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Diabetes prevention through digital therapy for high-risk individuals: Study protocol for the Malaysia Diabetes Prevention Programme (MyDiPP)

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ABSTRACT

Introduction: Intervention approaches that integrate human coaching into technology are considered as a convenient, accessible and scalable method to reach a larger population at risk. The objective of this paper is to present the protocol for a randomised controlled trial that evaluates the efficacy of a lifestyle intervention programme via a mobile phone app (MyDiPP), which aims to prevent diabetes among adults at risk of developing diabetes. **Methods:** MyDiPP intervention is to be delivered for 12 months with multiple approaches (weight loss, dietary modification, physical activity, and quality of life). Eligible adults aged 18-65 years, overweight/obese (body mass index, BMI ≥ 23kg/m^2), and at high risk of type 2 diabetes [American Diabetes Association (ADA) Diabetes Risk Score ≥5, or haemoglobin A1c (HbA1c) of 5.6-6.2%], will be randomly assigned to one of two study groups (intervention or usual care control groups) in a 1:1 ratio using simple randomisation. **Results:** Changes in weight and HbA1c level (primary outcomes), and changes in physical activity level, dietary intake, and quality of life (secondary outcomes) will be assessed at 6 and 12 months. **Conclusion:** This study protocol describes the first digital therapy for diabetes prevention in Malaysia, which will determine whether the effect of this intervention is larger than the effect of usual care in reducing body weight and HbA1c level, and improving dietary intake, physical activity, and quality of life of high-risk individuals. Results from this trial may be useful for preventing type 2 diabetes mellitus in Malaysia.

Keywords: lifestyle intervention, prediabetes, protocol, randomised controlled trial, T2DM

INTRODUCTION

In 2017, diabetes affected 8.4% of the world's population, or 451 million adults aged 18-99 years, and it is growing rapidly in low- and middle-income countries. The prevalence of diabetes is expected to rise to 693 million by 2045, representing 9.9% of the same population (Cho *et al.* 2018). In Malaysia, according to the National

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Health and Morbidity Survey (NHMS) 2019, 18.3% or 3.6 million Malaysians have diabetes, the highest incidence rate in Asia and one of the highest in the world (IPH, 2020). Individuals who have blood glucose higher than normal level, but not as high to be classified as diabetes, are regarded as having pre-diabetes. A person diagnosed with pre-diabetes has a higher risk of developing diabetes. Worldwide, over 260 million or 6.4% adults have pre-diabetes (IDF, 2011). A recent study conducted in Terengganu reported that the prevalence of pre-diabetes in Kuala Terengganu is double (7.6%) (Wan Nur Atirah & Wafa, 2020) that reported by NHMS in 2015 (3.5%) (IPH, 2015). Being overweight is one of the factors that is associated with a higher probability of both diabetes and pre-diabetes. In Malaysia, the prevalence of overweight and obesity among adults aged 18 years and above had increased from 30% in 2015 to 30.4% in 2019, and from 17.7% in 2015 to 19.7% in 2019, respectively (IPH, 2020; IPH, 2015).

A study has shown that approximately 37% of individuals with pre-diabetes will have diabetes in four years if they do not change their lifestyle through any intervention (Knowler *et al.*, 2002). Lifestyle modification intervention such as the Diabetes Prevention Programme (DPP) has been shown to be effective in reducing or delaying the onset of type 2 diabetes mellitus (T2DM) among high-risk individuals by 58% over a long-term period (Knowler *et al.*, 2002). Furthermore, a 10-year DPP study reduced the prevalence of T2DM by 34% (Knowler *et al.*, 2009). Similarly, the English National Health Service Diabetes Prevention Programme also reported a favourable impact in reducing body weight (3.3 kg) and haemoglobin A1c (HbA1c) level (2.04 mmol/mol) of subjects who had non-diabetic hyperglycaemia (Valabhji *et al.*, 2020). DPP is the first large-scale trial to demonstrate the efficacy of intensive behavioural counselling in reducing weight and risk of diabetes that involves in-person and group meetings in a research setting. Since then, many translations of the DPP have been further developed in order to provide approaches that can be used widely, including a community setting that involves group face-to-face sessions (Katula *et al.*, 2011).

However, such programmes also have several barriers such as lack of professional staffs, institutional resources, substantial costs incurred, participants' reluctance to allocate their time to attend a series of in-person meetings, as well as transportation, distance, and childcare issues (Venditti *et al.*, 2014). To overcome these problems, an intervention approach known as digital therapy has integrated human coaching with the use of technology such as website, email, or short message service (SMS) to enable a wider reach (Castro *et al.*, 2017). It is considered as a convenient, accessible and scalable method that can reach a larger population at risk (Sepah *et al.*, 2017).

The purpose of this article is to present the Malaysia Diabetes Prevention Programme (MyDiPP) study protocol. The objective of the MyDiPP randomised controlled trial (RCT) is to implement and evaluate the efficacy of lifestyle intervention programme to prevent T2DM among adults who are at risk of developing diabetes via a mobile phone app. The study is an assessor-blinded, parallel-group RCT for overweight/obese adults who are at high risk of having T2DM. The eligible participants will be randomised in a 1:1 ratio to either undergo a 12-month MyDiPP intervention or receive standard health education from primary care providers at a university clinic. The design conduct and reporting will adhere to the consolidated standards of reporting trials (CONSORT) guidelines. We used the SPIRIT checklist when writing our report (Chan *et al.*, 2013).

MATERIALS AND METHODS

Study setting

The trial will be carried out in the district of Kuala Terengganu, in the state of Terengganu, Malaysia. This location was selected due to continuous urbanisation, improved socioeconomic status, and adoption of more sedentary lifestyle and unhealthy dietary habits, where obesity might develop. In addition, Terengganu has a prevalence of diabetes (10.5%) that is higher compared to the national prevalence (9.4%), as well as the highest prevalence of diabetes compared to the other East Coast states - Kelantan (9.7%) and Pahang (9.5%) (IPH, 2020). According to NHMS 2015, diabetes and obesity have a moderate prevalence in the East Coast states (IPH, 2015).

Eligibility criteria

Participants are deemed eligible if they: (1) are 18-65 years old who live, work, or study in Kuala Terengganu, Terengganu, Malaysia with a body mass index (BMI) of ≥23 kg/m^2; (2) have a high risk for diabetes [diabetes risk test score ≥5 (Lindström & Tuomilehto, 2003) or HbA1c of 38-44 mmol/mol or 5.6-6.2%]; (3) own a smartphone (only Android); (4) are fluent in the Malay or English language; and (5) are willing to participate in the weight management programme or physical activities. BMI ≥23 kg/m^2 was chosen, as it is the World Health Organization (WHO) BMI cut-off for the Asian and Pacific populations.

The exclusion criteria include: (1) those with a clinical history of diabetes or newly diagnosed with diabetes at the time of screening, with their HbA1c level ≥45 mmol/mol or ≥6.3%; (2) those taking oral anti-diabetic agents; (3) those participating in other weight management programmes or interventional research; (4) those on a prescribed medical diet or anti-obesity or diabetes therapy in the past four months; (5) those who had a clinical history of cardiovascular diseases in the past six months; (6) those who used to undergo any treatments for cancer, dementia or probable Alzheimer's disease, advanced arthritis; (7) those who are pregnant, had given birth in the recent six weeks, or are planning to become pregnant in the next twelve months; or (8) those with liver and renal diseases or hyperthyroidism, or other causes that can interfere with their participation (for being physically disabled or have any mental health conditions that include eating disorder or alcohol/substance abuse).

Development of the Malaysia Diabetes Prevention Program (MyDiPP) mobile app

The development of the MyDiPP mobile app was outsourced to Trivotec Technology, which is a website and software/app development company based in Kota Bharu, Kelantan, Malaysia. The MyDiPP mobile app has the following components:

a. Backend (server) and database

The backend was developed using a Javascript-based stack based on NodeJS. As opposed to more traditional technologies, Javascript is newer, and one that is growing quickly on the server-side. It was selected because of its stellar performance and better scalability.

b. Admin area and website (web client)

The admin area has a simple user interface and functionality, and is implemented using a template based on Bootstrap 4.0. Both the website and the admin area can run on all current major browsers: Chrome, Firefox, Safari, and Internet Explorer.

c. Mobile app

The Android mobile client application can run on all phones with Android 5.0 or newer that includes Google services. It was developed using the native development tools provided by Google. The app runs in portrait mode and has

a common layout, as well as look-and-feel across all form factors (phones and tablets).

During the development, there were two important milestones: alpha milestone and beta milestone. For the alpha milestone, around 40-60% of the features were working; for the beta milestone, 100% of the features were working, but with chances of bugs. After the beta milestone, the app went through a quality assurance testing and identified bugs were fixed. After fixing these bugs, the app went through a pilot testing among target users to evaluate its usability. After the pilot test, the app is now ready to be used by participants during the intervention programme.

Interventions

The intervention group will access the MyDiPP app that consists of educational lessons, health coaches, peer group, and technology-enabled tools to track their nutritional intake, physical activities, body weight, as well as HbA1c level. The educational lessons have been adopted from publicly available materials from the United States Diabetes Prevention Programme (US DPP) of Centre for Disease Control and Prevention (CDC), combined with the Malaysian Dietary Guidelines (MDG) 2020 and the 5th edition of the Management of T2DM Clinical Practice Guidelines (CPG) from the Ministry of Health Malaysia by referring to Diabetes Malaysia. The materials have been modified to meet the needs and cultural sensitivity of Malaysians. A few consultations will be conducted with the stakeholders (i.e., dietitian, nutritionist, physiotherapist, psychologist, and clinician) prior to the intervention. The educational materials will be refined and pre-tested on high-risk individuals who have volunteered prior to the delivery of the intervention.

