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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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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) .

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3 Self-efficacy has been found to correlate with self-management behaviours(11–14) and being
4 negatively correlated with physical distress(15), depression(12), and diabetes distress(16). The
5 role of self-efficacy as a mediator between self-management behaviours and diabetes related
6 distress, depression, and anxiety were also reported(13,17). Therefore, an intervention that
7 enhances self-efficacy would be expected to improve depression, diabetes distress, and self-
8 management behaviours. Hence, inclusion of self-efficacy as a treatment outcome in a diabetes
9 intervention program is crucial as this allows researchers to evaluate the effectiveness of such
10 program accurately(4).
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19 **POHON SIHAT – Cross-culturally adapted Malay Optimal Health Program (OHP)**

20 The Optimal Health Program (OHP) is a biopsychosocial program that promotes patients to be
21 actively involved in their own healthcare and overall well-being. The aim of OHP is to improve
22 individual’s self-efficacy and to build on their strengths and values which in turn enhance their
23 overall wellbeing. Initially developed and found effective in mental health patients(18,19), the
24 OHP has extended its treatment in managing physical health and chronic illnesses(20,21).
25 Having a platform to discuss the multiple areas of a person’s life and associated psychosocial
26 barriers creates tremendous potential in the management of diabetes.
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34 In a preliminary study that assessed the needs of OHP in Malaysia, the OHP was found to hold a
35 promising framework in building the capacity of the mental health care services in Malaysia(22).
36 Following a process of translation and cultural adaptation, the Malaysian OHP program was
37 developed (henceforth referred to as Pohon Sihat). Being a culturally sensitive tool, Pohon Sihat
38 provides a promising low intensity self-efficacy enhancing psychosocial intervention conducted
39 within the primary care setting.
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46 **Objectives**

47 Pohon Sihat is designed to address the gap in the management of mental health issues in diabetes
48 patients within a limited resource setting. This study will examine the effectiveness of this
49 program for diabetes patients within a primary care setting in Malaysia.
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3 The intervention will be offered to patients with diabetes who are currently attending health
4 clinics within the Putrajaya district. Specifically, this study aims to investigate the effectiveness
5 of Pohon Sihat in addition to treatment-as-usual (TAU) as compared to TAU alone. It will also
6 examine the effectiveness of Pohon Sihat in reducing anxiety, depression, diabetes-related
7 distress, and in increasing self-care behaviours and glycemic control.
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13 **METHODS**

14 **Study design**

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

30 The Federal Territory of Putrajaya is Malaysia's federal administrative center. Based on the
31 National Health and Morbidity survey(8), Putrajaya has high prevalence for diabetes (19.2%)
32 and has the highest prevalence for overweight (37%), obesity (43%) and abdominal obesity
33 (61.3%).
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39 **Participants**

40 *Sampling frame*

41 The sampling frame will be patients with Type 2 Diabetes Mellitus (T2DM) registered at the
42 primary healthcare clinics within the Federal Territory of Putrajaya. Approximately 35% of the
43 Malaysian population receives treatment within the government health clinics located within the
44 community, for easy accessibility and communal location(23).
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51 The services and facilities provided within the clinics differ according to the size of the clinics
52 which is based on the number of patient visits per day. Health Clinic Presint 9 (KKP9) and
53 Health Clinic Presint 18 (KKP18) have 500-800 patient visits per day. These Health Clinics are
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3 fully equipped with Primary Health Care services, Family Medicine Specialists, Laboratory,
4 Diagnostic Imaging, Rehabilitation, Dietary, Pharmacy, and Dental services. Health Clinic
5 Presint 11 (KKP11) and Health Clinic Presint 14 (KKP14) have fewer than 150 patient visits per
6 day. These clinics are limited to outpatient services (non-complex cases and/or stabil chronic
7 cases) and pharmacy services.
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13 According to the 2018 National Diabetes Registry, registered diabetes patients (both Type 1 and
14 Type 2) are unevenly distributed based on the type of the health clinics, the facility available and
15 the services provided. Sizes of the diabetes clinic of each health clinics differ with KKP9 having
16 the largest portion of diabetes patients in Putrajaya (64%) and KKP11 having the smallest
17 portion (2%).
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23 24 **Eligibility Criteria**

