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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
16/12/2024

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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
https://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
https://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

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

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

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

Primary study design
Interventional

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
Adult

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
Singapore
Singapore
308433

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?
Participant information sheet	version 7	11/03/2022	16/12/2024	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes