

# A Randomised Controlled Trial of a Digital Therapy for Diabetes Prevention Among High Risk Individual: Study Protocol (the Mydipp Trial)

**Nurul Fatimah Mohd Fauzi**

Universiti Sultan Zainal Abidin

**Sharifah Wajihah Wafa** (✉ [sharifahwajihah@unisza.edu.my](mailto:sharifahwajihah@unisza.edu.my))

Universiti Sultan Zainal Abidin <https://orcid.org/0000-0002-1791-2714>

**Naresh Bhaskar Raj**

Universiti Sultan Zainal Abidin

**Mohd Ibrahim Abdullah**

Universiti Sultan Zainal Abidin

**Barakatun Nisak Mohd Yusof**

Universiti Putra Malaysia

**Norkhairani Abdul Rawi**

Universiti Sultan Zainal Abidin

**Nurulhuda Mat Hassan**

Universiti Sultan Zainal Abidin

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## Study protocol

**Keywords:** Protocol, randomised controlled trial, prediabetes, overweight, obese, T2DM, prevention of diabetes, lifestyle intervention

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# Abstract

**Background:** Approximately 37% of the individuals with prediabetes will have diabetes in four years if they do not change their lifestyle through any intervention. Lifestyle modification intervention has shown to be effective in reducing or delaying the onset of type 2 diabetes mellitus (T2DM) among high-risk individuals. Some intervention approaches integrate human coaching into technology using phone or email to enable wider reach, known as digital therapy. It is considered as a scalable method to reach a larger population who are at risk, convenient and accessible. This study aims to determine the feasibility and efficacy of lifestyle intervention to prevent type 2 diabetes among adults who are at risk of developing diabetes, an assessor-blinded, parallel-group, randomised controlled trial using the Malaysia Diabetes Prevention Programme (MyDiPP) app.

**Methods:** 'MyDiPP' is a 12-month lifestyle intervention digital therapy with multiple approaches (weight loss, dietary modification, physical activity and quality of life). Eligible adults are aged 18-65 years, overweight/obese ( $BMI \geq 23 \text{ kgm}^2$ ) and at high-risk for type 2 diabetes (American Diabetes Association (ADA) Diabetes Risk Score  $\geq 5$ , or HbA1c of 5.6-6.2%). Each participant will be randomly assigned to one of two study groups in 1:1 ratio using simple randomisation to intervention or usual care control groups. The primary outcome is the change in weight at 6 months and 12 months, while the secondary outcomes are changes in HbA1c level, physical activity level, dietary intake and quality of life. The MyDiPP programme is an assessor-blinded, parallel-group, randomised controlled trial, in which the app consists of educational lessons, group, technology-enabled discussions, tools to track nutritional intake, physical activity, body weight and blood glucose level as well as platform to communicate with the health coaches.

**Discussion:** This study is necessary to determine to what extent the intervention programme reduces risks of diabetes risk in comparison to the usual care.

**Trial registration details:** This trial was prospectively registered with Clinical Trial Registry (CTR) on 21<sup>st</sup> June 2019 with trial registration number NCT03997656.

## Administrative Information

### Note

the numbers in curly brackets in this protocol refer to SPIRIT checklist item numbers. The order of the items has been modified to group similar items (see <http://www.equator-network.org/reporting-guidelines/spirit-2013-statement-defining-standard-protocol-items-for-clinical-trials/>).

Title {1}	<b>A randomised controlled trial of a digital therapy for diabetes prevention among high risk individual: Study Protocol (the MyDiPP trial)</b>
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Author details {5a}	<p>Nurul Fatihah Mohd Fauzi<sup>1</sup>, Sharifah Wafa<sup>1</sup>, Naresh Bhaskar Raj<sup>2</sup>, Mohd Ibrahim Abdullah<sup>1</sup>, Barakatun Nisak Mohd Yusof<sup>3</sup>, Norkhairani Abdul Rawi<sup>4</sup>, Noor Aini Mohd Yusuff<sup>1</sup>, Nurulhuda Mat Hassan<sup>5</sup></p> <p><sup>1</sup>School of Nutrition and Dietetics, Faculty of Health Sciences, Gong Badak Campus, University Sultan Zainal Abidin, 21300 Kuala Terengganu, Malaysia; E-mail: <a href="mailto:nurul.fauzi147@yahoo.com">nurul.fauzi147@yahoo.com</a></p> <p><sup>1</sup>School of Nutrition and Dietetics, Faculty of Health Sciences, Gong Badak Campus, University Sultan Zainal Abidin, 21300 Kuala Terengganu, Malaysia; E-mail: <a href="mailto:sharifahwajihah@unisza.edu.my">sharifahwajihah@unisza.edu.my</a></p> <p><sup>1</sup>School of Nutrition and Dietetics, Faculty of Health Sciences, Gong Badak Campus, University Sultan Zainal Abidin, 21300 Kuala Terengganu, Malaysia; E-mail: <a href="mailto:ibrahimabdullah@unisza.edu.my">ibrahimabdullah@unisza.edu.my</a></p> <p><sup>2</sup>School of Rehabilitation Science, Faculty of Health Sciences, Gong Badak Campus, University Sultan Zainal Abidin, 21300 Kuala Terengganu, Malaysia; E-mail: <a href="mailto:bnaresh@unisza.edu.my">bnaresh@unisza.edu.my</a></p> <p><sup>3</sup>School of Nutrition and Dietetics, Faculty of Medicine and Health Sciences, Universiti Putra Malaysia, 43400 Serdang, Selangor, Malaysia; E-mail: <a href="mailto:bnisak@upm.edu.my">bnisak@upm.edu.my</a></p> <p><sup>4</sup>Faculty of Informatics and Computing, Besut Campus, University Sultan Zainal Abidin, 22200 Besut, Terengganu, Malaysia. E-mail: <a href="mailto:khairani@unisza.edu.my">khairani@unisza.edu.my</a></p> <p><sup>5</sup>Faculty of Medicine, University Sultan Zainal Abidin, Jalan Sultan Mahmud, 20400 Kuala Terengganu, Malaysia; E-mail: <a href="mailto:nurulhudamh@unisza.edu.my">nurulhudamh@unisza.edu.my</a></p> <p>Corresponding author: Full Name: Sharifah Wajihah Wafa Syed Saadun Tarek Wafa; Postal Address: School of Nutrition and Dietetics, Faculty of Health Sciences, Gong Badak Campus, University Sultan Zainal Abidin, 21300 Kuala Terengganu, Malaysia; E-mail: <a href="mailto:sharifahwajihah@unisza.edu.my">sharifahwajihah@unisza.edu.my</a>; Phone Number: +60126911510</p>
Name and contact information for the trial sponsor {5b}	Not applicable as this study is not sponsored by any organization

Title {1}	<b>A randomised controlled trial of a digital therapy for diabetes prevention among high risk individual: Study Protocol (the MyDiPP trial)</b>
Role of sponsor {5c}	Not applicable as this study is not sponsored by any organization.

## Introduction

### Background and rationale {6a}

The number of adults having diabetes increased from 108 million in 1980 to 422 million in 2014 worldwide,[1] with 80% of the cases occurred in developing countries.[2] In fact, 60% of the world’s diabetes patients are from Asian countries and this is expected to increase by few decades.[2] According to the latest data of 17.5%, Malaysia has a similar trend of diabetes mellitus as other Asia-Pacific countries such as Japan, Brunei Darussalam, Singapore and Republic of Korea, in which the highest prevalence goes to China and followed by India.[3]

Individuals who have blood glucose higher than normal level, but not as high to be classified as diabetes, they are regarded as having prediabetes. A person diagnosed with prediabetes has a higher risk of developing diabetes.[4, 5] It is estimated that more than 260 million or 6.4% adults have been diagnosed with prediabetes worldwide.[6] The increased prevalence of prediabetes and diabetes was probably is due to the increase in the prevalence of overweight and obesity.[7] In Malaysia, the prevalence of overweight and obesity among adults aged 18 years and above were estimated to be 30% and 17.7% respectively.[8]

The study had shown that approximately 37% of the individuals with prediabetes will have diabetes in four years if they do not change their lifestyle through any intervention.[9] Lifestyle modification intervention such as the Diabetes Prevention Programme (DPP) has shown to be effective in reducing or delaying the onset of type 2 diabetes mellitus (T2DM) among high-risk individuals by 58%,[9] over a long-term period. Meanwhile, a 10-year follow-up reduces the prevalence of T2DM 34%.[10] DPP is the first large-scale trial to demonstrate the efficacy of intensive behavioural counselling in reducing weight and risks of diabetes, which involves in-person and group meetings in a research setting. Since then, many translations of the DPP is further developed to provide approaches that can be used widely. DPP has been translated into a community setting such as Diabetes Care Centre,[11] Young Men’s Christian Association (YMCA),[12] and churches.[13, 14] However, such programmes have several barriers such as lack of professional staff, institutional resources, incur substantial costs, participants’ reluctance to allocate their time to attend a series of in-person meetings as well as transportation, distance and childcare issues.[15, 16, 17]

To overcome these problems, some intervention approaches integrate human coaching into technology using phone or email to enable wider reach, known as digital therapy. It is considered as a scalable

method to reach a larger population who are at risk,[18] convenient and accessible. The purpose of this article is to present the MyDiPP study protocol.

## **Objectives {7}**

The MyDiPP trial aims to determine the feasibility and efficacy of lifestyle intervention to prevent type 2 diabetes among adults who are at risk of developing diabetes.

## **Trial Design {8}**

This study is an assessor-blinded, parallel-group randomised controlled trial (RCT) for overweight/obese adults who are at high risk of having type 2 diabetes. The eligible participants are stratified (age, BMI) and randomised in a 1:1 ratio to either 12-month MyDiPP intervention or receive standard health education from primary care providers in the clinic.

The study will be conducted in two phases. The first phase will involve preparation of intervention modules, development of the mobile app, training and recruitment of participants. The second phase will involve implementation of the intervention, data collection, follow-up and data analyses. The study is approved by the Universiti Sultan Zainal Abidin Human Research Ethics Committee (UHREC) UniSZA/UHREC/2018/77). The study is registered with the Clinical Trials Registry (CTR): NCT03997656. 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. [19]

## **Methods: Participants, Interventions And Outcomes**

### **Study setting {9}**

The study will be conducted among individuals aged between 18 and 65, living, working or studying in Kuala Terengganu who is at risk developing diabetes recruited through online advertisement.

### **Eligibility criteria {10}**

Participants are deemed eligible if they are 18–65 years old, with body mass index (BMI) of  $\geq 23$  kg/m<sup>2</sup>, [20] high risk for diabetes (diabetes risk test score  $\geq 5$ , [21] or HbA1c of 38–44 mmol/mol or 5.6–6.2%, [22]) own a smartphone (only Android) for communication purpose by logging in at least once a day, fluent in Malay or English language and willing to participate in weight management programme or physical activity. The exclusion criteria are those with clinical history of diabetes or newly diagnosed with diabetes at the time of screening where their HbA1c level  $\geq 45$  mmol/mol or  $\geq 6.3\%$ , [22] take oral antidiabetic agents, participate in other weight management programme or interventional research, on a prescribed medical diet, anti-obesity or diabetes therapy in the past 4 months, had clinical history of cardiovascular diseases in the past 6 months, used to undergo any treatments for cancer, dementia or

probable Alzheimer's disease, advanced arthritis, being pregnant or had given birth for 6 weeks or plan to become pregnant in the next 12 months, have liver and renal disease, or hyperthyroidism or other causes which can interfere with their participation (for being physically disabled or have any mental health conditions that include eating disorder or alcohol/substance abuse).

## **Who will take informed consent? {26a}**

Participants will be given consent form. After they signed the form, a copy of signed consent form will be given to them and kept for their records.

## **Additional consent provisions for collection and use of participant data and biological specimens {26b}**

Not applicable since the researchers will use the same consent form provided by the participants at the time of recruitment and there is no biological specimens were collected as part of this trial.

## **Interventions**

### **Intervention description {11a}**

Phase 1: Development of the Malaysian Diabetes Prevention Programme (MyDiPP) module

The MyDiPP module was developed by a group of healthcare professionals including a nutritionist, dietitian, clinician, physiotherapist and psychologist based on available materials from the United States Diabetes Prevention Programme (US DPP) of Centre for Disease Control and Prevention (CDC), Malaysian Dietary Guidelines (MDG) and the current Management of T2DM Clinical Practice Guidelines (CPG) from the Ministry of Health Malaysia by referring to the Malaysian Diabetes Association (MDA) and the module will be featured in a mobile app. The materials were modified to meet the needs and cultural sensitivity of Malaysians, refined and pretested prior to delivery.

After the MyDiPP app development, a training session for trainers will be conducted. The training content outlines a detailed explanation of the MyDiPP study, dietary modification and weight reduction strategy, physical activity and the roles of trainers. The trainers in this study include dietitians, clinicians, physiotherapist and psychologists.

Phase 2: Implementation phase

This phase consists of; i) recruitment of adults with a high risk of diabetes, ii) screening of high-risk adults for eligibility, iii) allocation of participants to intervention and usual care group and v) intervention to both groups. The 12-month intervention programme consists of two parts; 6-month active period and 6-month maintenance period. For the first 6-months, 8 sessions will be conducted once a week and 8 sessions will be conducted every fortnight. During the maintenance period, the sessions will be held

monthly (sessions 17 to 22). The contact schedule, objectives and action in the core and post-core lessons are summarised in Table 1 and Table 2 respectively.

