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TITLE

Effectiveness of a culturally adapted biopsychosocial intervention (POHON SIHAT) in improving self-efficacy in patients with diabetes: Study protocol of a randomised controlled trial.

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ABSTRACT

Introduction

People with diabetes are often associated with multifaceted factors and comorbidities, hence management frameworks have moved towards a biopsychosocial patient-centered approach. Despite increasing efforts in promotion and diabetes education, interventions integrating both physical and mental health components are still lacking in Malaysia. Identified as relevant within the primary care system, the Optimal Health Program (OHP) offers an innovative biopsychosocial framework to promote overall well-being and self-efficacy, going beyond education alone. Following a comprehensive cultural adaptation process, Malaysia's first OHP known as Pohon Sihat was developed. The study aims to evaluate the effectiveness of the program in improving self-efficacy and well-being in primary care patients with diabetes mellitus.

Methods and Analysis

This biopsychosocial intervention randomised controlled trial engages patients (n = 156) diagnosed with type 2 diabetes mellitus (T2DM) from four primary healthcare clinics in Putrajaya. Participants will be randomised to either Pohon Sihat plus treatment-as-usual (OHP+TAU) or treatment as usual (TAU). The 2-hour sessions conducted over 5 consecutive weeks and booster session post three months will be facilitated by trained mental health practitioners and diabetes educators. Primary outcomes include self-efficacy measures, while secondary outcomes include well-being, anxiety, depression, self-care behaviours and haemoglobin A1c glucose test (HbA1c). These outcome measures will be assessed at baseline, immediately post-intervention, as well as at 3 months, and 6 months post intervention. Where appropriate, intention to treat analyses will be performed.

Ethics and Dissemination

This study has obtained ethics approval from the Medical Research and Ethics Committee (MREC), Ministry of Health Malaysia (NMRR-17-3426-38212). Study findings will be shared with the Ministry of Health Malaysia and participating health clinics. Outcome will also be shared through publication, conference presentations and publication within a peer-reviewed journal.

Trial Registration - ClinicalTrials.gov NCT03601884

Keywords: self-efficacy, diabetes, biopsychosocial, self-management, primary care

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Article Summary

Strengths and limitations of this study

- This study is a randomised controlled trial that assesses the effectiveness of a culturally sensitive biopsychosocial intervention in primary care patients with diabetes
- The intervention is a self-efficacy enhancing program that has underwent a thorough process of translation and cultural adaptation.
- The intervention provides a low intensity intervention that addresses the mental health issues and promote overall wellbeing that goes beyond just education.
- The population is limited to Putrajaya, an urban state in Malaysia with high prevalence of health literacy but however has high prevalence in diabetes and highest prevalence in obesity in the country.

INTRODUCTION

Background and Rationale

There is an increasing global trend in the prevalence of diabetes notably amongst low and middle-income countries, contributing towards significant impact at both the individual and the population levels(1). There are challenges that proponents of diabetes management will have to face routinely.

With the increasing awareness of psychosocial issues related to diabetes within the last decade, there has been a greater demand for a transformation from a principally reactive-based healthcare system to a proactive-based healthcare system(2). Thus, diabetes management has moved from essentially biological to a more broad biopsychosocial approach(3). Psychosocial elements are central to diabetes management, with an emphasis on collaborative partnerships and patient-centered care in achieving optimal health and well-being(4).

Adding to the conundrum of the rapidly growing rate of diabetes prevalence, low and middle-income countries also face limited mental health resources(5). Hence, there has been a call to build the capacity of the health care system especially within the primary healthcare setting, for an integration of mental health and diabetes care services(6). Despite increasing efforts in diabetes education and health literacy as well as allocation of diabetes educators in health clinics and hospitals(7), improvements in diabetes care have been marginal(8). Diabetes educators and primary healthcare professionals are mainly trained in physical health and medical knowledge of the illness but many of them do not have the skills and training needed in handling emotional and psychological aspects of the illness(9). This limitation has become a significant barrier in addressing mental health issues in patients with diabetes(9).

The nature of current diabetes care sets up the expectation that diabetes patients hold 95% control over their own illness throughout the course of their illness(10), therefore self-efficacy holds a vital role in the ability to cope with diabetes(11), managing emotions, and making a commitment to self-care behaviours(12) .

Self-efficacy has been found to correlate with self-management behaviours(11–14) and being negatively correlated with physical distress(15), depression(12), and diabetes distress(16). The role of self-efficacy as a mediator between self-management behaviours and diabetes related distress, depression, and anxiety were also reported(13,17). Therefore, an intervention that enhances self-efficacy would be expected to improve depression, diabetes distress, and self-management behaviours. Hence, inclusion of self-efficacy as a treatment outcome in a diabetes intervention program is crucial as this allows researchers to evaluate the effectiveness of such program accurately(4).

POHON SIHAT – Cross-culturally adapted Malay Optimal Health Program (OHP)

The Optimal Health Program (OHP) is a biopsychosocial program that promotes patients to be actively involved in their own healthcare and overall well-being. The aim of OHP is to improve individual's self-efficacy and to build on their strengths and values which in turn enhance their overall wellbeing. Initially developed and found effective in mental health patients(18,19), the OHP has extended its treatment in managing physical health and chronic illnesses(20,21). Having a platform to discuss the multiple areas of a person's life and associated psychosocial barriers creates tremendous potential in the management of diabetes.

In a preliminary study that assessed the needs of OHP in Malaysia, the OHP was found to hold a promising framework in building the capacity of the mental health care services in Malaysia(22). Following a process of translation and cultural adaptation, the Malaysian OHP program was developed (henceforth referred to as Pohon Sihat). Being a culturally sensitive tool, Pohon Sihat provides a promising low intensity self-efficacy enhancing psychosocial intervention conducted within the primary care setting.

Objectives

Pohon Sihat is designed to address the gap in the management of mental health issues in diabetes patients within a limited resource setting. This study will examine the effectiveness of this program for diabetes patients within a primary care setting in Malaysia.

The intervention will be offered to patients with diabetes who are currently attending health clinics within the Putrajaya district. Specifically, this study aims to investigate the effectiveness of Pohon Sihat in addition to treatment-as-usual (TAU) as compared to TAU alone. It will also examine the effectiveness of Pohon Sihat in reducing anxiety, depression, diabetes-related distress, and in increasing self-care behaviours and glycemic control.

METHODS

Study design

This single blind, randomised controlled trial will employ a stratified randomisation (by size of Health Clinic) approach. The trial will be carried out at all four health clinics in Putrajaya, Malaysia from February 2018 to August 2020. Participants will be individually randomised to one of two parallel groups: treatment as usual (TAU) or Pohon Sihat (OHP) plus TAU. Figure 1 shows the flow chart of participants through the study and Figure 2 shows the enrolment, interventions, and assessments schedule.

Study setting

The Federal Territory of Putrajaya is Malaysia's federal administrative center. Based on the National Health and Morbidity survey(8), Putrajaya has high prevalence for diabetes (19.2%) and has the highest prevalence for overweight (37%), obesity (43%) and abdominal obesity (61.3%).

Participants

Sampling frame

The sampling frame will be patients with Type 2 Diabetes Mellitus (T2DM) registered at the primary healthcare clinics within the Federal Territory of Putrajaya. Approximately 35% of the Malaysian population receives treatment within the government health clinics located within the community, for easy accessibility and communal location(23).

The services and facilities provided within the clinics differ according to the size of the clinics which is based on the number of patient visits per day. Health Clinic Presint 9 (KKP9) and Health Clinic Presint 18 (KKP18) have 500-800 patient visits per day. These Health Clinics are

fully equipped with Primary Health Care services, Family Medicine Specialists, Laboratory, Diagnostic Imaging, Rehabilitation, Dietary, Pharmacy, and Dental services. Health Clinic Presint 11 (KKP11) and Health Clinic Presint 14 (KKP14) have fewer than 150 patient visits per day. These clinics are limited to outpatient services (non-complex cases and/or stabil chronic cases) and pharmacy services.

According to the 2018 National Diabetes Registry, registered diabetes patients (both Type 1 and Type 2) are unevenly distributed based on the type of the health clinics, the facility available and the services provided. Sizes of the diabetes clinic of each health clinics differ with KKP9 having the largest portion of diabetes patients in Putrajaya (64%) and KKP11 having the smallest portion (2%).

Eligibility Criteria

Inclusion criteria

Eligible patients include patients with a diagnosis of Diabetes Mellitus Type 2 as assessed by their attending physicians based on the National Clinical Practice Guidelines for Type 2 Diabetes Mellitus(24); aged between 18 to 60 years old; and currently registered to be receiving services in the health clinics in Putrajaya. Patients also need to be able to provide informed consent to participate in the study.

The criteria for diagnosing Diabetes Mellitus Type 2 is based on the Malaysia's Clinical Practice Guidelines for Type 2 Diabetes Mellitus. The guideline defines Diabetes Mellitus Type 2 patients as people who have been diagnosed with diabetes mellitus, and have had/have a confirmed A1C level FPG $\geq$ 7.0mmol/L.

Exclusion Criteria

Patients unable to write and read, unable to speak Malay or English, those who are medically unstable or who cannot provide informed consent, will be excluded. Patients who are currently attending intensive psychological treatment will also be excluded from the study.

Withdrawal Criteria

Participants can choose to withdraw at any time. Participants may be withdrawn if the research team deems that it is detrimental or risky for them to continue; arrangements will be made for their future care. Withdrawn participants will not be replaced and will be incorporated in the intention-to-treat analysis.

Interventions

POHON SIHAT

Participants from the intervention group will receive treatment as usual and will attend the Pohon Sihat Program. Treatment as usual refers to the pharmacological treatment received or prescribed by the patients' attending doctor in accordance with the Clinical Practice Guideline in Managing Diabetes Mellitus in adult patients(24).

The OHP will be delivered in groups consists of 10 to 12 participants. The group sessions will be facilitated by at least two trained Optimal Health program facilitators, at least one trained mental health practitioner (i.e., clinical psychologist), and at least one trained diabetes care expert (i.e., diabetes educator, medical practitioner).

Participants will attend a five, weekly sessions (one session per week) and a booster session. An outline of sessions is shown in *Table 1*. Each session lasts for 2 hours. Sessions will be conducted outside of routine clinic follow-ups.

Participants' treatment outcome will be assessed before the start of the group program (T1) at the end of the group session (T2), at the booster session (T3). Three months after T2, participants will receive the booster session. At 6-month follow-up (T4) participants will be asked to complete the final assessments, via mail (Refer *Figure 2*)

Control Group or Treatment-as-usual (TAU) refers to the pharmacological treatment received or prescribed by the patients' attending doctor. To improve standardisation of treatment, attending doctors were prompted to manage patients in accordance with the Clinical practice Guideline in Managing Diabetes Mellitus in adult patients(24).

Outcomes

Primary and secondary outcomes as listed in *Figure 2* are self-reported outcomes that will be measured at 4 time points, baseline (pre-treatment), 5 weeks (post-treatment), 3 months and 6 months follow-up. Description of measurements that will be used is outlined in *Table 2.*

Primary outcomes

Self-efficacy will be measured by two scales: the 8-item Diabetes Empowerment Scale – Short Form (DES-SF)(25,26) and the 20-item Diabetes Management Self-Efficacy Scale (DMSES)(17,27).

Secondary outcomes

Secondary outcome will include depression (Patient Health Questionnaire; PHQ-9)(28), anxiety (General Anxiety Disorder scale; GAD-7)(29), diabetes distress (Problem Areas in Diabetes; PAID-5)(30), and general well-being (WHO-5 Wellbeing Index)(31). Self-management behaviors will be measured by the Summary of Diabetes Self-Care Activities (SDSCA) Scale(32,33).

Data on glycaemic control will be collected from patient records while demographic details, co-morbidities, duration, and diabetes complications are assessed using a standard questionnaire assessed once participants have been allocated to the treatment or control group.

Sample size

Considering the study outcomes, the sample size is calculated based on a similar study(34) by using the formula proposed by Zhong(35).

As far as response rate is concerned, in studies using OHP, a 12 months follow up protocol experienced a 14% drop out rate for patients with mental illness(36). Similarly, Moriyama et al.'s(37) study reported a 16% drop out rate for a self-management program in patients with diabetes. Other studies showed that a 6 month follow-up, self-management program in T2DM yielded an attrition rate that ranged between 10% to 20%(34,38). Within local setting, the attrition rate was 10% for a 12-week follow-up education-based program in patients with diabetes(39).

Taking into consideration a conservative approach and duration of follow-ups, this study will estimate a 30% attrition rate for the loss to follow-up at 6 months.

Based on the study by Wu et al.(34), with an expected medium effect size of 0.40 (μ diff = 16.19, s.d. =37.01), the current study will calculate the sample size required in this study using a study-wide type 1 error rate (α) of 0.05 and a type II error rate (β) of 0.20 (power of 0.80). The current study will require a total of 59 participants for each group. With an expected attrition rate of 30%, the study aims to recruit a total of 172 participants, with 86 participants for each group.

Recruitment

Study procedure

Recruitment will take place at the clinics during patient's routine check-ups at the diabetes clinic, for a period of 6 months or until the required number of participants are achieved.

Based on the list of registered patients during a clinic day, people with diabetes will first be screened based on age and type of diabetes. Eligible participants will be asked for consent to be approached by a research assistant. Those who fulfill the criteria and are able to give written informed consent for participation, will be included in the study.

After enrolment, participants will be given an opaque, sealed and numbered envelope containing allocation of groups, given in numerical sequence. Thus each participant will be assigned into the intervention or control group based on the random sequence of enrolment in the study.

Allocation

Allocation sequence generation

To ensure concealment of allocation, co-authors will conduct the randomisation using digit random sampling. The randomisation sequence is created with simple randomisation procedure and computerised random numbers using Excel 2010 (Microsoft, Redmond, WA, USA) with participants assigned to either Treatment as usual (TAU) or Pohon Sihat plus TAU.

To ensure inclusion of the different types of the health clinics within Putrajaya, the four health clinics will first be stratified by the size of the clinic. To ensure a balanced representation of diabetes patients within each clinics, randomisation will be conducted based on the size of the diabetes clinic as reported in the National Diabetes Registry. KKP9 with the largest portion of registered diabetes patients (64%) will be allocated 110 participants (64% of 172 participants), followed by KKP18 (31%) allocated 53 participants, KKP 14 (3%) allocated 5 participants and KKP11 (2%) with an allocation of 4 participants.

Allocation concealment mechanism and implementation of random allocation

To ensure that clinics are assigned with a balanced number of allocated intervention and control, two lists of randomisation sequences were made 1) clinics with 500-800 patient visits per day – KKP9 and KKP18, and 2) clinics with less than 150 visits per day – KKP11 and KKP14.

Research assistants involved in the recruitment will be blinded from the sequence allocation. Sealed envelopes will only be opened after eligible participants provide and sign the informed consent form.

Contamination Bias

To minimise the effect of a contamination bias, the Pohon Sihat plus TAU (experimental group) sessions will be scheduled outside of the participating health clinics. Intervention sessions will be conducted in either a community based rehabilitation center or a central health district center situated within Putrajaya. Participants will also be informed of the study parameters, with directives not to discuss the content of the materials or to exchange materials with other diabetes patients outside of the group.

Blinding

Blinding will be adopted to reduce bias of participants performing better or worse when they are informed which group they are allocated to after the randomisation process. This study will thus incorporate a single blinding process. Participants will not know which group is considered the experimental group and the control group.

Statistical Analysis

The intention-to-treat principle and per-protocol analyses will be performed. Any deviations from the random allocation and missing data will be fully reported as outlined in the Consolidated Standards of Reporting Trials (CONSORT) guidelines.