In order to successfully engage high-risk individuals in the process of lifestyle behaviour change, the content focus was based on Bandura's Social Cognitive Theory (SCT) (Bandura, 2004). SCT framework is the most used framework in digital diabetes prevention intervention (Van Rhoon *et al.*, 2020). It states that an individual, the environment, and the cognitive and emotional processes interact with each other to influence behaviour. SCT sets a framework of key constructs based on the determinants of behaviour, the mechanism of action, and the optimal strategies for effecting positive health behaviour changes. Self-efficacy, which refers to the confidence of a person in his or her ability to act and persevere in an action despite obstacles or challenges, is thought to be the most important construct of SCT and is suggested to impact health behaviour directly (Glanz, 2016). Other constructs include knowledge, outcome expectation, goal setting and planning, barriers and opportunities, social support, feedback on behaviour, feedback on outcome of behaviour, and self-monitoring. The taxonomy for behaviour change techniques was used for the operationalisation of SCT for MyDiPP (Michie *et al.*, 2013).

The intervention group will undergo 22 lessons that consist of two parts: (1) a six-month active period, and (2) a six-month maintenance period. Each lesson will take about 30 to 60 minutes to complete. For the first six months during the core programme, the participants will undergo 16 lessons that need to be completed within the first 24 weeks after randomisation by focusing on dietary change, increased physical activity, and relapse prevention. Eight sessions will be conducted once a week, and eight more sessions will be conducted every fortnight (Table 1). Meanwhile, during the maintenance period, which consists of six months of post-core lessons, the participants will focus on maintaining their lifestyle and weight loss achieved during the core programme. The sessions

Table 1. First six months of the MyDiPP intervention programme

Social Cognitive Theory Construct Targeted	*Behaviour Change Technique*	*Module*	*Content*	*Action*	*Week*
• Knowledge • Self-efficacy • Outcome expectation • Goal-setting and -planning • Barriers and opportunities • Social support • Feedback on behaviour and on outcome of behaviour • Self-monitoring	• Providing information about health consequences • Encouraging goal-setting and -planning • Providing information to create positive outcome expectations • Providing information about social and environmental consequences • Offering tips on behaviour substitution • Encouraging negative habit reversal • Encouraging positive habit formation • Giving instructions on how to perform a behaviour • Prompt goal-setting (behaviour and outcome) • Action-planning • Encouraging social support • Encouraging self-monitoring (behaviour and outcome of behaviour) • Prompt self-monitoring of behaviour and outcome of behaviour • Repetition of behaviour • Behavioural practice • Problem-solving/coping-planning • Providing information about emotional consequences • Regulate negative emotions • Reviewing behaviour goals	Introduction to the Programme	• Introduction to MyDiPP. • What are prediabetes and T2DM.	Dietitian	1
		Be Active!	• The meaning of physical activity and sedentary lifestyle. • Ways to get active. • Types of physical activities for adults. • Types of physical activities that are recommended for general population. • Ways to work out safely. • Benefits of getting active.	Physiotherapist	2
		Track Your Activity	• The purpose of tracking physical activity. • How to track physical activity.	Physiotherapist	3
		Eat Well	• How to eat well to prevent or delay T2DM. • Ways to eat right according to the Malaysian Food Pyramid and Malaysian Healthy Plate. • The items in each food group. • How to make healthy meals.	Dietitian	4
		Track Your Food	• The purpose of tracking food. • How to track food. • How to understand and use Food Label.	Dietitian	5
		Be More Active!	• The purpose of getting more active. • Some ways to get more active.	Physiotherapist	6
		Burn More Calories than You Take In	• The link between calories and weight. • How to track burned calories. • How to burn more calories than take in. • How to reduce calories intake through the changes of dietary habits. • Examples of physical activities that can be done to burn calories in foods.	Dietitian and Physiotherapist	7
		Healthy Shopping and Cooking	• Healthy food. • How to shop for healthy food and ways to save time and money before and during shopping. • How to cook healthy food.	Dietitian	8

Table 1. First six months of the MyDiPP intervention programme *(continued)*

Social Cognitive Theory Construct Targeted	*Behaviour Change Technique*	*Module*	*Content*	*Action*	*Week*
		Manage Stress	• Causes of stress. • The link between stress and T2DM. • Ways to reduce stress. • Healthy ways to cope with stress. • Ways to calm down.	Psychologist	10
		Find Time for Fitness	• Benefits of being active. • Challenges of fitting in fitness. • How to find time for fitness.	Physiotherapist	12
		Cope with Triggers	• Examples of unhealthy food shopping triggers and ways to cope with them. • Examples of unhealthy eating triggers and ways to cope with them. • Examples of triggers of sitting still and ways to cope with them.	Psychologist	14
		Take Care of Your Heart!	• Why hearth health matters. • How to keep heart healthy. • How to be heart smart about fat.	Dietitian	16
		Take Charge of Your Thoughts	• The difference between harmful and helpful thoughts. • How to replace harmful thoughts with helpful thoughts.	Psychologist	18
		Get Support	• How to get support from family, friends and co-workers. • How to get support from groups, classes and clubs. • How to get support from professionals.	Psychologist	20
		Eat Well Away from Home	• Challenges of eating well at restaurants and social events. • How to plan for and cope with the challenges.	Dietitian	22
		Stay Motivated	• Reflect on the progress. • How to keep making positive changes over the next 6 months.	Psychologist	24