25 *Inclusion criteria*

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27 Eligible patients include patients with a diagnosis of Diabetes Mellitus Type 2 as assessed by
28 their attending physicians based on the National Clinical Practice Guidelines for Type 2 Diabetes
29 Mellitus(24); aged between 18 to 60 years old; and currently registered to be receiving services
30 in the health clinics in Putrajaya. Patients also need to be able to provide informed consent to
31 participate in the study.
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37 The criteria for diagnosing Diabetes Mellitus Type 2 is based on the Malaysia's Clinical Practice
38 Guidelines for Type 2 Diabetes Mellitus. The guideline defines Diabetes Mellitus Type 2
39 patients as people who have been diagnosed with diabetes mellitus, and have had/have a
40 confirmed A1C level FPG ≥ 7.0 mmol/L.
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45 *Exclusion Criteria*

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

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3 Taking into consideration a conservative approach and duration of follow-ups, this study will
4 estimate a 30% attrition rate for the loss to follow-up at 6 months.
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8 Based on the study by Wu et al.(34), with an expected medium effect size of 0.40 (μ diff =
9 16.19, s.d. =37.01), the current study will calculate the sample size required in this study using a
10 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
11 current study will require a total of 59 participants for each group. With an expected attrition rate
12 of 30%, the study aims to recruit a total of 172 participants, with 86 participants for each group.
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18 **Recruitment**

19 *Study procedure*

20 Recruitment will take place at the clinics during patient's routine check-ups at the diabetes clinic,
21 for a period of 6 months or until the required number of participants are achieved.
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27 Based on the list of registered patients during a clinic day, people with diabetes will first be
28 screened based on age and type of diabetes. Eligible participants will be asked for consent to be
29 approached by a research assistant. Those who fulfill the criteria and are able to give written
30 informed consent for participation, will be included in the study.
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36 After enrolment, participants will be given an opaque, sealed and numbered envelope containing
37 allocation of groups, given in numerical sequence. Thus each participant will be assigned into the
38 intervention or control group based on the random sequence of enrolment in the study.
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43 **Allocation**

44 *Allocation sequence generation*

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

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

21 Taking into consideration that many diabetes educators have minimal training in mental health
22 especially engaging in effective health communication(9), an additional day was added to the
23 facilitator's training. The additional day included more in-depth content, including collaborative
24 therapy principles and motivational interviewing based health coaching techniques. This is to
25 ensure that the program delivery will maintain fidelity and stay aligned with its intention.
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32 Each group program will be facilitated by a trained mental health practitioner and diabetes care
33 expert to further strengthen the program's fidelity.
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37 *Pilot study*

38 A pilot study was conducted to assess the feasibility and content of the culturally adapted OHP
39 amongst people with diabetes. Eight participants ($n=8$) were recruited, five completing all 5
40 sessions of the program (three withdrew due to work commitments). Challenges were identified
41 with the (1) recruitment process, (2) duration of the program and the (3) content of the material.
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48 Participants' feedback suggested that the 1.5 hour sessions be increased to 2 hours to allow more
49 discussion. This was also echoed by the facilitators, who felt that an additional half an hour will
50 allow greater coverage, improved ease of delivery and a better sense of not being constricted by
51 time. Generally, participants provided valuable feedback on the content of the workbook,
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3 structure of the program and ease of delivery. An additional information sheet on healthy eating
4 habit and lifestyle tips was also suggested by participants.
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8 Based on the feedback provided by both participants and facilitators, recruitment process was
9 improved through several steps. First, during recruitment, participants were informed that an
10 official letter and time-slips can be provided to allow time off work to attend the program.
11 Ensuring several groups programs are run throughout the week is an important factor to allow
12 flexibility to attend sessions that were suitable to their time. Logistical constraints were also
13 improved by choosing venues that will have ample parking space. Sessions were also extended
14 from a 1.5 hours to two hours. Content of the workbook was improved with additional health
15 information such as the food pyramid and the local healthy eating habits. This additional
16 information and some minor language changes were deemed to increase feasibility, and improve
17 the Pohon Sihat Malay workbook.
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27 **ETHICS AND DISSEMINATION**

