BMJ Open

A digital health-supported community pharmacy-based lifestyle intervention program for overweight or obese adults with prediabetes, the PRediabetes Intervention, Management and Evaluation (PRIME) Program: a study protocol for a cluster randomized controlled trial

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2024-083921
Article Type:	Protocol
Date Submitted by the Author:	03-Jan-2024
Complete List of Authors:	Teoh, Kah Woon; Monash University Malaysia, Ng, Choon Ming; Monash University Malaysia Chong, Chun Wie; Monash University Malaysia, Cheong, Mark Wing Loong; Monash University Malaysia, School of Pharmacy Ng, Yi Ling; Caring Pharmacy Sdn. Bhd. Bell, J Simon; Monash University, Centre for Medicine Use and Safety Lee, Shaun Wen Huey ; Monash University, School of Pharmacy
Keywords:	Clinical trials < THERAPEUTICS, DIABETES & ENDOCRINOLOGY, EPIDEMIOLOGY, Primary Prevention, eHealth, Behavior

Title: A digital health-supported community pharmacy-based lifestyle intervention program for overweight or obese adults with prediabetes, the PRediabetes Intervention, Management and Evaluation (PRIME) Program: a study protocol for a cluster randomized controlled trial

Kah Woon, Teoh[a], Choon Ming, Ng[a], Chun Wie, Chong[a], Wing Loong, Cheong[a], Yi Ling, Ng[c], J Simon, Bell[b], Shaun Wen Huey, Lee[a]

[a]School of Pharmacy, Monash University Malaysia, Jalan Lagoon Selatan, 47500, Selangor, Malaysia.

[b]Centre for Medicine Use and Safety, Faculty of Pharmacy and Pharmaceutical Sciences, Monash University, Parkville, Australia

[c]Pharmacy Practice Department, CARiNG Pharmacy Head Office, No 1, Jalan 51/203A, Kawasan Perindustrian Tiong Nam, Seksyen 51, 46050 Petaling Jaya, Selangor, Malaysia

Corresponding author:

Shaun Wen Huey Lee, School of Pharmacy, Monash University Malaysia, Jalan Lagoon Selatan, 47500, Selangor, Malaysia.

Email: shaun.lee@monash.edu

Twitter: @nuahSeelL

Twitter handles for other authors:

Kah Woon Teoh: @carmenteoh

Wing Loong Cheong: @markcheongwl

Abstract

Introduction: People with prediabetes are at risk of developing type-2 diabetes. While lifestyle interventions are effective in preventing type-2 diabetes, prediabetes management initiatives in Malaysia are currently lacking. The PRediabetes Intervention, Management and Evaluation (PRIME) Program is a community pharmacy-based prediabetes management program, and involves a mobile application that allows for self-monitoring and access to a structured prediabetes curriculum.

Methods and analysis: This study aims to evaluate the impact and sustainability of PRIME program on the clinical outcomes of overweight or obese adults with prediabetes. This study also explores participants' views towards the implementation of PRIME program. This protocol describes the development of the PRIME program and the mobile app, user acceptance tests, piloting, and the implementation of a cluster randomized controlled trial. Fourteen community pharmacies from Selangor and Kuala Lumpur will be randomized to either the intervention arm or standard care. Overweight or obese adults with prediabetes will be included in this study. Participants from the intervention arm will have access to the prediabetes education modules through the PRIME mobile app and will be invited to join the peer support chatgroup. The primary clinical outcome includes changes in body weight at 6-month, while the secondary clinical outcomes include changes in blood glucose profile, lipid profile, blood pressure, and adiposity measures. The sustainability of the PRIME program will be accessed using a follow-up questionnaire. Focus group discussions and one-to-one interviews will be conducted for process evaluation. This study will inform the impact of community pharmacists-led digital health intervention in prediabetes management.

Ethics and dissemination: This study has been registered with clinicaltrial.gov (NCT04832984) and approved by the Monash University Human Research Ethics Committee (MUHREC) (Project ID: 27512).

Keywords

Behavior, clinical trials, epidemiology, primary prevention, diabetes, eHealth

Strength and limitations of this study

- This is the first study that examines the real-world impact of incorporating a mobile app and utilizing the role of community pharmacists to deliver a prediabetes management program.
- Stakeholders and members of the public were involved during the development process of the intervention.
- This protocol will comprehensively detail the development process, feasibility and implementation of the interventions, as well as evaluation of the clinical and behavioral outcomes of PRIME program.

INTRODUCTION

Type-2 diabetes (T2D) is a global health emergency affecting 537 million people worldwide [1, 2]. While most people newly diagnosed with T2D are typically aged 55 years and older, the increasing number of people with early-onset T2D is posing a new public health challenge [3, 4]. Consensus guidelines recommend that high-risk individuals, including those who are overweight or obese, those with a previous history of gestational diabetes, strong family history of T2D and ethnic groups susceptible to T2D, be screened for diabetes and prediabetes [2]. A fasting plasma glucose reading of 5.6mmol/L – 6.9mmol/L, 2-hour post-load glucose of 7.8mmol/L – 11.0mmol/L and/or elevated glycated haemoglobin (HbA1c) of 5.7% - 6.4% is consistent with prediabetes, with values above these threshold indicative of diabetes [2].

One in ten people with impaired glucose tolerance develops T2D yearly, with a lifetime risk of 70% [5]. Interventions that target pathophysiological factors such as those that reduce weight, promote a balanced diet and increase physical activity provide a more sustainable and longer-term benefits than using anti-diabetic medications.[6-10] For example, the Diabetes Prevention Program [6, 7], the Finnish Diabetes Prevention Study [8], and the Da Qing study [9] reduced the risk of progression to T2D by up to 58% over three years, with the protective benefit persisting for up to 10 years [7, 11, 12]. The implementation of lifestyle interventions in these studies prevented diabetes related-complications and prolonged life [13]. With the advent of new technologies, many of these interventions are now supported through digital health platforms [14-16].

Malaysia has one of the highest rates of obesity and T2D in Southeast Asia [17, 18]. With nearly 3.9 million Malaysians diagnosed with diabetes, effective interventions are needed to alleviate the burden of T2D [17]. The Diabetes Medication Therapy Adherence Clinic (DMTAC), a pharmacists-led diabetes management service was introduced since the year 2006 in appointed government-funded healthcare facilities in Malaysia. By emphasizing on diabetes education and medication adherence, patients enrolled into the DMTAC service showed improved glycaemic control [19-21]. However, the DMTAC service is only available for people with diabetes, and there are currently no initiatives to manage prediabetes in Malaysia.

Community pharmacy services are increasingly involved in health promotion, disease prevention and management activities [22]. In the USA, guidelines have been developed for prediabetes screening and diabetes prevention to be carried out by community pharmacies [23]. Although community pharmacists in Malaysia participate in health promotion activities such as weight management, diabetes counselling, and lifestyle counselling, they remain largely underutilized in campaigns to prevent diabetes [24]. Evidence on the effectiveness of utilizing community pharmacies to deliver prediabetes management programs in Malaysia, however, remains limited. Community pharmacies in Malaysia are more readily available that public health clinics and hospitals [25], and are the first point of access to healthcare to vulnerable groups who do not consult regularly with a general practitioner, diabetes educator or other healthcare professionals [26, 27]. Therefore, a community pharmacy-based prediabetes intervention could potentially complement with the other diabetes prevention strategies.

Recognizing this gap, we developed a digital health-supported prediabetes management program based in community pharmacies. The PRediabetes Intervention, Management and Evaluation (PRIME) program is a partnership between Monash University and Malaysian community pharmacies working to prevent T2D. The PRIME program uses a mobile-based application to promote weight loss and modify risk factors in people with prediabetes. It delivers a structured curriculum to educate people with prediabetes on their condition, with community pharmacists providing support as prediabetes health coaches.

Objectives

- To evaluate the impact of the PRIME program on the clinical and behavioral outcomes of overweight or obese participants with prediabetes after the 6-month study period
- To explore the participants' experiences and perceptions regarding the implementation of the PRIME program
- To evaluate the sustainability of weight loss, lifestyle changes and PRIME app usage post-intervention

METHODS AND ANALYSIS

This protocol is designed and reported according to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) checklist (Supplementary Materials Fig. S1) [28].

Analysis framework

The development of the PRIME program study is underpinned by the Framework for Developing and Evaluating Complex Interventions jointly commissioned by the Medical Research Council and National Institute for Health Research (MRC-NIHR) (Fig. 1) [29].

This framework describes how complex interventions can be divided into four non-sequential phases: developing or identifying an intervention, feasibility, evaluation, and implementation. The framework emphasizes six core elements at each phase, which consists of: the context where the intervention will be delivered, testing and refining program theory, involving important stakeholders, identifying key uncertainties, refining intervention and economic considerations. This paper will describe the development of the current study using the MRC-NIHR framework [29].

Development of intervention

Theoretical framework

The program will use the principles of the Behavior Change Wheel (BCW) as the foundation of this study [30]. Based on the framework, the PRIME program will be designed to promote behavioural change and targets four main barriers against prediabetes management, namely: 'education', 'training', 'enablement', and 'persuasion'. These four areas are selected based on a previous review that found that the most common barriers of prediabetes management were related to psychological and physical capability, and social and physical opportunity [31]. As such, the PRIME program will focus on four main intervention functions that targets these four barriers. A brief explanation and examples of how these barriers will be addressed by components of the PRIME program are shown in Table 1.

Stakeholders engagement

The PRIME program will be co-designed by the research team from the School of Pharmacy and the School of Information Technology from Monash University Malaysia, healthcare professionals, and members of the public. Inputs from healthcare professionals (nutritionists, community pharmacists and dietitians), and members of the public will be collected and used to refine the PRIME program and its mobile application throughout the development process.

Patient and public involvement

Members of the public will be involved during the mobile app and intervention development process of the study. Interview sessions with members of the public will be conducted, where they preview a prototype of the PRIME app to provide insights on its feasibility for a community pharmacy-based digital health supported prediabetes management program. During the interviews, participants will provide feedback on their acceptance towards the burden of the intervention (for example, frequencies of blood glucose monitoring) and time required to participate in the study. User acceptance tests of PRIME mobile app will also be conducted with the general public before the implementation of PRIME program.

Phase 1: Feasibility

User acceptance tests

The prototype of the PRIME app will be tested on the users from the general public. Participants will be asked to install the PRIME app into their mobile phones, and to complete a set of tasks using the features available within the app. Feedback will be collected from each participant via a user feedback survey that utilizes Likert scales and open-ended questions to assess user experience, acceptability, and usability of the app.

Pilot study

In line with the MRC guidance, a month-long pilot study will be carried out. The pilot study will be conducted with the aim of testing the feasibility of the PRIME program at two community pharmacies. The recruitment strategies, data collection procedures, time taken, pharmacists' capacity to deliver the intervention, adherence, retention and app engagement, and participants' feedback will be assessed and used to optimize the study design.

Phase 2: Implementation

Study design and setting

The PRIME program is designed as a pragmatic digital health-supported prediabetes cluster randomized controlled study that will be delivered through community pharmacies. Fourteen community pharmacies from Selangor and Kuala Lumpur will be randomized to either the intervention arm or standard care. The locations of the community pharmacies can be found in Supplementary Materials Fig. S2. Community pharmacies will be selected to participate if they 1) have at least a locally registered pharmacist willing to participate and 2) have suitable facilities available for pharmacist counselling, point of care tests, body weight and other anthropometry measurements.

Sample size calculation

Based on a previous prediabetes intervention study, it was reported that 8% of individuals in the usual care group and 35% in the intervention group achieved a 5% weight loss at 6 months [14]. Assuming an intracluster correlation coefficient of 0.007 [32], a design effect of 1.035, a power of 80% and alpha of 5%, a total of 72 participants will need to be recruited. After accounting for a 25% loss to follow-up in each arm, a total of 90 participants will be recruited across 14 community pharmacies. Fig. 2 shows the study flowchart.

Recruitment strategies

To identify for potential participants, we plan to conduct prediabetes awareness campaigns and blood glucose screening activities at community centers, community pharmacies and workplaces. Promotional materials such as posters and brochures will be placed in community pharmacies, and the program will be advertised through social media platforms. Participants may also be self-referred.

KWT and a research assistant (RA) will explain the trial purposes and procedures to eligible prospective participants who fulfilled the inclusion criteria (Table 2), and provide them with a written explanatory statement. KWT and RA will collect written consent forms from the participants who have decided to join the study, however, they are free to withdraw from the study at any time during the study period. The schedule of enrolment, interventions and assessment is outlined in Fig. 3 and the flowchart of screening, recruitment and follow-up visit processes is detailed in Fig. 4.

Randomization and blinding

In this study, a cluster-randomized design will be adopted where randomization will occur at the community pharmacy level instead of individual level. This is to prevent any potential cross contamination, especially in the event two individuals receiving different interventions may visit the same community pharmacy at the same time.

Using a web-based randomization tool [33], the 14 participating community pharmacies will be randomized through variable block randomization based on their geographical areas. Participants who are recruited through other channels other than from pharmacy screenings (for example, health campaigns at community centres) will be given a list of participating community pharmacies to choose from for their baseline visit and subsequent follow-ups. The participants will be blinded from the groups that the community pharmacies are randomized into, and will only be informed of their allocation only at the end of the study. Given the nature of the intervention, community pharmacists will not be blinded.

Pharmacist coaching

Before the study commencement, all community pharmacists who will be involved in the study will undergo a 3-hour online coaching session conducted by the research implementation team comprising of the PRIME Program Pharmacist and PRIME Program Nutritionist. The pharmacists will be coached on lifestyle counselling points and

techniques, given a demonstration of the PRIME app and briefed on the operation procedures of the PRIME program at the pharmacy.

Treatment

At baseline visit, both control and intervention groups will be provided a glucometer (Bionime GE Max Plus, Taiwan) and a fitness tracker (XiaoMi Miband 6, China) for self-monitoring of their blood glucose and physical activity levels.

Both arms will be introduced to the PRIME app that includes the core features for self-monitoring of physical activities, weight, blood glucose levels, and food intake. All participants will be required to download the PRIME app and taught how to self-monitor their health parameters using the app. Participants' blood glucose readings, step counts, hours of sleep and food intake will also be synchronised and recorded into PRIME app. These data will then be portrayed in real-time on the PRIME dashboard and will be accessible to the community pharmacists at the pharmacies. The PRIME app will also set an individualized daily calorie allowance for each participant, calculated based on participants' age, body weight, height, gender, and physical activity level. A total of 500kcal will be deducted from each participant's daily calorie intake goals to encourage weight loss.

As part of the program, participants will also meet their community pharmacist at baseline, 1-month, 3-months and 6-months, which will be scheduled in advanced with the PRIME Program Pharmacist. At each visit, the participants will be encouraged to practise the healthy plate model and engage in 150 minutes of moderate intensity exercises each week. After the 6-month visit, participants will no longer have to attend the face-to-face visits. To determine whether participants are able to sustain the lifestyle changes they developed throughout the PRIME program, a researcher will conduct a follow-up questionnaire at 9-months. This questionnaire will examine their current lifestyle practices, self-monitoring habits, and engagement with the PRIME app.

Intervention arm

Participants in the intervention group will be provided with 14 in-app prediabetes education modules comprising of infographics, videos and quizzes (Supplementary Materials Fig. S3). A team of nutritionists, dietitians and pharmacists derive the content of the education modules based on the findings of a mixed-method cross-sectional study that was conducted to understand the public needs on prediabetes knowledge and lifestyle management. These modules will provide education on the pathophysiology and complications of prediabetes, and information on healthy food choices, physical activities, importance of sleep and stress management, and the detrimental effect of smoking. The modules will be designed to stimulate positive and negative feelings among participants and to stimulate behavioural actions. For example, photos of delicious healthy meals with vivid colours will be displayed.

The participants will also be invited to join a peer support chatgroup, which will be led by the PRIME Program Pharmacist and PRIME Program Nutritionist. The chatgroup will serve as a platform for participants to share their experiences such as successful lifestyle modification, as well as to help address any difficulties and encourage one another. The PRIME Program Pharmacist and PRIME Program Nutritionist will also use the chatgroup to disseminate any additional prediabetes related information and motivational messages on a bi-weekly basis. Table 3 shows the different elements delivered in control and intervention group.

At each scheduled face-to-face visit, the community pharmacists will provide in-depth lifestyle counselling focusing on lifestyle changes in the areas of diet, exercise, sleep, and stress based on each participant's self-monitoring records as portrayed on the PRIME dashboard. The pharmacists will also work with the participants to set SMART (Specific, Measurable, Realistic, Achievable and Timely) goals during each visit, by choosing small changes that are thought achievable by the participants in their daily lives. For example, as the participants work towards the goal of achieving 10,000 step counts per day by the end of 6 months, they should inform their pharmacists their plans to increase their step count targets based on their current capabilities.

Control arm

Similar to the intervention arm, participants in the control arm will be provided with the PRIME app which will enable them to track their blood glucose, physical activities, weight and food. However, they will not have access

to the in-app educational modules as well as peer support. They will be counselled on lifestyle changes based upon the participating pharmacy's usual practice, which typically includes simple advice on lifestyle changes.

Evaluation

Primary objective

The primary objective of this study is to evaluate the impact of the PRIME program on the clinical outcomes of the participants. The data collection forms for primary and secondary clinical outcome measures of the PRIME program can be found in Supplementary Materials Fig. S4. The clinical outcome measures are described below:

Primary clinical outcome

Changes in body weight

Evidence from studies have shown that modest weight loss is highly associated with a lower risk of developing diabetes [34]. The Finnish Diabetes Study found that a 5% weight loss was associated with a 70% reduction in diabetes incidence compared to those who did not achieve at least 5% weight loss [8]. In this study, a 5% reduction in body weight at 6 months is chosen as the primary outcome of the study.