Table 2. Final six months of the MyDiPP intervention programme

Social Cognitive Theory Construct Targeted	*Behaviour Change Technique*	*Module*	*Content*	*Action*	*Week*
• Knowledge • Self-efficacy • Outcome expectation • Goal-setting and -planning • Barriers and opportunities • Social support • Feedback on behaviour and on outcome of behaviour • Self-monitoring	• Providing feedback on behaviour and outcome of behaviour • Reviewing behaviour goals • Reviewing outcome goals • Renewing goal-setting and -planning • Prompt goal-setting (behaviour and outcome) • Action-planning • Problem-solving/coping-planning • Offering tips on behaviour substitution • Providing information about social and environmental consequences • Providing information to create positive outcome expectations • Maintaining negative habit reversal • Maintaining and improving positive habit formation • Giving instructions on how to perform a behaviour • Maintaining self-monitoring (behaviour and outcome of behaviour) • Maintaining social support • Repetition of behaviour • Behavioural practice • Providing information about emotional consequences • Regulate negative emotions	When Your Weight Loss Stalls	• Why weight loss can slow down or stall. • How to start losing weight again.	Dietitian and Physiotherapist	28
		Steal Your Time for Fitness Break!	• The link between sitting still and T2DM. • Challenges of taking fitness breaks and ways to cope with them.	Physiotherapist	32
		Eat Healthy Food that You Enjoy!	• Healthy approach to eating. • How to have healthy food that you enjoy.	Dietitian	36
		Get Enough Sleep	• Why sleep matters. • Challenges of getting enough sleep and ways to cope with them.	Psychologist	40
		Get Back on Track!	• Stay positive. • Five steps of problem solving.	Psychologist	44
		Prevent T2DM for Life!	• Reflect on the progress. • How to keep making healthy lifestyle going once the program ends. • How to keep making positive changes over the long term.	Dietitian and Psychologist	48

will be held monthly (sessions 17 to 22) (Table 2).

During the first week of intervention, participants will receive online orientation on what MyDiPP entails and learn how to use the app, interact with their coach, and stay motivated throughout the programme. Once the participants have registered the app, they will be alternately divided into either blue or red teams. The purpose for the group division is to motivate the participants into making healthy lifestyle changes. The team members can compete with those in the other team to achieve their group's diet and activity goals.

The participants are encouraged to aim for a minimum of 5-10% weight loss of their starting weight on the 6th month and to keep working on losing weight even if their target has not been reached on the 12th month. Participants can set their target for percentage weight loss for the first and last six months in the app. After they have set this target, a target body weight that they are required to achieve will be automatically calculated. Participants are also encouraged to increase their physical activity to a minimum of 150 minutes per week and aim for moderate-intensity exercises. They have the option to do more. Meanwhile, for dietary intervention, participants are advised to eat well by following the Malaysian Food Pyramid, as well as the Malaysian Healthy plate (module 4), to track their food by understanding and using food label (module 5), to burn more calories than they consume by changing their dietary habits and engaging in physical activities (module 7), to do healthy shopping and cooking by learning how to shop and prepare healthy food (module 8), to eat well while dining outside by educating them about potential obstacles to their weight loss goals and how to overcome them (module 15), and also to eat healthy foods that they enjoy by learning how to make them healthier (module 19). The contents for each module are described in Table 1 and Table 2.

At their convenience where internet connection is available, participants will be encouraged to complete the curriculum lessons on lifestyle and behavioural change, communicate with health coaches or group mates through private messaging or group discussions, self-monitor their diet and physical activities, and view their weight loss progress (Sepah *et al.*, 2017). The development of the MyDiPP mobile app, as well as its feasibility study, will be published elsewhere.

Participants in the control group will receive standard health education from primary care providers at the university's clinic with regards to weight loss, increasing physical activity, and dietary advice, undergo anthropometric and laboratory tests, as well as comprehensive surveys at baseline, six months, and twelve months after commencement of the intervention. They will also be provided with pamphlets and booklets about various health topics such as diabetes, hypertension, dyslipidaemia, cardiovascular disease, and kidney disease.

Participants are given the freedom to withdraw voluntarily at any time during the trial by informing the research team that he/she wishes to withdraw. The participant is also given the choice whether to provide the research team with the reason(s) for leaving the study. Participants who do not log in to the app for one month and/or are not present at evaluation will be contacted by telephone. After three unsuccessful calls, the participant will be considered a dropout.

The research team can also, at any time, withdraw (remove) the subject from the study at its discretion. The criteria for withdrawing include: when a subject's health may be compromised, such as when a subject experience related adverse events requiring discontinuation

of intervention, when the research team ends the study due to increased risk to the participant, or when the subject does not comply with the required study schemes or procedures.