28 **Consent**

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

44 Ethical approval for this study was obtained from the Medical Research and Ethics Committee
45 (MREC), Ministry of Health Malaysia.
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50 **Data Management**

51 All participant information will be treated as strictly confidential. All research materials that
52 provide personal information will be coded to ensure the confidentiality of the participants and
53 no individuals will be identifiable in any reports or publications. No information collected will
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3 be shown to anyone apart from the research team. Data from the study will be stored securely in
4 locked cabinets and electronic data will be kept on password protected drives accessible only by
5 the research team.
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11 **Dissemination Plan**

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

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27 The complexity of diabetes mellitus itself is associated with not just the patient's physical health
28 but also their emotional well-being and mental health, social, occupational and overall quality of
29 life(40). The growing diabetes population with increasing psychosocial barriers are associated
30 with greater complexity of diabetes contributing to greater health impact on the individual,
31 family and community. Moreover, even though Putrajaya was found to be a state that ranked
32 high in health literacy, prevalence rates of diabetes and obesity within Putrajaya are still the
33 highest in the country. With its mediating role between health literacy and self-care
34 behaviours(41), self-efficacy may be the missing link in understanding the dissonance between
35 illness education, and the ability to utilize the knowledge to commit to healthy lifestyle.
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44 The OHP is a self-efficacy enhancing psychological intervention that is low-intensity, structured
45 and can be delivered by trained facilitators. Its recovery-based approach emphasizes the
46 language of hope and well-being as compared to illness and disease which is suitable to be given
47 within a primary health care setting. It may offer a platform for wide range of health care
48 providers within the primary care to engage in a discussion with patients regarding their well-
49 being through a patient centered collaborative approach. Through the OHP, a psychological
50 intervention program for primary health care providers can be provided to address the mental
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3 health issues and promote overall wellbeing in these chronic ill patients. The Pohon Sihat will be
4 the first engagement tool in Malaysia with potential to act in a curative and preventative role
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8 In addition to providing further understanding in the effectiveness of an add-on psychological
9 intervention, the outcome of the study will also provide information on the effectiveness of the
10 current standard of practice within the primary health care as guided by the latest version of the
11 Clinical Practice Guideline in the management of Type 2 Diabetes Mellitus.
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15 16 17 **Trial Status**

18 Patient recruitment commenced October 2018 and data collection will continue until August
19 2020. ClinicalTrials.gov NCT03601884
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23 24 **Acknowledgements**

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26 The OHP was developed at the Mental Health Research Institute of Victoria and St Vincent's
27 Hospital Melbourne.
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29 We would like to thank the Director General of Health Malaysia for his permission to publish
30 this article.
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34 35 36 **Figure**

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39 **Figure 1.** Flow chart of participants

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41 **Figure 2.** Schedule of enrolment, interventions, and assessments.
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44 45 **Tables**

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

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48 **Table 2.** Description of measurements
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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, Allergan, 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	<p>What is Optimal Health?</p> <ul style="list-style-type: none"> • Introduction to the Collaborative Therapy Optimal Health 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	<p>The I-Can-Do Model</p> <ul style="list-style-type: none"> • 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	<p>Medication and Metabolic Monitoring</p> <ul style="list-style-type: none"> • 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 <p>Collaborative Partners and Strategies</p> <ul style="list-style-type: none"> • Identify collaborative partners • Introduce TOOL 4: Eco-Mapping • Discussion on role of collaborative partners in maintaining one's optimal health
4	Visioning & Goal Setting	<p>Change Enhancement – Time line activity</p> <ul style="list-style-type: none"> • 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