Secondary clinical and non-clinical outcomes

Blood glucose parameters (HbA1c, fasting blood glucose (FBG)):

Among the three main blood glucose tests recommended by the ADA guidelines to define prediabetes, HbA1c and FBG are chosen as secondary clinical outcomes as it is not feasible to conduct OGTT in a community pharmacy. Both HbA1c and FBG will be measured using point-of-care test (POCT) devices which will be calibrated to ensure comparability. HbA1c tests will be tested every 12 weeks during participant visits at the pharmacy, while FBG will be monitored through participants' self-monitoring record using a glucometer.

Lipid profile and blood pressure:

The ADA guidelines recommend close monitoring of cardiovascular risks among adults with prediabetes who are overweight or obese [35], as these individuals have increased cardiovascular risks including hypertension and dyslipidemia [36]. In addition, several lifestyle intervention studies reported improved cardiometabolic outcomes among people with prediabetes- post-intervention [37]. The participants' lipid profile will be monitored at baseline and 6 months. Blood pressure readings will be collected at baseline, 1 month, 3 months, and 6 months. Three blood pressure recordings will be obtained from the participant in a sitting position after 3 minutes of rest, at 1-minute intervals, and then the mean value will be calculated for all three readings will be calculated.

Adiposity measures (body mass index (BMI), waist circumference, waist-to-hip ratio, body composition):

Adiposity is closely associated with insulin resistance. Measures of obesity and central obesity such as body fat percentage, BMI, waist circumference and waist-to-hip ratio predict the risk of T2D [38-40]. Body composition, including body fat percentage, body water percentage, muscle mass index, visceral fat, and lean body weight will be measured using a bioelectrical impedance analysis machine. Waist circumference will be measured with a soft tape on standing participants, mid-way between the lowest rib and iliac crest to the nearest 0.1 cm. Hip circumference will be measured over the widest part of the gluteal region, and the waist-to-hip ratio calculated.

Behaviour changes (diet, physical activities, sleep, illness perception, psychological outcomes):

To measure the impact of PRIME program towards lifestyle behaviour change, several questionnaires will be administered to the participants:

Alongside with the step counts data from the PRIME app, the International Physical Activity Questionnaire (IPAQ) [41] will be administered to participants at baseline, 1-month, 3-month and 6-month to gather information on their physical activities.

EQ-5D-5L [42] questionnaires will be administered at baseline, 1-month, 3-month and 6-month to assess the quality of life of participants.

Hospital Anxiety and Depression Scores (HADS) [43] and Brief Illness Perception Scores (BIPQ) [44] will be administered at baseline, 3-month and 6-month to inform participants' psychosocial changes over the duration of PRIME program.

Pittsburgh Sleep Quality Index (PSQI) [45] will be administered at baseline, and 6-month to assess participants' sleep habits. The sleep data collected from their PRIME app will also be used to assess changes in sleep duration. Multiple 24-hour dietary recall (three days) will be used to detect changes in dietary habits from participants at baseline and 6-month of the study.

Secondary objectives

Process evaluation

In line with the MRC framework, the process evaluation captures whether the PRIME program is delivered as designed, the changes produced by the PRIME program, and contextual factors that affect the implementation and outcomes of the study [46].

Focus group discussions and individual qualitative interviews will be conducted with the participants of each study arm after the conclusion of the PRIME program. The focus groups and interviews will be held at times convenient to the participants, and will last approximately one and a half to two hours. Each focus group session will consist of not more than eight consenting participants. A semi-structured topic guide using open-ended questions will be used to elicit participation. The moderator will facilitate the participants' answers, keeping the discussion on the topics under consideration, but will otherwise be non-directive, supportive, and non-evaluative. All interviews will be audiotaped for transcription and analysis.

Sustainability of weight loss, lifestyle changes, and app usage

Participants who have completed the PRIME program will be approached via text messages or phone call to complete an online follow-up questionnaire. Information on self-reported weight, current lifestyle habits, and PRIME app usage will be collected to determine the sustainability of the clinical outcomes achieved through the PRIME program.

Data analysis

This study analysis will be conducted using the intention-to-treat approach. All participants randomized into the study will be included into the analysis regardless of their compliance to the study protocol. In the event of missing data, multiple imputations will be used. Outcomes will be analysed using generalised linear model, adjusted for confounders if necessary. Any difference will be presented along with corresponding 95% confidence intervals. In addition, planned subgroup analyses include stratification of groups based upon age, gender, BMI, ethnicity and educational levels. All baseline characteristics will be summarised using descriptive statistics.

Qualitative data from the focus group discussions and individual interviews will be analysed using content analysis techniques to determine the participants' perceptions, and contextual feasibility.

Confidentiality

The collected data will be de-identified and labeled with codes assigned by KWT. All participants' data will only be accessible to the research team members. The pharmacists at the participating community pharmacies will only be able to access information of the participants from their respective pharmacies. Only the study investigators will have the access to the final dataset.

Ethics and dissemination

This study has been registered with clinicaltrial.gov (NCT04832984) and approved by the Monash University Human Research Ethics Committee (MUHREC) (Project ID: 27512). Any substantial amendments to the protocol will be agreed upon by the research team members and submitted to MUHREC for approval.

Research findings will be published in peer-reviewed journals and shared through presentations in conferences and seminars. The publication will also be disseminated to the participating community pharmacies and to interested participants.

DISCUSSION

To our best knowledge, this pragmatic cluster RCT will be the first study to determine the impact of a community pharmacy-based, digital health-supported prediabetes lifestyle intervention program in Malaysia. While evidence suggests that community pharmacies may play a valuable role in provide preventing diabetes [47-50], data on the impact of community pharmacy-based diabetes prevention programs remains scarce and inconclusive.

Prediabetes management requires a multifaceted approach targeting physical, psychological and social factors that shape behaviour. Although digital health-supported lifestyle interventions have been shown to improve the health of people with prediabetes [16], face-to-face interactions and support from healthcare professionals and peers remain important to support the effectiveness of these interventions [51, 52]. Community pharmacies are frequently lauded for the high level of convenience and accessibility that they offer to the public [50]. The convenience and accessibility of community pharmacies allow for opportunistic screening of prediabetes among individuals especially the regular patrons, and enable routine monitoring and follow-up among those detected with prediabetes. The PRIME program brings together the benefits of using digital health technology, community pharmacy support, and peer support to implement a prediabetes management program in the real-world setting. The 6-month PRIME program follows a mixed-method approach by using both quantitative and qualitative methods, which will provide valuable information on the impact and acceptance of a community pharmacy-based prediabetes management program in Malaysia. Results of this study will provide insights that will help to further improve the effectiveness of the PRIME program, and ensure that delivery of the intervention is appropriate for culturally-diverse community.

There are some potential limitations in this study. Participants who are less technologically savvy may be less willing to participate in this study. Participants may also be non-adherent to the intervention during the follow-up period. To address this, the participants will be given reminders and ample opportunity to address any queries related to the mobile application and the intervention during their face-to-face visits at the pharmacy.

In summary, the rising prevalence of T2D necessitates the implementation of effective programs that promote the early detection and management of prediabetes. The PRIME program provides a solution that is convenient, readily available and easily accessible to the public.

DECLARATIONS

Competing interests

None.

Funding

This work was supported by the Monash University Malaysia Network for Equity through Digital Health (NEED) Grant (Project code: I-M010-MTC-000007). Funding for this trial covers the purchase of equipment and consumables needed in the study, hiring of a research assistant and fieldwork travel expenses only. The design, collection, management, analysis, data interpretation, and reporting of this protocol are conducted independently from the funding body.

Data availability

No datasets were analyzed as this article is a protocol of an ongoing study since the year 2022. Hence, data sharing is not applicable.

Contributorship

KWT: Conceptualization, methodology, investigation, ethical approval, writing- original draft, writing - review & editing, visualization and project administration, resources. SWHL: Conceptualization, methodology, writing - review & editing, resources, supervision. CMN: Conceptualization, writing - review & editing, supervision. CWC: Conceptualization, funding acquisition, writing - review & editing, supervision. YLN: Conceptualization, writing - review & editing, resources. JSB: Methodology, writing – reviews and edits, supervision. WLC: Methodology, writing - review & editing. All authors read and approved the final manuscript.

References:

1. International Diabetes Federation. IDF Diabetes Atlas. 10th ed2021.
2. ElSayed NA, Aleppo G, Aroda VR, et al. Classification and Diagnosis of Diabetes: Standards of Care in Diabetes—2023. *Diabetes Care*. 2022;46(Supplement_1):S19-S40.doi:10.2337/dc23-S002
3. Khan MAB, Hashim MJ, King JK, et al. Epidemiology of Type 2 Diabetes - Global Burden of Disease and Forecasted Trends. *J Epidemiol Glob Health*. 2020;10(1):107-11.doi:10.2991/jegh.k.191028.001
4. Xie J, Wang M, Long Z, et al. Global burden of type 2 diabetes in adolescents and young adults, 1990-2019: systematic analysis of the Global Burden of Disease Study 2019. *BMJ*. 2022;379:e072385.doi:10.1136/bmj-2022-072385
5. Tuso P. Prediabetes and lifestyle modification: time to prevent a preventable disease. *The Permanente journal*. 2014;18(3):88-93.doi:10.7812/TPP/14-002
6. Knowler WC, Fowler SE, Hamman RF, et al. 10-year follow-up of diabetes incidence and weight loss in the Diabetes Prevention Program Outcomes Study. *Lancet*. 2009;374(9702):1677-86.doi:10.1016/s0140-6736(09)61457-4
7. Knowler WC, Barrett-Connor E, Fowler SE, et al. Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. *The New England journal of medicine*. 2002;346(6):393-403.doi:10.1056/NEJMoa012512
8. Tuomilehto J, Lindström J, Eriksson JG, et al. Prevention of type 2 diabetes mellitus by changes in lifestyle among subjects with impaired glucose tolerance. *N Engl J Med*. 2001;344(18):1343-50.doi:10.1056/nejm200105033441801
9. Pan XR, Li GW, Hu YH, et al. Effects of diet and exercise in preventing NIDDM in people with impaired glucose tolerance. The Da Qing IGT and Diabetes Study. *Diabetes Care*. 1997;20(4):537-44.doi:10.2337/diacare.20.4.537
10. Echouffo-Tcheugui JB, Perreault L, Ji L, et al. Diagnosis and management of prediabetes: a review. *JAMA*. 2023;329(14):1206-16.doi:10.1001/jama.2023.4063
11. Glechner A, Keuchel L, Affengruber L, et al. Effects of lifestyle changes on adults with prediabetes: A systematic review and meta-analysis. *Primary Care Diabetes*. 2018;12(5):393-408.doi:10.1016/j.pcd.2018.07.003
12. Nuzhat BA, Rebecca Spong, Patrice Carter, et al. A systematic review and meta-analysis assessing the effectiveness of pragmatic lifestyle interventions for the prevention of type 2 diabetes mellitus in routine practice. 2015
13. Gong Q, Zhang P, Wang J, et al. Morbidity and mortality after lifestyle intervention for people with impaired glucose tolerance: 30-year results of the Da Qing Diabetes Prevention Outcome Study. *Lancet Diabetes Endocrinol*. 2019;7(6):452-61.doi:10.1016/s2213-8587(19)30093-2
14. Block G, Azar KMJ, Romanelli RJ, et al. Diabetes prevention and weight loss with a fully automated behavioral intervention by email, web, and mobile phone: a randomized controlled trial among persons with prediabetes. *J Med Internet Res*. 2015;17(10):e240.doi:10.2196/jmir.4897
15. Shan R, Sarkar S, Martin SS. Digital health technology and mobile devices for the management of diabetes mellitus: state of the art. *Diabetologia*. 2019;62(6):877-87.doi:10.1007/s00125-019-4864-7
16. Cheong MWL, Chong CW, Gan SH, et al. Distal technologies for prediabetes: a systematic review and meta-analysis [preprint]. *JMIR Preprints*. 2021.doi:10.2196/preprints.28592
17. Institute for Public Health, National Institutes of Health. National Health and Morbidity Survey (NHMS) 2019: Non-Communicable Disease, Healthcare demand and Health Literacy. Malaysia: Institute of Public Health, National Institutes of Health, Ministry of Health; 2019.
18. Ng M, Fleming T, Robinson M, et al. Global, regional, and national prevalence of overweight and obesity in children and adults during 1980–2013: a systematic analysis for the Global Burden of Disease Study 2013. *The Lancet*. 2014;384(9945):766-81.doi:10.1016/S0140-6736(14)60460-8
19. Beh YS, Gopalsamy K, Lee SLF, et al. Impact of diabetes medication therapy adherence clinic (DMTAC) appointment intervals on glycemic control in public health clinics across Perak, Malaysia. *Malays Fam Physician*. 2022;17(3):105-13.doi:10.51866/oa134l
20. Lim PC, Lim K. Evaluation of a pharmacist-managed diabetes medication therapy adherence clinic. *Pharm Pract*. 2010;8(4):250-4.doi:10.4321/s1886-36552010000400008

21. Lee XY, Selvadurai S, Cheah KY, et al. Impact of pharmacist-managed diabetes medication therapy adherence clinic (DMTAC) in government health clinics. *Malay J Pharm Sci*. 2015;13(1):43-51
22. Shirdel A, Pourreza A, Daemi A, et al. Health-promoting services provided in pharmacies: a systematic review. *J Educ Health Promot*. 2021;10:234.doi:10.4103/jehp.jehp_1374_20
23. Centers for Disease Control and Prevention. Rx for national diabetes prevention program: action guide for community pharmacists. Atlanta, United States: Centers for Disease Control and Prevention, US Department of Health and Human Services; 2021.
24. Hamidi N, Tan YR, Jawahir S, et al. Determinants of community pharmacy utilisation among the adult population in Malaysia: findings from the National Health and Morbidity Survey 2019. *BMC Health Services Research*. 2021;21(1):649.doi:10.1186/s12913-021-06656-1
25. Tew MM, Hatah E, Arif F, et al. Geospatial analysis of distribution of community pharmacies and other health care facilities providing minor ailments services in Malaysia. *Journal of Pharmaceutical Policy and Practice*. 2021;14(1):24.doi:10.1186/s40545-021-00308-9
26. Whittemore R. A systematic review of the translational research on the Diabetes Prevention Program. *Translational behavioral medicine*. 2011;1(3):480-91.doi:10.1007/s13142-011-0062-y
27. Berg J, Dodd SA, Dodd S. The role of a community pharmacist in diabetes education : diabetes education. *Journal of Endocrinology, Metabolism and Diabetes in South Africa*. 2009;14(3):148-50.doi:10.10520/EJC64203
28. Chan AW, Tetzlaff JM, Altman DG, et al. SPIRIT 2013 statement: defining standard protocol items for clinical trials. *Ann Intern Med*. 2013;158(3):200-7.doi:10.7326/0003-4819-158-3-201302050-00583
29. Skivington K, Matthews L, Simpson SA, et al. A new framework for developing and evaluating complex interventions: update of Medical Research Council guidance. *BMJ*. 2021;374:n2061.doi:10.1136/bmj.n2061
30. Michie S, van Stralen MM, West R. The behaviour change wheel: a new method for characterising and designing behaviour change interventions. *Implementation science : IS*. 2011;6:42.doi:10.1186/1748-5908-6-42
31. Teoh KW, Ng CM, Chong CW, et al. Knowledge, attitude, and practice toward pre-diabetes among the public, patients with pre-diabetes and healthcare professionals: a systematic review. *BMJ Open Diabetes Research & Care*. 2023;11(1):e003203.doi:10.1136/bmjdrc-2022-003203
32. Katzmarzyk PT, Denstel KD, Martin CK, et al. Intraclass correlation coefficients for weight loss cluster randomized trials in primary care: The PROPEL trial. *Clinical Obesity*. 2022;12(4):e12524.doi:10.1111/cob.12524
33. Singh J. Randomization and online databases for clinical trials. *J Pharmacol Pharmacother*. 2014;5(2):173-4.doi:10.4103/0976-500x.130155
34. Hamman RF, Wing RR, Edelstein SL, et al. Effect of weight loss with lifestyle intervention on risk of diabetes. *Diabetes Care*. 2006;29(9):2102-7.doi:10.2337/dc06-0560
35. ElSayed NA, Aleppo G, Aroda VR, et al. Prevention or delay of type 2 diabetes and associated comorbidities: standards of care in diabetes—2023. *Diabetes Care*. 2022;46(Supplement_1):S41-S8.doi:10.2337/dc23-S003
36. Ali MK, Bullard KM, Saydah S, et al. Cardiovascular and renal burdens of prediabetes in the USA: analysis of data from serial cross-sectional surveys, 1988-2014. *Lancet Diabetes Endocrinol*. 2018;6(5):392-403.doi:10.1016/s2213-8587(18)30027-5
37. Nathan DM, Bennett PH, Crandall JP, et al. Does diabetes prevention translate into reduced long-term vascular complications of diabetes? *Diabetologia*. 2019;62(1432-0428 (Electronic)):1319-28.doi:10.1007/s00125-019-4928-8
38. Tulloch-Reid MK, Williams DE, Looker HC, et al. Do measures of body fat distribution provide information on the risk of type 2 diabetes in addition to measures of general obesity?: comparison of anthropometric predictors of type 2 diabetes in Pima Indians. *Diabetes Care*. 2003;26(9):2556-61.doi:10.2337/diacare.26.9.2556
39. Al Hommos NA, Ebenibo S, Edeoga C, et al. Trajectories of body weight and fat mass in relation to incident prediabetes in a biracial cohort of free-living adults. *J Endocr Soc*. 2021;5(2):bvaa164.doi:10.1210/jendso/bvaa164