### Intervention group

MyDiPP app will be used by participants in the intervention group. The app consists of educational lessons, peer group, technology-enabled tools to track nutritional intake, physical activity, body weight, blood glucose level and health coaches. The intervention group stayed connected to the app for 12 months. The participants will go through 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 whereas the 6-month post-core lessons focus on maintaining lifestyle and weight loss achieved during the core programme. Each lesson takes about 30 to 60 minutes to complete. The lesson is considered complete when the participants have clicked all the pages and answered the multiple-choice questions, which indicate their engagement and understanding.

Table 1  
First six months of programme

<b>Modules</b>	<b>Action</b>	<b>Week</b>
Introduction to the program	Dietitian	1
Be active!	Physiotherapist	2
Track your activity	Physiotherapist	3
Eat well	Dietitian	4
Track your food	Dietitian	5
Be more active!	Physiotherapist	6
Burn more calories than you take in	Dietitian and Physiotherapist	7
Healthy shopping and cooking	Dietitian	8
Manage stress	Psychologist	10
Find time for fitness	Physiotherapist	12
Cope with Triggers	Psychologist	14
Take care of your heart!	Clinician	16
Take Charge of Your Thoughts	Psychologist	18
Get support	Psychologist	20
Eat Well Away from Home	Dietitian	22
Stay motivated	Psychologist	24

Table 2  
Last six months of programme

Modules	Action	Week
When your weight loss stalls	Dietitian and Physiotherapist	28
Steal your time for fitness break!	Physiotherapist	32
Eat healthy food that you enjoy!	Dietitian	36
Get enough sleep	Psychologist	40
Get back in track!	Psychologist	44
Prevent T2DM for life!	Dietitian and Psychologist	48

During the first week, participants will receive the orientation on MyDiPP and learned how to use the app, interact with their coach and stay motivated throughout the programme. Participants will be asked to weigh themselves every week, key in their meal and physical activity in the app every day and log their blood glucose test result in-app on 0, 6- and 12-month time points. The health coach will be communicated with the participants daily via in-app private message and group discussion. Coaches will securely monitor participants' progress (their weight, nutritional intake, physical activity level and blood glucose level) through the app dashboard. At their convenience where the internet connection is available, participants completed the weekly curriculum lessons on lifestyle and behavioural change, communicate with the health coach and/or groupmates, self-monitor their diet and physical activity, and view their weight loss progress. [18, 23, 24]

The participants are encouraged to aim for a minimum of 5–7% weight loss of their starting weight at 6-month and keep working to lose weight if they have not reached the target until month 12. Participants are also encouraged to increase their physical activity to a minimum of 150 minutes per week and aim for moderate-intensity exercises. They had the option to do more.

#### Control group

Participants in the control group will receive standard health education from primary care providers in the clinic. In addition, they also will be provided with pamphlets and booklets about various health topics. They will be given a diary to record their weight, diet, physical activities and blood test result.

## Criteria for discontinuing or modifying allocated interventions {11b}

Participants can withdraw voluntarily at any time during the trial. When withdrawing from the study, the participant should inform the research team that he/she wishes to withdraw. The participant may provide the research team with the reason(s) for leaving the study but is not required to provide their reason. For the intervention group, participants who are not log in the apps for one month are considered dropouts.

Meanwhile, for control group, participants who are not present at the clinic for consultation with the doctor or dietitian are contacted by telephone and after three unsuccessful calls participants are considered dropouts.

The research team may, at any time, withdraw (remove) the subject from the study at its discretion. Circumstances may 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 participants, or when the subject does not comply with the required study schemes or procedures.

## **Strategies to improve adherence to interventions {11c}**

The health coaches will be responsible for overseeing the progress of the trial. The health coaches include nutritionists, dietitians, clinicians, physiotherapist and psychologists which are also the co-investigators for this study. MyDiPP mobile app was integrated with social media features such as message and status update. Through these two platforms, participants can communicate with either their health coaches or other participants to share their progress, get support to improve their adherence with the intervention and get real-time feedback on their progress from the health coaches.

Moreover, participants in the intervention group are urged to key in their diet and physical activity in the app daily as well as weigh-in and key in their weight once a week. The mobile app also incorporated with the reminder message. When the participants are not log in for a week, the reminder message will automatically pop-up on their phone.

At the end of the first and last six month, the participants will be contacted via telephone call to remind them to come to the Universiti Sultan Zainal Abidin Medical Centre to get HbA1c test and answer several questionnaires related to the study.

## **Outcomes {12}**

The primary outcome is the change in weight measured at months 0, 6 and 12 after the intervention. The changes in HbA1c level, physical activity level, dietary intake and health-related quality of life (HRQoL) are the secondary outcomes in this study, which are also measured at months 0, 6 and 12 after the intervention. The changes in HbA1c level are determined via laboratory measurement.