		<p>Visioning and Goal Setting</p> <ul style="list-style-type: none"> • 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	<p>Maintaining well-being</p> <ul style="list-style-type: none"> • 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	<p>Review of Health Plans</p> <ul style="list-style-type: none"> • 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 assesses 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

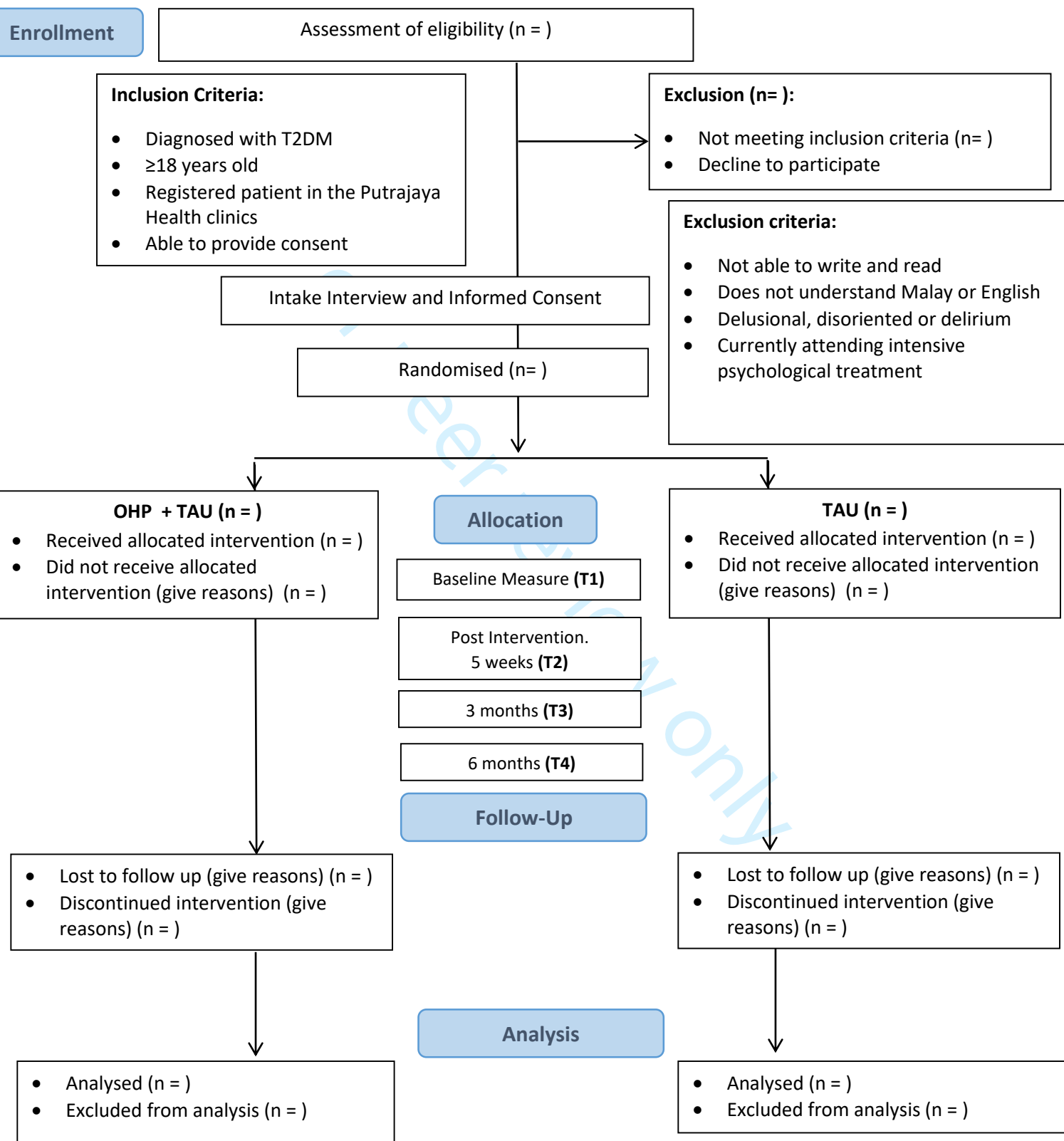


Figure 2. Schedule of enrolment, interventions, and assessments.