40. Nayak VKR, Raghurama Nayak K, Vidyasagar S, et al. Body composition analysis, anthropometric indices and lipid profile markers as predictors for prediabetes. *PLoS One*. 2018;13(8):e0200775.doi:10.1371/journal.pone.0200775
41. Craig CL, Marshall AL, SjÖStrÖM M, et al. International Physical Activity Questionnaire: 12-Country Reliability and Validity. *Medicine & Science in Sports & Exercise*. 2003;35(8)
42. Herdman M, Gudex C, Lloyd A, et al. Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). *Qual Life Res*. 2011;20(10):1727-36.doi:10.1007/s11136-011-9903-x
43. Zigmond AS, Snaith RP. The Hospital Anxiety and Depression Scale. *Acta Psychiatr Scand*. 1983;67(6):361-70.doi:10.1111/j.1600-0447.1983.tb09716.x
44. Broadbent E, Petrie KJ, Main J, et al. The Brief Illness Perception Questionnaire. *Journal of Psychosomatic Research*. 2006;60(6):631-7.doi:https://doi.org/10.1016/j.jpsychores.2005.10.020
45. Buysse DJ, Reynolds CF, Monk TH, et al. The Pittsburgh sleep quality index: A new instrument for psychiatric practice and research. *Psychiatry Research*. 1989;28(2):193-213.doi:https://doi.org/10.1016/0165-1781(89)90047-4
46. Moore GF, Audrey S, Barker M, et al. Process evaluation of complex interventions: Medical Research Council guidance. *BMJ : British Medical Journal*. 2015;350:h1258.doi:10.1136/bmj.h1258
47. Roszak SE, Ferreri SP. Community pharmacy engagement in diabetes prevention: key informant interviews with pharmacy executives. *Prev Chronic Dis*. 2020;17:E90.doi:10.5888/pcd17.200050
48. Katangwe T, Family H, Sokhi J, et al. The community pharmacy setting for diabetes prevention: views and perceptions of stakeholders. *PLoS One*. 2019;14(7):e0219686.doi:10.1371/journal.pone.0219686
49. Franch-Nadal J, Fornos JA, Melogno Klinkas M, et al. Management of prediabetes from the perspective of Spanish physicians and community pharmacists: Detecta2 study. *Endocrinol Diabetes Nutr (Engl Ed)*. 2021.doi:10.1016/j.endinu.2020.12.007
50. Katangwe T, Family H, Sokhi J, et al. The community pharmacy setting for diabetes prevention: a mixed methods study in people with 'pre-diabetes'. *Research in Social and Administrative Pharmacy*. 2020;16(8):1067-80.doi:10.1016/j.sapharm.2019.11.001
51. Lakka TA, Aittola K, Järvelä-Reijonen E, et al. Real-world effectiveness of digital and group-based lifestyle interventions as compared with usual care to reduce type 2 diabetes risk – a stop diabetes pragmatic randomised trial. *The Lancet Regional Health - Europe*. 2023;24:100527.doi:10.1016/j.lanepe.2022.100527
52. Samarasinghe SNS, Miras AD. Type 2 diabetes prevention goes digital. *The Lancet Regional Health - Europe*. 2023;24:100538.doi:10.1016/j.lanepe.2022.100538

Table 1: Examples of how PRIME components are applied as each intervention functions based on the BCW.

Intervention functions based on BCW	PRIME component	Examples
Education	• Face-to-face prediabetes management counselling provided by community pharmacists	• Counselling sessions focus on lifestyle changes in the areas of diet, exercise, sleep, and stress
	• Education modules from PRIME app	• Module contents include topics on prediabetes pathophysiology and its complications, healthy food, physical activities, sleep, smoke and stress management
Training	• Face-to-face prediabetes management counselling provided by community pharmacists	• Counselling sessions focus on lifestyle changes in the areas of diet, exercise, sleep, and stress
	• Education modules from PRIME app	• Practical tips on developing a healthier lifestyle given in the education modules, such as reading nutritional labels and choosing healthier food choices
Enablement	• Food diary, blood glucose, weight and physical activity trackers from PRIME app	• Tracking of calories intake and their daily calories allowance via the food diary. Participants are given a wearable activity tracker and a glucometer that can be linked to PRIME app for self-monitoring
	• Peer support chatgroups	• Participants are able to share best practices, motivations and their experiences in lifestyle modifications here. The researcher will also be sharing prediabetes health information and motivational messages in the chatgroups
Persuasion	• Infographics, quizzes and videos in PRIME app	• Designed to stimulate positive and negative feelings among participants and to stimulate behavioural actions. For example, photos of delicious healthy meals with vivid colours are displayed

Table 2: Inclusion and exclusion criteria of PRIME program.

Inclusion criteria	Exclusion Criteria

• Age 18 years or older
• Body Mass Index ≥ 23
• Found to have prediabetes, defined by:
  ○ HbA1c of 5.7% - 6.4%
  OR
  ○ Fasting plasma glucose of 5.6mmol/L – 6.9mmol/L
	• Unable to give informed consent due to lack of capacity
	• Previously diagnosed with Type-1 or Type-2 diabetes mellitus
	• Taking any antidiabetic medications
	• Taking medications that may affect glucose tolerance (e.g. antipsychotics or high dose steroids)
	• Pregnant or intention to get pregnant
	• Advised by their doctors on health grounds that participant should not take part

Table 3: Difference between control and intervention group.

PRIME features	Control group	Intervention group
Blood glucose tracker	/	/
Physical activity tracker	/	/
Weight tracker	/	/
Food diary	/	/
Education modules	X	/
Peer support chatgroup	X	/
Lifestyle change counselling	As per pharmacists' usual practise	/

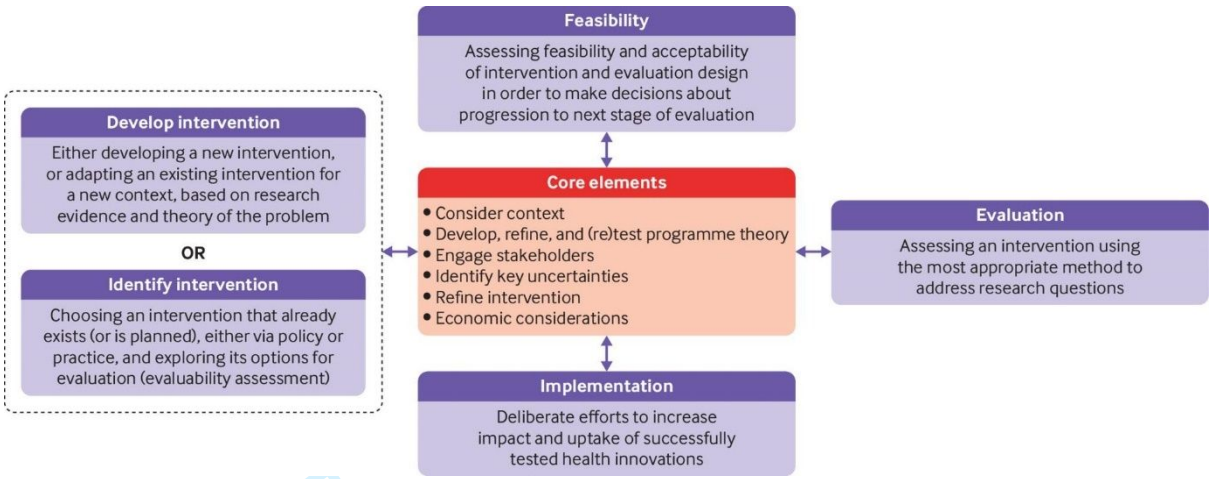


Fig. 1 Framework for developing and evaluating complex interventions reproduced with permission from Skivington et al [29]

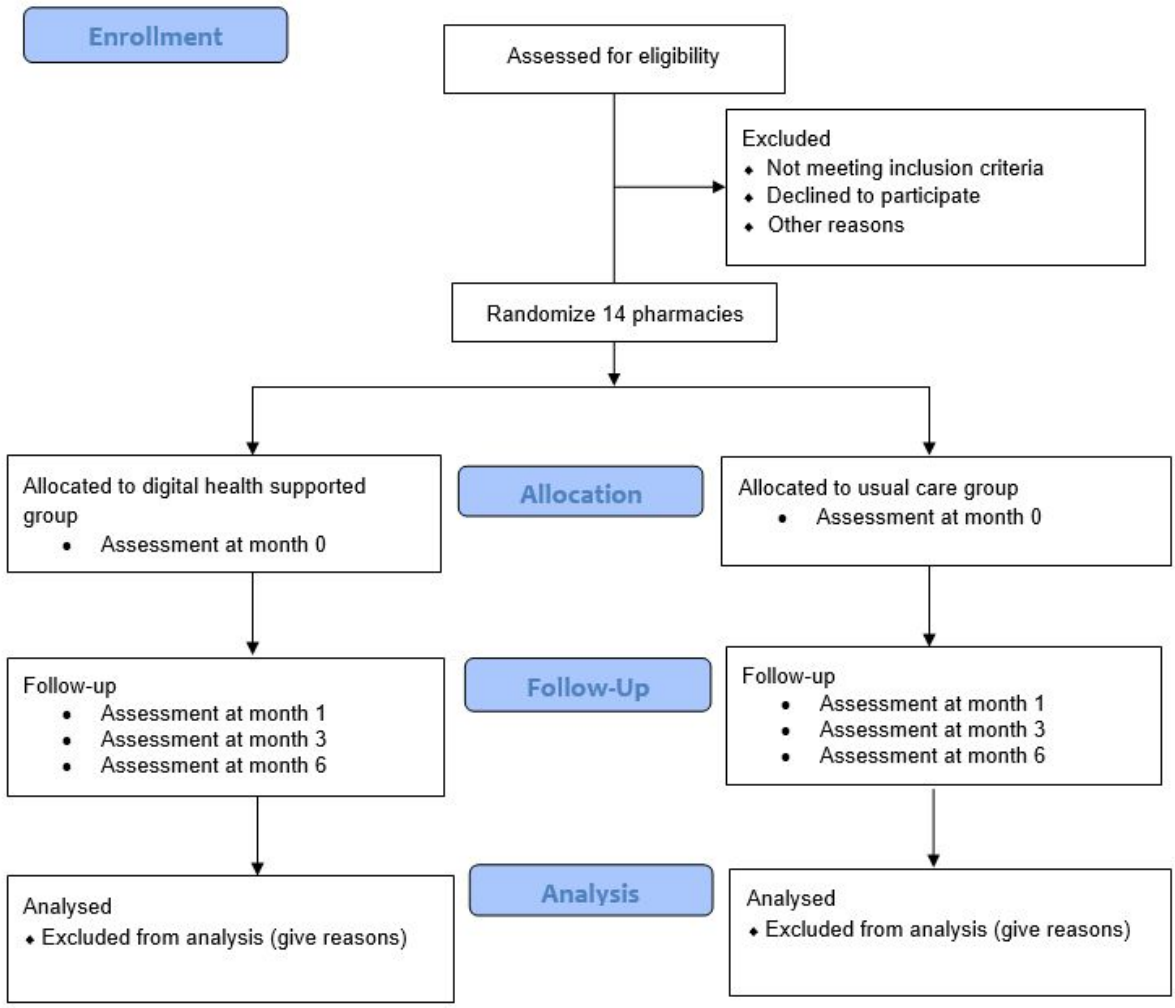


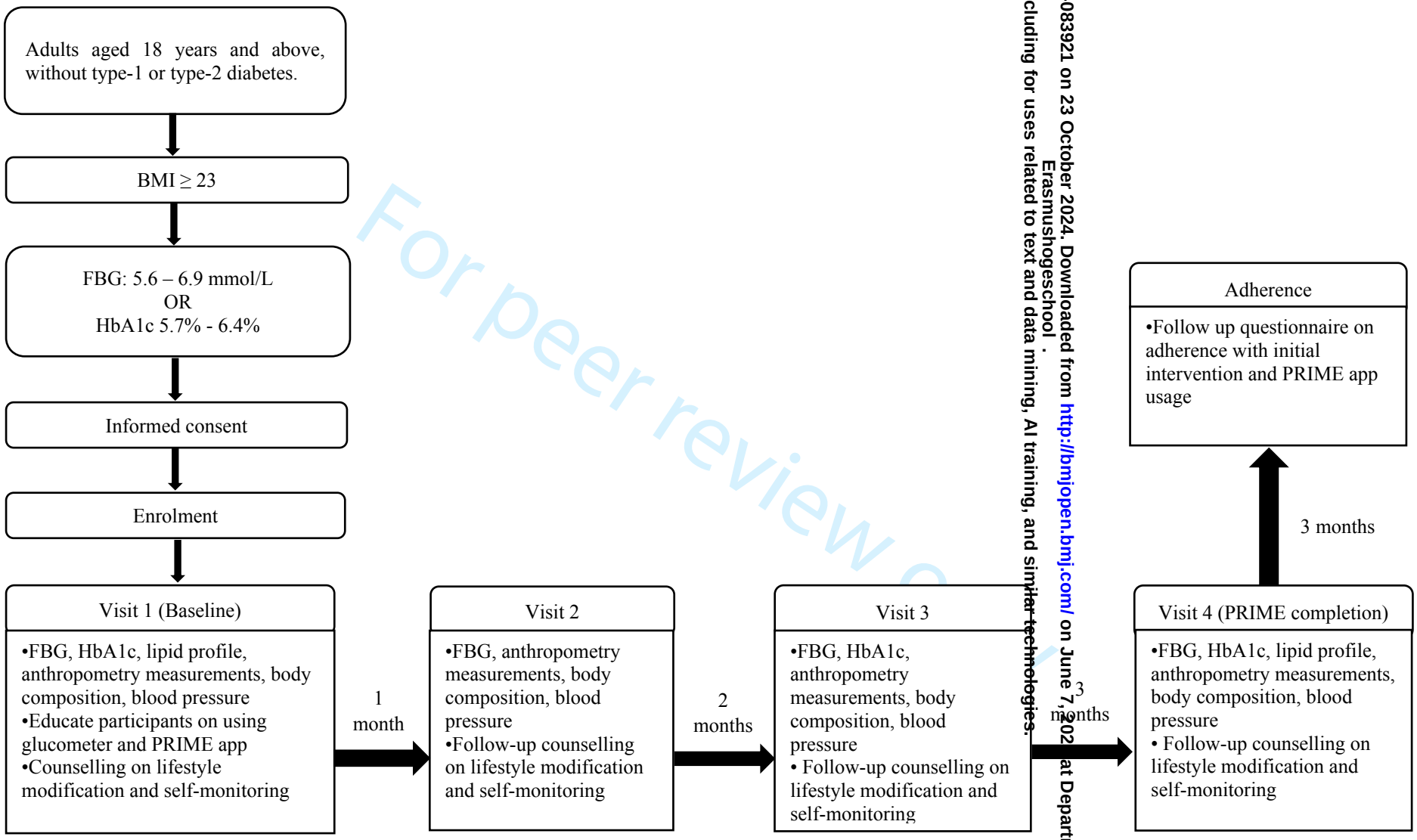
Fig. 2 Flowchart of PRIME study

	STUDY PERIOD						
	Enrolment	**Allocation**	**Post-allocation**			**Final Assessment**	**Adherence**
TIMEPOINT**	$-t_1$	**0**	t_1	t_2	t_3	t_4	t_5
ENROLMENT:							
Eligibility screen	X						
Provide explanatory statement	X						
Informed consent	X						
Allocation		X					
INTERVENTIONS:							
Digital health-supported group			←	—	—	→	
Usual care			←	—	—	→	
ASSESSMENTS:							
Weight	X		X	X	X	X	X (self-reported)
BMI	X		X	X	X	X	
FBG	X		X	X	X	X	
HbA1c	X		X		X	X	
Lipid profile (TC, TG, LDL, HDL)			X			X	
Body composition			X	X	X	X	
Waist and hip circumferences			X	X	X	X	
Blood pressure			X	X	X	X	
Multiple 24-hour dietary recall (three days)			X			X	
QUESTIONNAIRES:							
Follow-up questionnaire on app usage and lifestyle changes							X
IPAQ			X	X	X	X	

EQ-5D-5L			X	X	X	X	
HADS			X		X	X	
BIPQ			X		X	X	
PSQI			X			X	

t_1: Baseline; t_2:1-month visit; t_3: 3-month visit; t_4: 6-month follow up visit, t_5: 9-month follow up questionnaire. BMI: body mass index; FBG: fasting blood glucose; HbA1c: glycated haemoglobin A1c; TC: total cholesterol, TG: triglycerides; LDL: low-density lipoprotein; HDL: high-density lipoprotein; IPAQ: International Physical Activity Questionnaire**;** HADS**:** The Hospital Anxiety and Depression Score, BIPQ: The Brief Illness Perception Questionnaire; PSQI: Pittsburgh Sleep Quality Index**.**

Fig. 3 Schedule of enrolment, interventions and assessments for PRIME Program



BMI: body mass index, FBG: fasting blood glucose, HbA1c: glycated haemoglobin A1c.