## **Sample size {14}**

The sample size was estimated using the study by Norliza,[2] who performed a community-based lifestyle intervention programme study to prevent T2DM occurrence in Malaysia. Sample size calculation is based on each objective and the data on HbA1c results in the largest sample size for this study. Based on expert judgment (a clinician), considering the difference in the change in % HbA1c by -0.25% between groups and SD of the change in % HbA1c by 0.4, a sample size of 47 high-risk adults per group will give 80% power at 0.05 significance level for the 12-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, Eq. (1) is used,[25]:

$$n \text{ (sample size in each group)} = \frac{2 [(a + b)^2 \times \sigma^2]}{(\mu_1 - \mu_2)^2} \quad (1)$$

where:

a = conventional multiplier for alpha (0.05) = 1.96

b = conventional multiplier for power (0.90) = 1.28

## Recruitment {15}

The target sample is 100 adults who live, work or study in Kuala Terengganu, they are those who are at high risk of type 2 diabetes. They are identified by two-stage screening process. In the first stage, patients who are at high risk of type 2 diabetes were assessed via the American Diabetes Association (ADA) diabetes risk score, distributed via Google Form. The risk score is based on a set of the variable not requiring laboratory tests that are used as a tool to predict risks of type 2 diabetes risks or identify undetected type 2 diabetes. The researcher will invite those who scored  $\geq 5$  in the second stage screening test via the HbA1c test. In this stage, patients attending the eligibility screening with HbA1c in the range of 38–44 mmol/mol or 5.6–6.2% are invited to volunteer. Figure 1 and Fig. 2 describe SPIRIT flow diagram of MyDiPP trial and study flow chart from recruitment process at the baseline stage and assessments at 6 and 12 months (primary time point) respectively.

## Assignment of interventions: allocation

### Sequence Generation {16a}

Randomisation will be performed by the co-investigator once the baseline data collection has been completed. Each participant will be randomly assigned to one of two study groups in a 1:1 ratio using simple randomisation. Random numbers are generated by Research Randomiser software,[26] which uses the “Math.random” method with JavaScript programming language to generate random numbers.

### Concealment mechanism {16b}

The random number and instructions for the participants are placed in sealed envelopes. The co-investigator will select the next sequential envelope to be attributed to a new participant indicating which group (intervention or control) the participant is allocated to and the next processes in this study.

## Assignment of interventions: Blinding

## Who Will Be Blinded {17a}

This study uses single-blind approach. All measurements are taken at baseline, 6- and 12-month of the study by the main researcher who remained blinded to group allocation throughout the study. However, nutritionists, dietitians, clinicians, physiotherapist and psychologists are for obvious reasons not blinded to group allocation. The participants are reminded regularly to not tell the main researcher of the group they are in.

## Procedure for unblinding if needed {17b}

Not applicable as this study uses single-blind approach.

## Data collection and management

## Plans For Assessment And Collection Of Outcomes {18a}

The participants timeline is presented in Table 3

### Anthropometric measurements

Participants in the intervention group weighed themselves on a weekly basis. Then, they weigh-in, they need to key in their weight in the app to have their BMI automatically calculated.

### Laboratory measurement

HbA1c level will be tested using the A1CNow<sup>+</sup> test kit from finger-prick blood samples collected in a capillary tube according to the manufacturer's guidelines. The participants' finger will be cleaned with alcohol swab, left to dry and lanced with a sterile lancet to obtain a drop of blood. A 5 µL-capillary blood sample will be collected and added to the dilution buffer. The diluted sample will be mixed and added to the monitor using transfer pipette. Once the sample was applied, the monitor will begin the analyses. Digital results will be displayed in the display window after 5 minutes and then recorded.

### Evaluation of physical activity (PA)

Physical activity (PA) will be assessed using the translated and validated version of the international physical activity questionnaire (IPAQ).[27] It consists of seven items that identify frequency and time spent on three types of physical activity (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. Subjects will be categorised as "active" if they achieved  $\geq 600$  MET-minutes/week, "moderately active" if they achieved  $\geq 150$  MET-minutes/week and "inactive" if they achieved  $< 150$  MET-minutes/week.

## Evaluation of dietary intake

The dietary intake status of the participants will be accessed from their food diary record from the app and the diary for intervention and control participants respectively. Participants will be asked to record their dietary intake for three days (two on weekdays and one on weekend) and the average measurement will be taken. A dietary analysis software, Nutritionist Pro Inc. will be used to analyse energy and nutrient intake.

## Evaluation of health-related quality of life (HRQoL)

HRQoL will be assessed using the translated and validated version of SF-36 health survey questionnaire. [28] 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 the score from 0 to 100 indicating worst to best state of health. The scores will be further summarised in the physical component summary (PCS) and mental component summary (MCS) scores.