Outcomes

The primary outcome measures for this study are the changes in weight and HbA1c level. Secondary outcome measures include physical activity level, dietary intake, and health-related quality of life (HRQoL). All these will be taken at baseline, sixth month, and twelfth month. The study's primary assessment time point is at sixth month in order to assess the immediate impact of the intervention. The final visit that will take place at the twelfth month will be used to assess the intervention's sustainability.

Sample size

The sample size was estimated using the study by Ibrahim *et al.* (2016), who performed a community-based lifestyle intervention programme study to prevent T2DM occurrence in Malaysia. It is the only available long-term (twelve-month) diabetes prevention study that focuses on the Malaysian population. Considering the difference in the change in % HbA1c by 0.27% between groups and standard deviation (SD) of the change in % HbA1c by 0.4, a sample size of 35 high-risk adults per group will give 80% power at 0.05 significance level for the twelve-month study. Assuming a dropout rate of 30%, 100 high-risk adults (50 in each group) is required. Probability sampling method will be applied.

To determine the sample size, equation (1) was used (Florey, 1993):

$$n \text{ (sample size in each group)} = \frac{2\,[(a + b)^2 \times \sigma^2]}{(\mu 1 - \mu 2)^2} \quad (1)$$

where:

a = conventional multiplier for alpha (0.05) = 1.96

b = conventional multiplier for power (0.80) = 0.842

Recruitment

The target sample comprises 100 adults who live in Kuala Terengganu, Terengganu, Malaysia, and are at high risk of T2DM. They will be identified by a two-stage screening process. In the first stage, patients who are at high risk of T2DM will be assessed via the American Diabetes Association (ADA) diabetes risk score distributed using Google Forms through social media (Facebook). Google Forms will be used due to its advantages: easy to build the questionnaire, has unlimited surveys, and is free. ADA diabetes risk test was translated and validated into the Malay language by two experts in the fields of nutrition and dietetics, as well as 35 target users (Nurul Fatihah *et al.,* 2022). The risk score is based on a set of variables not requiring laboratory tests that are used as a tool to predict the risk of T2DM or identify undetected T2DM; these variables are age, gender, and family history of diabetes, history of gestational diabetes in women, history of hypertension, physical activity, and BMI. The researcher will invite those who scored ≥5 via telephone call to attend a second stage screening test via a HbA1c test at the UniSZA Medical Specialist Clinic. At this stage, blood will be extracted by pricking the finger to assess HbA1c level for those with BMI ≥23 kg/m^2. Those with HbA1c level in the range of 20-44 mmol/mol or 4.0%-6.2% will be invited to participate in the study. However, individuals with HbA1c level ≥45 mmol/mol or ≥6.3% will be referred to healthcare providers immediately for follow-up. Figures 1 and 2 describe the SPIRIT flow diagram of the MyDiPP trial and the study flowchart from recruitment process at baseline stage to assessments at the sixth and twelfth months (primary time point), respectively.

Randomisation will be performed by the co-investigator (NBR) in this trial, once the baseline data collection is completed. Each participant will be randomly assigned to one of two study