Fig. 4 Flowchart of PRIME screening, recruitment and follow-up

Supplementary Materials

Table of content:

Fig. S1 Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) checklist

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Location where item is reported
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	Title
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	Methods subsection study design
	2b	All items from the World Health Organization Trial Registration Data Set	Methods subsection study design
Protocol version	3	Date and version identifier	NA
Funding	4	Sources and types of financial, material, and other support	Declarations
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	Title page and author contribution
	5b	Name and contact information for the trial sponsor	NA
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	Funding
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	NA

Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	Introduction paragraph 1-4
	6b	Explanation for choice of comparators	Introduction paragraph 3-4.
Objectives	7	Specific objectives or hypotheses	Objectives
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	Methods; subsection 'study design'
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	Methods; subsection 'study design and setting'
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	Methods; Table 1, paragraphs 2 and 3 of subsection 'intervention arm'
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	Methods; subsection 'intervention arm'
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	Methods; subsection 'recruitment strategies'
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	Methods; paragraph 3 of subsection 'intervention arm' and Discussion; paragraph 3.

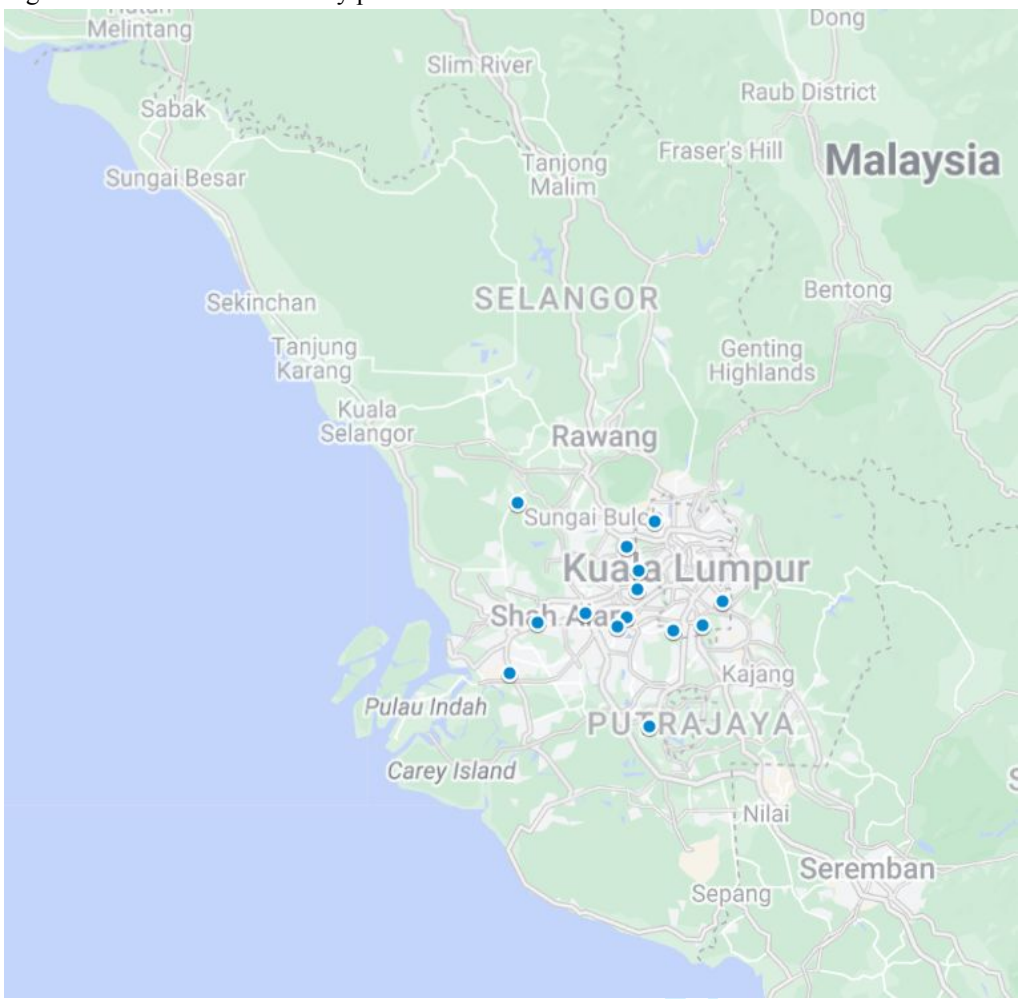
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	NA
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	Methods; subsection 'evaluation'
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Fig.)	Fig. 3
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	Methods; subsection 'sample size calculation'
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	Methods; subsection 'recruitment strategies'
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	Methods; subsection 'randomization and blinding'
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	Methods; subsection 'randomization and blinding'
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	Methods; subsection 'randomization and blinding'
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	Methods; subsection 'randomization and blinding'

	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	Methods; subsection 'randomization and blinding'
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	Methods; subsection 'Evaluation-Primary Objective'
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	Discussion; paragraph 3
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	Methods; subsection 'confidentiality'
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	Methods; subsection 'data analysis'
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	Methods; subsection 'data analysis'
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	Methods; subsection 'data analysis'
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	NA
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	NA
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	NA

Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	NA
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	Ethics and dissemination
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	Ethics and dissemination
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	Methods; subsection 'recruitment strategy'
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	NA
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	Methods; 'confidentiality'
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	Competing interests
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	Methods; subsection 'confidentiality'
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	NA
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	Ethics and dissemination
	31b	Authorship eligibility guidelines and any intended use of professional writers	NA
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	NA
Appendices			

Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Supplementary material Fig. S5 and S6
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	NA

Fig. S2 Locations of community pharmacies



Community pharmacies within Kuala Lumpur:

- CARiNG Pharmacy, Lakefield, Sungai Besi
- CARiNG Pharmacy Kepong Baru, Kuala Lumpur
- CARiNG Pharmacy EkoCheras Mall, Cheras
- CARiNG Pharmacy Pavilion, Bukit Jalil

Community pharmacies within Selangor:

- CARiNG Pharmacy Central i-City, Shah Alam
- CARiNG Pharmacy Aeon Mall Shah Alam, Shah Alam
- CARiNG Pharmacy Damen USJ, Subang Jaya, Petaling Jaya
- CARiNG Pharmacy Sunway Pyramid, Subang Jaya, Petaling Jaya
- CARiNG Pharmacy Eco Grandeur, Puncak Alam
- CARiNG Pharmacy The Starling Mall, Damansara Uptown, Petaling Jaya
- CARiNG Pharmacy Seapark, Petaling Jaya
- CARiNG Pharmacy Damansara Perdana, Petaling Jaya
- CARiNG Pharmacy Tamarind Square, Cyberjaya
- CARiNG Pharmacy AEON Bukit Tinggi, Klang

Fig. S3 List of topics included in PRIME education modules

Module 1: What is Prediabetes?

Module 2: Nutrition

Module 3: Physical Activity

Module 4: Sugar

Module 5: Ways to Get Active

Module 6: Starchy Food

Module 7: Glycaemic Index

Module 8: No More Excuses!

Module 9: Fiber

Module 10: Sodium & Salt

Module 12: Food Label

Module 13: Wrapping Up: Meal Examples

Module 14: Alcohol, Smoking, Stress & Sleep

Fig. S4 Data collection forms

Patient's details

Name:	
Date of birth:	
Age:	
Contact number:	
Sex:	☐ Male ☐ Female
Ethnicity:	☐ Malay ☐ Chinese ☐ Indian ☐ Others: _____
Education Status:	☐ Primary ☐ Secondary ☐ Tertiary
Employment Status:	☐ Employed ☐ Unemployed ☐ Retired
Marital Status:	☐ Single ☐ Married ☐ Divorced ☐ Widowed
Household income:	☐ Below RM 4850 ☐ Rm 4850 to RM 10,959 ☐ RM 10,960 and above
Study subject ID number:	
Family history of diabetes:	YES / NO (If yes, who: _____)

Blood investigations

Parameters	**Values**				
Full lipid profile	**Baseline**		**6m**		**12m**
Date:					
Total cholesterol (mmol/L) (<5.2)					
Triglycerides (mmol/L) (<1.7)					
HDL (mmol/L) (>1.5)					
LDL (mmol/L) (<2.6 at risk CAD, < 3.3)					
Non-HDL					
HDL/LDL ratio					
Chol/ HDL ratio					
Blood glucose profile	**Baseline**	**3m**	**6m**	**9m**	**12m**
Dates					
Fasting blood glucose (mmol/L)					
HbA1c (%)					

Anthropometric measurements

Parameters	**Values**					
Visits	**Baseline**	**1m**	**3m**	**6m**	**9m**	**12m**
Dates						
Height (cm)						
Weight (kg)						
Waist circumference (cm)						
Hip circumference (cm)						

Body fat composition

Parameters	**Values**					
Visits	**Baseline**	**1m**	**3m**	**6m**	**9m**	**12m**
Dates						
BMI (kg/m^2)						
Body fat (%)						
Water (%)						
Muscle (%)						
Bone (kg)						
BMR (kcal)						
Visceral fat						
Protein (%)						
Obesity degree (%)						
Body age						
Lean body weight (%)						

Other measurements

Blood pressure and pulse rate (3 readings)						
Visits	**Baseline**	**1m**	**3m**	**6m**	**9m**	**12m**
Dates						
Reading 1						
Reading 2						
Reading 3						
Average BP reading						
Medical history (underlying diseases) – **to update during every visit** *Eg. Eczema, hypertension, dyslipidaemia*						
Medication history (drug GENERIC name, dosage form, dose and frequency) – **to update during every visit** Eg. *T. Atorvastatin 40mg ON*						
Supplements or complementary medicines (including herbal medicine) *(supplement name, dosage form, dose and frequency)* – **to update during every visit** *Eg. T. Vitamin C 1000mg OD*						

Fig. S5 Explanatory statement

EXPLANATORY STATEMENT

Adults at Risk of Pre-Diabetes

Project ID: 27512

Project Title: Addressing disparity in diabetes prevention through Digital health supported PRe-diabetes Intervention, Management and Evaluation (PRIME) program based in Malaysian community pharmacies

You are invited to take part in this study. Please read this Explanatory Statement in full before deciding whether or not to participate in this research. If you would like further information regarding any aspect of this project, you are encouraged to contact the researchers via the phone numbers or email addresses listed above.

Chief Investigator:

Dr Chong Chun Wie
School of Pharmacy
Phone: +60 3 5514 6188
email: Chong.ChunWie@monash.edu

PhD Researcher:

Teoh Kah Woon

School of Pharmacy, Monash University Malaysia

Email: kah.teoh@monash.edu

What does the research involve?
The aim of the study is to evaluate the effectiveness of a digital health supported prediabetes intervention program delivered through community pharmacies in improving the glycaemic markers and other related measurements. The program will provide you with educational information/instructions regarding healthy diet, healthy lifestyle and exercise for you. Your progress will be monitored with check-in sessions to motivate you to follow the instructions throughout the study period of 6 months.

A fitness tracker (MiBand6) will be given to you to monitor your diet, physical activities and sleep qualities. You will also be given a glucometer to track and monitor your fasting blood sugar levels from home.

You will be asked to fill in a series of questionnaires that will take approximately 40 minutes of your time. These questionnaires will be administered to you at 4 time-point: before the start of the study, 1 month, 3 months, and 6 months. These questionnaires include:

- 3-day diet recall: to assess your dietary patterns
- EQ-5D-5L: to assess your quality of life
- The Hospital Anxiety and Depression Score: to assess any depression and anxiety relating to the diagnosis of condition and the care provided to you thereafter
- The Brief Illness Perception Questionnaire: to assess your thoughts and emotions towards prediabetes
- Internation Physical Activity Questionnaire
- Pittsburg Sleep Quality Index: to assess your sleeping patterns

You will also be undergoing some physical assessments. Your blood sugar levels (fasting blood glucose, random blood sugar, HbA1c) and full lipid profile (total cholesterol, LDL-cholesterol, HDL-cholesterol, triglycerides) will be taken via a finger prick test, which may cause minimal discomfort. Additionally, your body mass index (BMI) (height and weight), body fat compositions, waist and hip circumference will also be measured. These physical assessments will be done in Caring Pharmacy at four time-point: before the start of study and 1 month, 3 months and 6 months.

Why were you chosen for this research?
You were chosen to be screened for eligibility for the study as a customer/patient visiting the pharmacy. If you are a Malaysian adult with prediabetes and a BMI of 23 or above, you will be invited to participate in this program.

Source of funding
Monash University's Network for Equity through Digital Health (NEED) Grant. No conflict of interest of researchers.

Consenting to participate in the project and withdrawing from the research

You will be asked to sign a consent form if you agree to take part in this research project specified above. Participant has the right to withdraw from further participation at any stage, along with any implications of withdrawal by informing the investigator. The data collected from this project will not be possible to be withdrawn once they have been submitted to the investigator.

Possible benefits and risks to participants
The findings from this research helps to evaluate the effectiveness of a digital health supported prediabetes intervention program. The findings help to provide evidence to support the use of the program, if it is shown to be effective. There is no obvious risk foreseen in this project.

Payment
There is no payment reimbursement for this project. However, participants who completed this research study will receive a MiBand6 and a glucometer used for this study.

Confidentiality
The collected data will be de-identified without participant-identifiable information before being used in a research report and may be published in a conference or journal article. The results accessible to public will be anonymous and de-identified.

Storage of data
The data will be stored in a network storage and only the investigators have access to the data. The data may be kept for an infinite period or may be destroyed if necessary.

Use of data for other purposes
The findings of this research may be used for future study. Only anonymous data will be used where ethics approval has been granted.

Results
The results of this research will be used in a research report and may be published in a conference or journal article. Participants may request for the aggregate results to investigators.

Complaints

Should you have any concerns or complaints about the conduct of the project, you are welcome to contact the Executive Officer, Monash University Human Research Ethics Committee (MUHREC):

Associate Professor Poh Phaik Eong
Director, Research Excellence
Monash University Malaysia
Jalan Lagoon Selatan
46150 Bandar Sunway
Selangor Darul Ehsan, Malaysia
Tel: +603 5514 6272 Email: poh.phaik.eong@monash.edu

Thank you.

Fig. S6 Consent form

CONSENT FORM

Adults at Risk of Pre-Diabetes

Project ID: 27512
Project title: Addressing disparity in diabetes prevention through Digital health supported PRe-diabetes Intervention, Management and Evaluation (PRIME) program based in Malaysian community pharmacies

Chief Investigator:

Dr Chong Chun Wie
School of Pharmacy
Phone: +60 3 5514 6188
Email: Chong.ChunWie@monash.edu

I have been asked to take part in the Monash University research project specified above. I have read and understood the Explanatory Statement and I hereby consent to participate in this project.

I consent to the following:	Yes	No
• Taking part in this research study which will last for 6 months.	☐	☐
Getting my physical activities and sleep qualities measured for 6 months using the fitness tracker (MiBand6) given to me.	☐	☐
Getting my blood sample (for blood sugar and full lipid profile), body mass index (height and weight) measured in Caring Pharmacy and filling up questionnaires at 4 time-points: before the start of study, 1 month, 3 months, and 6 months.	☐	☐
The anonymous and de-identified data that I provide during this research may be used by the research team in future research projects.	☐	☐

Name of Participant _____

Participant Signature _____ Date _____

BMJ Open

A digital health-supported, community pharmacy-based lifestyle intervention program for adults with prediabetes: a study protocol for a cluster randomized controlled trial

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2024-083921.R1
Article Type:	Protocol
Date Submitted by the Author:	23-Aug-2024
Complete List of Authors:	Teoh, Kah Woon; Monash University Malaysia, Ng, Choon Ming; Monash University Malaysia Chong, Chun Wie; Monash University Malaysia, Cheong, Mark Wing Loong; Monash University Malaysia, School of Pharmacy Ng, Yi Ling; Caring Pharmacy Sdn. Bhd. Bell, J Simon; Monash University, Centre for Medicine Use and Safety Lee, Shaun Wen Huey ; Monash University Malaysia, School of Pharmacy
Primary Subject Heading:	Diabetes and endocrinology
Secondary Subject Heading:	Research methods, Public health, Health services research, Epidemiology
Keywords:	Clinical trials < THERAPEUTICS, DIABETES & ENDOCRINOLOGY, EPIDEMIOLOGY, Primary Prevention, eHealth, Behavior

Title: A digital health-supported, community pharmacy-based lifestyle intervention program for adults with prediabetes: a study protocol for a cluster randomized controlled trial

Kah Woon, Teoh[a], Choon Ming, Ng[a], Chun Wie, Chong[a], Wing Loong, Cheong[a], Yi Ling, Ng[c], J Simon, Bell[b], Shaun Wen Huey, Lee[a]

[a]School of Pharmacy, Monash University Malaysia, Jalan Lagoon Selatan, 47500, Selangor, Malaysia.

[b]Centre for Medicine Use and Safety, Faculty of Pharmacy and Pharmaceutical Sciences, Monash University, Parkville, Australia

[c]Pharmacy Practice Department, CARiNG Pharmacy Head Office, No 1, Jalan 51/203A, Kawasan Perindustrian Tiong Nam, Seksyen 51, 46050 Petaling Jaya, Selangor, Malaysia

Corresponding author:

Shaun Wen Huey Lee, School of Pharmacy, Monash University Malaysia, Jalan Lagoon Selatan, 47500, Selangor, Malaysia.