Any differences between individuals in the intervention and control conditions at baseline (socio-demographics, clinical details, psychosocial self-efficacy, diabetes management self-efficacy, anxiety, depression, diabetes-related distress, well-being, self-care behaviours and HbA1C) will be assessed using one-way analysis of variance ANOVA or chi-square test as appropriate. Assumptions of normality and homogeneity of variance will be assessed and adjusted accordingly.

A Mixed model ANOVA will be used to investigate the effectiveness of Pohon Sihat (OHP plus TAU) vs Treatment as usual (TAU)) on all continuous variables at four points (i.e. baseline, 5 weeks, 3 months and 6 months). For all mixed effect repeated measures analyses, condition and time will be specified as fixed effects.

A one-way analysis of covariance (ANCOVA) will be used to assess the effectiveness of the intervention group compared to control, when covariates included duration of diabetes and diabetes complication are expected to impact on outcome measures.

Patient involvement

Program assessment, treatment fidelity and cultural adaptation

Considerations in the adaptation of the OHP for the Malaysian community were informed based on (1) review by Malaysia's primary and mental health care professionals, (2) translation and cultural adaptation of the program.

The panel of reviewers included endocrinologist, family medicine specialists and physicians, and the OHP was considered to be a valuable engagement tool that could further enhance the primary health care services inclusive of mental health(22). Following this feedback, the OHP underwent a thorough translation and adaptation process.

The translation and cultural adaptation process involved multiple stages (1) development of a panel of experts from Malaysia and Australia, (2) forward and back translation of the program workbook, (3) cultural adaptation through the review and comparison by both content and local experts, including revision and harmonisation of the workbook, (4) pre-testing the program in a group of mental health practitioners, patient support group representatives as well as representatives from the Ministry of health and finally (5) proofreading and finalising of design. Based on thorough translation and adaptation process, the program was assessed as matching the intention and the fidelity of the program

Training of Diabetes Educators

Taking into consideration that many diabetes educators have minimal training in mental health especially engaging in effective health communication(9), an additional day was added to the facilitator's training. The additional day included more in-depth content, including collaborative therapy principles and motivational interviewing based health coaching techniques. This is to ensure that the program delivery will maintain fidelity and stay aligned with its intention.

Each group program will be facilitated by a trained mental health practitioner and diabetes care expert to further strengthen the program's fidelity.

Pilot study

A pilot study was conducted to assess the feasibility and content of the culturally adapted OHP amongst people with diabetes. Eight participants (n=8) were recruited, five completing all 5 sessions of the program (three withdrew due to work commitments). Challenges were identified with the (1) recruitment process, (2) duration of the program and the (3) content of the material.

Participants' feedback suggested that the 1.5 hour sessions be increased to 2 hours to allow more discussion. This was also echoed by the facilitators, who felt that an additional half an hour will allow greater coverage, improved ease of delivery and a better sense of not being constricted by time. Generally, participants provided valuable feedback on the content of the workbook,

structure of the program and ease of delivery. An additional information sheet on healthy eating habit and lifestyle tips was also suggested by participants.

Based on the feedback provided by both participants and facilitators, recruitment process was improved through several steps. First, during recruitment, participants were informed that an official letter and time–slips can be provided to allow time off work to attend the program. Ensuring several groups programs are run throughout the week is an important factor to allow flexibility to attend sessions that were suitable to their time. Logistical constraints were also improved by choosing venues that will have ample parking space. Sessions were also extended from a 1.5 hours to two hours. Content of the workbook was improved with additional health information such as the food pyramid and the local healthy eating habits. This additional information and some minor language changes were deemed to increase feasibility, and improve the Pohon Sihat Malay workbook.

ETHICS AND DISSEMINATION

Consent

All eligible participants will be fully informed verbally that they are being asked to participate in a randomised controlled trial. The process of obtaining consent is in line with the Declaration of Helsinki. Information regarding the study, and random allocation of participants will be explained based on a Patient Information Sheet as approved by the Ethics committee. A signed informed consent will be obtained from each participant. At the end of the study, participants within the control group (Treatment-as-usual) will be invited to participate in POHON SIHAT.

Ethics approval

Ethical approval for this study was obtained from the Medical Research and Ethics Committee (MREC), Ministry of Health Malaysia.

Data Management

All participant information will be treated as strictly confidential. All research materials that provide personal information will be coded to ensure the confidentiality of the participants and no individuals will be identifiable in any reports or publications. No information collected will

be shown to anyone apart from the research team. Data from the study will be stored securely in locked cabinets and electronic data will be kept on password protected drives accessible only by the research team.

Dissemination Plan

The findings of the study will be shared with stakeholders within the country through publication and conference presentations. The outcomes of the study will be shared through publication within a peer-reviewed journal within 12 months of the last data collected. As part of the ethics approval requirements, outcome will also be shared with the Malaysia Ministry of Health and participating health clinics.

DISCUSSION

The complexity of diabetes mellitus itself is associated with not just the patient's physical health but also their emotional well-being and mental health, social, occupational and overall quality of life(40). The growing diabetes population with increasing psychosocial barriers are associated with greater complexity of diabetes contributing to greater health impact on the individual, family and community. Moreover, even though Putrajaya was found to be a state that ranked high in health literacy, prevalence rates of diabetes and obesity within Putrajaya are still the highest in the country. With its mediating role between health literacy and self-care behaviours(41), self-efficacy may be the missing link in understanding the dissonance between illness education, and the ability to utilize the knowledge to commit to healthy lifestyle.

The OHP is a self-efficacy enhancing psychological intervention that is low-intensity, structured and can be delivered by trained facilitators. Its recovery-based approach emphasizes the language of hope and well-being as compared to illness and disease which is suitable to be given within a primary health care setting. It may offer a platform for wide range of health care providers within the primary care to engage in a discussion with patients regarding their well-being through a patient centered collaborative approach. Through the OHP, a psychological intervention program for primary health care providers can be provided to address the mental

health issues and promote overall wellbeing in these chronic ill patients. The Pohon Sihat will be the first engagement tool in Malaysia with potential to act in a curative and preventative role

In addition to providing further understanding in the effectiveness of an add-on psychological intervention, the outcome of the study will also provide information on the effectiveness of the current standard of practice within the primary health care as guided by the latest version of the Clinical Practice Guideline in the management of Type 2 Diabetes Mellitus.

Trial Status

Patient recruitment commenced October 2018 and data collection will continue until August 2020. ClinicalTrials.gov NCT03601884

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Figure

Figure 1. Flow chart of participants

Figure 2. Schedule of enrolment, interventions, and assessments.

Tables

Table 1. Outline of POHON SIHAT sessions for patients with diabetes

Table 2. Description of measurements

Contributors

AFS, NI, TKA and UAS took part in designing the study. AFS wrote the first draft of the manuscript and coordinated the development of the study protocol. BG, TKA, GM and DC contributed a thorough review of the manuscript which AFS revised in the second version. UAS, NI, TKA and BR then provided further written feedback. All authors critically reviewed, revised and approved the final version of the manuscript to be submitted by AFS.

Competing Interests:

DC has received grant monies for research from Eli Lilly, Janssen Cilag, Roche, Allergen, Bristol-Myers Squibb, Pfizer, Lundbeck, Astra Zeneca, Hospira; Travel Support and Honoraria for Talks and Consultancy from Eli Lilly, Bristol-Myers Squibb, Astra Zeneca, Lundbeck, Janssen Cilag, Pfizer, Organon, Sanofi-Aventis, Wyeth, Hospira, Servier; and is a current Advisory Board Member for Lu AA21004: Lundbeck; Varenicline: Pfizer; Asenapine: Lundbeck; Bitopertin: Roche Aripiprazole LAI: Lundbeck; Lisdexamfetamine: Shire; Lurasidone: Servier. He has no stocks or shares in any pharmaceutical company.

This study had no other conflict of interest.

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Data sharing statement

There are no data available in this study protocol.

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Table 1. Outline of POHON SIHAT sessions for patients with diabetes

WEEK	SESSION	SESSION OUTLINE
1	Optimal Health	What is Optimal Health? • Introduction to the Collaborative Therapy Optimal Heath Program • Introduce TOOL 1: The Optimal Health Wheel • Reflection of one's own health based on 6 domains – physical, emotional, intellectual, social, spiritual and occupational health and identifying possible areas for change • Exploration of one's satisfaction level within each health domains • Identify possible areas for change
2	I-CAN-DO Model Strengths and vulnerabilities Stressors and strategies	The I-Can-Do Model • Introduction to concepts of one's strengths, vulnerabilities, stressors and strategies and how it may impact on their over wellbeing • Introduce TOOL 2: I-Can-Do Model • Identify one's strengths and vulnerabilities • Identify one's source of stress and how stress may impact diabetes and overall wellbeing • Identify and building one's own strategies to cope with stressors • Reflection on achieving balance within the I-CAN-DO MODEL
3	Factors of Wellbeing	Medication and Metabolic Monitoring • Psychoeducation on medication – understanding what, why and how one's own medication works • Introduce TOOL 3: Medication & Metabolic Monitoring Table • Emphasize on the metabolic monitoring that needs to be done routinely within the health clinics • Addressing common myths amongst diabetes patients • Further emphasis on healthy lifestyle and eating habits Collaborative Partners and Strategies • Identify collaborative partners • Introduce TOOL 4: Eco-Mapping • Discussion on role of collaborative partners in maintaining one's optimal health
4	Visioning & Goal Setting	Change Enhancement – Time line activity • Introduction to identifying past events and its impact on health • Stages of Health: Optimal Health, Sub Optimal Health and Episode of Illness • Introduce TOOL 5: Time Line Activity

		Visioning and Goal Setting • Introduction to creative problem solving and setting SMARTER goals • Introduce TOOL 6: Cost-benefit Table • Discussion on barriers to achieving goals • Identify steps and strategies to achieve future goals
5	Maintain well-being	Maintaining well-being • Understanding one's own stages of health • Introduce TOOL 7: Health Plans: Optimal Health (Health Plan 1); Sub-optimal Health (Health Plan 2) and Episode of Illness (Health Plan 3) • Build skills and strategies at different stages of health • Review of session 1-4 and tools introduced
Booster	Review Health Plans	Review of Health Plans • Reflection on the application of knowledge and skills learned and its impact on optimal health. • Discussion on possible barriers and strategies

Table 2. Description of measurements

OUTCOME AND DESCRIPTION OF MEASUREMENTS	
Primary Outcome – Self-efficacy	
Psychosocial Self-efficacy	**The Diabetes Empowerment Scale (DES-SF)** is an 8 item self-administered measurement that assesses the perceived ability to manage psychosocial issues such as managing stress, coping with emotional distress, engaging with family and friends for support and discussion with health care providers(25). Participants rate items on a 4-point likert scale ranging from 0 (strongly disagree) to 4 (strongly agree). The sum of all items ranged from 0 to 32. Previous research reported the DES-SF Chronbach's alpha is at 0.84(26).
Diabetes Management Self-Efficacy	**The Diabetes Management Self-efficacy Scale (DMSES)** is a 20-item self-administered measurement that assess self-efficacy in managing specific diabetes self-care behaviours such as glucose monitoring, general and specific diet, medication adherence, exercise and foot care(27). Participants rate items on a 10-point likert scale ranging from 0 (Not at all confident) to 10 (Totally confident). The Malay validated DMSES has a Chronbach's α estimate of 0.951(17).
Secondary Outcomes	
Depression	**Patient Health Questionnaire –PHQ-9** is a 9 item self-administered measurement that assseses the presentation of depression symptoms and the impairments related to the symptoms. Participants rate items on a 4-point likert scale ranging from 0 to 3. The sum of all items range between 0 to 27. The Malay validated PHQ-9 has a Chronbach's α estimate of 0.70, sensitivity of 87% and specificity of 82%(28).
Anxiety	**General Anxiety Disorder – GAD-7** is a 7 item self-administered measurement that assesses the presentation of anxiety symptoms and the impairments related to the symptoms. Participants rate items on a 4-point likert scale ranging from 0 to 3. The sum of all items range between 0 to 21. The Malay validated GAD-7 has a Chronbach's α estimate of 0.74, sensitivity of 76% and specificity of 94%(29).
Diabetes-related distress	**Problem Areas in Diabetes (PAID) – 20** is a 20 item self-administered measurement that assesses emotional problems in patients with diabetes. Participants rate items on a 5-point likert scale ranging between 0 (Not a problem) to 4 (serious problem). The

	sum of all items range from 0 to 80. The Malay validated PAID-MY 20 has a Chronbach's α estimate of 0.921(30).
Well-being	**WHO-5 Wellbeing Index (WHO-5)** is a 5 item self-administered measurement that assesses emotional wellbeing and mental health (31). Participants rate items on a 5-point likert scale ranging between 0 (none of the time) to 5 (all of the time). The raw score that ranges from a minimum of 0 (absence of well-being) to a maximum of 25 (maximum well-being) are then multiplied by 4 to obtain the percentage scale. The recommended cut off score of ≤50 is an indication of poor well-being.
Self-management behaviours	**Summary of Diabetes Self-Care Activities (SDSCA)** is an 11 item self-administered measurement that assess aspects of diabetes regimen including general diet, specific diet, exercise, blood-glucose testing, foot care and smoking(32). Participants responds based on engagement to self-management behaviours related to diabetes in the last seven days. The Malay validated SDSCA Chronbach's α estimate for the main domains ranged between 0.651 and 0.905(33).
Glycaemic control	Glycaemic control will be reported in SI units (mmol A1c/mol Hb) that will be collected from patient records. Based on the guideline, the target that needs to be achieved for control of T2DM is a HbA1C level of not more than 6.5%.

Figure 1 Flow chart of participants

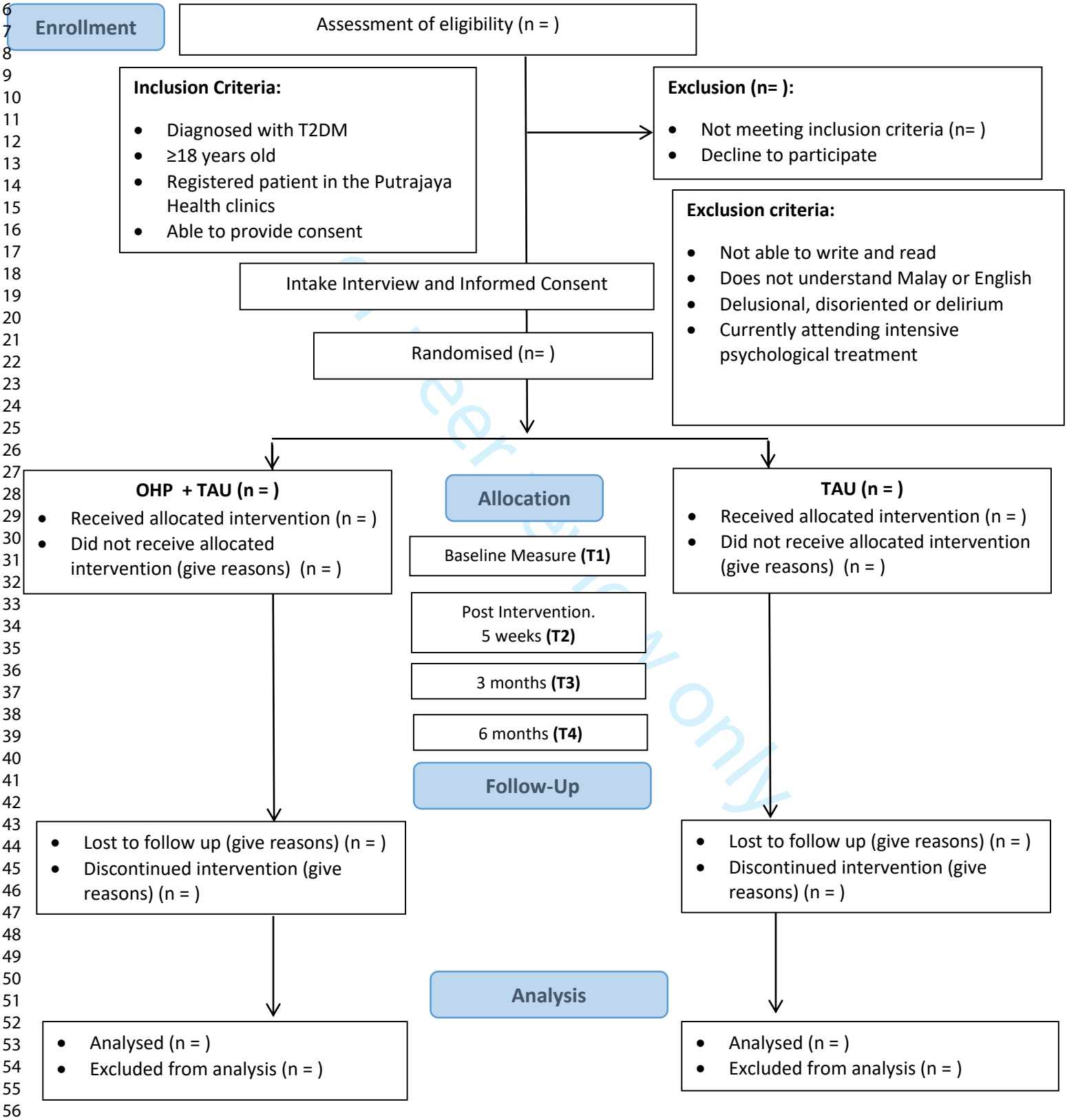

Figure 2. Schedule of enrolment, interventions, and assessments.