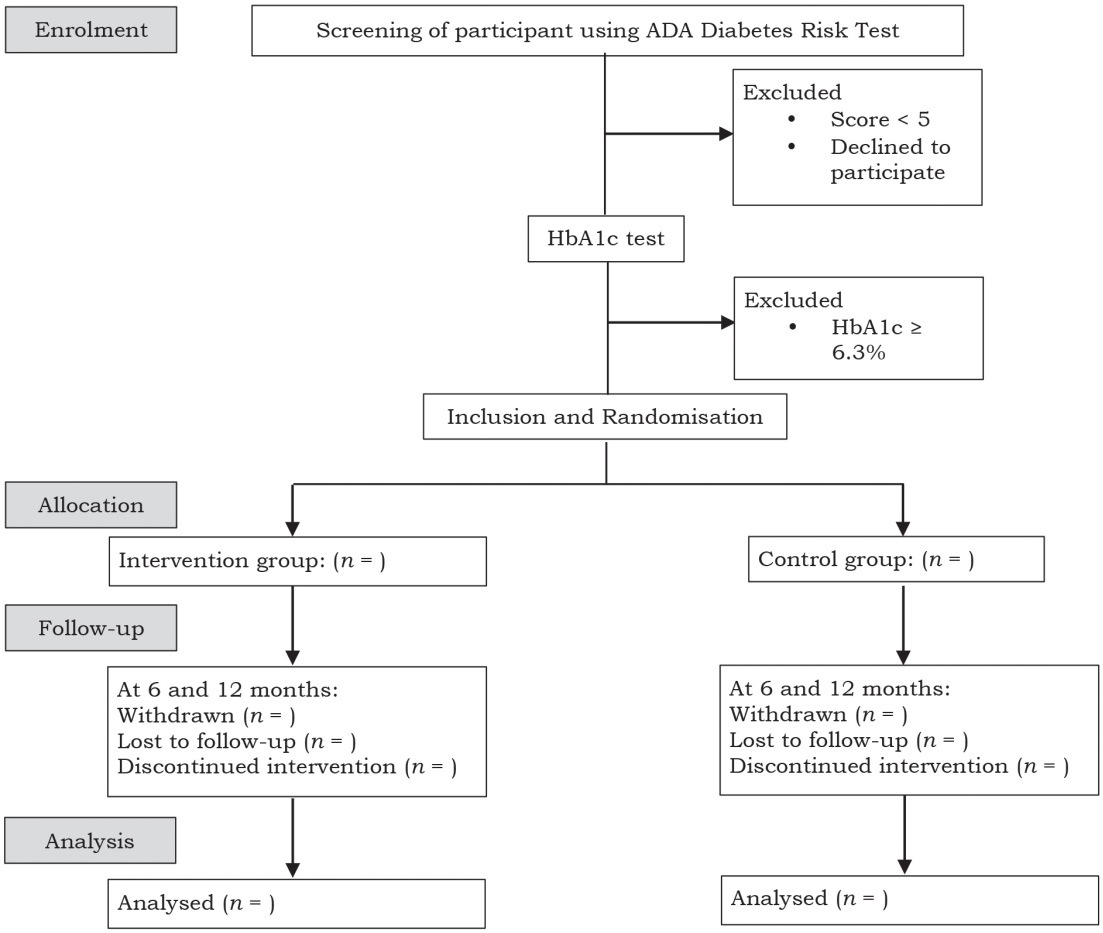

Figure 1. SPIRIT Flow Diagram of the MyDiPP Trial

groups in a 1:1 ratio using simple randomisation. Random numbers will be generated by the Research Randomiser software, which uses the "Math.random" method with JavaScript programming language to generate random numbers. The random number and instructions for the participants will be placed in sealed envelopes. The co-investigator will select the envelope sequentially to be distributed to each participant indicating which group (intervention or control) he/she will be allocated to and the next processes in this study.

This study uses the single-blind approach. All measurements will be taken at baseline, sixth and twelfth months of the study by the main researcher (NFMF), who will remain blinded to group allocations throughout the study. However, the nutritionists, dietitians, clinicians, physiotherapists, and psychologists are, for obvious reasons, not blinded to group allocations.

Data collection and management

The participants' timeline is presented in Table 3.

Anthropometric measurements

During the tests, participants are instructed to wear light clothing and no

shoes. By using a digital stadiometer and SECA scale, height and weight will be measured to the nearest 0.1 cm and 0.1 kg, respectively; these measurements will be used to calculate BMI (kg/m^2). BMI classification is based on the updated cut-off points for Asian. Those with BMI ranging from 23.0 kg/m^2 to