Email: shaun.lee@monash.edu

Twitter: @nuahSeelL

Twitter handles for other authors:

Kah Woon Teoh: @carmenteoh

Wing Loong Cheong: @markcheongwl

Abstract

Introduction: Prediabetes indicates an elevated risk of developing type-2 diabetes and presents a window for preventive actions. The PRIME Program is a community pharmacy-based prediabetes management program that utilizes a mobile application for self-monitoring and prediabetes education, aiming to promote lifestyle changes among participants with prediabetes.

Methods and analysis: This is a protocol for a cluster randomized controlled trial that aims to evaluate the impact of PRIME program on participants' clinical outcomes and explore participants and pharmacists' views towards its implementation. This protocol describes the development of the PRIME program and mobile app, its feasibility and implementation in community pharmacy settings. Sixteen pharmacies from two states in Malaysia will be randomized to the intervention arm or standard care. The study will include overweight or obese adults with prediabetes. During each follow-up visits at the pharmacy, intervention participants will receive in-depth counselling from pharmacists after reviewing their self-monitoring data recorded in the PRIME app. They will also receive prediabetes education through the app and join a peer support chatgroup. The primary clinical outcome includes changes in body weight at 6-month, while the secondary clinical outcomes include changes in blood glucose profile, lipid profile, blood pressure, and adiposity measures. The sustainability of the PRIME program will be accessed using a follow-up questionnaire while participants' engagement with the intervention will be evaluated using attendance rate and the app data. Focus group discussions and one-to-one interviews will be conducted for process evaluation. This study will inform the impact of community pharmacists-led digital health intervention in prediabetes management.

Ethics and dissemination: This study has been registered with clinicaltrials.gov (NCT04832984) and approved by the Monash University Human Research Ethics Committee (MUHREC) (Project ID: 27512).

Keywords

Behavior, clinical trials, epidemiology, primary prevention, diabetes, eHealth

Strength and limitations of this study

- This is the first study that examines the real-world impact of incorporating a mobile app and utilizing the role of community pharmacists to deliver a prediabetes management program.
- Stakeholders and members of the public were involved during the development process of the intervention.
- This protocol will comprehensively detail the development process, feasibility and implementation of the interventions, as well as evaluation of the clinical and behavioral outcomes of PRIME program.
- This study will not specifically identify participants with impaired glucose tolerance, as administering oral-glucose tolerance tests was not feasible in a community pharmacy setting.

INTRODUCTION

Type-2 diabetes (T2D) is a global health emergency affecting 537 million people worldwide.[1, 2] While most people newly diagnosed with T2D are typically aged 55 years and older, the increasing number of people with early-onset T2D is posing a new public health challenge.[3, 4] Consensus guidelines recommend that high-risk individuals, including those who are overweight or obese, those with a previous history of gestational diabetes, strong family history of T2D and ethnic groups susceptible to T2D, be screened for diabetes and prediabetes.[2] Prediabetes is presented as impaired fasting glucose (IFG) and/or impaired glucose tolerance (IGT), and is a condition when an individuals' blood glucose levels rise above normal without exceeding the diabetes threshold. a fasting blood glucose reading of 5.6mmol/L – 6.9mmol/L (IFG), 2-hour post-load glucose of 7.8mmol/L – 11.0mmol/L (IGT) and/or elevated glycated haemoglobin (HbA1c) of 5.7% - 6.4% is consistent with prediabetes, with values above these thresholds indicative of diabetes.[2]

One in ten people with impaired glucose tolerance develops T2D yearly, with a lifetime risk of 70%.[5] This high risk progression to T2D is an alarming sign that calls for concerted preventive efforts. Interventions that target pathophysiological factors such as those that reduce weight, promote a balanced diet and increase physical activity provide a more sustainable and longer-term benefits than using anti-diabetic medications.[6-10] For example, the Diabetes Prevention Program [6, 7], the Finnish Diabetes Prevention Study,[8] and the Da Qing study [9] reduced the risk of progression to T2D by up to 58% over three years, with the protective benefit persisting for up to 10 years.[7, 11, 12] The implementation of lifestyle interventions in these studies prevented diabetes related-complications and prolonged life.[13] With the advent of new technologies, many of these interventions are now supported through digital health platforms.[14-16]

Malaysia has one of the highest rates of obesity and T2D in Southeast Asia.[17, 18] With nearly 3.9 million Malaysians diagnosed with diabetes, effective interventions are needed to alleviate the burden of T2D.[17] The Diabetes Medication Therapy Adherence Clinic (DMTAC), a pharmacists-led diabetes management service was introduced since the year 2006 in appointed government-funded healthcare facilities in Malaysia. By emphasizing on diabetes education and medication adherence, patients enrolled into the DMTAC service showed improved glycaemic control.[19-21] Currently, the DMTAC service in Malaysia is focused on supporting individuals with diabetes, highlighting opportunities for preventive actions through initiatives in prediabetes management.[22]

Community pharmacy services are increasingly involved in health promotion, disease prevention and management activities.[23] In the USA, guidelines have been developed for prediabetes screening and diabetes prevention to be carried out by community pharmacies.[24] Although community pharmacists in Malaysia participate in health promotion activities such as weight management, diabetes counselling, and lifestyle counselling, they remain largely underutilized in campaigns to prevent diabetes.[25] Evidence on the effectiveness of utilizing community pharmacies to deliver prediabetes management programs in Malaysia, however, remains limited. Community pharmacies in Malaysia are more readily available that public health clinics and hospitals,[26] and are the first point of access to healthcare to vulnerable groups who do not consult regularly with a general practitioner, diabetes educator or other healthcare professionals.[27, 28] Therefore, a community pharmacy-based prediabetes intervention could potentially complement with the other diabetes prevention strategies.

Recognizing this gap, we developed a digital health-supported prediabetes management program based in community pharmacies. The PRediabetes Intervention, Management and Evaluation (PRIME) program is a partnership between Monash University and Malaysian community pharmacies working to prevent T2D. The PRIME program uses a mobile-based application to promote weight loss and modify risk factors in people with prediabetes. It delivers a structured curriculum to educate people with prediabetes on their condition, with community pharmacists providing support as prediabetes health coaches.

Objectives

The primary objective of this study is to evaluate the effects of a digital health-supported and community pharmacy-based prediabetes management program on individuals with prediabetes in Malaysia. In addition, this study also aims to explore the participants' and pharmacists' experiences and perceptions regarding the implementation, adoption and participation of the PRIME program.

METHODS AND ANALYSIS

This protocol is designed and reported according to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) checklist (Supplementary Materials Fig. S1).[29]

Analysis framework

The development of the PRIME program study is underpinned by the Framework for Developing and Evaluating Complex Interventions jointly commissioned by the Medical Research Council and National Institute for Health Research (MRC-NIHR) (Fig. 1).[30]

This framework describes how complex interventions can be divided into four non-sequential phases: developing or identifying an intervention, feasibility, evaluation, and implementation. The framework emphasizes six core elements at each phase, which consists of: the context where the intervention will be delivered, testing and refining program theory, involving important stakeholders, identifying key uncertainties, refining intervention and economic considerations. This paper will describe the development of the current study using the MRC-NIHR framework.[30]

Development of intervention

Theoretical framework

The program will use the principles of the Behavior Change Wheel (BCW) as the foundation of this study.[31] Based on the framework, the PRIME program will be designed by targeting four main intervention functions on prediabetes management, namely: 'education', 'training', 'enablement', and 'persuasion'. These were key areas that could facilitate lifestyle behavioral change and the implementation of a prediabetes management program based on a previous review.[32] A brief explanation and examples of how these barriers will be addressed by components of the PRIME program are shown in Table 1.

Stakeholders engagement

The PRIME program will be co-designed by the research team from the School of Pharmacy and the School of Information Technology from Monash University Malaysia, healthcare professionals, and members of the public. Inputs from healthcare professionals (endocrinologists, community pharmacists, nutritionists, and dietitians), and members of the public will be collected and used to refine the PRIME program and its mobile application throughout the development process.

Patient and public involvement

Members of the public will be involved during the mobile app and intervention development process of the study. Interview sessions with members of the public will be conducted, where they preview a prototype of the PRIME app to provide insights on its feasibility for a community pharmacy-based digital health supported prediabetes management program. During the interviews, participants will provide feedback on their acceptance towards the burden of the intervention (for example, frequencies of blood glucose monitoring) and time required to participate in the study. User acceptance tests of PRIME mobile app will also be conducted with the general public before the implementation of PRIME program.

Phase 1: Feasibility

User acceptance tests

The prototype of the PRIME app will be tested on the users from the general public. Participants will be asked to install the PRIME app on their mobile phones, and to complete a set of tasks using the features available within the app. Feedback will be collected from each participant via a user feedback survey that utilizes Likert scales and open-ended questions to assess user experience, acceptability, and usability of the app.

Pilot study

In line with the MRC guidance, a month-long pilot study will be carried out. The pilot study will be conducted with the aim of testing the feasibility of the PRIME program at two community pharmacies. The recruitment

strategies, data collection procedures, time taken, pharmacists' capacity to deliver the intervention, adherence, retention and app engagement, and participants' feedback will be assessed and used to optimize the study design.

Phase 2: Implementation

Study design and setting

The PRIME program is designed as a pragmatic digital health-supported prediabetes cluster randomized controlled study that will be delivered through community pharmacies. Sixteen community pharmacies from Selangor and Kuala Lumpur will be randomized to either the intervention arm or standard care. The locations of the community pharmacies can be found in Supplementary Materials Fig. S2. Community pharmacies will be selected to participate if they 1) have at least a locally registered pharmacist willing to participate and 2) have suitable facilities available for pharmacist counselling, point of care tests, body weight and other anthropometry measurements.

Sample size calculation

Based on a previous prediabetes intervention study, it was reported that 8% of individuals in the usual care group and 35% in the intervention group achieved a 5% weight loss at 6-month.[14] Assuming an intracluster correlation coefficient of 0.007,[33] a design effect of 1.035, a power of 80% and alpha of 5%, a total of 72 participants will need to be recruited. After accounting for a 25% loss to follow-up in each arm, a total of 90 participants will be recruited across at least 14 community pharmacies. Fig. 2 shows the study flowchart.

Recruitment strategies

To identify for potential participants, we plan to conduct prediabetes awareness campaigns and blood glucose screening activities at community centers, community pharmacies and workplaces. Promotional materials such as posters and brochures will be placed in community pharmacies, and the program will be advertised through social media platforms. Participants may also be self-referred.

The first author, KWT, and a research assistant (RA) will explain the trial purposes and procedures to eligible prospective participants who fulfilled the inclusion criteria (Table 2), and provide them with a written explanatory statement. KWT and RA will collect written consent forms from the participants who have decided to join the study, and all consented participants will undergo four face-to-face visits across six months with their pharmacists at the pharmacy. However, they are free to withdraw from the study at any time during the study period. The schedule of enrolment, interventions and assessment is outlined in Fig. 3 and the flowchart of screening, recruitment and follow-up visit processes is detailed in Fig. 4.

Randomization and blinding

In this study, a cluster-randomized design will be adopted where randomization will occur at the community pharmacy level instead of individual level. This is to prevent any potential cross-contamination, especially in the event two individuals receiving different interventions may visit the same community pharmacy at the same time.

Using a web-based randomization tool [34], the 16 participating community pharmacies will be stratified based on their geographical areas and randomized to either the intervention or control groups (1:1). Participants who are recruited through other channels other than from pharmacy screenings (for example, health campaigns at community centres) will be given a list of participating community pharmacies to choose from for their baseline visit and subsequent follow-ups. The participants will be blinded from the groups that the community pharmacies are randomized into, and will only be informed of their allocation only at the end of the study. Given the nature of the intervention, community pharmacists will not be blinded.

Pharmacist coaching

Before the study commencement, all community pharmacists who will be involved in the study will undergo a 3-hour online coaching session conducted by the research implementation team comprising of the PRIME Program Pharmacist and PRIME Program Nutritionist. The pharmacists will be coached on lifestyle counselling points and techniques, given a demonstration of the PRIME app and briefed on the operation procedures of the PRIME program at the pharmacy.

Treatment

At baseline visit, both control and intervention groups will be provided a glucometer (Bionime GE Max Plus, Taiwan) and a fitness tracker (XiaoMi Miband 6, China) for self-monitoring of their blood glucose and physical activity levels.

Both arms will be introduced to the PRIME app that includes the core features for self-monitoring of physical activities, weight, blood glucose levels, and food intake. All participants will be required to download the PRIME app and taught how to self-monitor their health parameters using the app. Participants' blood glucose readings, step counts, hours of sleep and food intake will also be synchronised and recorded into PRIME app. These data will then be portrayed in real-time on the PRIME dashboard and will be accessible to the community pharmacists at the pharmacies. The PRIME app will also set an individualized daily calorie allowance for each participant, calculated based on participants' age, body weight, height, gender, and physical activity level. A total of 500kcal will be deducted from each participant's daily calorie intake goals to encourage weight loss.[35]

As part of the program, participants will also meet their community pharmacist at baseline, 1-month, 3-months and 6-months, which will be scheduled in advanced with the PRIME Pharmacist. At each visit, the participants will be encouraged to practise the healthy plate model and engage in 150 minutes of moderate intensity exercises each week. After the 6-month visit, participants will no longer have to attend the face-to-face visits. To determine whether participants are able to sustain the lifestyle changes they developed throughout the PRIME program, a researcher will conduct a follow-up questionnaire at 9-months. This questionnaire will examine their current lifestyle practices, self-monitoring habits, and engagement with the PRIME app.

Intervention arm

Participants in the intervention group will be provided with 14 in-app prediabetes education modules comprising of infographics, videos and quizzes (Supplementary Materials Fig. S3). A team of nutritionists, dietitians and pharmacists derive the content of the education modules based on the findings of a mixed-method cross-sectional study that was conducted to understand the public needs on prediabetes knowledge and lifestyle management. These modules will provide education on the pathophysiology and complications of prediabetes, and information on healthy food choices, physical activities, importance of sleep and stress management, and the detrimental effect of smoking. The modules will be designed to stimulate positive and negative feelings among participants and to stimulate behavioural actions. For example, photos of delicious healthy meals with vivid colours will be displayed.

The participants will also be invited to join a peer support chatgroup, which will serve as a platform for participants to share their experiences, such as successful lifestyle modification, as well as to help address any difficulties and encourage one another. Before obtaining consents, all concerns will be addressed and participants will be briefed on the rules and the purpose of the chatgroups. Those who consent will be organized into centralized groups of 10 in the order of their enrolment. The chatgroups will be hosted on Whatsapp and will be moderated by a core team of PRIME personnel, including a PRIME pharmacist and a PRIME nutritionist. The PRIME personnel will use the chatgroup to disseminate any additional prediabetes-related information and motivational messages on a bi-weekly basis. They will also monitor the discussion and address any questions as they arise. In cases where misinformation and inappropriate behaviour arise, the PRIME personnel will discuss the issue to reach a consensus on the best course of action.

At each scheduled face-to-face visit, the community pharmacists will provide in-depth lifestyle counselling focusing on lifestyle changes in the areas of diet, exercise, sleep, and stress based on each participant's self-monitoring records as portrayed on the PRIME dashboard. The pharmacists will also work with the participants to set SMART (Specific, Measurable, Realistic, Achievable and Timely) goals during each visit, by choosing small changes that are thought achievable by the participants in their daily lives. For example, as the participants work towards the goal of achieving 10,000 step counts per day by the end of 6 months, they should inform their pharmacists their plans to increase their step count targets based on their current capabilities. Table 3 shows the different elements delivered in control and intervention group.

Control arm

Similar to the intervention arm, participants in the control arm will be provided with the PRIME app which will enable them to track their blood glucose, physical activities, weight and food. However, they will not have access to the in-app educational modules and peer support. They will be counselled on lifestyle changes based upon the participating pharmacy's usual practice, which typically includes simple advice on lifestyle changes.

Evaluation

Primary objective

The primary objective of this study is to evaluate the impact of the PRIME program on the clinical outcomes of the participants. The data collection forms for primary and secondary clinical outcome measures of the PRIME program can be found in Supplementary Materials Fig. S4. The clinical outcome measures are described below:

Primary clinical outcome

Changes in body weight

Evidence from studies have shown that modest weight loss is highly associated with a lower risk of developing diabetes.[36] The Finnish Diabetes Study found that a 5% weight loss was associated with a 70% reduction in diabetes incidence compared to those who did not achieve at least 5% weight loss.[8] Similarly, several consensus guidelines defined 5% weight reduction as clinically meaningful due to its association with better cardiovascular outcomes, including glycaemic control.[35, 37] Therefore, weight changes at 6-month is chosen as the primary outcome of the study, defined by 1) the percentage of participants achieving ≥5% reduction in body weight, and 2) differential change in weight loss between the intervention and control group.

Secondary clinical and non-clinical outcomes

Blood glucose parameters (HbA1c, fasting blood glucose (FBG)):

Among the three main blood glucose tests recommended by the ADA guidelines to define prediabetes, HbA1c and FBG are chosen as secondary clinical outcomes as it is not feasible to conduct oral-glucose tolerance test (OGTT) in a community pharmacy. An improvement in blood glucose parameters, including HbA1c and FBG have been shown diabetes prevention studies involving lifestyle interventions.[7, 8] Both HbA1c and FBG will be measured using point-of-care test devices which will be calibrated to ensure comparability. HbA1c tests will be tested every 3 months during participant visits at the pharmacy, while FBG will be monitored through participants' self-monitoring record using a glucometer.