	STUDY PERIOD					
	Enrolment	Allocation	Post-allocation			Follow up
TIMEPOINT	$-t_1$	0	*1 wk*	*5 wk*	*18 wk*	*30 wk*
ENROLMENT:						
Eligibility screen	X					
Informed sheet	X					
Informed consent	X					
Randomisation	X					
Allocation		X				
INTERVENTIONS:						
Pohon Sihat and Treatment as usual			◆—	—	—◆	
Treatment as usual						
ASSESSMENTS:						
Sociodemographic data		X				
DES-SF			X	X	X	X
DMSES			X	X	X	X
GAD-7			X	X	X	X
PHQ-9			X	X	X	X
PAID-20			X	X	X	X
WH0-5			X	X	X	X
SDSCA			X	X	X	X
HbA1C		X				X

Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SPIRITreporting guidelines, and cite them as:

Chan A-W, Tetzlaff JM, Altman DG, Laupacis A, Gøtzsche PC, Krleža-Jerić K, Hróbjartsson A, Mann H, Dickersin K, Berlin J, Doré C, Parulekar W, Summerskill W, Groves T, Schulz K, Sox H, Rockhold FW, Rennie D, Moher D. SPIRIT 2013 Statement: Defining standard protocol items for clinical trials. Ann Intern Med. 2013;158(3):200-207

		Reporting Item	Page Number
Administrative information			
Title	#1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1

Trial registration	#2a	Trial identifier and registry name. If not yet registered, name of intended registry	4
Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	
Protocol version	#3	Date and version identifier	1
Funding	#4	Sources and types of financial, material, and other support	2
Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	1-2
Roles and responsibilities: sponsor contact information	#5b	Name and contact information for the trial sponsor	
Roles and responsibilities: sponsor and funder	#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	
Roles and responsibilities: committees	#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)	
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	5
Background and rationale: choice of comparators	#6b	Explanation for choice of comparators	6
Objectives	#7	Specific objectives or hypotheses	6
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, non-inferiority, exploratory)	7
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	7

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)	8
Interventions: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	9
Interventions: modifications	#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)	
Interventions: adherance	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	
Interventions: concomitant care	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	
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	10

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 Figure)	10 Figure 2
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	10
Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	11
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	11
Allocation concealment mechanism	#16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque,	12

		sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	12
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	12
Blinding (masking): emergency unblinding	#17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	
Methods: Data collection, management, and analysis			
Data collection plan	#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	15

Data collection plan: retention	#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	13
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	15
Statistics: outcomes	#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	13
Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	13
Statistics: analysis population and missing data	#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)	13
Methods: Monitoring			
Data monitoring: formal committee	#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	
Data monitoring: interim analysis	#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	
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	
Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	
Ethics and dissemination			
Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	15
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)	15

Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	15
Consent or assent: ancillary studies	#26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	
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	15
Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	2
Data access	#29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	15
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	
Dissemination policy: trial results	#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	16

Dissemination policy: authorship	#31b	Authorship eligibility guidelines and any intended use of professional writers	16
Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	16
Appendices			
Informed consent materials	#32	Model consent form and other related documentation given to participants and authorised surrogates	
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	

BMJ Open

Effectiveness of a culturally adapted biopsychosocial intervention (POHON SIHAT) in improving self-efficacy in patients with diabetes attending primary healthcare clinics in Putrajaya, Malaysia: Study protocol of a randomised controlled trial

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Primary Subject Heading:	Diabetes and endocrinology
Secondary Subject Heading:	Mental health
Keywords:	self-efficacy, diabetes, biopsychosocial, self-management, PRIMARY CARE

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TITLE

Effectiveness of a culturally adapted biopsychosocial intervention (POHON SIHAT) in improving self-efficacy in patients with diabetes attending primary healthcare clinics in Putrajaya, Malaysia: Study protocol of a randomised controlled trial

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ABSTRACT

Introduction

People with diabetes are often associated with multifaceted factors and comorbidities, hence management frameworks have moved towards a biopsychosocial patient-centered approach. Despite increasing efforts in promotion and diabetes education, interventions integrating both physical and mental health components are still lacking in Malaysia. Identified as relevant within the primary care system, the Optimal Health Program offers an innovative biopsychosocial framework to promote overall well-being and self-efficacy, going beyond education alone. Following a comprehensive cultural adaptation process, Malaysia's first Optimal Health Program was developed under the name 'Pohon Sihat' (OHP). The study aims to evaluate the effectiveness of the mental-health based self-management and wellness program in improving self-efficacy andwell-being in primary care patients with diabetes mellitus.

Methods and Analysis

This biopsychosocial intervention randomised controlled trial will engage patients (n = 156) diagnosed with type 2 diabetes mellitus (T2DM) from four primary healthcare clinics in Putrajaya. Participants will be randomised to either OHP plus treatment-as-usual (OHP+TAU) or TAU. The 2-hour weekly sessions conducted over 5 consecutive weeks, and 2-hour booster session post three months will be facilitated by trained mental health practitioners and diabetes educators. Primary outcomes will include self-efficacy measures, while secondary outcomes will include well-being, anxiety, depression, self-care behaviours and haemoglobin A1c glucose test (HbA1c). These outcome measures will be assessed at baseline, immediately post-intervention, as well as at 3 months, and 6 months post intervention. Where appropriate, intention to treat analyses will be performed.

Ethics and Dissemination

This study has obtained ethics approval from the Medical Research and Ethics Committee (MREC), Ministry of Health Malaysia (NMRR-17-3426-38212). Study findings will be shared with the Ministry of Health Malaysia and participating health clinics. Outcomes will also be shared through publication, conference presentations and publication in a peer-reviewed journal.

Trial Registration - ClinicalTrials.gov NCT03601884

Keywords: self-efficacy, diabetes, biopsychosocial, self-management, primary care

Word Count: (excluding title page, abstract (3000 words), references, figures and tables) - 3723

Article Summary

Strengths and limitations of this study

- This study has a strong design as a randomised controlled trial to assess the effectiveness of the intervention, including pre and post-test effects to explore cause–effect relationships.
- The intervention has been tested for construct validity during a thorough process of translation and cultural adaptation.
- The intervention provides an innovative strength-based recovery-oriented framework through collaborative therapy principles addressing the mental health issues and promote overall wellbeing that goes beyond just education provided by the 'traditional' approaches
- The intervention is delivered by mental health and non-mental professionals, integrating holistic patient-centred care.
- The study is limited to community clinics in Putrajaya, an urban state in Malaysia, which currently records high rates of health literacy in conjunction with high rates of diabetes and the highest prevalence of obesity in the country.

INTRODUCTION

Background and Rationale

There is an increasing global trend in the prevalence of diabetes notably amongst low and middle-income countries, contributing towards significant impact at both the individual and the population levels(1).

With the increasing awareness of psychosocial issues associated with diabetes within the last decade, there has been a greater demand for a transformation from a principally reactive-based healthcare system to a proactive-based healthcare system(2). Thus, diabetes management has moved from essentially biological to a more broad biopsychosocial approach(3). Psychosocial elements are central to diabetes management, with an emphasis on collaborative partnerships and patient-centered care in achieving optimal health and well-being(4).

Adding to the challenge of rapidly growing rate of diabetes prevalence, low and middle-income countries also face limited mental health resources(5). Hence, there has been a call to build the capacity of the health care systems especially within the primary healthcare settings, and for the integration of mental health and diabetes care services(6). Despite increasing efforts in diabetes education and health literacy, with allocated diabetes educators in health clinics and hospitals(7), improvements in diabetes care have been marginal(8). Diabetes educators and primary healthcare professionals are mainly trained in physical health and medical knowledge of the illness but many do not have the skills and knowledge for emotional and psychological aspects of the illness(9). These limitations have become a significant barrier in addressing mental health issues in patients with diabetes(9).

Often diabetes care will set up the expectation for diabetes patients to hold 95% control over their own illness throughout the course of their illness(10), therefore self-efficacy holds a vital role in the ability to manage diabetes well(11), including managing emotions, and making a commitment to self-care behaviours(12) .

Self-efficacy has been found to correlate with self-management behaviours(11–14) and being negatively correlated with physical distress(15), depression(12), and diabetes distress(16). The role of self-efficacy as a mediator between self-management behaviours and diabetes related distress, depression, and anxiety have also been reported(13,17). Therefore, an intervention that enhances self-efficacy would be expected to improve depression, diabetes distress, as well as enhance self-management behaviours. The inclusion of self-efficacy as a treatment outcome in a diabetes intervention program is crucial as this allows researchers to evaluate the effectiveness of the program accurately(4).

POHON SIHAT – Cross-culturally adapted Malay Optimal Health Program (OHP)

The Optimal Health Program (OHP) is a biopsychosocial program that promotes patients to be actively involved in their own healthcare and overall well-being. The aim of OHP is to improve individual self-efficacy and to build on strengths and values which in turn enhances overall wellbeing. Initially developed to integrate physical and mental health, the OHP has been found effective with mental health care(18,19), and extended to managing physical health and chronic illnesses(20,21). Having a platform to discuss the multiple areas of a person's life and associated psychosocial barriers creates tremendous potential in the management of diabetes.

In a preliminary study that assessed the needs of OHP in Malaysia, the OHP was found to hold a promising framework in building the capacity of the mental health care services in Malaysia(22). Following a process of translation and cultural adaptation, the Malaysian OHP program was developed (henceforth referred to as Pohon Sihat). Being a culturally sensitive tool, Pohon Sihat provides a promising low intensity self-efficacy enhancing psychosocial intervention conducted within the primary care setting.

Objectives

Pohon Sihat is designed to address the gap in the management of mental health issues in diabetes care within a limited resource setting. This study will examine the effectiveness of this program for diabetes patients within a primary care setting in Malaysia.

The intervention will be offered to patients with diabetes who are currently attending health clinics within the Putrajaya district. Specifically, this study aims to investigate the effectiveness of Pohon Sihat in addition to treatment-as-usual (TAU) as compared to TAU alone. It will also examine the effectiveness of Pohon Sihat in reducing anxiety, depression, diabetes-related distress, and in increasing self-care behaviours and glycemic control.

METHODS

Study design

This single blind, randomised controlled trial will employ a stratified randomisation approach (stratified by size of the Health Clinics). The trial will be carried out at all four health clinics in Putrajaya, Malaysia from February 2018 to August 2020. Participants will be individually randomised to one of two parallel groups: treatment as usual (TAU) or Pohon Sihat (OHP) plus TAU.

Figure 1 shows the flow chart of participants through the study and Figure 2 shows the enrolment, interventions, and assessments schedule.

Study setting

The Federal Territory of Putrajaya is Malaysia's federal administrative center. Based on the National Health and Morbidity survey(8), Putrajaya has high prevalence for diabetes (19.2%) and has the highest prevalence for overweight (37%), obesity (43%) and abdominal obesity (61.3%).

Participants

Sampling frame

The sampling frame will be patients with Type 2 Diabetes Mellitus (T2DM) registered at the primary healthcare clinics within the Federal Territory of Putrajaya. With easy accessibility and communal location, approximately 35% of the Malaysian population receives treatment within the government health clinics located in the community(23).

The services and facilities within the clinics differ according to the size of the clinic, which is based on the number of patient visits per day. Health Clinic Presint 9 (KKP9) and Health Clinic

Presint 18 (KKP18) have 500-800 patient visits per day. These health clinics are fully equipped .2with primary health care services, family medicine specialists, laboratory, diagnostic imaging, rehabilitation, dietary, pharmacy, and dental services. Health Clinic Presint 11 (KKP11) and Health Clinic Presint 14 (KKP14) have fewer than 150 patient visits per day. These clinics are limited to outpatient services (non-complex cases and/or stable chronic cases) and pharmacy services.

According to the 2018 National Diabetes Registry, registered diabetes patients (both Type 1 and Type 2) are unevenly distributed in terms of the type of the health clinics, the facilities available and the services provided. The size of the diabetes clinic in each health clinic differ with KKP9 having the largest portion of diabetes patients in Putrajaya (64%) and KKP11 having the smallest proportion (2%).

Eligibility Criteria

Inclusion criteria

Eligible patients will have a diagnosis of Diabetes Mellitus Type 2 as assessed by their attending physicians based on the Malaysian Clinical Practice Guidelines for Type 2 Diabetes Mellitus(24); and be aged between 18 to 60 years old; and currently registered to be receiving services in the health clinics in Putrajaya. Patients also need to be able to provide informed consent to participate in the study.

The criteria for diagnosing Diabetes Mellitus Type 2 are based on the Malaysia's Clinical Practice Guidelines for Type 2 Diabetes Mellitus. The guideline defines Diabetes Mellitus Type 2 patients as people who have been diagnosed with diabetes mellitus, and have had/have a confirmed glycohemoglobin test (HbA1c) level of ≥6.3% (45 mmol/mol) and FPG ≥ 7.0mmol/L.

Exclusion Criteria

Patients unable to read, write and speak Malay or English, those who are medically unstable or who cannot provide informed consent, will be excluded. Patients who are currently attending intensive psychological treatment will also be excluded from the study.

Withdrawal Criteria

Participants can choose to withdraw at any time. Participants may be withdrawn if the research team deems that it is detrimental or risky for them to continue; arrangements will be made for their future care. Withdrawn participants will not be replaced and will be included in the intention-to-treat analysis.

Interventions

POHON SIHAT (OHP)

Participants from the intervention group will receive treatment as usual and will attend the OHP. Treatment as usual refers to the pharmacological treatment received or prescribed by the patients' attending doctor and education session with diabetes educators at each visit. Diabetes educators facilitate knowledge on healthy eating, physical activity, medication usage and risk reduction practices(24). To improve standardisation of treatment, attending doctors and diabetes educators were prompted to manage patients in accordance with the Clinical practice Guideline in Managing Diabetes Mellitus in adult patients(24).