## Baseline sociodemographic assessment

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

Table 3  
Participants timeline

	Study period			
	Enrolment	Allocation	Follow-Up	
Timepoint	$t_{inclusion}$	$t_0$	$t_6$	$t_{12}$
Enrolment:				
Eligibility screen	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

### Data management {19}

No personal identifying information will be mentioned where each participant participated in the study will be given an identification number that starts from 1 to 100. HbA1c test results will be stored securely at Universiti Sultan Zainal Abidin Medical Center. Paper-based study documents will be stored in a secure filing cabinet at Faculty of Health Sciences, Universiti Sultan Zainal Abidin. Access to these test results and documents will be restricted to research staff involved in the study. The study statistician will have access to the data set for the final analysis of the study outcomes.

### Plans for collection, laboratory evaluation and storage of biological specimens for genetic or molecular analysis in this trial/future use {33}

Not applicable as no biological specimens were collected as part of this trial.

## Statistical methods

## **Statistical Methods For Primary And Secondary Outcomes {20a}**

Analyses will be performed using SPSS version 24. The generalised linear mixed models will be used to assess the primary outcome (weight loss) and secondary outcomes of the impact of treatment (intervention vs. control), time (regarded as categorical with levels at baseline, 6 and 12 months) and the treatment-by-time interaction, these three form the base model. This ensures the outcomes from participants who withdraw from the trial stage prior to the 6 or 12-month time points are retained in the analysis. This is consistent with the 'intention-to-treat' approach. Age and socioeconomic status will also be examined to determine any significant interactions in the models. If a covariate is significant, a term will be added to the model to adjust for the effects and two-way interactions with time and treatment will also be examined. If the interactions are significant, they will also be adjusted in the model [19]. The coefficient and P-value of the treatment-by-time interaction term will be used to determine the efficacy of the intervention using a significance level of  $P = 0.05$ . All secondary analyses will be performed using a significance level of  $P = 0.05$ .

Exploratory analyses will be conducted to determine the characteristics of participants who lost a significant amount of weight ( $> 5\%$ ) and the associated changes in the secondary health outcomes. The characteristics of completers versus dropouts will be tested using the independent t-test for continuous variables and chi-squared ( $\chi^2$ ) tests for categorical variables, using the significance level of  $P = 0.05$ .

## **Interim analyses {21b}**

No interim analysis or harms are expected and therefore no early termination of the trial is anticipated.

## **Plans to give access to the full protocol, participant level-data and statistical code {31c}**

There are no current plans to allow public access to the full protocol, participant-level data set or statistical code. Nonetheless, this will be supported by the project management committee if the researchers want to access the data set (e.g. to perform a secondary analysis or meta-analysis).

## **Oversight and monitoring**

## **Frequency And Plans For Auditing Trial Conduct {23}**

No auditing by an independent committee is needed.

## **Plans for communicating important protocol amendments to relevant parties (e.g. trial participants, ethical committees) {25}**

Important changes to the protocol will be conveyed to the relevant parties by providing a modified protocol to the investigators.

## **Dissemination plans {31 a}**

The principal investigator will have access to the data and will be fully responsible for interpreting the findings and reporting them. Data will be available upon reasonable request once the main analyses have been undertaken. Results will be reported through scientific publications.

## **Discussion**

This study is necessary because it is important to know if this intervention program leads to a reduction in diabetes risk, whether this reduction is larger than the effect of usual care. If successful, the results of this trial will open the window of opportunity to other researchers to test MyDiPP on 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, MyDiPP mobile app is designed to engage its audiences and guide them to a 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 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 reduce the risks of diabetes.

The incorporation of diabetes prevention's modules into the mobile app may leads to greater engagement of the participant with the program because it frees them from the requirement of travelling to a specific location and more flexible with the time to participate. A greater engagement has the potential to reduce the risk of progression to diabetes. Moreover, this mobile app can convincingly improve the daily quality of life for millions of people, not to mention drive billions of ringgits in system-wide savings.

Despite its aforementioned strengths, this study may encounter some challenges in terms of recruitment process, engagement and long-term retention with the program as addressed by the previous study [29]. Finally, since this study is not funded by any grant, so this study only focuses on resident in Kuala Terengganu only. Kuala Terengganu is the capital city of Terengganu, Malaysia. Therefore, the findings of the study will not represent the whole population.

## **Trial status**

The RCT MyDiPP is currently recruiting. The first enrolment was realized on 1 September 2019, and this article was submitted on 26 March 2020.

The recruitment will be completed at the approximate date of 1 May 2020.

ClinicalTrials.gov, ID: NCT03997656.