Lipid profile and blood pressure:

The ADA guidelines recommend close monitoring of cardiovascular risks among adults with prediabetes who are overweight or obese,[38] as these individuals have increased cardiovascular risks including hypertension and dyslipidemia.[39] In addition, several lifestyle intervention studies reported improved cardiometabolic outcomes among people with prediabetes- post-intervention.[40] The participants' lipid profile will be monitored at baseline and 6-month. Blood pressure readings will be collected at baseline, 1-month, 3-month, and 6-month. To ensure consistency, all blood pressure measurements will be taken from the right arm with the midpoint of the cuff aligned with the heart level.[41] Three blood pressure recordings will be obtained from the participant in a sitting position after 3 minutes of silent rest, at 1-minute intervals, and then the mean value will be calculated for all three readings will be calculated.[41, 42] The pharmacist will remain silent in the room with participants during the blood pressure checks to monitor the procedure and ensure accuracy.

Adiposity measures (body mass index (BMI), waist circumference, waist-to-hip ratio, body composition):

Adiposity is closely associated with insulin resistance. Measures of obesity and central obesity such as body fat percentage, BMI, waist circumference and waist-to-hip ratio predict the risk of T2D.[43-45] Body composition, including body fat percentage, body water percentage, muscle mass index, visceral fat, and lean body weight will be measured using a bioelectrical impedance analysis machine (Novoplus Intellyz, Malaysia). Waist circumference will be measured with a soft tape on standing participants, mid-way between the lowest rib and iliac crest to the nearest 0.1 cm. Hip circumference will be measured over the widest part of the gluteal region, and the waist-to-hip ratio calculated.

Behaviour changes (diet, physical activities, sleep, illness perception, psychological outcomes):
To measure the impact of PRIME program towards lifestyle behaviour change, several questionnaires will be administered to the participants:
Alongside with the step counts data from the PRIME app, the International Physical Activity Questionnaire (IPAQ)[46] will be administered to participants at baseline, 1-month, 3-month and 6-month to gather information on their physical activities.
EuroQol-5 Dimension-5 Level (EQ-5D-5L)[47] questionnaires will be administered at baseline, 1-month, 3-month and 6-month to assess participants' health-related quality of life.
Hospital Anxiety and Depression Scores (HADS) [48] and Brief Illness Perception Scores (BIPQ)[49] will be administered at baseline, 3-month and 6-month to inform participants' psychosocial changes over the duration of PRIME program.
Pittsburgh Sleep Quality Index (PSQI)[50] will be administered at baseline, and 6-month to assess participants' sleep habits. The sleep data collected from their PRIME app will also be used to assess changes in sleep duration.
Multiple 24-hour dietary recall (three days) will be used to detect changes in dietary habits from participants at baseline and 6-month of the study.

Sustainability and durability of weight loss and lifestyle changes
Participants who have completed the PRIME program will be approached via text messages or phone call to complete an online follow-up questionnaire. Information on self-reported weight, current lifestyle habits, and PRIME app usage will be collected to determine the sustainability of the clinical outcomes achieved through the PRIME program.

Engagement with intervention
The level of participant engagement with the intervention will be measured based on attendance rate at pharmacy visits and interaction metrics from the PRIME mobile app. Data on app usage will be retrieved from the PRIME app, including frequency of blood glucose monitoring, food diary entries, sleep tracking and completion rates of education modules and quiz scores. In addition, the relationship between participant engagement levels and the primary outcome will be assessed. All results on engagement will be summarized descriptively.

Secondary objectives
Process evaluation
In line with the MRC framework, the process evaluation captures whether the PRIME program is delivered as designed, the changes produced by the PRIME program, and contextual factors that affect the implementation and outcomes of the study.[51]

Focus group discussions and individual qualitative interviews will be conducted with the participants and pharmacists of each study arm after the conclusion of the PRIME program. The focus groups and interviews will be held at times convenient to the participants and will last approximately one to one and a half hours. Each focus group session will consist of not more than eight consenting participants. A semi-structured topic guide using open-ended questions will be used to elicit participation. The topic guide will focus on three main areas: their experience participating in the PRIME program, using digital health tools for self-management and peer support, and utilizing community pharmacy service for prediabetes care. The moderator will facilitate the participants' answers, keeping the discussion on the topics under consideration, but will otherwise be non-directive, supportive, and non-evaluative. All interviews will be audiotaped for transcription and analysis.

Data analysis
This study analysis will be conducted using the intention-to-treat approach. All participants randomized into the study will be included into the analysis regardless of their compliance to the study protocol. In the event of missing data, multiple imputations will be used to generate 20 imputed datasets. To account for cluster effect, mixed effect modelling will be used to compare the changes in primary and secondary outcomes between both groups. Clusters (pharmacies) will be included as random effect and confounders will be controlled. The differential change between two groups, odd ratio, and proportion of participants losing ≥5% weight will be presented along with

corresponding 95% confidence intervals. In addition, sensitivity analyses will be conducted for the primary outcome using unadjusted per-protocol data, adjusted per-protocol data, and adjusted and imputed data. All baseline characteristics will be summarised using descriptive statistics.

Qualitative data from the focus group discussions and individual interviews will be analysed using content analysis techniques to determine the participants' perceptions, and contextual feasibility.

Confidentiality

The collected data will be de-identified and labeled with codes assigned by KWT. All participants' data will only be accessible to the research team members. The pharmacists at the participating community pharmacies will only be able to access information of the participants from their respective pharmacies. Only the study investigators will have the access to the final dataset.

Ethics and dissemination

This study has been registered with clinicaltrial.gov (NCT04832984) and approved by the Monash University Human Research Ethics Committee (MUHREC) (Project ID: 27512). Any substantial amendments to the protocol will be agreed upon by the research team members and submitted to MUHREC for approval.

Research findings will be published in peer-reviewed journals and shared through presentations in conferences and seminars. The publication will also be disseminated to the participating community pharmacies and to interested participants.

DISCUSSION

To our best knowledge, this pragmatic cluster RCT will be the first study to determine the impact of a community pharmacy-based, digital health-supported prediabetes lifestyle intervention program in Malaysia. While evidence suggests that community pharmacies may play a valuable role in provide preventing diabetes [52-55], data on the impact of community pharmacy-based diabetes prevention programs remains scarce and inconclusive.

Prediabetes management requires a multifaceted approach targeting physical, psychological and social factors that shape behaviour. Although digital health-supported lifestyle interventions have been shown to improve the health of people with prediabetes [16], face-to-face interactions and support from healthcare professionals and peers remain important to support the effectiveness of these interventions.[56, 57] Community pharmacies are frequently lauded for the high level of convenience and accessibility that they offer to the public.[55] The convenience and accessibility of community pharmacies allow for opportunistic screening of prediabetes among individuals especially the regular patrons, and enable routine monitoring and follow-up among those detected with prediabetes. The PRIME program brings together the benefits of using digital health technology, community pharmacy support, and peer support to implement a prediabetes management program in the real-world setting. The 6-month PRIME program follows a mixed-method approach by using both quantitative and qualitative methods, which will provide valuable information on the impact and acceptance of a community pharmacy-based prediabetes management program in Malaysia. Results of this study will provide insights that will help to further improve the effectiveness of the PRIME program, and ensure that delivery of the intervention is appropriate for culturally-diverse community.

There are some potential limitations in this study. Participants who are less technologically savvy may be less willing to participate in this study. This study will not specifically identify participants with impaired glucose tolerance, as administering OGTT is not feasible in a community pharmacy setting. Participants may also be non-adherent to the intervention during the follow-up period. To address this, the participants will be given reminders and ample opportunity to address any queries related to the mobile application and the intervention during their face-to-face visits at the pharmacy.

In summary, the rising prevalence of T2D necessitates the implementation of effective programs that promote the early detection and management of prediabetes. The PRIME program provides a solution that is convenient, readily available and easily accessible to the public.

DECLARATIONS

Competing interests

None.

Funding

This work was supported by the Monash University Malaysia Network for Equity through Digital Health (NEED) Grant (Project code: I-M010-MTC-000007). Funding for this trial covers the purchase of equipment and consumables needed in the study, hiring of a research assistant and fieldwork travel expenses only. The design, collection, management, analysis, data interpretation, and reporting of this protocol are conducted independently from the funding body.

Data availability

No datasets were analyzed as this article is a protocol of an ongoing study since the year 2022. Hence, data sharing is not applicable.

Contributorship

KWT: Conceptualization, methodology, investigation, ethical approval, writing- original draft, writing - review & editing, visualization and project administration, resources. SWHL: Conceptualization, methodology, writing - review & editing, resources, supervision. CMN: Conceptualization, writing - review & editing, supervision. CWC: Conceptualization, funding acquisition, writing - review & editing, supervision. YLN: Conceptualization, writing - review & editing, resources. JSB: Methodology, writing – reviews and edits, supervision. WLC: Methodology, writing - review & editing. All authors read and approved the final manuscript.

The guarantor of the study is SWHL; accepts full responsibility for the finished work and/or the conduct of the study, had access to the data, and controlled the decision to publish.

References:

1. International Diabetes Federation. IDF Diabetes Atlas. 10th ed2021.
2. ElSayed NA, Aleppo G, Aroda VR, et al. Classification and Diagnosis of Diabetes: Standards of Care in Diabetes—2023. *Diabetes Care*. 2022;46(Supplement_1):S19-S40. doi:10.2337/dc23-S002
3. Khan MAB, Hashim MJ, King JK, et al. Epidemiology of Type 2 Diabetes - Global Burden of Disease and Forecasted Trends. *J Epidemiol Glob Health*. 2020;10(1):107-11. doi:10.2991/jegh.k.191028.001
4. Xie J, Wang M, Long Z, et al. Global burden of type 2 diabetes in adolescents and young adults, 1990-2019: systematic analysis of the Global Burden of Disease Study 2019. *BMJ*. 2022;379:e072385. doi:10.1136/bmj-2022-072385
5. Tuso P. Prediabetes and lifestyle modification: time to prevent a preventable disease. *The Permanente journal*. 2014;18(3):88-93. doi:10.7812/TPP/14-002
6. Knowler WC, Fowler SE, Hamman RF, et al. 10-year follow-up of diabetes incidence and weight loss in the Diabetes Prevention Program Outcomes Study. *Lancet*. 2009;374(9702):1677-86. doi:10.1016/s0140-6736(09)61457-4
7. Knowler WC, Barrett-Connor E, Fowler SE, et al. Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. *The New England journal of medicine*. 2002;346(6):393-403. doi:10.1056/NEJMoa012512
8. Tuomilehto J, Lindström J, Eriksson JG, et al. Prevention of type 2 diabetes mellitus by changes in lifestyle among subjects with impaired glucose tolerance. *N Engl J Med*. 2001;344(18):1343-50. doi:10.1056/nejm200105033441801
9. Pan XR, Li GW, Hu YH, et al. Effects of diet and exercise in preventing NIDDM in people with impaired glucose tolerance. The Da Qing IGT and Diabetes Study. *Diabetes Care*. 1997;20(4):537-44. doi:10.2337/diacare.20.4.537
10. Echouffo-Tcheugui JB, Perreault L, Ji L, et al. Diagnosis and management of prediabetes: a review. *JAMA*. 2023;329(14):1206-16. doi:10.1001/jama.2023.4063
11. Glechner A, Keuchel L, Affengruber L, et al. Effects of lifestyle changes on adults with prediabetes: A systematic review and meta-analysis. *Primary Care Diabetes*. 2018;12(5):393-408. doi:10.1016/j.pcd.2018.07.003
12. Nuzhat BA, Rebecca Spong, Patrice Carter, et al. A systematic review and meta-analysis assessing the effectiveness of pragmatic lifestyle interventions for the prevention of type 2 diabetes mellitus in routine practice. 2015.
13. Gong Q, Zhang P, Wang J, et al. Morbidity and mortality after lifestyle intervention for people with impaired glucose tolerance: 30-year results of the Da Qing Diabetes Prevention Outcome Study. *Lancet Diabetes Endocrinol*. 2019;7(6):452-61. doi:10.1016/s2213-8587(19)30093-2
14. Block G, Azar KMJ, Romanelli RJ, et al. Diabetes prevention and weight loss with a fully automated behavioral intervention by email, web, and mobile phone: a randomized controlled trial among persons with prediabetes. *J Med Internet Res*. 2015;17(10):e240. doi:10.2196/jmir.4897
15. Shan R, Sarkar S, Martin SS. Digital health technology and mobile devices for the management of diabetes mellitus: state of the art. *Diabetologia*. 2019;62(6):877-87. doi:10.1007/s00125-019-4864-7
16. Cheong MWL, Chong CW, Gan SH, et al. Distal technologies for prediabetes: a systematic review and meta-analysis [preprint]. *JMIR Preprints*. 2021. doi:10.2196/preprints.28592
17. Institute for Public Health, National Institutes of Health. National Health and Morbidity Survey (NHMS) 2019: Non-Communicable Disease, Healthcare demand and Health Literacy. Malaysia: Institute of Public Health, National Institutes of Health, Ministry of Health; 2019.
18. Ng M, Fleming T, Robinson M, et al. Global, regional, and national prevalence of overweight and obesity in children and adults during 1980–2013: a systematic analysis for the Global Burden of Disease Study 2013. *The Lancet*. 2014;384(9945):766-81. doi:10.1016/S0140-6736(14)60460-8
19. Beh YS, Gopalsamy K, Lee SLF, et al. Impact of diabetes medication therapy adherence clinic (DMTAC) appointment intervals on glycemic control in public health clinics across Perak, Malaysia. *Malays Fam Physician*. 2022;17(3):105-13. doi:10.51866/oa134l
20. Lim PC, Lim K. Evaluation of a pharmacist-managed diabetes medication therapy adherence clinic. *Pharm Pract*. 2010;8(4):250-4. doi:10.4321/s1886-36552010000400008

21. Lee XY, Selvadurai S, Cheah KY, et al. Impact of pharmacist-managed diabetes medication therapy adherence clinic (DMTAC) in government health clinics. *Malay J Pharm Sci*. 2015;13(1):43-51.
22. Timpel P, Harst L, Reifegerste D, et al. What should governments be doing to prevent diabetes throughout the life course? *Diabetologia*. 2019;62:1842–53. doi:10.1007/s00125-019-4941-y
23. Shirdel A, Pourreza A, Daemi A, et al. Health-promoting services provided in pharmacies: a systematic review. *J Educ Health Promot*. 2021;10:234. doi:10.4103/jehp.jehp_1374_20
24. Centers for Disease Control and Prevention. Rx for national diabetes prevention program: action guide for community pharmacists. Atlanta, United States: Centers for Disease Control and Prevention, US Department of Health and Human Services; 2021.
25. Hamidi N, Tan YR, Jawahir S, et al. Determinants of community pharmacy utilisation among the adult population in Malaysia: findings from the National Health and Morbidity Survey 2019. *BMC Health Services Research*. 2021;21(1):649. doi:10.1186/s12913-021-06656-1
26. Tew MM, Hatah E, Arif F, et al. Geospatial analysis of distribution of community pharmacies and other health care facilities providing minor ailments services in Malaysia. *Journal of Pharmaceutical Policy and Practice*. 2021;14(1):24. doi:10.1186/s40545-021-00308-9
27. Whittemore R. A systematic review of the translational research on the Diabetes Prevention Program. *Translational behavioral medicine*. 2011;1(3):480-91. doi:10.1007/s13142-011-0062-y
28. Berg J, Dodd SA, Dodd S. The role of a community pharmacist in diabetes education : diabetes education. *Journal of Endocrinology, Metabolism and Diabetes in South Africa*. 2009;14(3):148-50. doi:10.10520/EJC64203
29. Chan AW, Tetzlaff JM, Altman DG, et al. SPIRIT 2013 statement: defining standard protocol items for clinical trials. *Ann Intern Med*. 2013;158(3):200-7. doi:10.7326/0003-4819-158-3-201302050-00583
30. Skivington K, Matthews L, Simpson SA, et al. A new framework for developing and evaluating complex interventions: update of Medical Research Council guidance. *BMJ*. 2021;374:n2061. doi:10.1136/bmj.n2061
31. Michie S, van Stralen MM, West R. The behaviour change wheel: a new method for characterising and designing behaviour change interventions. *Implementation science : IS*. 2011;6:42. doi:10.1186/1748-5908-6-42
32. Teoh KW, Ng CM, Chong CW, et al. Knowledge, attitude, and practice toward pre-diabetes among the public, patients with pre-diabetes and healthcare professionals: a systematic review. *BMJ Open Diabetes Research & Care*. 2023;11(1):e003203. doi:10.1136/bmjdrc-2022-003203
33. Katzmarzyk PT, Denstel KD, Martin CK, et al. Intraclass correlation coefficients for weight loss cluster randomized trials in primary care: The PROPEL trial. *Clinical Obesity*. 2022;12(4):e12524. doi:10.1111/cob.12524
34. Singh J. Randomization and online databases for clinical trials. *J Pharmacol Pharmacother*. 2014;5(2):173-4. doi:10.4103/0976-500x.130155
35. Malaysia Health Technology Assessment Section, Ministry of Health Malaysia. Management of obesity: Malaysia Health Technology Assessment Section, Ministry of Health Malaysia; 2023.
36. Hamman RF, Wing RR, Edelstein SL, et al. Effect of weight loss with lifestyle intervention on risk of diabetes. *Diabetes Care*. 2006;29(9):2102-7. doi:10.2337/dc06-0560
37. Yurista Salva R, Eder Robert A, Feeley M, et al. A closer look at ACC/AHA and ESC guidelines for managing obesity and overweight in adults. *JACC: Advances*. 2023;2(7):100570. doi:10.1016/j.jacadv.2023.100570
38. ElSayed NA, Aleppo G, Aroda VR, et al. Prevention or delay of type 2 diabetes and associated comorbidities: standards of care in diabetes—2023. *Diabetes Care*. 2022;46(Supplement_1):S41-S8. doi:10.2337/dc23-S003
39. Ali MK, Bullard KM, Saydah S, et al. Cardiovascular and renal burdens of prediabetes in the USA: analysis of data from serial cross-sectional surveys, 1988-2014. *Lancet Diabetes Endocrinol*. 2018;6(5):392-403. doi:10.1016/s2213-8587(18)30027-5
40. Nathan DM, Bennett PH, Crandall JP, et al. Does diabetes prevention translate into reduced long-term vascular complications of diabetes? *Diabetologia*. 2019;62(1432-0428 (Electronic)):1319-28. doi:10.1007/s00125-019-4928-8