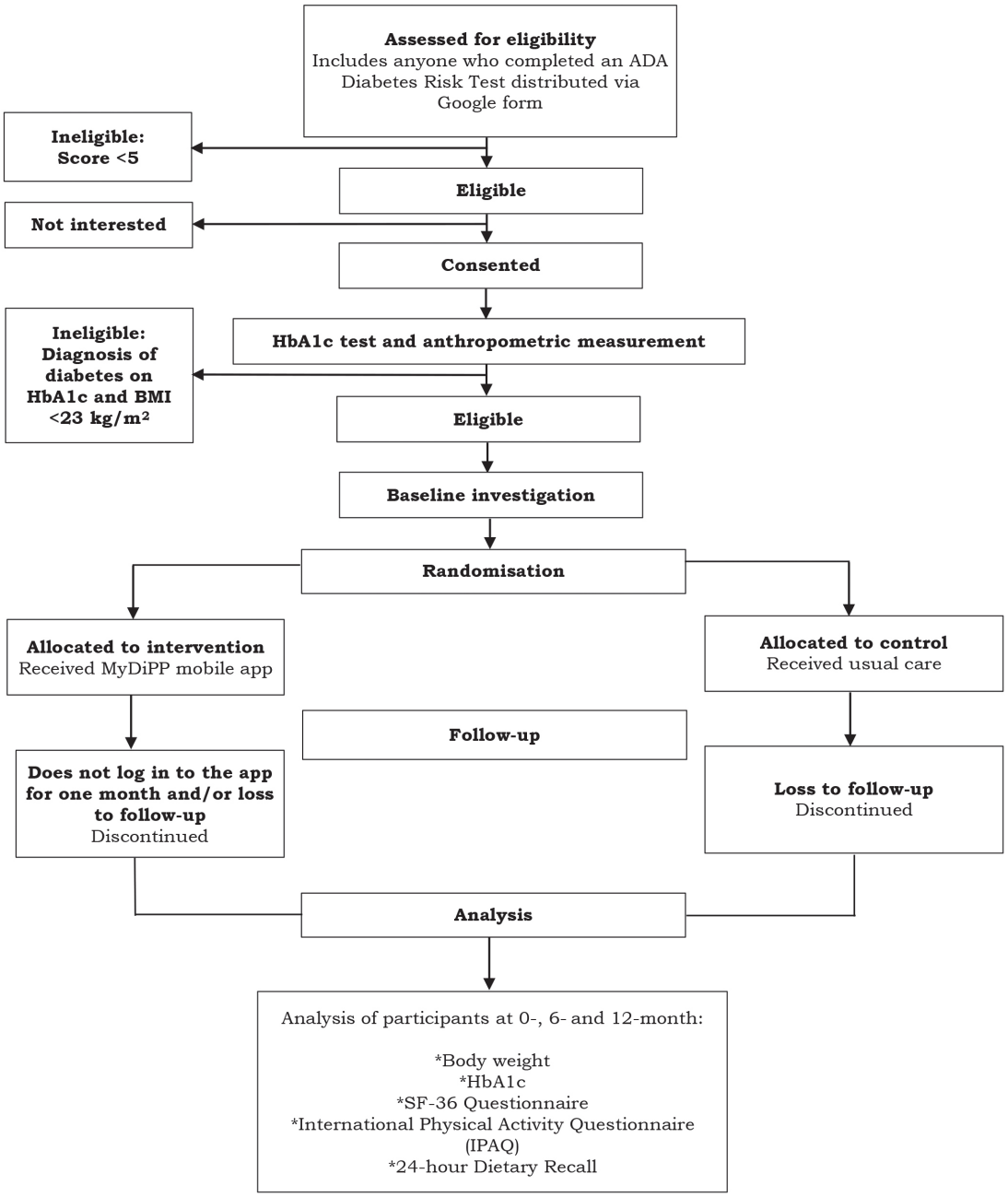

Figure 2. Study flow chart

Table 3. Participants' timeline

	Study Period			
	Enrolment	*Allocation*	*Follow-Up*	
Time-Point	$t_{inclusion}$	t_0	t_6	t_{12}
Enrolment:				
Eligibility screening	x			
Informed consent	x			
Allocation		x		
Interventions:				
Intervention group		x	x	x
Control group		x	x	x
Assessments:				
Baseline sociodemographic assessment		x		
Body weight		x	x	x
HbA1c		x	x	x
Physical activity questionnaire		x	x	x
Dietary intake status		x	x	x
Health-related quality of life questionnaire		x	x	x

24.9 kg/m^2 is classified as overweight, while a BMI of ≥25 kg/m^2 is obese (WHO Expert Consultation, 2004).

Laboratory measurement

HbA1c level will be tested using the point-of-care technology, which is PTS Diagnostics A1CNow$^+$ test kit from finger-prick blood samples collected in a capillary tube according to the manufacturer's guidelines. It is a lightweight, portable, and disposable handheld immunoassay device certified by the National Glycohaemoglobin Standardisation programme and is Clinical Laboratory Improvement Amendments (CLIA)-waived. It does not require calibration. The participants' fingers will be cleaned with an alcohol swab, left to dry, and lanced with a sterile lancet in order to obtain a drop of blood using the finger-prick method. A 5 µl blood sample is then mixed with a reagent supplied with the test kit and then transferred to a sample well in the testing device with a pipette provided. The results is provided in 5 minutes and then recorded.

Evaluation of physical activity (PA)

Physical activity (PA) will be assessed using the Malay-translated and validated version of the IPAQ (Chu & Moy, 2015). The questionnaire demonstrated good reliability with intra-class correlation coefficient (ICC) of 0.54-0.92 on items categorised by intensities and domains, as well as good validity across intensities and domains with Spearman correlation coefficient (ρ) of 0.67-0.98 (Chu & Moy, 2015). It consists of seven items that identify frequency and time spent on three types of physical activities (walking, moderate-intensity activity, and vigorous-intensity activity) during the past seven days. The metabolic equivalent (MET) values will be measured. The participants' total physical activity (MET-minute/week) will be calculated by summing up the walking, moderate-, and vigorous-intensity activity scores. The subjects will be categorised as "high physical activity", "moderate physical activity", and "low physical activity" if they achieved ≥1500 MET-minutes/ week, 600-1500 MET-minutes/ week, and <600 MET-minutes/week,

respectively (IPAQ Research Committee, 2005).

Evaluation of dietary intake

The dietary intake of the participants will be measured using a 24 hours diet recall. They will be asked to record their dietary intake for three days (two weekdays and one weekend), and the average measurement will be taken. Dietary analysis software Nutritionist Pro Inc. will be used to analyse energy and nutrient intakes (carbohydrate, fat, protein, and fibre).

Evaluation of Health-Related Quality of Life (HRQoL)

HRQoL will be assessed using the translated and validated version of the SF-36 health survey questionnaire (Sararaks *et al.*, 2005). It consists of 36 items with eight health domains: physical functioning (PF), role physical (RP), bodily pain (BP), general health (GH), vitality (VT), social functioning (SF), role emotional (RE), and mental health (MH), with a score from 0 to 100 indicating the worst to the best state of health. The scores are further summarised in the physical component summary (PCS) and mental component summary (MCS) scores.

