Cover letter:

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Technological-based Personalized Care Intervention for Supporting Older People with Diabetes Mellitus
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HONG KONG METROPOLITAN UNIVERSITY

Study protocol

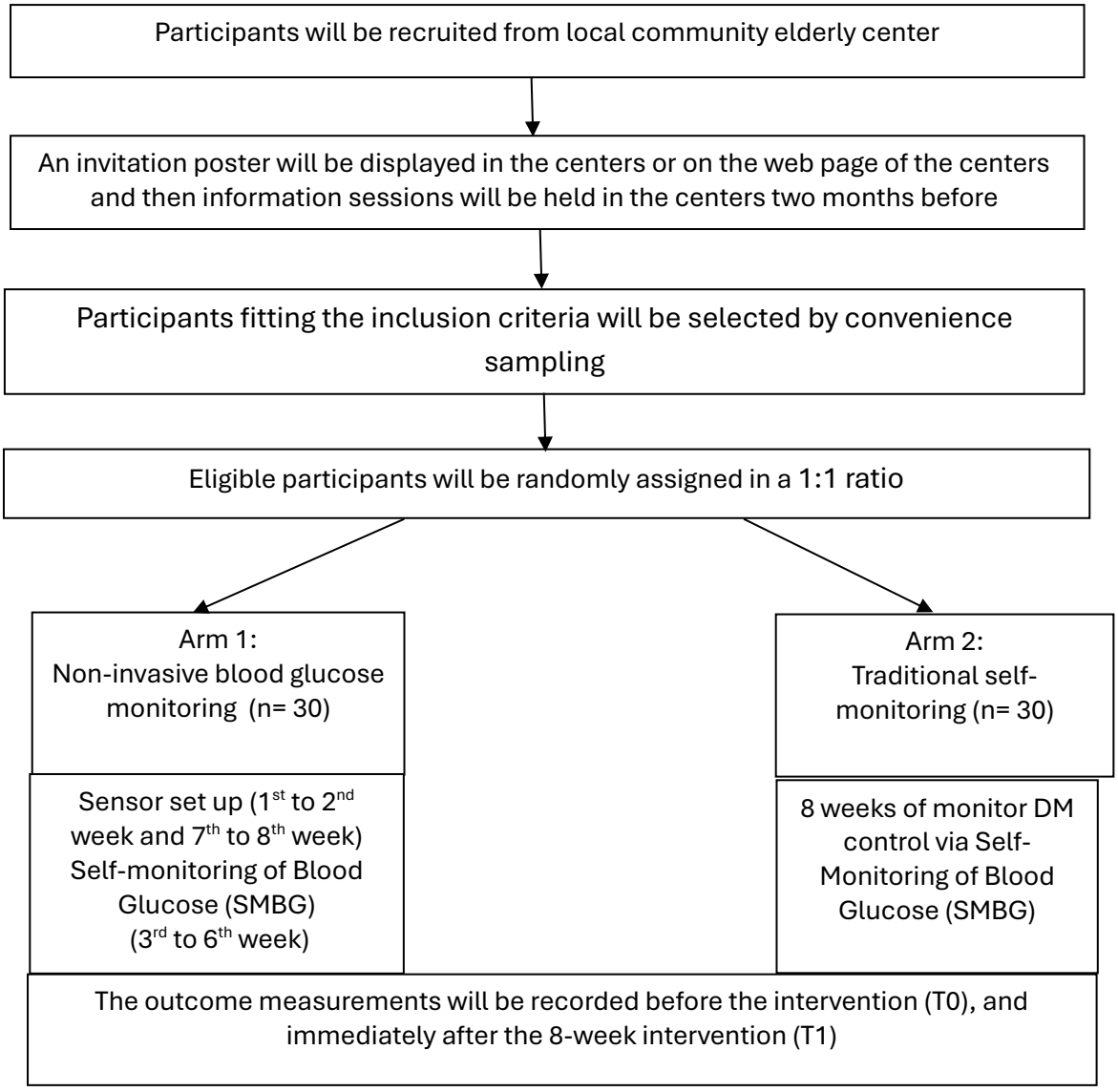

Figure 1: A flow diagram of the study

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1. Research methodology

Diabetes mellitus (DM) has been declared a growing public health threat. DM affects approximately 463 million people around the world (1). Regarding the World Health Organization (WHO), DM is defined as fasting glucose equal to or higher than 7.0 mmol/L or a glucose level equal to or higher than 11.1 mmol/L two hours after a meal. A1C reflects the average blood glucose control in the last 2 to 3 months. As stated by American Diabetes Association (ADA), the optimal A1C level should be less than 7%. The prediabetes stage defines as an A1C level between 5.7 and less than 6.5%. WHO calls upon to strengthen, share and disseminate standards and to support interventions for diabetes management, preventing and slowing the progression of complications of DM through population and individual approaches (2). DM affects about 8.4% of the total population in Hong Kong (1). DM virtually affects the physiology of every body system mainly due to metabolic disturbances caused by hyperglycemia (2, 3).

Individuals with diabetes can make a dramatic impact on the disease progression and complications via self-management, which includes activities and behaviors of an individual undertakes to control and manage his or her health conditions. Poor diabetes management frequently causes more issues, which ultimately result in prolonged hospital admissions, more frequent outpatient visits, and higher prescription expenses.

Common self-management behaviors for individuals with diabetes are blood sugar monitoring, adopting healthy eating, being physically active, compliance with medications and healthy coping skills with good knowledge. Participating in all these five care has been demonstrated to have a significant effect on the progression and development of diabetes for individuals, as all of these five factors are associated with improved glycemic control, reduced complications and enhanced quality of life.