TIMEPOINT	STUDY PERIOD					
	Enrolment	Allocation	Post-allocation			Follow up
	$-t_1$	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:						
<i>Sociodemographic data</i>		X				
<i>DES-SF</i>			X	X	X	X
<i>DMSES</i>			X	X	X	X
<i>GAD-7</i>			X	X	X	X
<i>PHQ-9</i>			X	X	X	X
<i>PAID-20</i>			X	X	X	X
<i>WHO-5</i>			X	X	X	X
<i>SDSCA</i>			X	X	X	X
<i>HbA1C</i>		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 SPIRIT reporting 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

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

1	Trial registration	#2a	Trial identifier and registry name. If not yet registered,	4
2			name of intended registry	
3				
4				
5				
6	Trial registration:	#2b	All items from the World Health Organization Trial	
7			Registration Data Set	
8	data set			
9				
10				
11				
12	Protocol version	#3	Date and version identifier	1
13				
14				
15	Funding	#4	Sources and types of financial, material, and other	2
16			support	
17				
18				
19				
20	Roles and	#5a	Names, affiliations, and roles of protocol contributors	1-2
21				
22	responsibilities:			
23				
24	contributorship			
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27				
28	Roles and	#5b	Name and contact information for the trial sponsor	
29				
30	responsibilities:			
31				
32	sponsor contact			
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34	information			
35				
36				
37				
38	Roles and	#5c	Role of study sponsor and funders, if any, in study	
39			design; collection, management, analysis, and	
40	responsibilities:		interpretation of data; writing of the report; and the	
41			decision to submit the report for publication, including	
42	sponsor and funder		whether they will have ultimate authority over any of	
43			these activities	
44				
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52	Roles and	#5d	Composition, roles, and responsibilities of the	
53			coordinating centre, steering committee, endpoint	
54	responsibilities:		adjudication committee, data management team, and	
55				
56	committees			
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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