41. Brady TM, Charleston J, Ishigami J, et al. Effects of different rest period durations prior to blood pressure measurement: The best rest trial. *Hypertension*. 2021;78(5):1511-9. doi:10.1161/HYPERTENSIONAHA.121.17496
42. Ministry of Health Malaysia, Malaysian Society of Hypertension, Academy of Medicine of Malaysia. Management of hypertension: Ministry of Health Malaysia; 2018.
43. Tulloch-Reid MK, Williams DE, Looker HC, et al. Do measures of body fat distribution provide information on the risk of type 2 diabetes in addition to measures of general obesity?: comparison of anthropometric predictors of type 2 diabetes in Pima Indians. *Diabetes Care*. 2003;26(9):2556-61. doi:10.2337/diacare.26.9.2556
44. Al Hommos NA, Ebenibo S, Edeoga C, et al. Trajectories of body weight and fat mass in relation to incident prediabetes in a biracial cohort of free-living adults. *J Endocr Soc*. 2021;5(2):bvaa164. doi:10.1210/jendso/bvaa164
45. Nayak VKR, Raghurama Nayak K, Vidyasagar S, et al. Body composition analysis, anthropometric indices and lipid profile markers as predictors for prediabetes. *PLoS One*. 2018;13(8):e0200775. doi:10.1371/journal.pone.0200775
46. Craig CL, Marshall AL, SjÖStrÖM M, et al. International Physical Activity Questionnaire: 12-Country Reliability and Validity. *Medicine & Science in Sports & Exercise*. 2003;35(8).
47. Herdman M, Gudex C, Lloyd A, et al. Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). *Qual Life Res*. 2011;20(10):1727-36. doi:10.1007/s11136-011-9903-x
48. Zigmond AS, Snaith RP. The Hospital Anxiety and Depression Scale. *Acta Psychiatr Scand*. 1983;67(6):361-70. doi:10.1111/j.1600-0447.1983.tb09716.x
49. Broadbent E, Petrie KJ, Main J, et al. The Brief Illness Perception Questionnaire. *Journal of Psychosomatic Research*. 2006;60(6):631-7. doi:https://doi.org/10.1016/j.jpsychores.2005.10.020
50. Buysse DJ, Reynolds CF, Monk TH, et al. The Pittsburgh sleep quality index: A new instrument for psychiatric practice and research. *Psychiatry Research*. 1989;28(2):193-213. doi:https://doi.org/10.1016/0165-1781(89)90047-4
51. Moore GF, Audrey S, Barker M, et al. Process evaluation of complex interventions: Medical Research Council guidance. *BMJ : British Medical Journal*. 2015;350:h1258. doi:10.1136/bmj.h1258
52. Roszak SE, Ferreri SP. Community pharmacy engagement in diabetes prevention: key informant interviews with pharmacy executives. *Prev Chronic Dis*. 2020;17:E90. doi:10.5888/pcd17.200050
53. Katangwe T, Family H, Sokhi J, et al. The community pharmacy setting for diabetes prevention: views and perceptions of stakeholders. *PLoS One*. 2019;14(7):e0219686. doi:10.1371/journal.pone.0219686
54. Franch-Nadal J, Fornos JA, Melogno Klinkas M, et al. Management of prediabetes from the perspective of Spanish physicians and community pharmacists: Detecta2 study. *Endocrinol Diabetes Nutr (Engl Ed)*. 2021. doi:10.1016/j.endinu.2020.12.007
55. Katangwe T, Family H, Sokhi J, et al. The community pharmacy setting for diabetes prevention: a mixed methods study in people with 'pre-diabetes'. *Research in Social and Administrative Pharmacy*. 2020;16(8):1067-80. doi:10.1016/j.sapharm.2019.11.001
56. Lakka TA, Aittola K, Järvelä-Reijonen E, et al. Real-world effectiveness of digital and group-based lifestyle interventions as compared with usual care to reduce type 2 diabetes risk – a stop diabetes pragmatic randomised trial. *The Lancet Regional Health - Europe*. 2023;24:100527. doi:10.1016/j.lanepe.2022.100527
57. Samarasinghe SNS, Miras AD. Type 2 diabetes prevention goes digital. *The Lancet Regional Health - Europe*. 2023;24:100538. doi:10.1016/j.lanepe.2022.100538

Table 1: Examples of how PRIME components are applied as each intervention functions based on the BCW.

Intervention functions based on BCW	PRIME component	Examples
Education	• Face-to-face in-depth prediabetes management counselling provided by community pharmacists • Education modules from PRIME app	• Counselling sessions focus on lifestyle changes in the areas of diet, exercise, sleep, and stress; feedback based on health progress reviews • Module contents include topics on prediabetes pathophysiology and its complications, healthy food, physical activities, sleep, smoke and stress management
Training	• Face-to-face in-depth prediabetes management counselling provided by community pharmacists • Education modules from PRIME app	• Counselling sessions focus on lifestyle changes in the areas of diet, exercise, sleep, and stress; feedback based on health progress reviews • Practical tips on developing a healthier lifestyle given in the education modules, such as reading nutritional labels and choosing healthier food choices
Enablement	• Food diary, blood glucose, weight and physical activity trackers from PRIME app • Peer support chatgroups	• Tracking of calories intake and their daily calories allowance via the food diary. Participants are given a wearable activity tracker and a glucometer that can be linked to PRIME app for self-monitoring • Participants are able to share best practices, motivations and their experiences in lifestyle modifications here. The researcher will also be sharing prediabetes health information and motivational messages in the chatgroups
Persuasion	• Infographics, quizzes and videos in PRIME app	• Designed to stimulate positive and negative feelings among participants and to stimulate behavioural actions. For example, photos of delicious healthy meals with vivid colours are displayed

Table 2: Inclusion and exclusion criteria of PRIME program.

Inclusion criteria	Exclusion Criteria

• Age 18 years or older
• Overweight or obese, defined by BMI ≥ 23[35]
• Found to have prediabetes, defined by:
  ○ HbA1c of 5.7% - 6.4%
  OR
  ○ FBG of 5.6mmol/L – 6.9mmol/L
	• Unable to give informed consent due to lack of capacity
	• Previously diagnosed with Type-1 or Type-2 diabetes mellitus
	• Taking any antidiabetic medications
	• Taking medications that may affect glucose tolerance (e.g. antipsychotics or high dose steroids)
	• Pregnant or intention to get pregnant
	• Advised by their doctors on health grounds that participant should not take part

***BMI: body mass index; HbA1c: haemoglobin A1c; FBG: fasting blood glucose.**

Table 3: Difference between control and intervention group.

PRIME features	Control group	Intervention group
Blood glucose tracker	/	/
Physical activity tracker	/	/
Weight tracker	/	/
Food diary	/	/
Education modules	X	/
Peer support chatgroup	X	/
Pharmacist counselling	As per pharmacists' usual practise	In-depth lifestyle change counselling and feedback based on health progress review

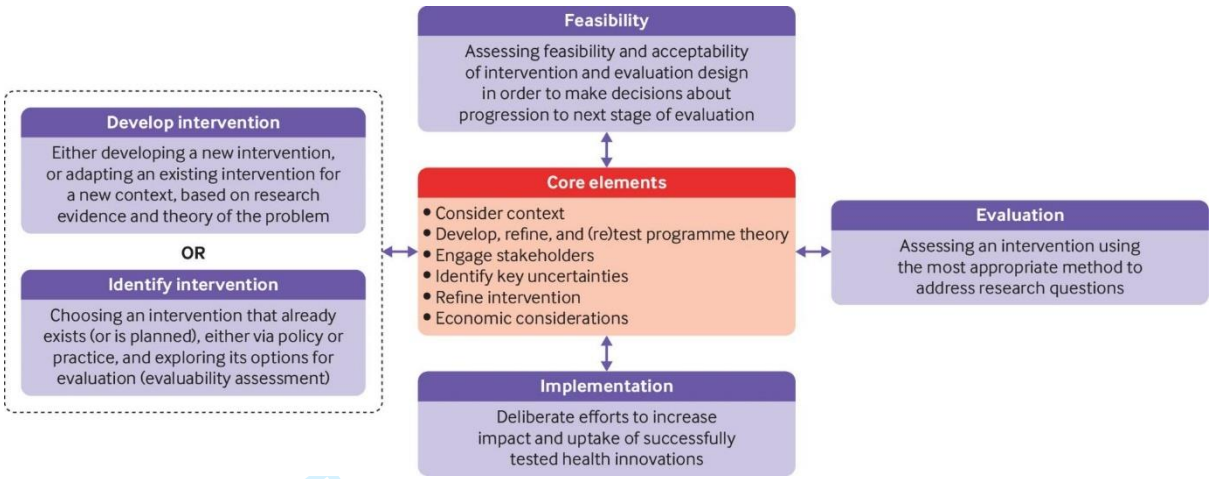


Fig. 1 Framework for developing and evaluating complex interventions reproduced with permission from Skivington et al [29]

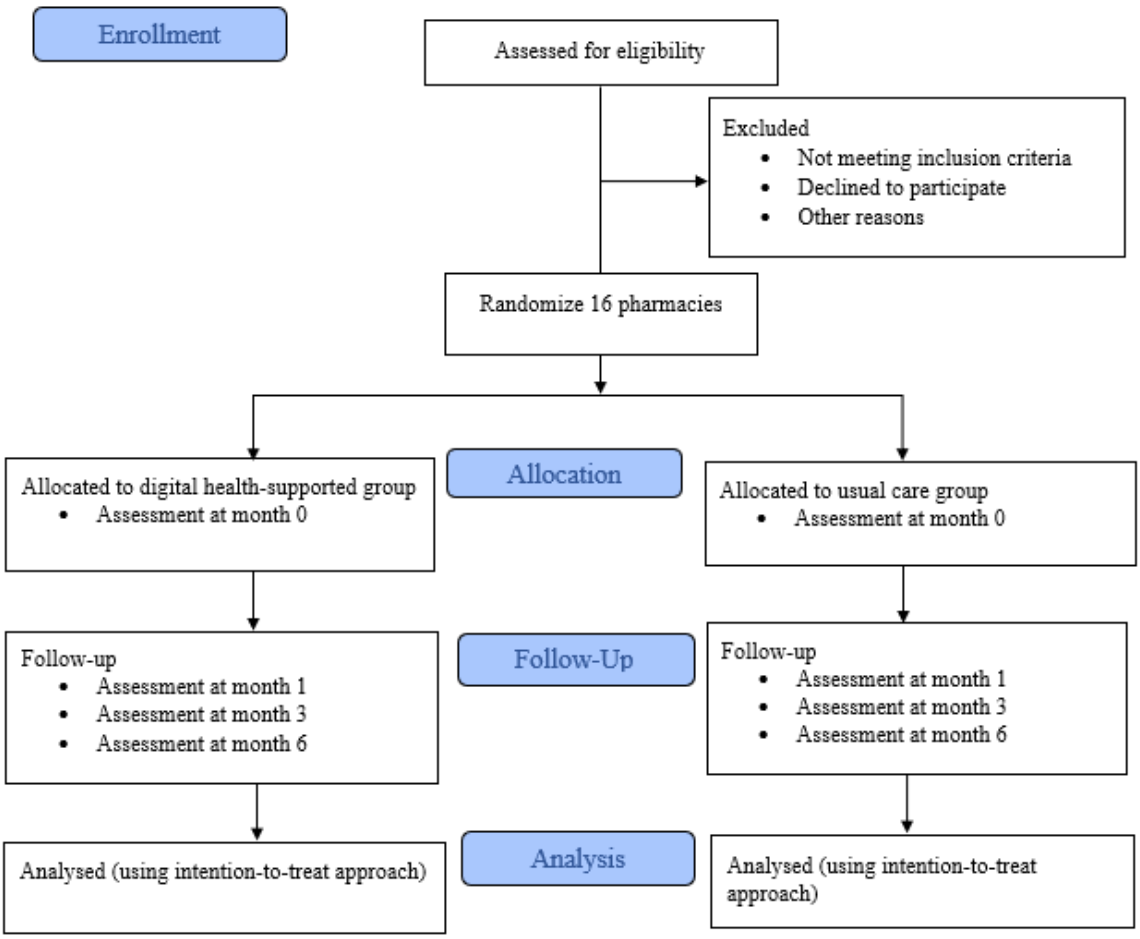


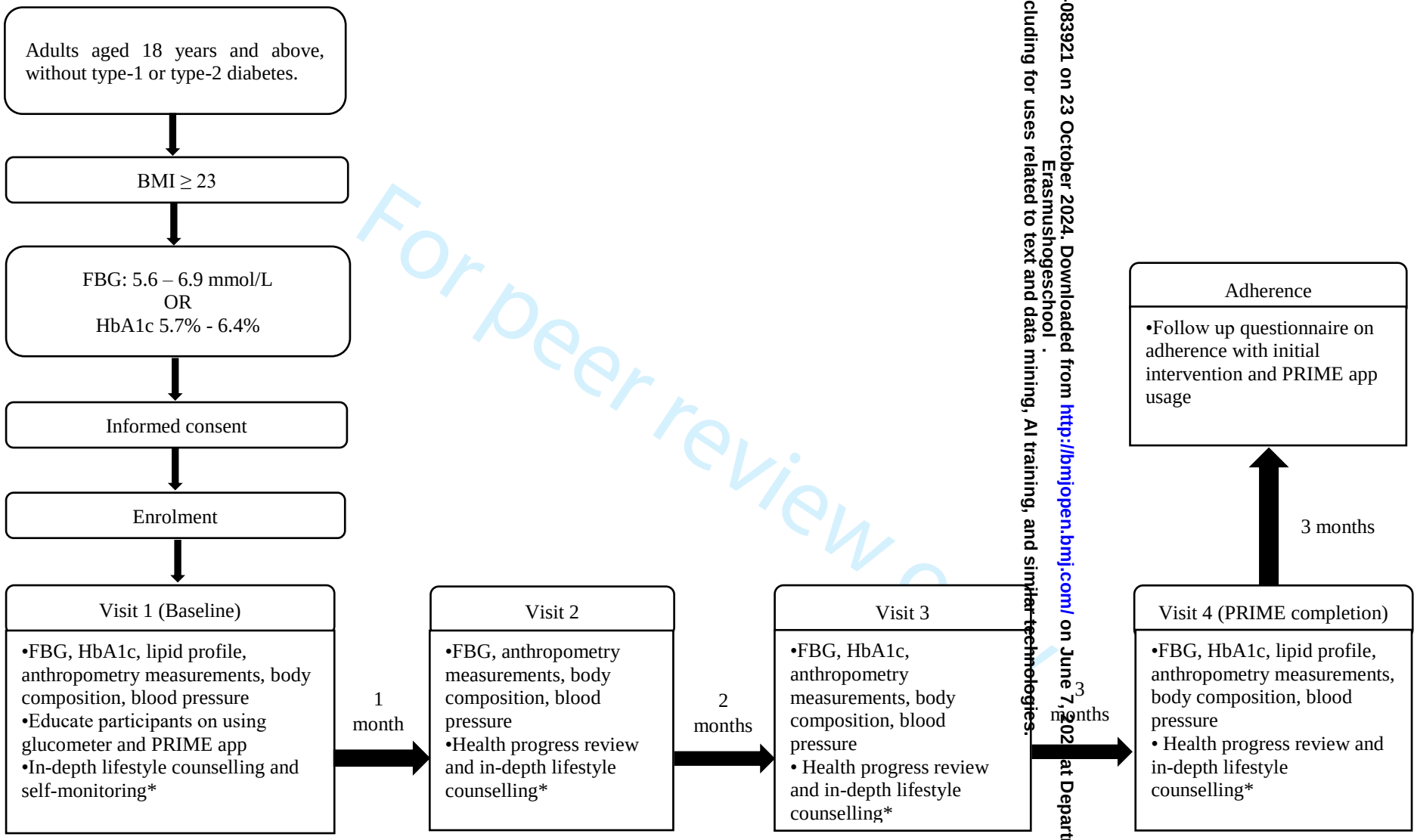
Fig. 2 Flowchart of PRIME study

	STUDY PERIOD						
	Enrolment	**Allocation**	**Post-allocation**			**Final Assessment**	**Adherence**
TIMEPOINT**	$-t_1$	**0**	t_1	t_2	t_3	t_4	t_5
ENROLMENT:							
Eligibility screen	X						
Provide explanatory statement	X						
Informed consent	X						
Allocation		X					
INTERVENTIONS:							
Digital health-supported group			←	—	—	→	
Usual care			←	—	—	→	
ASSESSMENTS:							
Weight	X		X	X	X	X	X (self-reported)
BMI	X		X	X	X	X	
FBG	X		X	X	X	X	
HbA1c	X		X		X	X	
Lipid profile (TC, TG, LDL, HDL)			X			X	
Body composition			X	X	X	X	
Waist and hip circumferences			X	X	X	X	
Blood pressure			X	X	X	X	
Multiple 24-hour dietary recall (three days)			X			X	
QUESTIONNAIRES:							
Follow-up questionnaire on app usage and lifestyle changes							X
IPAQ			X	X	X	X	

EQ-5D-5L			X	X	X	X	
HADS			X		X	X	
BIPQ			X		X	X	
PSQI			X			X	

t_1: Baseline; t_2:1-month visit; t_3: 3-month visit; t_4: 6-month follow up visit, t_5: 9-month follow up questionnaire. BMI: body mass index; FBG: fasting blood glucose; HbA1c: glycated haemoglobin A1c; TC: total cholesterol, TG: triglycerides; LDL: low-density lipoprotein; HDL: high-density lipoprotein; IPAQ: International Physical Activity Questionnaire**;** HADS**:** The Hospital Anxiety and Depression Score, BIPQ: The Brief Illness Perception Questionnaire; PSQI: Pittsburgh Sleep Quality Index**.**

Fig. 3 Schedule of enrolment, interventions and assessments for PRIME Program



BMI: body mass index, FBG: fasting blood glucose, HbA1c: glycated haemoglobin A1c.