The OHP will be delivered in groups consisting of 10 to 12 participants. The group sessions will be facilitated by at least two trained OHP facilitators. There will be at least one trained mental health practitioner (i.e., clinical psychologist), and at least one trained diabetes care expert (i.e., diabetes educator, medical practitioner).

Participants will attend a five, weekly sessions (one session per week) and a booster session. The outline of sessions is shown in *Table 1*. Each session lasts for 2 hours. Sessions will be conducted outside of routine clinic follow-ups.

Participant's treatment outcomes will be assessed before the start of the group program (T1) at the end of the group session (T2), and at the booster session (T3), which is three months after T2. At 6-month follow-up (T4) participants will be asked to complete the final assessments, via mail (Refer *Figure 2*)

Control Group or Treatment-as-usual (TAU) refers to the pharmacological treatment received or prescribed by the patients' attending doctor and the education session with diabetes educators at each visit. Diabetes educators facilitate knowledge on healthy eating, physical activity, medication usage and risk reduction practices(24). To improve standardisation of treatment, attending doctors and diabetes educators will be prompted to manage patients in accordance with the Malaysian Clinical Practice Guideline in Managing Diabetes Mellitus in Adult Patients(24).

Outcomes

Primary and secondary outcomes as listed in *Figure 2* are self-reported outcomes that will be measured at 4 time points: 1) baseline (pre-treatment), 2) 5 weeks (post-treatment), 3) 3 months and 4) 6 months follow-up. Table 2 is a description of measurements that will be used.

Primary outcomes

Self-efficacy will be measured by two scales: 1) 8-item Diabetes Empowerment Scale – Short Form (DES-SF)(25,26) and 2) 20-item Diabetes Management Self-Efficacy Scale (DMSES)(17,27).

Secondary outcomes

Secondary outcome will include: 1) depression (Patient Health Questionnaire; PHQ-9)(28), 2) anxiety (General Anxiety Disorder scale; GAD-7)(29), 3) diabetes distress (Problem Areas in Diabetes; PAID-5)(30), and 4) general well-being (WHO-5 Wellbeing Index)(31). Self-management behaviors will be measured by the Summary of Diabetes Self-Care Activities (SDSCA) Scale(32,33).

Data on glycaemic control will be collected from patient records while demographic details, co-morbidities, duration, and diabetes complications will be assessed using a standard questionnaire, once participants have been allocated to the treatment or control group.

Sample size

Considering the study outcomes, the sample size is calculated based on a similar study(34) by using the formula proposed by Zhong(35).

As far as response rate is concerned, in studies using OHP, a 12 months follow up protocol experienced a 14% drop out rate for patients with mental illness(36). Similarly, Moriyama et al.(37) reported a 16% drop out rate for a self-management program in patients with diabetes. Other studies showed that a 6 month follow-up, self-management program in T2DM yielded an attrition rate that ranged between 10% to 20%(34,38). Within local government settings, the attrition rate was 10% for a 12-week follow-up education-based program in patients with diabetes(39).

Taking into consideration the duration of follow-ups and a conservative approach, this study will estimate a 30% attrition rate for the loss to follow-up at 6 months.

Based on the study by Wu et al.(34), with an expected medium effect size of 0.40 (μ diff = 16.19, s.d. =37.01), the sample size required in this study is calculated using a study-wide type 1 error rate (α) of 0.05 and a type II error rate (β) of 0.20 (power of 0.80). The current study will require a total of 59 participants for each group. With an expected attrition rate of 30%, the study aims to recruit a total of 172 participants, with 86 participants for each group.

Recruitment

Study procedure

Recruitment will take place at the clinics during a patient's routine check-ups at the diabetes clinic, over a period of 6 months or until the required number of participants is achieved.

Based on the list of registered patients during a clinic day, patients with diabetes will be screened based on age and type of diabetes. Eligible participants will be asked for consent to be approached by a research assistant. Those who fulfill the criteria and are able to give written informed consent for participation, will be included in the study.

After enrolment, participants will be given an opaque, sealed and numbered envelope containing allocation of groups, in numerical sequence. Each participant will be assigned into the intervention or control group based on the random sequence.

Allocation

Allocation sequence generation

To ensure concealment of allocation, co-authors will conduct the randomisation using digit random sampling. The randomisation sequence is created with simple randomisation procedure and computerised random numbers using Excel 2010 (Microsoft, Redmond, WA, USA) with participants assigned to either treatment as usual (TAU) or Pohon Sihat plus TAU.

The four health clinics will first be stratified by the size of the clinic. To ensure a balanced representation of diabetes patients within each clinics, randomisation will be conducted based on the size of the diabetes clinic as reported in the National Diabetes Registry. KKP9 with the largest portion of registered diabetes patients (64%) will be allocated 110 participants (64% of 172 participants), followed by KKP18 (31%) allocated 53 participants, KKP 14 (3%) allocated 5 participants and KKP11 (2%) with an allocation of 4 participants.

Allocation concealment mechanism and implementation of random allocation

To ensure that clinics are assigned with a balanced number of allocated intervention and control, two lists of randomisation sequences were made 1) clinics with 500-800 patient visits per day – KKP9 and KKP18, and 2) clinics with less than 150 visits per day – KKP11 and KKP14.

Research assistants involved in the recruitment will be blinded from the sequence allocation. Sealed envelopes will only be opened after eligible participants provide and sign the informed consent form.

Contamination Bias

To minimise the effect of a contamination bias, the OHP plus TAU sessions will take place outside of the participating health clinics. Intervention sessions will be conducted in either a community based rehabilitation center or a central health district center situated within Putrajaya. Participants will also be informed of the study parameters, with directives not to discuss the content of the materials or to exchange materials with other diabetes patients outside of the group.

Blinding

Blinding will be adopted to reduce bias of participants performing better or worse when they are informed which group they are allocated to after the randomisation process. This study will thus incorporate a single blinding process. Participants will not know which group is considered the experimental group and the control group.

Statistical Analysis

The intention-to-treat principle and per-protocol analyses will be performed. Any deviations from the random allocation and missing data will be fully reported as outlined in the Consolidated Standards of Reporting Trials (CONSORT) guidelines.

Any differences between individuals in the intervention and control conditions at baseline (socio-demographics, clinical details, psychosocial self-efficacy, diabetes management self-efficacy, anxiety, depression, diabetes-related distress, well-being, self-care behaviours and HbA1C) will be assessed using one-way analysis of variance ANOVA or chi-square test as appropriate. Assumptions of normality and homogeneity of variance will be assessed and adjusted accordingly.

A Mixed model ANOVA will be used to investigate the effectiveness of Pohon Sihat (OHP plus TAU) vs Treatment as usual (TAU)) on all continuous variables at four points (i.e. baseline, 5 weeks, 3 months and 6 months). For all analysis of mixed effect, repeated measures, condition and time will be specified as fixed effects.

A one-way analysis of covariance (ANCOVA) will be used to assess the effectiveness of the intervention compared with the control group, when covariates included duration of diabetes and diabetes complication are expected to impact on outcome measures.

Patient involvement

Program assessment, treatment fidelity and cultural adaptation

The adaptation of the OHP for the Malaysian community was informed by: (1) review by Malaysia's primary and mental health care professionals, (2) structured translation and (3) cultural adaptation of the program.

The panel of reviewers included endocrinologist, family medicine specialists and physicians. The OHP was considered by this review to be a valuable engagement tool to further enhance the primary health care services, and to be more inclusive of mental health needs(22). Following this feedback, the OHP underwent a thorough translation and adaptation process.

The translation and cultural adaptation process involved multiple stages with (1) the development of a panel of experts from Malaysia and Australia, (2) forward and back translation of the program workbook, (3) cultural adaptation through the review and comparison by both content and local experts, including revision and harmonisation of the workbook, (4) pre-testing the program in a group of mental health practitioners, patient support group representatives as well as representatives from the Ministry of Health and finally (5) proofreading and finalising of design.

Based on a thorough translation and adaptation process, the program was assessed as matching the intention and the fidelity of the program

Training of Diabetes Educators

The facilitator training was modified to include an additional day taking into consideration minimal mental health training for diabetes educators especially psychological strategies for engaging in effective health communication(9). The additional day included more in-depth content, collaborative therapy principles and motivational interviewing based health coaching techniques. This modification was to ensure that the program delivery will maintain fidelity and stay aligned with its intention.

Each group program will be facilitated by a trained mental health practitioner and diabetes care expert to further strengthen the program's fidelity.

Pilot study

A pilot study was conducted to assess the feasibility and accessibility of the culturally adapted OHP amongst patients with diabetes. Eight participants (n=8) were recruited, five completing all 5 sessions of the program (three withdrew due to work commitments). Challenges were

identified with: (1) recruitment process, (2) duration of the program and (3) content of the material.

Generally, participants provided valuable feedback on the content of the workbook, structure of the program and ease of delivery. Participants' feedback suggested that the sessions be longer to allow more discussion. This was also echoed by the facilitators, who felt that additional time would allow greater coverage, and improve ease of delivery. An additional information sheet on healthy eating habit and lifestyle tips was also suggested by participants.

The recruitment process was improved based on the feedback provided by participants and facilitators. During recruitment, participants were informed that an official letter and time–slips would be provided to allow time off work to attend the program.
Several groups programs were offered throughout the week to allow people to attend the most convenient sessions. Logistical constraints were also improved by choosing venues with ample parking space. Sessions were extended from 1.5 hours to two hours. Content of the workbook was improved by additional health information such as the food pyramid and the local healthy eating habits. This additional information and some minor language changes improved the overall usability of the OHP Malay workbook.

ETHICS AND DISSEMINATION

Consent

The process of obtaining consent is in line with the Declaration of Helsinki. Information regarding the study, and random allocation of participants will be outlined in a Patient Information Sheet as approved by the Ethics Committee (refer Supplementary file). The randomization process will be clearly outlined to the eligible participants. A signed informed consent will be obtained from each participant. At the end of the study, participants in the control group (Treatment-as-usual) will be invited to participate in OHP.

Ethics approval

Ethical approval for this study was obtained from the Medical Research and Ethics Committee (MREC), Ministry of Health Malaysia.

Data Management

All participant information will be treated as strictly confidential. Personal information will be coded to ensure the confidentiality of the participants and no individuals will be identifiable in any research material, reports or publications. No information collected will be shown to anyone apart from the research team. Data from the study will be stored securely in locked cabinets and electronic data will be kept on password protected drives accessible only by the research team. Permission to share information with appropriate health professionals will be sought if health concerns arise for participants.

Dissemination Plan

The findings of the study will be shared with stakeholders through publication and conference presentations. The outcomes of the study will be shared through publication within a peer-reviewed journal within 12 months of the last data collected. As part of the ethics approval requirements, the outcomes will be shared with the Malaysia Ministry of Health and participating health clinics.

DISCUSSION

The complexity of diabetes mellitus is associated with not just the patient's physical health but also their emotional well-being and mental health, social, occupational and overall quality of life(40). The growing numbers of people with diabetes and increasing psychosocial barriers are associated with greater health impacts for the individual, family and community. Moreover, even though Putrajaya as a state that ranks high in health literacy, the prevalence rates of diabetes and obesity are the highest in the country. With its mediating role between health literacy and self-care behaviours(41), self-efficacy may be the missing link in understanding the dissonance between illness education, and the ability to utilise the knowledge to commit to a healthy lifestyle.

The OHP is a self-efficacy enhancing psychological intervention that is low-intensity, structured and can be delivered by trained facilitators. The recovery-based approach emphasises the language of hope and well-being rather than illness and disease, and is suitable for a primary health care setting. Through a patient centered, collaborative approach, the OHP may offer a

platform for a wide range of primary health care providers to engage in a discussion with patients regarding their well-being. As a psychological intervention program for primary health care providers, OHP can address mental health concerns and promote overall wellbeing for people experiencing chronic illness. The OHP will be the first engagement tool in Malaysia with potential to act in a curative and preventative role

In addition to providing further understanding in the effectiveness of an add-on psychological intervention, the study will also provide information on the effectiveness of the current standard of practice within the primary health care as guided by the Malaysian Clinical Practice Guideline in the Management of Type 2 Diabetes Mellitus.

Trial Status

Patient recruitment commenced October 2018 and data collection will continue until August 2020. ClinicalTrials.gov NCT03601884

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Figure

Figure 1. Flow chart of participants

Figure 2. Schedule of enrolment, interventions, and assessments.

Tables

Table 1. Outline of POHON SIHAT sessions for patients with diabetes

Table 2. Description of measurements

Contributors

AFS, NI, TKA and UAS designed the study. AFS wrote the first draft of the manuscript and coordinated the development of the study protocol. BR, TKA, GM and DC contributed a thorough review of the manuscript which AFS revised in the second version. UAS, NI, TKA and BR then provided further written feedback. All authors critically reviewed, revised and approved the final version of the manuscript to be submitted by AFS. AFS, TKA, BR, UAS, GM and DC further reviewed and contributed towards the revised version of the manuscript.

Competing Interests:

DC has received grant monies for research from Eli Lilly, Janssen Cilag, Roche, Allergen, Bristol-Myers Squibb, Pfizer, Lundbeck, Astra Zeneca, Hospira; Travel Support and Honoraria for Talks and Consultancy from Eli Lilly, Bristol-Myers Squibb, Astra Zeneca, Lundbeck, Janssen Cilag, Pfizer, Organon, Sanofi-Aventis, Wyeth, Hospira, Servier; and is a current Advisory Board Member for Lu AA21004: Lundbeck; Varenicline: Pfizer; Asenapine: Lundbeck; Bitopertin: Roche Aripiprazole LAI: Lundbeck; Lisdexamfetamine: Shire; Lurasidone: Servier. He has no stocks or shares in any pharmaceutical company.

This study had no other conflict of interest.

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Data sharing statement

There are no data available in this study protocol.