This is the second version of the protocol, approved by Universiti Sultan Zainal Abidin (UniSZA) Human Resources Ethics Committee (UHREC) on 21 July 2019.

When the last participant undergoes his final evaluation (at month 12), the trial will be completed.

## Abbreviations

T2DM

Type 2 diabetes mellitus; MyDiPP:Malaysia Diabetes Prevention Programme; American Diabetes Association:ADA; DPP:Diabetes Prevention Program; YMCA:Young Men's Christian Association; RCT:Randomised controlled trial; UHREC:Universiti Sultan Zainal Abidin Human Research Ethics Committee; CTR:Clinical trial registry; CONSORT:Consolidated standards of reporting trials; BMI:Body mass index; US DPP:United States Diabetes Prevention Program; CDC:Centre for Disease Control and Prevention; MDA:Malaysian Diabetes Association; HRQoL:Health-related quality of life; PA:Physical activity; IPAQ:International physical activity questionnaire; MET:Metabolic equivalent; PF:Physical functioning; RP:Role physical; BP:Blood pressure; GH:General health; VT:Vitality; SF:Social functioning; RE:Role emotion; MH:Mental health; PCS:Physical component summary; MCS:Mental component summary

## Declarations

## Acknowledgements

The module for this study was adopted from United States Diabetes Prevention Program (US DPP) of Centres for Disease Control and Prevention (CDC) and was translated into the Malay language as well as underwent forward-backward translation by Khuzaiton Zakaria, Aveleena Afzan Hassan and Nor Fazura Md Zulkifle who were language lecturers at University Malaysia Kelantan, Malaysia.

## Authors' contributions {31b}

N.F.M.F. and S.W. designed the entire study, N.B.R. designed the physical activities, M.I.A. and N.A.M.Y. designed the diet, N.A.R. designed the mobile app, N.M.H. designed the HbA1c method. All authors reviewed the manuscript.

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## Availability of data and materials {29}

The data sets used and/or analysed during the current study available from the corresponding author on reasonable request.

## Ethics approval and consent to participate {24}

Ethical approval was obtained from the (Universiti Sultan Zainal Abidin (UniSZA) Human Resources Ethics Committee (UHREC) (UniSZA/UHREC/2018/77). Eligible participants are contacted to about discussing the study, confirm eligibility criteria and arrange for baseline testing. They are provided with consent form approved by UHREC at the time of recruitment.

## Consent for publication {32}

Researchers will use the same written informed consent form provided by the participants at the time of recruitment.

## Competing interests {28}

The authors declare that they have no competing interests.

## Author details

<sup>1</sup>School of Nutrition and Dietetics, Faculty of Health Sciences, Gong Badak Campus, University Sultan Zainal Abidin, 21300 Kuala Terengganu, Malaysia.

<sup>2</sup>School of Rehabilitation Science, Faculty of Health Sciences, Gong Badak Campus, University Sultan Zainal Abidin, 21300 Kuala Terengganu, Malaysia.

<sup>3</sup>School of Nutrition and Dietetics, Faculty of Medicine and Health Sciences, Universiti Putra Malaysia, 43400 Serdang, Selangor, Malaysia

<sup>4</sup>Faculty of Informatics and Computing, Besut Campus, University Sultan Zainal Abidin, 22200 Besut, Terengganu, Malaysia.

<sup>5</sup>Faculty of Medicine, University Sultan Zainal Abidin, Jalan Sultan Mahmud, 20400 Kuala Terengganu, Malaysia.