Just-in-time adaptive intervention (JITAI) is an evidence-based intervention to help intervention designers design to provide behavior change at right type/amount of support needed at right time at individual level (4). Mobile technologies such as smart-phones, mobile apps and various sensors can be used to provide interventions whenever and wherever needed (5). The core component of adaptive intervention embraces decision points (point in time at which treatment decisions made), intervention options (types, sources and modes of support delivery), tailoring variables (information concerning the participant that is used to make treatment decisions) and decision rules (which intervention option to offer based on the tailoring variables) (6). JITAI facilitates intervention designers to offer support in a timely manner and help the participant maintaining healthy behaviors. JITAI have been used to develop different interventions including physical activity and dietary counselling (5), mental health (7), and harmful substances (8). In recent study, the authors used JITAI to improve physical activity in older adults with type II DM via a mobile application (9).

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Setting and Participants: Convenience sampling will be used to select participants who meet the inclusion criteria for a two-arm randomized controlled trial (RCT). A block randomization approach will be utilized to allocate participants into either the intervention or control group. This will be accomplished using a computer program that generates random block sizes of 2 or 4 in a 1:1 ratio. The study will be conducted as a single-blind trial, with assessors being the only ones blinded to treatment allocation. Community centers will display promotional flyers to recruit potential participants, who will then undergo a screening process. The participants will provide written informed consent before the study starts. We propose to conduct an RCT with two treatment arms to clarify the effects of non-invasive blood glucose device on blood glucose monitoring. The two arms will be the non-invasive blood glucose monitoring (arm 1) and traditional self-monitoring (arm 2) as a control. The outcome measurements will be recorded before the intervention (T0) and immediately after the 8-week intervention (T1).

Project plan and methodology

Quantitative arm – Setting and Participants: A block randomization, single-blind design will be used. A two-arm RCT with equal allocation between the intervention and control groups (1:1) will be used; only the assessors will be blinded to the treatment assignment. Convenience sampling with fitting the inclusion criteria will be selected as subjects.

Potential participants will be screened for fasting blood glucose and health history at baseline assessment. The potential participants who meet the inclusion criteria will be asked to sign a consent form before participation in this study.