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Table 1. Outline of POHON SIHAT sessions for patients with diabetes

WEEK	SESSION	SESSION OUTLINE
1	Optimal Health	What is Optimal Health? • Introduction to the Collaborative Therapy Optimal Heath Program • Introduce TOOL 1: The Optimal Health Wheel • Reflection of one's own health based on 6 domains – physical, emotional, intellectual, social, spiritual and occupational health and identifying possible areas for change • Exploration of one's satisfaction level within each health domains • Identify possible areas for change
2	I-CAN-DO Model Strengths and vulnerabilities Stressors and strategies	The I-Can-Do Model • Introduction to concepts of one's strengths, vulnerabilities, stressors and strategies and how it may impact on their over wellbeing • Introduce TOOL 2: I-Can-Do Model • Identify one's strengths and vulnerabilities • Identify one's source of stress and how stress may impact diabetes and overall wellbeing • Identify and building one's own strategies to cope with stressors • Reflection on achieving balance within the I-CAN-DO MODEL
3	Factors of Wellbeing	Medication and Metabolic Monitoring • Psychoeducation on medication – understanding what, why and how one's own medication works • Introduce TOOL 3: Medication & Metabolic Monitoring Table • Emphasize on the metabolic monitoring that needs to be done routinely within the health clinics • Addressing common myths amongst diabetes patients • Further emphasis on healthy lifestyle and eating habits Collaborative Partners and Strategies • Identify collaborative partners • Introduce TOOL 4: Eco-Mapping • Discussion on role of collaborative partners in maintaining one's optimal health
4	Visioning & Goal Setting	Change Enhancement – Time line activity • Introduction to identifying past events and its impact on health • Stages of Health: Optimal Health, Sub Optimal Health and Episode of Illness • Introduce TOOL 5: Time Line Activity

	Visioning & Goal Setting	Visioning and Goal Setting • Introduction to creative problem solving and setting SMARTER goals • Introduce TOOL 6: Cost-benefit Table • Discussion on barriers to achieving goals • Identify steps and strategies to achieve future goals
5	Maintain well-being	Maintaining well-being • Understanding one's own stages of health • Introduce TOOL 7: Health Plans: Optimal Health (Health Plan 1); Sub-optimal Health (Health Plan 2) and Episode of Illness (Health Plan 3) • Build skills and strategies at different stages of health • Review of session 1-4 and tools introduced
Booster	Review Health Plans	Review of Health Plans • Reflection on the application of knowledge and skills learned and its impact on optimal health. • Discussion on possible barriers and strategies

Table 2. Description of measurements

OUTCOME AND DESCRIPTION OF MEASUREMENTS	
Primary Outcome – Self-efficacy	
Psychosocial Self-efficacy	**The Diabetes Empowerment Scale (DES-SF)** is an 8 item self-administered measurement that assesses the perceived ability to manage psychosocial issues such as managing stress, coping with emotional distress, engaging with family and friends for support and discussion with health care providers(42). Participants rate items on a 4-point likert scale ranging from 0 (strongly disagree) to 4 (strongly agree). The sum of all items ranged from 0 to 32. Previous research reported the DES-SF Chronbach's alpha is at 0.84(26).
Diabetes Management Self-Efficacy	**The Diabetes Management Self-efficacy Scale (DMSES)** is a 20-item self-administered measurement that assess self-efficacy in managing specific diabetes self-care behaviours such as glucose monitoring, general and specific diet, medication adherence, exercise and foot care(27). Participants rate items on a 10-point likert scale ranging from 0 (Not at all confident) to 10 (Totally confident). The Malay validated DMSES has a Chronbach's α estimate of 0.951(17).
Secondary Outcomes	
Depression	**Patient Health Questionnaire –PHQ-9** is a 9 item self-administered measurement that assseses the presentation of depression symptoms and the impairments related to the symptoms. Participants rate items on a 4-point likert scale ranging from 0 to 3. The sum of all items range between 0 to 27. The Malay validated PHQ-9 has a Chronbach's α estimate of 0.70, sensitivity of 87% and specificity of 82%(28).
Anxiety	**General Anxiety Disorder – GAD-7** is a 7 item self-administered measurement that assesses the presentation of anxiety symptoms and the impairments related to the symptoms. Participants rate items on a 4-point likert scale ranging from 0 to 3. The sum of all items range between 0 to 21. The Malay validated GAD-7 has a Chronbach's α estimate of 0.74, sensitivity of 76% and specificity of 94%(29).
Diabetes-related distress	**Problem Areas in Diabetes (PAID) – 20** is a 20 item self-administered measurement that assesses emotional problems in patients with diabetes. Participants rate items on a 5-point likert scale ranging between 0 (Not a problem) to 4 (serious problem). The

	sum of all items range from 0 to 80. The Malay validated PAID-MY 20 has a Chronbach's α estimate of 0.921(30).
Well-being	**WHO-5 Wellbeing Index (WHO-5)** is a 5 item self-administered measurement that assesses emotional wellbeing and mental health (31). Participants rate items on a 5-point likert scale ranging between 0 (none of the time) to 5 (all of the time). The raw score that ranges from a minimum of 0 (absence of well-being) to a maximum of 25 (maximum well-being) are then multiplied by 4 to obtain the percentage scale. The recommended cut off score of ≤50 is an indication of poor well-being.
Self-management behaviours	**Summary of Diabetes Self-Care Activities (SDSCA)** is an 11 item self-administered measurement that assess aspects of diabetes regimen including general diet, specific diet, exercise, blood-glucose testing, foot care and smoking(43). Participants responds based on engagement to self-management behaviours related to diabetes in the last seven days. The Malay validated SDSCA Chronbach's α estimate for the main domains ranged between 0.651 and 0.905(33).
Glycaemic control	Glycaemic control will be reported in SI units (mmol A1c/mol Hb) that will be collected from patient records. Based on the guideline, the target that needs to be achieved for control of T2DM is a HbA1C level of not more than 6.5%.

Figure 1 Flow chart of participants

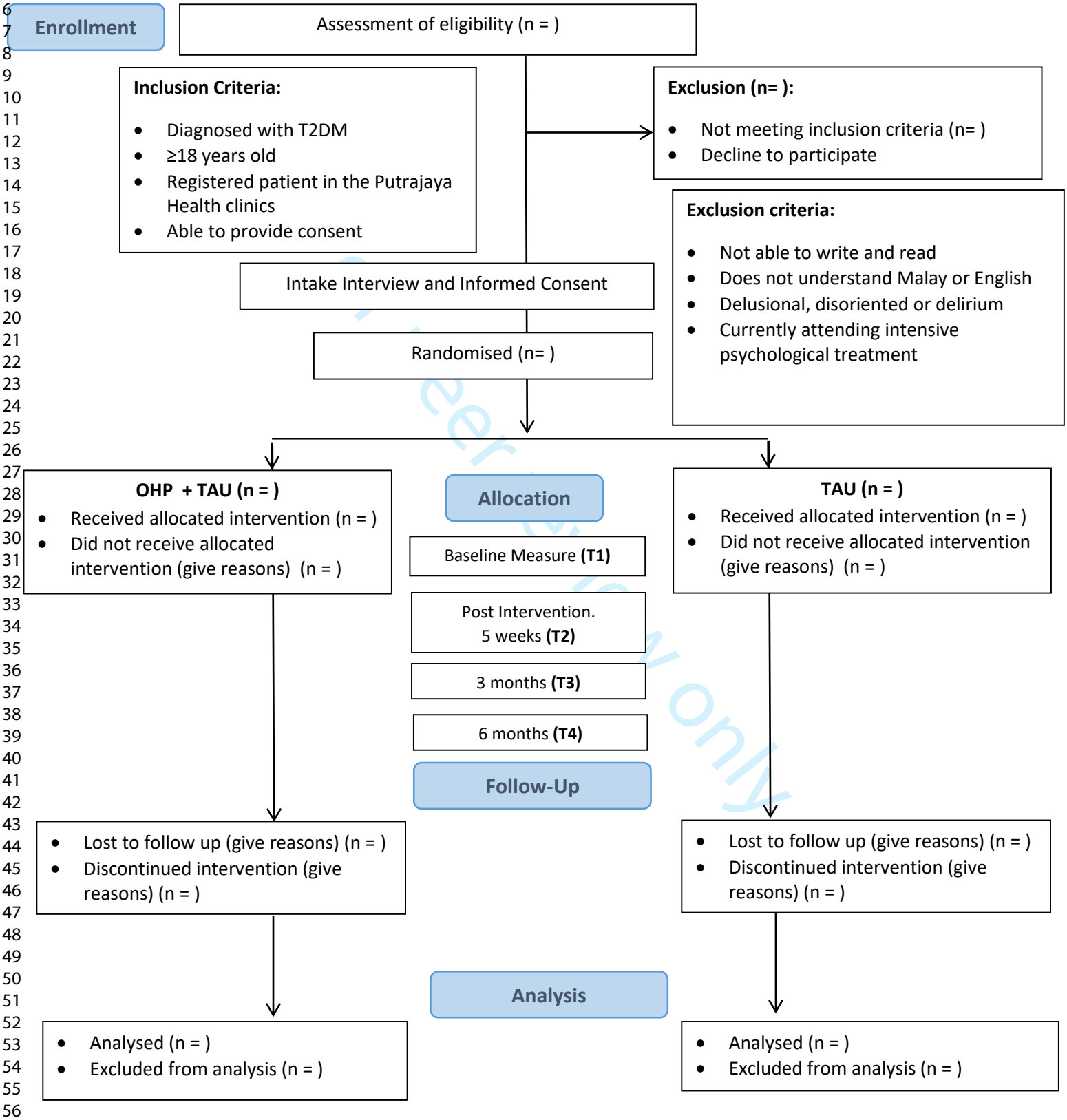

Figure 2. Schedule of enrolment, interventions, and assessments.

	STUDY PERIOD					
	Enrolment	Allocation	Post-allocation			Follow up
TIMEPOINT	$-t_1$	0	*1 wk*	*5 wk*	*18 wk*	*30 wk*
ENROLMENT:						
Eligibility screen	X					
Informed sheet	X					
Informed consent	X					
Randomisation	X					
Allocation		X				
INTERVENTIONS:						
Pohon Sihat and Treatment as usual			◆—	—	—◆	
Treatment as usual						
ASSESSMENTS:						
Sociodemographic data		X				
DES-SF			X	X	X	X
DMSES			X	X	X	X
GAD-7			X	X	X	X
PHQ-9			X	X	X	X
PAID-20			X	X	X	X
WH0-5			X	X	X	X
SDSCA			X	X	X	X
HbA1C		X				X

Participant Information Sheet SELF-EFFICACY IN DIABETES	  **Faculty of Medicine and Health Sciences** **University Putra Malaysia** **43400 Serdang Selangor**

Study title:	*The effectiveness of the Optimal Health Program in improving self-efficacy in patients with diabetes in Putrajaya, Malaysia.*
Locality:	**Wilayah Persekutuan Putrajaya**
Ethics ref.	NMRR-17-3426-38212
Investigator:	**Aida Farhana Binti Hj Suhaini**
Supervisor:	**Assoc. Prof. Dr. Normala Ibrahim**

WHAT IS THE PURPOSE OF THE STUDY?

The purpose of this study is to examine the effectiveness of the Optimal Health Program, a self-management program that promotes overall well-being and self-efficacy in the management of emotional distress in people with diabetes. The Optimal Health Program (OHP) enhances an individual's wellbeing through building on their strengths and values. It provides a framework that responds to individual needs and creates opportunities for conversation around areas of not just the physical health, but also psychological, social, occupational and spiritual health.

WHY WAS I ASKED TO PARTICIPATE?

You have been asked to participate because you have diabetes and may benefit from the Optimal Health Program.

WHAT WILL HAPPEN TO ME IF I AGREE TO TAKE PART?

Taking part in the study involves being randomly entered into one of two groups. The groups will be randomly selected (a bit like tossing a coin), so you cannot choose which group you are in. You will *not* know which group you are in before consenting to take part in the study.

This study will involve a total of 156 participants, with 78 participants for each group. The whole study will last about two years and your participation will be approximately 8 months from the point of first assessment.

If you agree to take part, you will be required to:

1. Complete a questionnaire on sociodemographic details and your diabetes.
2. Complete 7 questionnaires – WHO-5 well-being Index (WHO-5) (5 items), General Anxiety Disorder – 7 (GAD-7) (7 items), Patient Health Questionnaire – 9 (PHQ-9), Problem Areas in Diabetes (PAID) (20 items), Diabetes Empowerment Scale (DES) (8 items), Diabetes Management Self-Efficacy Scale (DMSES) – (20 items) and Summary of Diabetes Self-Care Activities (SDSCA) (12 items).

You will be asked to fill in these questionnaires at four points in time, in the beginning, at 5 weeks, 3 months and at 6 months. All questionnaire will require approximately 30 minutes to complete.

3. Attend either the

A) **Treatment as usual**

If you are randomly assigned to this group, you will receive treatment as usual. At the end of the study period (one year) we will offer you the chance of participating in the Optimal Health Program.

or

B) **The Optimal Health Program and Treatment as usual**.

If you are randomly assigned to the Optimal Health Program, you will receive treatment as usual. In addition, you will be required to attend a group program for 5 sessions, 1.5 hours for every week and a booster session after three months.

DO I HAVE TO TAKE PART?

Participation in this study is voluntary. It is completely up to you whether or not you participate. If you decide not to participate, it will not affect the treatment you receive now or in the future. You may withdraw from the study at any time and for any reason or no reason. Information that has been collected about you, prior to your withdrawal, will continue to be used in the data analysis. No new information will be collected or used after you have withdrawn from the study.

WILL MY TAKING PART IN THIS PROJECT BE KEPT CONFIDENTIAL?

If you agree to take part in the study you will need to sign and date the Informed Consent Form attached. Your medical records and data will need to be seen by the authorised members of our research team (i.e. treating team in the clinic and the researcher) so they can collect information needed for this research study. Your unique registration number will be used to make sure you cannot be identified outside the study. All information, which is collected, about you during the course of the research will be treated as strictly confidential. The confidentiality of your medical records will be respected at all times.

When publishing or presenting the study results, your identity will not be revealed without your expressed consent. No information collected will be shown to anyone apart from the research team. For regulatory purposes, data from the study will be stored securely for at least 3 years following the study and destroyed as confidential waste thereafter.

WILL I BE INFORMED OF THE STUDY FINDINGS?

You will not be informed individually of the study findings. Nonetheless if you are interested to be informed of your personal results at the end of this study, you can express your interest in the Consent form.

WHAT ARE THE POSSIBLE DISADVANTAGES AND RISKS OF TAKING PART IN THIS RESEARCH?

As with any psychosocial intervention, it is possible that discussing about your difficulties may cause you some distress. Similar studies have been conducted in Malaysia and have been shown to have

minimal to no risk. Nonetheless, if you pose any difficulties or discomfort, please inform the investigator.

WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART IN THIS RESEARCH?

The OHP has been shown to be effective in improving one's belief about their capabilities to cope and manage their illness and reduce distress. This study aims to further expand the depth of knowledge in the field of chronic illness specifically in the enhancement of patients' self-management. The study may not directly benefit you but the information we get from the study will help increase the understanding of self-efficacy enhancing program in the management of diabetes.

WILL TAKING PART IN THIS STUDY COST ME ANYTHING AND WILL I BE PAID?

Participation in this study will not cost you anything. For sessions and visits that are conducted outside of your routine clinic, you will be reimbursed for your time and reasonable travel.

WHO IS FUNDING THE RESEARCH?

This study is sponsored by a research grant from University Putra Malaysia who will pay for all study procedures except all other medication and procedures that are part of your routine medical care.

CAN THE RESEARCH OR MY PARTICIPATION BE TERMINATED EARLY?

The researcher may stop the study or your participation at any time possibly due to any safety concern. If the study is stopped early for any reason you will be informed and arrangements made for your future care. You may be asked to attend a final follow-up visit.

WHO DO I CONTACT FOR MORE INFORMATION OR IF I HAVE CONCERNS?

If you have any questions, concerns or complaints about the study at any stage, you can contact:

Prof Madya Normala Ibrahim
Consultant Psychiatrist
Faculty of Medicine and Health Sciences
University Putra Malaysia
43400 Serdang Selangor
normala_ib@upm.edu.my

Aida Farhana Suhaimi
Clinical Psychologist
PhD Psychological Medicine Candidate
Department of Medicine and Health Sciences
University Putra Malaysia
43400 Serdang Selangor
aida.hjsuhaimi@gmail.com

If you have any questions about your rights as a participant in this study, please contact: The Secretary, Medical Research & Ethics Committee, Ministry of Health Malaysia, at telephone number 03-2287 4032.

Consent Form SELF-EFFICACY IN DIABETES	 **Faculty of Medicine and Health Sciences** **University Putra Malaysia** **43400 Serdang Selangor**

Consent

Your signature below indicates that you have decided to volunteer as a research participant for this study, and that you have read and understood the information provided above. You will be given a signed and dated copy of this form to keep, along with any other printed materials deemed necessary by the study researchers.

Participant's Signature : _____

Participant's Name : _____

Participant's IC No. : _____

Date: :

Researcher's Signature :

_____

Date:

Are you interested in viewing your personal results at the end of this study?