Baseline sociodemographic assessment

Sociodemographic variables encompass age, sex, race, education level (primary, secondary, or tertiary), and household income.

Statistical methods

Independent *t*-test will be used to compare participants' demographic characteristics and baseline measurements between groups, while chi-square test will be used for categorical variables. The analysis will be performed according to the intention-to-treat (ITT) principle. Missing values will be replaced by carrying forward the last readings. Repeated measures ANCOVA will be performed to examine the changes over time within and between groups. The analyses will be performed using SPSS. Differences will be defined as statistically significant at $p<0.05$.

Ethics

Ethical approval was obtained from the UniSZA Human Research Ethics Committee (UHREC/2018/77).

Informed consent

A written consent will be obtained from participants before any intervention or procedures are conducted on them. Information sheets and consent forms will be provided to all participants involved in the trial. The participants will be informed regarding the purpose of the study and have the right to refuse participation in the study. The safety of the participants is the main concern of this study. Participants will be informed on the signs and symptoms of angina and heart attack, which they should promptly notify. They will be given a consent form during baseline visit at the UniSZA Medical Specialist Clinic. After they have signed the form, a copy of the signed consent form will be given to them and kept for their records.

Confidentiality

Participants' study information will be kept confidential by the researchers and will not be made publicly available unless disclosure is required by law. Data obtained from this study that do not identify them individually will be published in scientific journals for knowledge purposes. Participants' original records may be reviewed by the researchers, the Ethical Review Board for this study, and regulatory authorities for the purpose of verifying the study procedures and/or data. Their information may be held and processed on a computer. Only research

team members are authorised to access the information.

DISCUSSION

Intervention to prevent blood glucose increases must begin much earlier, ideally before glucose levels reach levels indicative of diabetes or disease symptoms. This study is necessary because it is important to know if this intervention programme leads to the reduction in body weight, as well as HbA1c level, and whether these reductions are larger than the effect of usual care, as weight loss is the main predictor of reduced diabetes incidence; a reduction of 5-10% of body weight can improve fitness and reduce HbA1c level (Wing *et al.*, 2011). If successful, the results of this trial will open a window of opportunity for other researchers to test MyDiPP on the whole population, or to healthcare providers to use it as a preventive approach on their patients.

While many other health apps are designed solely to monitor calories or fitness records, the MyDiPP mobile app is designed to engage its audiences and guide them to fun and realistic lifestyle changes. Furthermore, it allows individuals who are at increased risk of developing diabetes to be able to monitor their health, track their progress, and even connect with a personal health coach, where they can receive real-time feedback on behaviours related to wellness and diabetes prevention. This app makes them more aware of the easy changes they can make to their lifestyles and keep them motivated to prevent diabetes.

The incorporation of the diabetes prevention modules into the mobile app may lead to greater engagement of the participants with the programme because it frees them from the requirement of travelling to a specific location and thus more flexible with their time to participate. A greater engagement has the potential to reduce the risk of progression to diabetes (Katula *et al.,* 2022). Moreover, this mobile app can convincingly improve the daily quality of life for millions of people, not to mention drive billions of ringgit in system-wide savings (Bonoto *et al.,* 2017).

Despite its aforementioned strengths, this study may encounter some challenges in terms of recruitment, engagement, and long-term retention in the programme. However, providing incentives to participants may boost their engagement and long-term retention. A systematic review of effective recruitment strategies revealed that involving primary care practitioners may be the most effective recruitment strategy for managing study budget and timelines (Ngune *et al.,* 2012). They can help promote the programme on their clinic's Facebook Page or on their own Facebook, if they have one. Furthermore, there could be bias in the information provided for physical activities and dietary intake recall. This can happen when respondents do not provide the true or correct answers to questions, either because they have forgotten or refused to disclose information. Sometimes, the meaning of the questions may be interpreted differently by the respondents. However, properly training the interviewer to avoid inappropriate questioning techniques such as leading questions or judgmental comments, as well as conducting interviews in a private setting with no distractions, can help avoid or reduce bias in the information provided by respondents (Gibson, Charrondiere & Bell, 2017).

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lecturers at University Malaysia Kelantan, Malaysia. This trial was retrospectively registered with Clinical Trial Registry (NCT03997656) on 21 June 2019.

Authors' contributions

Nurul Fatihah MF, conceptualised and designed the study, and prepared the draft of the manuscript; Wafa SW, principal investigator, conceptualised and designed the study, and reviewed the manuscript; Raj NB, designed the study (physical activity) and reviewed the manuscript; Mohd Ibrahim A, designed the study (diet) and reviewed the manuscript; Norkhairani AR, designed the mobile app and reviewed the manuscript; Nurulhuda MH, designed the study (HbA1C) and reviewed the manuscript; Rohayah H, designed the study (psychology) and reviewed the manuscript.

Conflict of interest

The authors declare that they have no competing interests.

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