1	Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If	8
2			applicable, eligibility criteria for study centres and	
3			individuals who will perform the interventions (eg,	
4			surgeons, psychotherapists)	
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10				
11	Interventions:	#11a	Interventions for each group with sufficient detail to allow	9
12			replication, including how and when they will be	
13	description		administered	
14				
15				
16				
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18				
19	Interventions:	#11b	Criteria for discontinuing or modifying allocated	
20			interventions for a given trial participant (eg, drug dose	
21	modifications		change in response to harms, participant request, or	
22			improving / worsening disease)	
23				
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29	Interventions:	#11c	Strategies to improve adherence to intervention protocols,	
30			and any procedures for monitoring adherence (eg, drug	
31	adherence		tablet return; laboratory tests)	
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36	Interventions:	#11d	Relevant concomitant care and interventions that are	
37			permitted or prohibited during the trial	
38	concomitant care			
39				
40				
41				
42	Outcomes	#12	Primary, secondary, and other outcomes, including the	10
43			specific measurement variable (eg, systolic blood	
44			pressure), analysis metric (eg, change from baseline, final	
45			value, time to event), method of aggregation (eg, median,	
46			proportion), and time point for each outcome. Explanation	
47			of the clinical relevance of chosen efficacy and harm	
48			outcomes is strongly recommended	
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1	Participant timeline	#13	Time schedule of enrolment, interventions (including any	10
2			run-ins and washouts), assessments, and visits for	Figure 2
3			participants. A schematic diagram is highly recommended	
4			(see Figure)	
5				
6				
7				
8				
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10				
11	Sample size	#14	Estimated number of participants needed to achieve	10
12			study objectives and how it was determined, including	
13			clinical and statistical assumptions supporting any sample	
14			size calculations	
15				
16				
17				
18				
19				
20				
21	Recruitment	#15	Strategies for achieving adequate participant enrolment to	11
22			reach target sample size	
23				
24				
25				
26	Methods:			
27				
28	Assignment of			
29	interventions (for			
30	controlled trials)			
31				
32				
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36	Allocation: sequence	#16a	Method of generating the allocation sequence (eg,	11
37	generation		computer-generated random numbers), and list of any	
38			factors for stratification. To reduce predictability of a	
39			random sequence, details of any planned restriction (eg,	
40			blocking) should be provided in a separate document that	
41			is unavailable to those who enrol participants or assign	
42			interventions	
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53	Allocation	#16b	Mechanism of implementing the allocation sequence (eg,	12
54	concealment		central telephone; sequentially numbered, opaque,	
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56				
57	mechanism			
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1		sealed envelopes), describing any steps to conceal the	
2			
3		sequence until interventions are assigned	
4			
5			
6	Allocation:	#16c Who will generate the allocation sequence, who will enrol	12
7			
8	implementation	participants, and who will assign participants to	
9			
10		interventions	
11			
12			
13	Blinding (masking)	#17a Who will be blinded after assignment to interventions (eg,	12
14			
15		trial participants, care providers, outcome assessors, data	
16			
17		analysts), and how	
18			
19			
20			
21	Blinding (masking):	#17b If blinded, circumstances under which unblinding is	
22			
23	emergency	permissible, and procedure for revealing a participant's	
24			
25	unblinding	allocated intervention during the trial	
26			
27			
28			
29	Methods: Data		
30			
31	collection,		
32			
33	management, and		
34			
35	analysis		
36			
37			
38	Data collection plan	#18a Plans for assessment and collection of outcome,	15
39			
40		baseline, and other trial data, including any related	
41			
42		processes to promote data quality (eg, duplicate	
43			
44		measurements, training of assessors) and a description	
45			
46		of study instruments (eg, questionnaires, laboratory tests)	
47			
48		along with their reliability and validity, if known. Reference	
49			
50		to where data collection forms can be found, if not in the	
51			
52		protocol	
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1	Data collection plan:	#18b	Plans to promote participant retention and complete	13
2				
3	retention		follow-up, including list of any outcome data to be	
4			collected for participants who discontinue or deviate from	
5			intervention protocols	
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11	Data management	#19	Plans for data entry, coding, security, and storage,	15
12			including any related processes to promote data quality	
13			(eg, double data entry; range checks for data values).	
14			Reference to where details of data management	
15			procedures can be found, if not in the protocol	
16				
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23	Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary	13
24			outcomes. Reference to where other details of the	
25			statistical analysis plan can be found, if not in the protocol	
26				
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31	Statistics: additional	#20b	Methods for any additional analyses (eg, subgroup and	13
32	analyses		adjusted analyses)	
33				
34				
35				
36	Statistics: analysis	#20c	Definition of analysis population relating to protocol non-	13
37	population and		adherence (eg, as randomised analysis), and any	
38	missing data		statistical methods to handle missing data (eg, multiple	
39			imputation)	
40				
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46	Methods: Monitoring			
47				
48				
49	Data monitoring:	#21a	Composition of data monitoring committee (DMC);	
50	formal committee		summary of its role and reporting structure; statement of	
51			whether it is independent from the sponsor and	
52			competing interests; and reference to where further	
53				
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1 details about its charter can be found, if not in the
 2
 3 protocol. Alternatively, an explanation of why a DMC is
 4
 5 not needed
 6
 7