☐ **Yes** ☐ **No**

Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SPIRITreporting guidelines, and cite them as:

Chan A-W, Tetzlaff JM, Altman DG, Laupacis A, Gøtzsche PC, Krleža-Jerić K, Hróbjartsson A, Mann H, Dickersin K, Berlin J, Doré C, Parulekar W, Summerskill W, Groves T, Schulz K, Sox H, Rockhold FW, Rennie D, Moher D. SPIRIT 2013 Statement: Defining standard protocol items for clinical trials. Ann Intern Med. 2013;158(3):200-207

		Reporting Item	Page Number
Administrative information			
Title	#1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	#2a	Trial identifier and registry name. If not yet registered, name of intended registry	4
Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	n/a
Protocol version	#3	Date and version identifier	1
Funding	#4	Sources and types of financial, material, and other support	2

Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	1-2
Roles and responsibilities: sponsor contact information	#5b	Name and contact information for the trial sponsor	n/a
Roles and responsibilities: sponsor and funder	#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	n/a
Roles and responsibilities: committees	#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)	n/a
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	5
Background and rationale: choice of comparators	#6b	Explanation for choice of comparators	6
Objectives	#7	Specific objectives or hypotheses	6
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, non-inferiority, exploratory)	7
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	7
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)	8
Interventions: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	9
Interventions: modifications	#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)	n/a
Interventions: adherance	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	
Interventions: concomitant care	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	n/a
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	10
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 Figure)	10 Figure 2
Sample size	#14	Estimated number of participants needed to achieve study objectives and how it was determined, including	10

		clinical and statistical assumptions supporting any sample size calculations	
Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	11
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	11
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	12
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	12
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	12
Blinding (masking): emergency unblinding	#17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	n/a
Methods: Data collection, management, and analysis			
Data collection plan	#18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate	15

		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	
Data collection plan: retention	#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	13
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	15
Statistics: outcomes	#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	13
Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	13
Statistics: analysis population and missing data	#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)	13
Methods: Monitoring			
Data monitoring: formal committee	#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	n/a
Data monitoring: interim analysis	#21b	Description of any interim analyses and stopping guidelines, including who will have access to these	n/a

		interim results and make the final decision to terminate the trial	
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	16
Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	n/a
Ethics and dissemination			
Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	15
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)	15
Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	15
Consent or assent: ancillary studies	#26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	n/a
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	15
Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	2
Data access	#29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	15

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	n/a
Dissemination policy: trial results	#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	16
Dissemination policy: authorship	#31b	Authorship eligibility guidelines and any intended use of professional writers	16
Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	16
Appendices			
Informed consent materials	#32	Model consent form and other related documentation given to participants and authorised surrogates	Sup. 1
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	n/a

BMJ Open

Effectiveness of a culturally adapted biopsychosocial intervention (POHON SIHAT) in improving self-efficacy in patients with diabetes attending primary healthcare clinics in Putrajaya, Malaysia: Study protocol of a randomised controlled trial.

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Primary Subject Heading:	Diabetes and endocrinology
Secondary Subject Heading:	Mental health
Keywords:	self-efficacy, diabetes, biopsychosocial, self-management, PRIMARY CARE

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TITLE

Effectiveness of a culturally adapted biopsychosocial intervention (POHON SIHAT) in improving self-efficacy in patients with diabetes attending primary healthcare clinics in Putrajaya, Malaysia: Study protocol of a randomised controlled trial

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ABSTRACT

Introduction

People with diabetes are often associated with multifaceted factors and comorbidities, with management frameworks advocating for a biopsychosocial, patient-centered approach. Despite increasing efforts in promotion and diabetes education, interventions integrating both physical and mental health components are still lacking in Malaysia, the Optimal Health Program offers an innovative biopsychosocial framework to promote overall well-being and self-efficacy, going beyond education alone and has been identified as relevant within the primary care system. Following a comprehensive cultural adaptation process, Malaysia's first Optimal Health Program was developed under the name 'Pohon Sihat' (OHP). The study aims to evaluate the effectiveness of the mental-health based self-management and wellness program in improving self-efficacy and well-being in primary care patients with diabetes mellitus.

Methods and Analysis

This biopsychosocial intervention randomised controlled trial will engage patients (n = 156) diagnosed with type 2 diabetes mellitus (T2DM) from four primary healthcare clinics in Putrajaya. Participants will be randomised to either OHP plus treatment-as-usual (OHP+TAU) or TAU. The 2-hour weekly sessions over 5 consecutive weeks, and 2-hour booster session post three months will be facilitated by trained mental health practitioners and diabetes educators. Primary outcomes will include self-efficacy measures, while secondary outcomes will include well-being, anxiety, depression, self-care behaviours and haemoglobin A1c glucose test (HbA1c). Outcome measures will be assessed at baseline, immediately post-intervention, as well as at 3 months, and 6 months post intervention. Where appropriate, intention to treat analyses will be performed.

Ethics and Dissemination

This study has ethics approval from the Medical Research and Ethics Committee (MREC), Ministry of Health Malaysia (NMRR-17-3426-38212). Study findings will be shared with the Ministry of Health Malaysia and participating health clinics. Outcomes will also be shared through publication, conference presentations and publication in a peer-reviewed journal.

Trial Registration - ClinicalTrials.gov NCT03601884

Keywords: self-efficacy, diabetes, biopsychosocial, self-management, primary care

Word Count: 3723 **(**excluding title page, abstract (3000 words), references, figures and tables)

Article Summary

Strengths and limitations of this study

- This study is a randomised controlled trial to assess the effectiveness of the intervention, including pre and post-test effects to explore cause–effect relationships.
- The intervention has been tested for construct validity during a thorough process of translation and cultural adaptation.
- The intervention provides an innovative strength-based recovery-oriented framework employing collaborative therapy principles, aimed at addressing mental health issues and promoting overall wellbeing that goes beyond simply the provision of educational materials
- The study is limited to community clinics in Putrajaya, an urban state in Malaysia, which currently records high rates of health literacy in conjunction with high rates of diabetes and the highest prevalence of obesity in the country.

INTRODUCTION

Background and Rationale

The incidence of diabetes mellitus (DM) is increasing globally, notably in low- and middle-income countries, with significant impacts at both the individual and the population level(1).

With the increasing awareness of psychosocial issues associated with DM over the last decade, there has been a greater demand for a shift from a principally reactive-based healthcare system to a proactive-based approach to management (2). Thus, the management of DM has evolved from an essentially biological approach, to more holistic biopsychosocial models(3). Psychosocial elements are central to the management of DM, with an emphasis on collaborative partnerships and patient-centered care in achieving optimal health and well-being(4).

Adding to the challenge of rapidly rising rate of DM, low- and middle-income countries also have limited mental health resources(5). Hence, there has been a call to build the capacity of the health care systems especially within primary healthcare settings, and for the integration of mental health and DM care services(6). Despite increasing efforts in DM education and health literacy, with allocated diabetes educators in health clinics and hospitals(7), improvements in DM care have been marginal(8). Diabetes educators and primary healthcare professionals are mainly trained in physical health and have excellent medical knowledge of the illness, but many do not have the skills and knowledge to address the emotional and psychological aspects comprehensively (9). These limitations have become a significant barrier to addressing mental health issues in patients with DM(9).

Often diabetes care will set up the expectation for people with DM to hold the bulk of the control over their own illness throughout the course of their illness(10); hence, self-efficacy has a vital role in the ability to manage diabetes effectively(11), including managing emotions, and making a commitment to self-care behaviours(12) .

Self-efficacy has been found to correlate with self-management behaviours(11–14) and to be negatively correlated with physical distress(15), depression(12), and diabetes distress(16). The role of self-efficacy as a mediator between self-management behaviours and DM-related distress,

depression, and anxiety has also been reported(13,17). Therefore, an intervention that enhances self-efficacy would be expected to improve depression, diabetes distress, as well as enhance self-management behaviours. The inclusion of self-efficacy as a treatment outcome in a diabetes intervention program is crucial, as this allows researchers to evaluate the effectiveness of the program accurately(4).

POHON SIHAT – Cross-culturally adapted Malay Optimal Health Program (OHP)

The Optimal Health Program (OHP) is a biopsychosocial program that promotes patients to be actively involved in their own healthcare and overall well-being. The aim of OHP is to improve individual self-efficacy and to build on strengths and values which in turn serves to enhance overall wellbeing. Initially developed to integrate physical and mental health, the OHP has been found to be effective in mental health care settings(18,19), and has been extended to managing physical health and chronic illnesses(20,21). Having a platform to discuss the multiple areas of a person's life and associated psychosocial barriers creates tremendous potential in the management of DM.

In a preliminary study that assessed the needs of OHP in Malaysia, the OHP was found to provide a promising framework for building the capacity of the local mental health care services (22). Following a process of translation and cultural adaptation, the Malaysian OHP program was developed (henceforth referred to as Pohon Sihat). Being a culturally sensitive tool, Pohon Sihat is suited to use in local Malaysian clinical settings.

Objectives

Pohon Sihat is designed to address gaps in the management of mental health issues in diabetes care within a limited resource context. This study will examine the effectiveness of this program for diabetes patients within a primary care setting in Malaysia.

The intervention will be offered to patients with DM who are currently attending health clinics within the Putrajaya district. Specifically, this study aims to investigate the effectiveness of Pohon Sihat in addition to treatment-as-usual (TAU) as compared to TAU alone. It will examine

the effectiveness of Pohon Sihat in reducing anxiety, depression, diabetes-related distress, and in increasing self-care behaviours and glycemic control.

METHODS

Study design

This single blind, randomised controlled trial will employ a stratified randomisation approach (stratified by size of the Health Clinics). The trial will be carried out at four health clinics in Putrajaya, Malaysia from February 2018 to August 2020. Participants will be individually randomised to one of two parallel groups: treatment as usual (TAU) or Pohon Sihat (OHP) plus TAU.

Figure 1 shows the flow chart of participants through the study and Figure 2 shows the enrolment, interventions, and assessments schedule.

Study setting

The Federal Territory of Putrajaya is Malaysia's federal administrative center. Based on the National Health and Morbidity survey(8), Putrajaya has a high prevalence of DM (19.2%) and has the highest prevalence of overweight (37%), obesity (43%) and abdominal obesity (61.3%) in Malaysia.

Participants

Sampling frame

The sampling frame will be patients with Type 2 Diabetes Mellitus (T2DM) registered at the primary healthcare clinics within the Federal Territory of Putrajaya. With easy accessibility and communal location, approximately 35% of the Malaysian population receives treatment within the government health clinics located in the community(23).

The services and facilities within the clinics differ according to the size of the clinic, which is based on the number of patient visits per day. Health Clinic Presint 9 (KKP9) and Health Clinic Presint 18 (KKP18) have 500-800 patient visits per day. These health clinics are fully equipped with primary health care services, family medicine specialists, laboratory, diagnostic imaging, rehabilitation, dietary, pharmacy and dental services. Health Clinic Presint 11 (KKP11) and

Health Clinic Presint 14 (KKP14) have fewer than 150 patient visits per day. These clinics are limited to outpatient services (non-complex cases and/or stable chronic cases) and pharmacy services.

According to the 2018 National Diabetes Registry, registered patients with DM (both Type 1 and Type 2) are unevenly distributed in terms of the type of the health clinics, the facilities available and the services provided. The size of the diabetes clinic in each health clinic differ, with KKP9 having the largest portion of patients with DM in Putrajaya (64%), and KKP11 having the smallest proportion (2%).

Eligibility Criteria

Inclusion criteria

Eligible patients will have a diagnosis of T2DM as assessed by their attending physicians based on the Malaysian Clinical Practice Guidelines for T2DM (24); be aged between 18 and 60 years; and currently registered to receive services in the health clinics in Putrajaya. Patients also need to be able to provide informed consent to participate in the study.

The criteria for diagnosing T2DM are based on the Malaysia's Clinical Practice Guidelines, namely being diagnosed with DM and having had/having a confirmed glycohemoglobin test (HbA1c) level of ≥6.3% (45 mmol/mol) and FPG ≥ 7.0mmol/L.

Exclusion Criteria

Patients unable to read, write and speak Malay or English, those who are medically unstable or who cannot provide informed consent, will be excluded. Patients who are currently attending intensive psychological treatment will also be excluded from the study.

Withdrawal Criteria

Participants can choose to withdraw at any time. Participants may be withdrawn if the research team deems that it is detrimental or risky for them to continue; arrangements will be made for their future care. Withdrawn participants will not be replaced and will be included in the intention-to-treat analysis.

Interventions

POHON SIHAT (OHP)

Participants randomised to the intervention group will receive treatment as usual and will attend the OHP sessions. Treatment as usual refers to the pharmacological treatment received or prescribed by the patients' attending doctor and education session with diabetes educators at each visit. Diabetes educators facilitate knowledge on healthy eating, physical activity, medication usage and risk reduction practices(24). To improve standardisation of treatment, attending doctors and diabetes educators will be prompted to manage patients in accordance with the Malaysian Clinical Practice Guideline in Management of Type 2 Diabetes Mellitus(24).

The OHP will be delivered in groups consisting of 10 to 12 participants. The group sessions will be facilitated by at least two trained OHP facilitators. There will be at least one trained mental health practitioner (i.e., clinical psychologist), and at least one trained diabetes care expert (i.e., diabetes educator, medical practitioner).

Participants will attend a five, weekly sessions (one session per week) and a booster session. The outline of sessions is shown in *Table 1*. Each session will last for 2 hours. Sessions will be conducted outside of routine clinic follow-ups.

Participant's treatment outcomes will be assessed before the start of the group program (T1) at the end of the group session (T2), and at the booster session (T3), which is three months after T2. At 6-month follow-up (T4) participants will be asked to complete the final assessments, via mail (Refer *Figure 2*)

Control Group or Treatment-as-usual (TAU) refers to the pharmacological treatment received or prescribed by the patients' attending doctor and the education session with diabetes educators at each visit. Diabetes educators facilitate knowledge on healthy eating, physical activity, medication usage and risk reduction practices(24). To improve standardisation of treatment, attending doctors and diabetes educators will be prompted to manage patients in accordance with the Malaysian Clinical Practice Guideline in Management of Type 2 Diabetes Mellitus (24).

Outcomes

Primary and secondary outcomes as listed in *Figure 2* are self-reported outcomes that will be measured at 4 time points: 1) baseline (pre-treatment), 2) 5 weeks (post-treatment), 3) 3 months and 4) 6 months follow-up. Table 2 is a description of measurements that will be used.

Primary outcomes

Self-efficacy will be measured by two scales: 1) 8-item Diabetes Empowerment Scale – Short Form (DES-SF)(25,26) and 2) 20-item Diabetes Management Self-Efficacy Scale (DMSES)(17,27).

Secondary outcomes

Secondary outcome will include: 1) depression (Patient Health Questionnaire; PHQ-9)(28), 2) anxiety (General Anxiety Disorder scale; GAD-7)(29), 3) diabetes distress (Problem Areas in Diabetes; PAID-5)(30), and 4) general well-being (WHO-5 Wellbeing Index)(31). Self-management behaviors will be measured by the Summary of Diabetes Self-Care Activities (SDSCA) Scale(32,33).

Data on glycaemic control will be collected from patient records while demographic details, co-morbidities, duration, and diabetes complications will be assessed using a standard questionnaire, once participants have been allocated to the treatment or control group.

Sample size

Considering the study outcomes, the sample size is calculated based on a similar study(34) by using the formula proposed by Zhong(35). As far as response rate is concerned, in studies using OHP, a 12 month follow up protocol was associated with a 14% drop out rate for patients with mental illness(36). Similarly, Moriyama et al.(37) reported a 16% drop out rate for a self-management program in patients with diabetes. Other studies showed that at 6 month follow-up, a self-management program in T2DM yielded an attrition rate that ranged between 10% to 20%(34,38). Within local government settings, the attrition rate was 10% for a 12-week follow-up education-based program in patients with diabetes(39). Taking into consideration the duration

of follow-ups and a conservative approach, this study will estimate a 30% attrition rate for the loss to follow-up at 6 months.

