Single-centre two-armed open-labelled parallel randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)

Treatment

Participant information sheet

See outputs table

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

Pharmaceutical study type(s)

Not Applicable

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

ACCU-CHECK Instant Meter, ACCU-CHECK Performa

Primary outcome measure

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

Secondary outcome measures

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

Overall study start date

21/12/2020

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

Age group

Adult

Lower age limit

21 Years

Upper age limit

70 Years

Sex

Both

Target number of participants

120

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
Singapore
Singapore
308433

Sponsor information

Organisation
Tan Tock Seng Hospital

Sponsor details
11 Jalan Tan Tock Seng
Singapore
Singapore
308433
+65 (0)6256 6011
contact@ttsh.com.sg

Sponsor type
Hospital/treatment centre

Website
<https://www.ttsh.com.sg/>

ROR
<https://ror.org/032d59j24>

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Ng Teng Fong Healthcare Innovation Programme

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date

01/02/2025

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?
Participant information sheet	version 7	11/03/2022	16/12/2024	No	Yes