*****For participants in the intervention group only. Those in the control group may receive advise as per pharmacist's usual practice, which typically includes simple advice on lifestyle changes.

Fig. 4 Flowchart of PRIME screening, recruitment and follow-up

Supplementary Materials

Table of content:

Fig. S1 Items: for Trials

Standard Protocol Recommendations Interventional (SPIRIT) checklist

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Location where item is reported
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	Title; page 1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	Methods subsection 'study design and setting'; page 5
	2b	All items from the World Health Organization Trial Registration Data Set	Methods subsection 'study design and setting'; page 5
Protocol version	3	Date and version identifier	NA
Funding	4	Sources and types of financial, material, and other supp ort	Declarations; page 10
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	Title page and author contribution; page 1 & 10
	5b	Name and contact information for the trial sponsor	NA

	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	Funding; page 10
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	NA
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	Introduction paragraph 1-4; page 3
	6b	Explanation for choice of comparators	Introduction paragraph 3-4; page 3
Objectives	7	Specific objectives or hypotheses	Objectives; page 3 & 4
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	Methods; subsection 'study design and setting'; page 5
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	Methods; subsection 'study design and setting'; page 5
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	Methods; Table 1, paragraphs 2 and 3 of subsection 'intervention arm'; page 6

Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	Methods; subsection 'intervention arm'; page 6
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	Methods; subsection 'recruitment strategies'; page 5
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	Methods; paragraph 3 of subsection 'intervention arm' and Discussion; paragraph 3; page 6 & 9
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	NA
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	Methods; subsection 'evaluation'; page 7 & 8
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Fig.)	Fig. 3
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	Methods; subsection 'sample size calculation'; page 5
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	Methods; subsection 'recruitment strategies'; page 5

Methods: Assignment of interventions (for controlled trials)

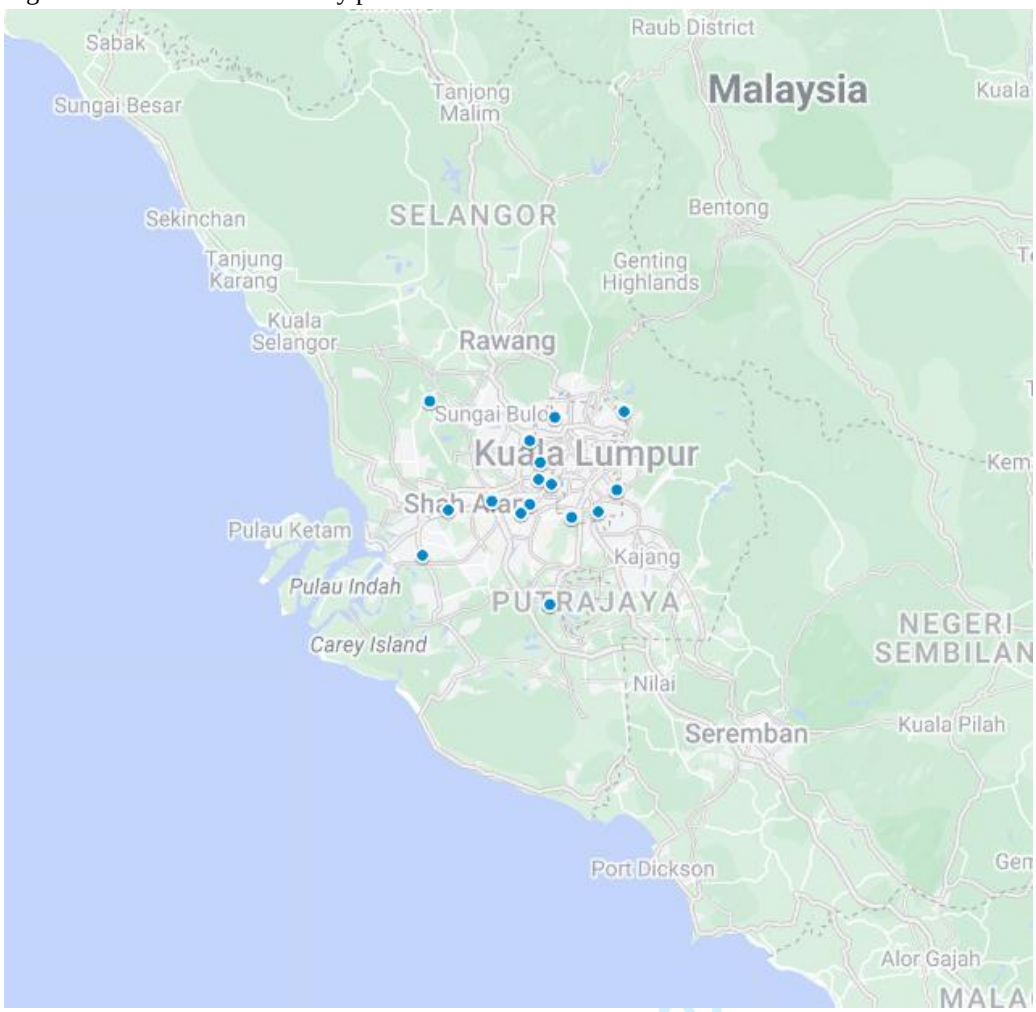
Allocation:

Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	Methods; subsection 'randomization and blinding'; page 5
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	Methods; subsection 'randomization and blinding'; page 5
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	Methods; subsection 'randomization and blinding'; page 5
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	Methods; subsection 'randomization and blinding'; page 5
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	Methods; subsection 'randomization and blinding'; page 5
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	Methods; subsection 'Evaluation-Primary Objective'; page 7
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	Discussion; paragraph 3; page 9
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	Methods; subsection 'confidentiality'; page 9

Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	Methods; subsection 'data analysis'; page 8 & 9
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	Methods; subsection 'data analysis'; page 8 & 9
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	Methods; subsection 'data analysis'; page 8 & 9
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	NA
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	NA
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	NA
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	NA
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	Ethics and dissemination; page 2
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	Ethics and dissemination; page 2

Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	Methods; subsection 'recruitment strategy'; page 5
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	NA
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	Methods; 'confidentiality '; page 9
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	Competing interests; page 10
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	Methods; subsection 'confidentiality '; page 9
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	NA
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	Ethics and dissemination; page 2
	31b	Authorship eligibility guidelines and any intended use of professional writers	NA
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	NA
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Supplementary material Fig. S5 and S6
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	NA

Fig. S2 Locations of community pharmacies



Community pharmacies within Kuala Lumpur:

- CARiNG Pharmacy, Lakefield, Sungai Besi
- CARiNG Pharmacy Kepong Baru, Kuala Lumpur
- CARiNG Pharmacy EkoCheras Mall, Cheras
- CARiNG Pharmacy Pavilion, Bukit Jalil
- CARiNG Pharmacy Taman Melawati, Kuala Lumpur

Community pharmacies within Selangor:

- CARiNG Pharmacy Central i-City, Shah Alam
- CARiNG Pharmacy Aeon Mall Shah Alam, Shah Alam
- CARiNG Pharmacy Damen USJ, Subang Jaya, Petaling Jaya
- CARiNG Pharmacy Sunway Pyramid, Subang Jaya, Petaling Jaya
- CARiNG Pharmacy Jalan Barat, Petaling Jaya
- CARiNG Pharmacy Eco Grandeur, Puncak Alam
- CARiNG Pharmacy The Starling Mall, Damansara Uptown, Petaling Jaya
- CARiNG Pharmacy Seapark, Petaling Jaya
- CARiNG Pharmacy Damansara Perdana, Petaling Jaya
- CARiNG Pharmacy Tamarind Square, Cyberjaya
- CARiNG Pharmacy AEON Bukit Tinggi, Klang

Fig. S3 List of topics included in PRIME education modules

Module 1: What is Prediabetes?

Module 2: Nutrition

Module 3: Physical Activity

Module 4: Sugar

Module 5: Ways to Get Active

Module 6: Starchy Food

Module 7: Glycaemic Index

Module 8: No More Excuses!

Module 9: Fiber

Module 10: Sodium & Salt

Module 12: Food Label

Module 13: Wrapping Up: Meal Examples

Module 14: Alcohol, Smoking, Stress & Sleep

Fig. S4 Data collection forms

Patient's details

Name:	
Date of birth:	
Age:	
Contact number:	
Sex:	☐ Male ☐ Female
Ethnicity:	☐ Malay ☐ Chinese ☐ Indian ☐ Others: _____
Education Status:	☐ Primary ☐ Secondary ☐ Tertiary
Employment Status:	☐ Employed ☐ Unemployed ☐ Retired
Marital Status:	☐ Single ☐ Married ☐ Divorced ☐ Widowed
Household income:	☐ Below RM 4850 ☐ Rm 4850 to RM 10,959 ☐ RM 10,960 and above
Study subject ID number:	
Family history of diabetes:	YES / NO (If yes, who: _____)

Blood investigations

Parameters	**Values**				
Full lipid profile	**Baseline**		**6m**		**12m**
Date:					
Total cholesterol (mmol/L) (<5.2)					
Triglycerides (mmol/L) (<1.7)					
HDL (mmol/L) (>1.5)					
LDL (mmol/L) (<2.6 at risk CAD, < 3.3)					
Non-HDL					
HDL/LDL ratio					
Chol/ HDL ratio					
Blood glucose profile	**Baseline**	**3m**	**6m**	**9m**	**12m**
Dates					
Fasting blood glucose (mmol/L)					
HbA1c (%)					

Anthropometric measurements

Parameters	**Values**					
Visits	**Baseline**	**1m**	**3m**	**6m**	**9m**	**12m**
Dates						
Height (cm)						
Weight (kg)						
Waist circumference (cm)						
Hip circumference (cm)						

Body fat composition

Parameters	**Values**					
Visits	**Baseline**	**1m**	**3m**	**6m**	**9m**	**12m**
Dates						
BMI (kg/m^2)						
Body fat (%)						
Water (%)						
Muscle (%)						
Bone (kg)						
BMR (kcal)						
Visceral fat						
Protein (%)						
Obesity degree (%)						
Body age						
Lean body weight (%)						

Other measurements

Blood pressure and pulse rate (3 readings)						
Visits	**Baseline**	**1m**	**3m**	**6m**	**9m**	**12m**
Dates						
Reading 1						
Reading 2						
Reading 3						
Average BP reading						
Medical history (underlying diseases) – **to update during every visit** *Eg. Eczema, hypertension, dyslipidaemia*						
Medication history (drug GENERIC name, dosage form, dose and frequency) – **to update during every visit** Eg. *T. Atorvastatin 40mg ON*						
Supplements or complementary medicines (including herbal medicine) *(supplement name, dosage form, dose and frequency)* – **to update during every visit** *Eg. T. Vitamin C 1000mg OD*						

Fig. S5 Explanatory statement

EXPLANATORY STATEMENT

Adults at Risk of Pre-Diabetes

Project ID: 27512

Project Title: Addressing disparity in diabetes prevention through Digital health supported PRe-diabetes Intervention, Management and Evaluation (PRIME) program based in Malaysian community pharmacies

You are invited to take part in this study. Please read this Explanatory Statement in full before deciding whether or not to participate in this research. If you would like further information regarding any aspect of this project, you are encouraged to contact the researchers via the phone numbers or email addresses listed above.

Chief Investigator:

Dr Chong Chun Wie
School of Pharmacy
Phone: +60 3 5514 6188
email: Chong.ChunWie@monash.edu

PhD Researcher:

Teoh Kah Woon

School of Pharmacy, Monash University Malaysia

Email: kah.teoh@monash.edu

What does the research involve?
The aim of the study is to evaluate the effectiveness of a digital health supported prediabetes intervention program delivered through community pharmacies in improving the glycaemic markers and other related measurements. The program will provide you with educational information/instructions regarding healthy diet, healthy lifestyle and exercise for you. Your progress will be monitored with check-in sessions to motivate you to follow the instructions throughout the study period of 6 months.

A fitness tracker (MiBand6) will be given to you to monitor your diet, physical activities and sleep qualities. You will also be given a glucometer to track and monitor your fasting blood sugar levels from home.

You will be asked to fill in a series of questionnaires that will take approximately 40 minutes of your time. These questionnaires will be administered to you at 4 time-point: before the start of the study, 1 month, 3 months, and 6 months. These questionnaires include:

- 3-day diet recall: to assess your dietary patterns
- EQ-5D-5L: to assess your quality of life
- The Hospital Anxiety and Depression Score: to assess any depression and anxiety relating to the diagnosis of condition and the care provided to you thereafter
- The Brief Illness Perception Questionnaire: to assess your thoughts and emotions towards prediabetes
- Internation Physical Activity Questionnaire
- Pittsburg Sleep Quality Index: to assess your sleeping patterns

You will also be undergoing some physical assessments. Your blood sugar levels (fasting blood glucose, random blood sugar, HbA1c) and full lipid profile (total cholesterol, LDL-cholesterol, HDL-cholesterol, triglycerides) will be taken via a finger prick test, which may cause minimal discomfort. Additionally, your body mass index (BMI) (height and weight), body fat compositions, waist and hip circumference will also be measured. These physical assessments will be done in Caring Pharmacy at four time-point: before the start of study and 1 month, 3 months and 6 months.

Why were you chosen for this research?

You were chosen to be screened for eligibility for the study as a customer/patient visiting the pharmacy. If you are a Malaysian adult with prediabetes and a BMI of 23 or above, you will be invited to participate in this program.

Source of funding

Monash University's Network for Equity through Digital Health (NEED) Grant. No conflict of interest of researchers.

Consenting to participate in the project and withdrawing from the research

You will be asked to sign a consent form if you agree to take part in this research project specified above. Participant has the right to withdraw from further participation at any stage, along with any implications of withdrawal by informing the investigator. The data collected from this project will not be possible to be withdrawn once they have been submitted to the investigator.

Possible benefits and risks to participants

The findings from this research helps to evaluate the effectiveness of a digital health supported prediabetes intervention program. The findings help to provide evidence to support the use of the program, if it is shown to be effective. There is no obvious risk foreseen in this project.

Payment

There is no payment reimbursement for this project. However, participants who completed this research study will receive a MiBand6 and a glucometer used for this study.

Confidentiality

The collected data will be de-identified without participant-identifiable information before being used in a research report and may be published in a conference or journal article. The results accessible to public will be anonymous and de-identified.

Storage of data

The data will be stored in a network storage and only the investigators have access to the data. The data may be kept for an infinite period or may be destroyed if necessary.

Use of data for other purposes

The findings of this research may be used for future study. Only anonymous data will be used where ethics approval has been granted.

Results

The results of this research will be used in a research report and may be published in a conference or journal article. Participants may request for the aggregate results to investigators.

Complaints

Should you have any concerns or complaints about the conduct of the project, you are welcome to contact the Executive Officer, Monash University Human Research Ethics Committee (MUHREC):

Associate Professor Poh Phaik Eong
Director, Research Excellence
Monash University Malaysia
Jalan Lagoon Selatan
46150 Bandar Sunway
Selangor Darul Ehsan, Malaysia
Tel: +603 5514 6272 Email: poh.phaik.eong@monash.edu

Thank you.

Fig. S6 Consent form

CONSENT FORM

Adults at Risk of Pre-Diabetes

Project ID: 27512
Project title: Addressing disparity in diabetes prevention through Digital health supported PRe-diabetes Intervention, Management and Evaluation (PRIME) program based in Malaysian community pharmacies

Chief Investigator:

Dr Chong Chun Wie
School of Pharmacy
Phone: +60 3 5514 6188
Email: Chong.ChunWie@monash.edu

I have been asked to take part in the Monash University research project specified above. I have read and understood the Explanatory Statement and I hereby consent to participate in this project.

I consent to the following:	Yes	No
• Taking part in this research study which will last for 6 months.	☐	☐
Getting my physical activities and sleep qualities measured for 6 months using the fitness tracker (MiBand6) given to me.	☐	☐
Getting my blood sample (for blood sugar and full lipid profile), body mass index (height and weight) measured in Caring Pharmacy and filling up questionnaires at 4 time-points: before the start of study, 1 month, 3 months, and 6 months.	☐	☐
The anonymous and de-identified data that I provide during this research may be used by the research team in future research projects.	☐	☐

Name of Participant _____

Participant Signature _____ Date _____