Based on the study by Wu et al.(34), with an expected medium effect size of 0.40 (μ diff = 16.19, s.d. =37.01), the sample size required in this study is calculated using a study-wide type 1 error rate (α) of 0.05 and a type II error rate (β) of 0.20 (power of 0.80). The current study will require a total of 59 participants for each group. With an expected attrition rate of 30%, the study aims to recruit a total of 172 participants, with 86 participants for each group.

Recruitment

Study procedure

Recruitment will take place at the clinics during a patient's routine check-up, over a period of 6 months or until the required number of participants is achieved.

Based on the list of registered patients during a clinic day, patients with diabetes will be screened based on age and type of diabetes. Eligible participants will be asked for consent to be approached by a research assistant. Those who fulfill the criteria and are able to give written informed consent for participation, will be included in the study.

After enrolment, participants will be given an opaque, sealed and numbered envelope containing allocation of groups, in numerical sequence. Each participant will be assigned into the intervention or control group based on the random sequence.

Allocation

Allocation sequence generation

To ensure concealment of allocation, randomisation will be conducted using digit random sampling. The randomisation sequence will be created with simple randomisation procedure and computerised random numbers using Excel 2010 (Microsoft, Redmond, WA, USA) with participants assigned to either treatment as usual (TAU) or Pohon Sihat plus TAU.

The four health clinics will first be stratified by the size of the clinic. To ensure a balanced representation of patients with DM within each clinic, randomisation will be conducted based on the size of the diabetes clinic as reported in the National Diabetes Registry. KKP9 with the largest portion of registered patients with DM (64%) will be allocated 110 participants (64% of 172 participants), followed by KKP18 (31%) allocated 53 participants, KKP 14 (3%) allocated 5 participants and KKP11 (2%) with an allocation of 4 participants.

Allocation concealment mechanism and implementation of random allocation

To ensure that clinics are assigned with a balanced number of allocated intervention and control, two lists of randomisation sequences will be made 1) clinics with 500-800 patient visits per day – KKP9 and KKP18, and 2) clinics with fewer than 150 visits per day – KKP11 and KKP14.

Research assistants involved in the recruitment will be blinded to the sequence allocation. Sealed envelopes will only be opened after eligible participants provide and sign the informed consent form.

Contamination Bias

To minimise contamination bias, the OHP plus TAU sessions will take place outside of the participating health clinics. Intervention sessions will be conducted in either a community-based rehabilitation center or a central health district center situated within Putrajaya. Participants will also be informed of the study parameters, with directives not to discuss the content of the materials or to exchange materials with other diabetes patients outside of the group.

Blinding

Blinding will be adopted to reduce bias of participants performing better or worse when they are informed which group they are allocated to after the randomisation process. This study will thus incorporate a single blinding process. Participants will not know which group is considered the experimental group and the control group.

Statistical Analysis

The intention-to-treat principle and per-protocol analyses will be performed. Any deviations from the random allocation and missing data will be fully reported as outlined in the Consolidated Standards of Reporting Trials (CONSORT) statement(40).

Any differences between individuals in the intervention and control conditions at baseline (socio-demographics, clinical details, psychosocial self-efficacy, diabetes management self-efficacy, anxiety, depression, diabetes-related distress, well-being, self-care behaviours and HbA1C) will be assessed using one-way analysis of variance ANOVA or chi-square test as appropriate. Assumptions of normality and homogeneity of variance will be assessed and adjusted accordingly.

A Mixed model ANOVA will be used to investigate the effectiveness of Pohon Sihat (OHP plus TAU) vs Treatment as usual (TAU) on all continuous variables at four points (i.e. baseline, 5 weeks, 3 months and 6 months). For all analysis of mixed effect, repeated measures, condition and time will be specified as fixed effects. A one-way analysis of covariance (ANCOVA) will be used to assess the effectiveness of the intervention compared with the control group, when covariates included duration of diabetes and diabetes complication are expected to impact on outcome measures.

Program assessment, treatment fidelity and cultural adaptation

Program assessment

The adaptation of the OHP for the Malaysian community was informed by: (1) review by Malaysia's primary and mental health care professionals, (2) structured translation and (3) cultural adaptation of the program.

The panel of reviewers included endocrinologist, family medicine specialists and physicians. The OHP was considered by this review to be a valuable engagement tool to further enhance the primary health care services, and to be more inclusive of mental health needs(22). Following this feedback, the OHP underwent a thorough translation and adaptation process.

Translation and cultural adaptation

The translation and cultural adaptation process involved multiple stages with (1) the development of a panel of experts from Malaysia and Australia, (2) forward and back translation of the program workbook, (3) cultural adaptation through the review and comparison by both content and local experts, including revision and harmonisation of the workbook, (4) pre-testing the program in a group of mental health practitioners, patient support group representatives as well as representatives from the Ministry of Health and finally (5) proofreading and finalising the design. Based on a thorough translation and adaptation process, the program was assessed as matching the intention and the fidelity of the original program

Training of Diabetes Educators

The facilitator training has been modified to include an additional day, taking into consideration minimal prior mental health training for diabetes educators, especially psychological strategies for engaging in effective health communication(9). The additional day includes collaborative therapy principles and motivational interviewing-based health coaching techniques. This modification ensures that the program delivery will maintain fidelity and stay aligned with its intention.

Each group program will be facilitated by a trained mental health practitioner and a diabetes care expert to further strengthen the program's fidelity.

Pilot study

A pilot study was conducted to assess the feasibility and accessibility of the culturally adapted OHP amongst patients with T2DM. Eight participants (n=8) were recruited, five completing all 5 sessions of the program (three withdrew due to work commitments). Challenges were identified with: (1) recruitment process, (2) duration of the program and (3) content of the material.

Generally, participants provided valuable feedback on the content of the workbook, structure of the program and ease of delivery. Participants' feedback suggested that the sessions be longer to allow more discussion. This was also echoed by the facilitators, who felt that additional time would allow greater coverage, and improve ease of delivery. An additional information sheet on healthy eating habit and lifestyle tips was also suggested by participants.

The recruitment process was improved based on the feedback provided by participants and facilitators. During recruitment, participants were informed that an official letter and time–slips would be provided to allow time off work to attend the program.

Several groups programs were offered throughout the week to allow people to attend the most convenient sessions. Logistical constraints were also improved by choosing venues with ample parking space. Sessions were extended from 1.5 hours to two hours. Content of the workbook was improved by additional health information such as the food pyramid and the local healthy eating habits. This additional information and some minor language changes improved the overall usability of the OHP Malay workbook.

Patient involvement

Patients were involved in the pre-testing stage of the culturally adapted program in which representatives from a patient support group were invited to review the materials and provide feedback. Participants also provided feedback on the feasibility and accessibility of the culturally adapted OHP amongst patients with DM during the pilot study. The feedback provided served to enhance the content of the workbook, the structure of the program and the delivery. The study results will be communicated to participating patients who have requested that we share the results of the study with them.

ETHICS AND DISSEMINATION

Consent

The process of obtaining consent is in line with the Declaration of Helsinki. Information regarding the study, and random allocation of participants will be outlined in a Patient Information Sheet as approved by the Ethics Committee (refer Supplementary file). The randomisation process will be clearly outlined to the eligible participants. A signed informed consent will be obtained from each participant. At the end of the study, participants in the control group (Treatment-as-usual) will be invited to participate in OHP.

Ethics approval

Ethical approval for this study has been obtained from the Medical Research and Ethics Committee (MREC), Ministry of Health Malaysia.

Data Management

All participant information will be treated as strictly confidential. Personal information will be coded to ensure the confidentiality of the participants and no individuals will be identifiable in any research material, reports or publications. No information collected will be shown to anyone apart from the research team. Data from the study will be stored securely in locked cabinets and electronic data will be kept on password protected drives accessible only by the research team. Permission to share information with appropriate health professionals will be sought if health concerns arise for participants.

Dissemination Plan

The findings of the study will be shared with stakeholders through publication and conference presentations. The outcomes of the study will be shared through publication within a peer-reviewed journal within 12 months of the last data collected. As part of the ethics approval requirements, the outcomes will be shared with the Malaysia Ministry of Health and participating health clinics.

DISCUSSION

The complexity of DM is associated with not just the patient's physical health but also their emotional well-being and mental health, social, occupational and overall quality of life(41). The growing numbers of people with DM, and increasing psychosocial barriers are associated with greater health impacts for the individual, family and community. Moreover, even though Putrajaya as a state that ranks high in health literacy, the prevalence rates of diabetes and obesity are the highest in the country. With its mediating role between health literacy and self-care behaviours(42), self-efficacy may be the missing link in understanding the dissonance between illness education, and the ability to utilise the knowledge to commit to a healthy lifestyle.

The OHP is a self-efficacy enhancing psychological intervention that is low-intensity, structured and can be delivered by trained facilitators. The recovery-based approach emphasises the language of hope and well-being rather than illness and disease, and is suitable for a primary health care setting. Through a patient centered, collaborative approach, the OHP may offer a platform for a wide range of primary health care providers to engage in a discussion with patients regarding their well-being. As a psychological intervention program for primary health care providers, OHP can address mental health concerns and promote overall wellbeing for people experiencing chronic illness. The OHP will be the first engagement tool in Malaysia with potential to act in a curative and preventative role

In addition to providing further understanding in the effectiveness of an add-on psychological intervention, the study will also provide information on the effectiveness of the current standard of practice within the primary health care as guided by the Malaysian Clinical Practice Guidelines in the Management of Type 2 Diabetes Mellitus.

Trial Status

Patient recruitment commenced October 2018 and data collection will continue until August 2020. ClinicalTrials.gov NCT03601884

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Figure

Figure 1. Flow chart of participants

Figure 2. Schedule of enrolment, interventions, and assessments.

Tables

Table 1. Outline of POHON SIHAT sessions for patients with diabetes

Table 2. Description of measurements

Contributors

AFS, NI, TKA and UAS designed the study. AFS wrote the first draft of the manuscript and coordinated the development of the study protocol. BR, TKA, GM and DC contributed a thorough review of the manuscript which AFS revised in the second version. UAS, NI, TKA and BR then provided further written feedback. All authors critically reviewed, revised and approved the final version of the manuscript to be submitted by AFS. AFS, TKA, BR, UAS, GM and DC further reviewed and contributed towards the revised versions of the manuscript.

Competing Interests:

DC has received grant monies for research from Eli Lilly, Janssen Cilag, Roche, Allergen, Bristol-Myers Squibb, Pfizer, Lundbeck, Astra Zeneca, Hospira; Travel Support and Honoraria for Talks and Consultancy from Eli Lilly, Bristol-Myers Squibb, Astra Zeneca, Lundbeck, Janssen Cilag, Pfizer, Organon, Sanofi-Aventis, Wyeth, Hospira, Servier; and is a current Advisory Board Member for Lu AA21004: Lundbeck; Varenicline: Pfizer; Asenapine: Lundbeck; Bitopertin: Roche Aripiprazole LAI: Lundbeck; Lisdexamfetamine: Shire; Lurasidone: Servier. He has no stocks or shares in any pharmaceutical company.

This study had no other conflict of interest.

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Data sharing statement

There are no data available in this study protocol.

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Table 1. Outline of POHON SIHAT sessions for patients with diabetes

WEEK	SESSION	SESSION OUTLINE
1	Optimal Health	What is Optimal Health? • Introduction to the Collaborative Therapy Optimal Heath Program • Introduce TOOL 1: The Optimal Health Wheel • Reflection of one's own health based on 6 domains – physical, emotional, intellectual, social, spiritual and occupational health and identifying possible areas for change • Exploration of one's satisfaction level within each health domains • Identify possible areas for change
2	I-CAN-DO Model Strengths and vulnerabilities Stressors and strategies	The I-Can-Do Model • Introduction to concepts of one's strengths, vulnerabilities, stressors and strategies and how it may impact on their over wellbeing • Introduce TOOL 2: I-Can-Do Model • Identify one's strengths and vulnerabilities • Identify one's source of stress and how stress may impact diabetes and overall wellbeing • Identify and building one's own strategies to cope with stressors • Reflection on achieving balance within the I-CAN-DO MODEL
3	Factors of Wellbeing	Medication and Metabolic Monitoring • Psychoeducation on medication – understanding what, why and how one's own medication works • Introduce TOOL 3: Medication & Metabolic Monitoring Table • Emphasize on the metabolic monitoring that needs to be done routinely within the health clinics

		• Addressing common myths amongst diabetes patients • Further emphasis on healthy lifestyle and eating habits Collaborative Partners and Strategies • Identify collaborative partners • Introduce TOOL 4: Eco-Mapping • Discussion on role of collaborative partners in maintaining one's optimal health
4	Visioning & Goal Setting	Change Enhancement – Time line activity • Introduction to identifying past events and its impact on health • Stages of Health: Optimal Health, Sub Optimal Health and Episode of Illness • Introduce TOOL 5: Time Line Activity Visioning and Goal Setting • Introduction to creative problem solving and setting SMARTER goals • Introduce TOOL 6: Cost-benefit Table • Discussion on barriers to achieving goals • Identify steps and strategies to achieve future goals
5	Maintain well-being	Maintaining well-being • Understanding one's own stages of health • Introduce TOOL 7: Health Plans: Optimal Health (Health Plan 1); Sub-optimal Health (Health Plan 2) and Episode of Illness (Health Plan 3) • Build skills and strategies at different stages of health • Review of session 1-4 and tools introduced
Booster	Review Health Plans	Review of Health Plans • Reflection on the application of knowledge and skills learned and its impact on optimal health. • Discussion on possible barriers and strategies

Table 2. Description of measurements

OUTCOME AND DESCRIPTION OF MEASUREMENTS	
Primary Outcome – Self-efficacy	
Psychosocial Self-efficacy	**The Diabetes Empowerment Scale (DES-SF)** is an 8 item self-administered measurement that assesses the perceived ability to manage psychosocial issues such as managing stress, coping with emotional distress, engaging with family and friends for support and discussion with health care providers(43). Participants rate items on a 4-point likert scale ranging from 0 (strongly disagree) to 4 (strongly agree). The sum of all items ranged from 0 to 32. Previous research reported the DES-SF Chronbach's alpha is at 0.84(26).
Diabetes Management Self-Efficacy	**The Diabetes Management Self-efficacy Scale (DMSES)** is a 20-item self-administered measurement that assess self-efficacy in managing specific diabetes self-care behaviours such as glucose monitoring, general and specific diet, medication adherence, exercise and foot care(27). Participants rate items on a 10-point likert scale ranging from 0 (Not at all confident) to 10 (Totally confident). The Malay validated DMSES has a Chronbach's α estimate of 0.951(17).
Secondary Outcomes	
Depression	**Patient Health Questionnaire –PHQ-9** is a 9 item self-administered measurement that assseses the presentation of depression symptoms and the impairments related to the symptoms. Participants rate items on a 4-point likert scale ranging from 0 to 3. The sum of all items range between 0 to 27. The Malay validated PHQ-9 has a Chronbach's α estimate of 0.70, sensitivity of 87% and specificity of 82%(28).
Anxiety	**General Anxiety Disorder – GAD-7** is a 7 item self-administered measurement that assesses the presentation of anxiety symptoms and the impairments related to the symptoms. Participants rate items on a 4-point likert scale ranging from 0 to 3. The sum of all items range between 0 to 21. The Malay validated GAD-7 has a Chronbach's α estimate of 0.74, sensitivity of 76% and specificity of 94%(29).