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## Figures

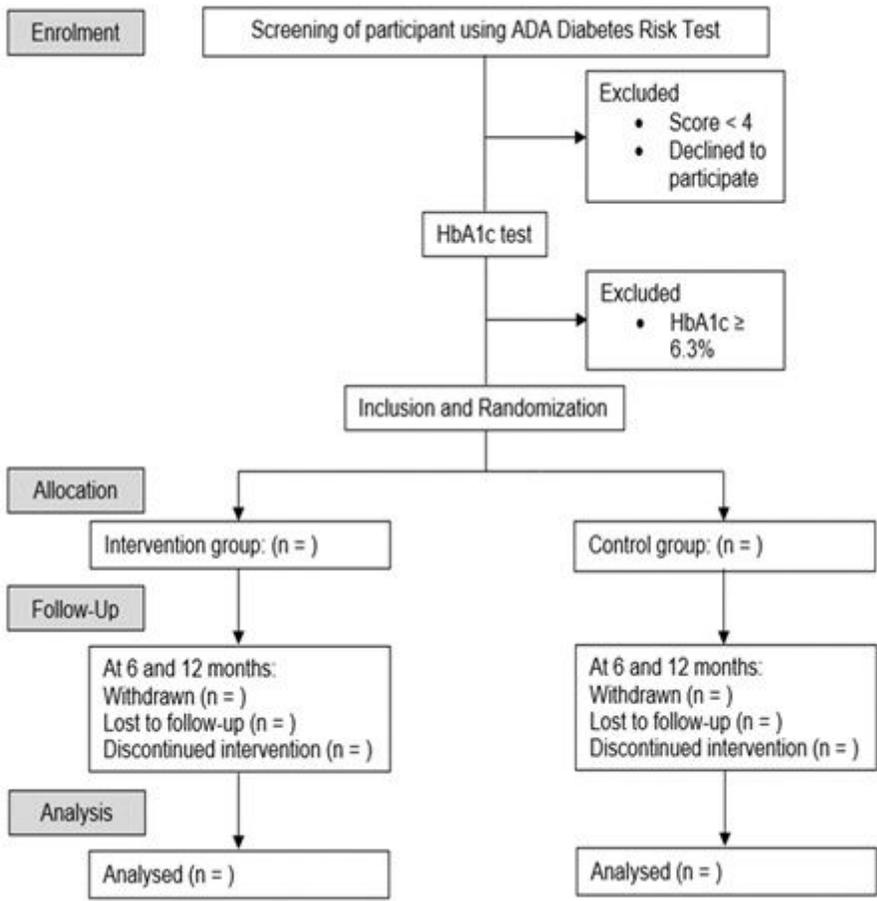
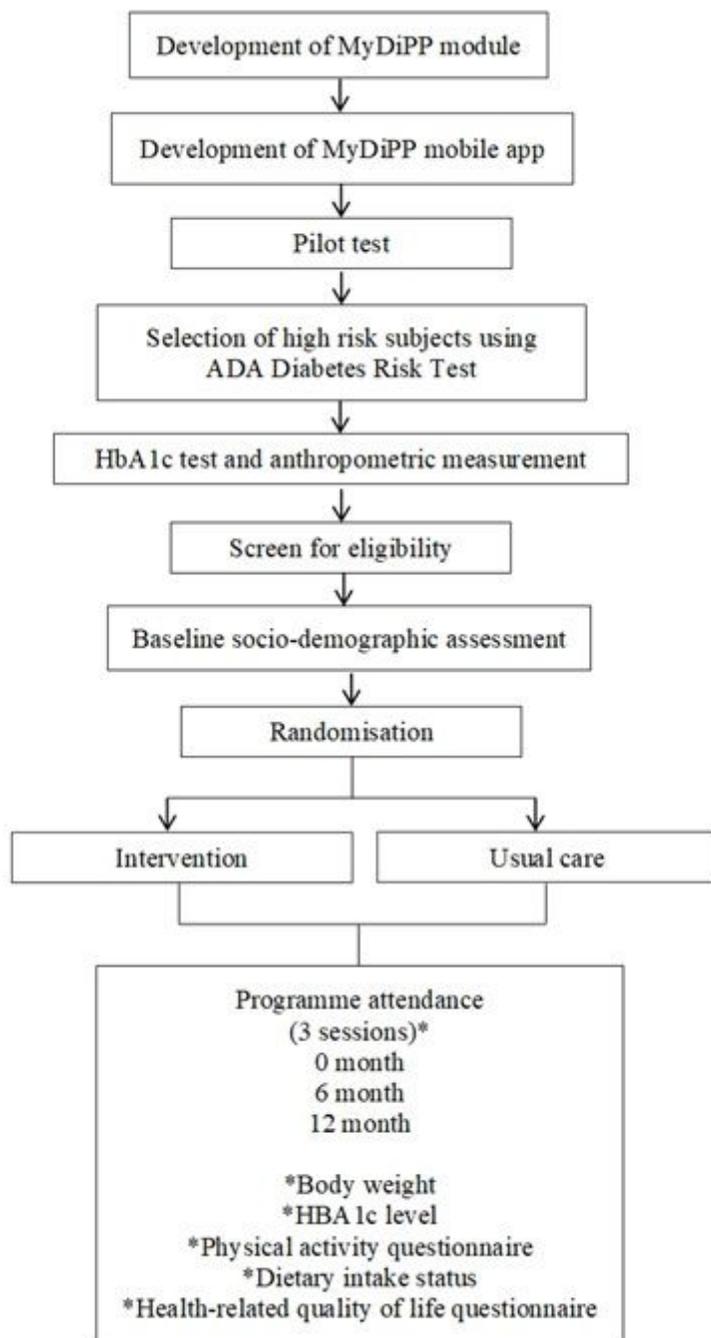


Figure 1

SPIRIT flow diagram of MyDiPP trial



**Figure 2**

Study flow chart

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