Inclusion and exclusion criteria

A total of 60 those who are aged 60 and above and meet the inclusion criteria will be asked to sign a consent form before participation in this study. The inclusion criteria are: (i) aged ≥ 60 years old; (ii) patients diagnosed with Type II DM (iii) patients experienced hypo (histix < 4.0 mmol/L) or hyperglycemia (histix ≥16.0 mmol/L); & (iV) The Abbreviated Mental Test (AMT) ≥ 6. The exclusion criteria are: (i) patient on dialysis; (ii) taking ascorbic acid > 500mg daily or (Not recommended by manufacturer as result may be affected); (iii) taking salicylic acid ≥ 650mg single dose or (Not recommended by manufacturer as result may be affected); or (iV) scheduled radiological therapy during CGM application (Not recommended by manufacturer as result may be affected).

Primary and secondary outcomes

The primary outcomes will be the point of care test (POCT) of HbA1C level and the secondary outcomes will be the fasting blood glucose, total cholesterol, blood pressure, anthropometric measurement, and Diabetes Self-Care activities questionnaire.

HbA1C level: The HbA1C will be measured by A1CNow system, which has been cleared by the Food and Drug Administration (FDA) and certified by National Glycohemoglobin Standardization Program.

Lipid and glucose panel: The POCT lipid panel includes total cholesterol and blood glucose will be measured by CardioChek, which has been cleared by the Food and Drug Administration (FDA) and certified by the Centers for Disease Control and Prevention, Cholesterol Reference Method Laboratory Network (CRMLN).

Basic anthropometric measurement: The basic anthropometric measurement includes height, weight and body mass index.

Blood pressure: blood pressure will be measured by blood pressure monitors (Omron M7, Intelli IT, Kyoto, Japan) for assessment of brachial blood pressure.

Breath and blood Ketone: breath and blood ketone will be used to detect the presence of ketones in the breath and blood as indicators of hyperglycemia or diabetic ketoacidosis in individuals with diabetes.

Summary of Diabetes Self-Care Activities (SDSCA) Chinese version: To assess participants' diabetes self-care activities. The SDSCA will generate scores for five subscales: i) general diet, ii) eating a diet high in fruits/vegetables and low in high-fat foods, iii) daily activity, non-leisure and leisure activity, using three categories namely 'most active', 'moderately active' and 'least active', iv) taking recommended medications, v) glucose self-monitoring. Scores will be calculated on a continuous scale from 0-7, with the numerical value for each item based on the number of days during the week that the behavior was practiced. The item scores will then be averaged to derive an overall score for each self-care activity. The internal

reliability of the SDSCA is robust, acceptable reliability (0.55–0.64), with Cronbach's alphas 0.7.

Demographic and other covariates
Apart from gathering socio-demographic information such as age, marital status, gender, family income and education attainment, we will obtain data from the participants regarding their physical activity level, alcohol consumption, self-reported medical diagnosis, current medication usage and family history of first-degree relatives.

Statistical analysis
The statistical analysis will be performed using SPSS (Version: 26, SPSS Inc, Chicago). The alpha level will be set at 0.05 for two-tailed tests. One way analysis of variance model (ANOVA) will be used to compare the post-treatment scores over two time points.

Interventions: Non-invasive blood glucose monitoring
Non-invasive wearable glucose monitoring device will be used to capture participants' blood glucose. This device is non-invasive with no consumables, which used to check for participants' compliance with blood glucose monitoring and trend of blood glucose.

The arrangement of the intervention will be (1) training for self-management of DM and phone consultation; (2) phone call (or WhatsApp) follow up of hypo-or hyper-glycemic situations; (3) using sensor data to guide personalized care intervention. We will monitor the health data collected by this device regularly. A mobile application will be uploaded and recorded to monitor their compliance with the blood glucose monitoring.

Control group: Traditional self-monitoring of blood glucose
A control group with traditional self-monitoring of blood glucose will be used. The arrangement of the control group will be (1) training for self-management of DM and phone consultation; (2) phone call (or WhatsApp) follow up; (3) traditional self-monitoring of blood glucose will be used to guide personalized care intervention. The control group will be used as a comparative group to assess the effect of the non-invasive device in blood glucose monitoring.

Trained research assistant will keep close contact with all 60 participants through the scheduled regular phone calls or WhatsApp messages to understand their compliance and commitment to the monitoring of blood glucose. Analysis will be done to evaluate the effectiveness of the non-invasive wearable blood glucose monitoring device.