Diabetes-related distress	**Problem Areas in Diabetes (PAID) – 20** is a 20 item self-administered measurement that assesses emotional problems in patients with diabetes. Participants rate items on a 5-point likert scale ranging between 0 (Not a problem) to 4 (serious problem). The sum of all items range from 0 to 80. The Malay validated PAID-MY 20 has a Chronbach's α estimate of 0.921(30).
Well-being	**WHO-5 Wellbeing Index (WHO-5)** is a 5 item self-administered measurement that assesses emotional wellbeing and mental health (31). Participants rate items on a 5-point likert scale ranging between 0 (none of the time) to 5 (all of the time). The raw score that ranges from a minimum of 0 (absence of well-being) to a maximum of 25 (maximum well-being) are then multiplied by 4 to obtain the percentage scale. The recommended cut off score of ≤50 is an indication of poor well-being.
Self-management behaviours	**Summary of Diabetes Self-Care Activities (SDSCA)** is an 11 item self-administered measurement that assess aspects of diabetes regimen including general diet, specific diet, exercise, blood-glucose testing, foot care and smoking(44). Participants responds based on engagement to self-management behaviours related to diabetes in the last seven days. The Malay validated SDSCA Chronbach's α estimate for the main domains ranged between 0.651 and 0.905(33).
Glycaemic control	Glycaemic control will be reported in SI units (mmol A1c/mol Hb) that will be collected from patient records. Based on the guideline, the target that needs to be achieved for control of T2DM is a HbA1C level of not more than 6.5%.

Figure 1 Flow chart of participants

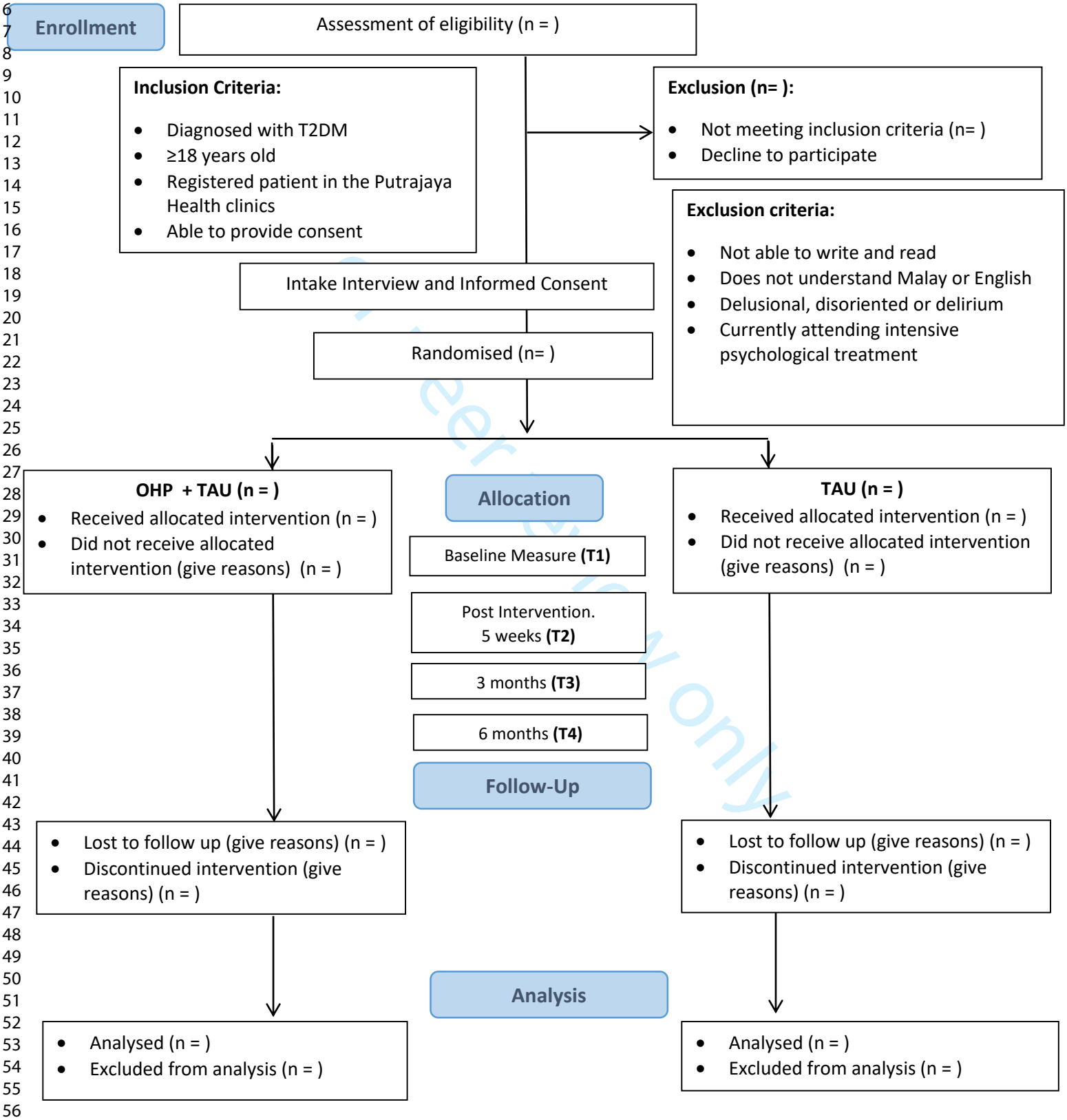

Figure 2. Schedule of enrolment, interventions, and assessments.

	STUDY PERIOD					
	Enrolment	Allocation	Post-allocation			Follow up
TIMEPOINT	$-t_1$	0	*1 wk*	*5 wk*	*18 wk*	*30 wk*
ENROLMENT:						
Eligibility screen	X					
Informed sheet	X					
Informed consent	X					
Randomisation	X					
Allocation		X				
INTERVENTIONS:						
Pohon Sihat and Treatment as usual			◆—	—	—◆	
Treatment as usual						
ASSESSMENTS:						
Sociodemographic data		X				
DES-SF			X	X	X	X
DMSES			X	X	X	X
GAD-7			X	X	X	X
PHQ-9			X	X	X	X
PAID-20			X	X	X	X
WH0-5			X	X	X	X
SDSCA			X	X	X	X
HbA1C		X				X

Participant Information Sheet SELF-EFFICACY IN DIABETES	  **Faculty of Medicine and Health Sciences** **University Putra Malaysia** **43400 Serdang Selangor**

Study title:	*The effectiveness of the Optimal Health Program in improving self-efficacy in patients with diabetes in Putrajaya, Malaysia.*
Locality:	**Wilayah Persekutuan Putrajaya**
Ethics ref.	NMRR-17-3426-38212
Investigator:	**Aida Farhana Binti Hj Suhaini**
Supervisor:	**Assoc. Prof. Dr. Normala Ibrahim**

WHAT IS THE PURPOSE OF THE STUDY?

The purpose of this study is to examine the effectiveness of the Optimal Health Program, a self-management program that promotes overall well-being and self-efficacy in the management of emotional distress in people with diabetes. The Optimal Health Program (OHP) enhances an individual's wellbeing through building on their strengths and values. It provides a framework that responds to individual needs and creates opportunities for conversation around areas of not just the physical health, but also psychological, social, occupational and spiritual health.

WHY WAS I ASKED TO PARTICIPATE?

You have been asked to participate because you have diabetes and may benefit from the Optimal Health Program.

WHAT WILL HAPPEN TO ME IF I AGREE TO TAKE PART?

Taking part in the study involves being randomly entered into one of two groups. The groups will be randomly selected (a bit like tossing a coin), so you cannot choose which group you are in. You will *not* know which group you are in before consenting to take part in the study.

This study will involve a total of 156 participants, with 78 participants for each group. The whole study will last about two years and your participation will be approximately 8 months from the point of first assessment.

If you agree to take part, you will be required to:

1. Complete a questionnaire on sociodemographic details and your diabetes.
2. Complete 7 questionnaires – WHO-5 well-being Index (WHO-5) (5 items), General Anxiety Disorder – 7 (GAD-7) (7 items), Patient Health Questionnaire – 9 (PHQ-9), Problem Areas in Diabetes (PAID) (20 items), Diabetes Empowerment Scale (DES) (8 items), Diabetes Management Self-Efficacy Scale (DMSES) – (20 items) and Summary of Diabetes Self-Care Activities (SDSCA) (12 items).

You will be asked to fill in these questionnaires at four points in time, in the beginning, at 5 weeks, 3 months and at 6 months. All questionnaire will require approximately 30 minutes to complete.

3. Attend either the

A) **Treatment as usual**

If you are randomly assigned to this group, you will receive treatment as usual. At the end of the study period (one year) we will offer you the chance of participating in the Optimal Health Program.

or

B) **The Optimal Health Program and Treatment as usual**.

If you are randomly assigned to the Optimal Health Program, you will receive treatment as usual. In addition, you will be required to attend a group program for 5 sessions, 1.5 hours for every week and a booster session after three months.

DO I HAVE TO TAKE PART?

Participation in this study is voluntary. It is completely up to you whether or not you participate. If you decide not to participate, it will not affect the treatment you receive now or in the future. You may withdraw from the study at any time and for any reason or no reason. Information that has been collected about you, prior to your withdrawal, will continue to be used in the data analysis. No new information will be collected or used after you have withdrawn from the study.

WILL MY TAKING PART IN THIS PROJECT BE KEPT CONFIDENTIAL?

If you agree to take part in the study you will need to sign and date the Informed Consent Form attached. Your medical records and data will need to be seen by the authorised members of our research team (i.e. treating team in the clinic and the researcher) so they can collect information needed for this research study. Your unique registration number will be used to make sure you cannot be identified outside the study. All information, which is collected, about you during the course of the research will be treated as strictly confidential. The confidentiality of your medical records will be respected at all times.

When publishing or presenting the study results, your identity will not be revealed without your expressed consent. No information collected will be shown to anyone apart from the research team. For regulatory purposes, data from the study will be stored securely for at least 3 years following the study and destroyed as confidential waste thereafter.

WILL I BE INFORMED OF THE STUDY FINDINGS?

You will not be informed individually of the study findings. Nonetheless if you are interested to be informed of your personal results at the end of this study, you can express your interest in the Consent form.

WHAT ARE THE POSSIBLE DISADVANTAGES AND RISKS OF TAKING PART IN THIS RESEARCH?

As with any psychosocial intervention, it is possible that discussing about your difficulties may cause you some distress. Similar studies have been conducted in Malaysia and have been shown to have

minimal to no risk. Nonetheless, if you pose any difficulties or discomfort, please inform the investigator.

WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART IN THIS RESEARCH?

The OHP has been shown to be effective in improving one's belief about their capabilities to cope and manage their illness and reduce distress. This study aims to further expand the depth of knowledge in the field of chronic illness specifically in the enhancement of patients' self-management. The study may not directly benefit you but the information we get from the study will help increase the understanding of self-efficacy enhancing program in the management of diabetes.

WILL TAKING PART IN THIS STUDY COST ME ANYTHING AND WILL I BE PAID?

Participation in this study will not cost you anything. For sessions and visits that are conducted outside of your routine clinic, you will be reimbursed for your time and reasonable travel.

WHO IS FUNDING THE RESEARCH?

This study is sponsored by a research grant from University Putra Malaysia who will pay for all study procedures except all other medication and procedures that are part of your routine medical care.

CAN THE RESEARCH OR MY PARTICIPATION BE TERMINATED EARLY?

The researcher may stop the study or your participation at any time possibly due to any safety concern. If the study is stopped early for any reason you will be informed and arrangements made for your future care. You may be asked to attend a final follow-up visit.

WHO DO I CONTACT FOR MORE INFORMATION OR IF I HAVE CONCERNS?

If you have any questions, concerns or complaints about the study at any stage, you can contact:

Prof Madya Normala Ibrahim
Consultant Psychiatrist
Faculty of Medicine and Health Sciences
University Putra Malaysia
43400 Serdang Selangor
normala_ib@upm.edu.my

Aida Farhana Suhaimi
Clinical Psychologist
PhD Psychological Medicine Candidate
Department of Medicine and Health Sciences
University Putra Malaysia
43400 Serdang Selangor
aida.hjsuhaimi@gmail.com

If you have any questions about your rights as a participant in this study, please contact: The Secretary, Medical Research & Ethics Committee, Ministry of Health Malaysia, at telephone number 03-2287 4032.

Consent Form SELF-EFFICACY IN DIABETES	 **Faculty of Medicine and Health Sciences** **University Putra Malaysia** **43400 Serdang Selangor**

Consent

Your signature below indicates that you have decided to volunteer as a research participant for this study, and that you have read and understood the information provided above. You will be given a signed and dated copy of this form to keep, along with any other printed materials deemed necessary by the study researchers.

Participant's Signature : _____

Participant's Name : _____

Participant's IC No. : _____

Date: :

Researcher's Signature :

_____

Date:

Are you interested in viewing your personal results at the end of this study?

☐ **Yes** ☐ **No**

Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SPIRITreporting guidelines, and cite them as:

Chan A-W, Tetzlaff JM, Altman DG, Laupacis A, Gøtzsche PC, Krleža-Jerić K, Hróbjartsson A, Mann H, Dickersin K, Berlin J, Doré C, Parulekar W, Summerskill W, Groves T, Schulz K, Sox H, Rockhold FW, Rennie D, Moher D. SPIRIT 2013 Statement: Defining standard protocol items for clinical trials. Ann Intern Med. 2013;158(3):200-207

		Reporting Item	Page Number
Administrative information			
Title	#1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	#2a	Trial identifier and registry name. If not yet registered, name of intended registry	4
Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	n/a
Protocol version	#3	Date and version identifier	1
Funding	#4	Sources and types of financial, material, and other support	2

Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	1-2
Roles and responsibilities: sponsor contact information	#5b	Name and contact information for the trial sponsor	n/a
Roles and responsibilities: sponsor and funder	#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	n/a
Roles and responsibilities: committees	#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)	n/a
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	5
Background and rationale: choice of comparators	#6b	Explanation for choice of comparators	6
Objectives	#7	Specific objectives or hypotheses	6
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, non-inferiority, exploratory)	7
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	7
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)	8
Interventions: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	9
Interventions: modifications	#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)	n/a
Interventions: adherance	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	
Interventions: concomitant care	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	n/a
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	10
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 Figure)	10 Figure 2
Sample size	#14	Estimated number of participants needed to achieve study objectives and how it was determined, including	10

		clinical and statistical assumptions supporting any sample size calculations	
Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	11
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	11
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	12
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	12
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	12
Blinding (masking): emergency unblinding	#17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	n/a
Methods: Data collection, management, and analysis			
Data collection plan	#18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate	15

		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	
Data collection plan: retention	#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	13
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	15
Statistics: outcomes	#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	13
Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	13
Statistics: analysis population and missing data	#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)	13
Methods: Monitoring			
Data monitoring: formal committee	#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	n/a
Data monitoring: interim analysis	#21b	Description of any interim analyses and stopping guidelines, including who will have access to these	n/a

		interim results and make the final decision to terminate the trial	
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	16
Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	n/a
Ethics and dissemination			
Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	15
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)	15
Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	15
Consent or assent: ancillary studies	#26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	n/a
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	15
Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	2
Data access	#29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	15

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	n/a
Dissemination policy: trial results	#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	16
Dissemination policy: authorship	#31b	Authorship eligibility guidelines and any intended use of professional writers	16
Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	16
Appendices			
Informed consent materials	#32	Model consent form and other related documentation given to participants and authorised surrogates	Sup. 1
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	n/a