8	Data monitoring:	#21b	Description of any interim analyses and stopping	
9	interim analysis		guidelines, including who will have access to these	
10			interim results and make the final decision to terminate	
11			the trial	
12				
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18	Harms	#22	Plans for collecting, assessing, reporting, and managing	
19			solicited and spontaneously reported adverse events and	
20			other unintended effects of trial interventions or trial	
21			conduct	
22				
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28	Auditing	#23	Frequency and procedures for auditing trial conduct, if	
29			any, and whether the process will be independent from	
30			investigators and the sponsor	
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35	Ethics and			
36	dissemination			
37				
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41	Research ethics	#24	Plans for seeking research ethics committee / institutional	15
42	approval		review board (REC / IRB) approval	
43				
44				
45				
46	Protocol	#25	Plans for communicating important protocol modifications	15
47	amendments		(eg, changes to eligibility criteria, outcomes, analyses) to	
48			relevant parties (eg, investigators, REC / IRBs, trial	
49			participants, trial registries, journals, regulators)	
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1	Consent or assent	#26a	Who will obtain informed consent or assent from potential	15
2			trial participants or authorised surrogates, and how (see	
3			Item 32)	
4				
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7				
8				
9	Consent or assent:	#26b	Additional consent provisions for collection and use of	
10	ancillary studies		participant data and biological specimens in ancillary	
11			studies, if applicable	
12				
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15				
16	Confidentiality	#27	How personal information about potential and enrolled	15
17			participants will be collected, shared, and maintained in	
18			order to protect confidentiality before, during, and after	
19			the trial	
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26	Declaration of	#28	Financial and other competing interests for principal	2
27	interests		investigators for the overall trial and each study site	
28				
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32	Data access	#29	Statement of who will have access to the final trial	15
33			dataset, and disclosure of contractual agreements that	
34			limit such access for investigators	
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39	Ancillary and post	#30	Provisions, if any, for ancillary and post-trial care, and for	
40	trial care		compensation to those who suffer harm from trial	
41			participation	
42				
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45				
46				
47	Dissemination policy:	#31a	Plans for investigators and sponsor to communicate trial	16
48	trial results		results to participants, healthcare professionals, the	
49			public, and other relevant groups (eg, via publication,	
50			reporting in results databases, or other data sharing	
51			arrangements), including any publication restrictions	
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1 Dissemination policy: [#31b](#) Authorship eligibility guidelines and any intended use of 16
 2 authorship professional writers
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5
 6 Dissemination policy: [#31c](#) Plans, if any, for granting public access to the full 16
 7 reproducible protocol, participant-level dataset, and statistical code
 8 research
 9
 10
 11
 12

13 Appendices

14
 15
 16
 17 Informed consent [#32](#) Model consent form and other related documentation
 18 materials given to participants and authorised surrogates
 19

20
 21
 22
 23 Biological specimens [#33](#) Plans for collection, laboratory evaluation, and storage of
 24 biological specimens for genetic or molecular analysis in
 25 the current trial and for future use in ancillary studies, if
 26 applicable
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32
 33 None The SPIRIT checklist is distributed under the terms of the Creative Commons Attribution
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 35 tool made by the [EQUATOR Network](#) in collaboration with [Penelope.ai](#)
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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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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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For peer review only

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 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 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) .

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3 Self-efficacy has been found to correlate with self-management behaviours(11–14) and being
4 negatively correlated with physical distress(15), depression(12), and diabetes distress(16). The
5 role of self-efficacy as a mediator between self-management behaviours and diabetes related
6 distress, depression, and anxiety have also been reported(13,17). Therefore, an intervention that
7 enhances self-efficacy would be expected to improve depression, diabetes distress, as well as
8 enhance self-management behaviours. The inclusion of self-efficacy as a treatment outcome in a
9 diabetes intervention program is crucial as this allows researchers to evaluate the effectiveness of
10 the program accurately(4).
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18 **POHON SIHAT – Cross-culturally adapted Malay Optimal Health Program (OHP)**

19 The Optimal Health Program (OHP) is a biopsychosocial program that promotes patients to be
20 actively involved in their own healthcare and overall well-being. The aim of OHP is to improve
21 individual self-efficacy and to build on strengths and values which in turn enhances overall
22 wellbeing. Initially developed to integrate physical and mental health, the OHP has been found
23 effective with mental health care(18,19), and extended to managing physical health and chronic
24 illnesses(20,21). Having a platform to discuss the multiple areas of a person's life and associated
25 psychosocial barriers creates tremendous potential in the management of diabetes.
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34 In a preliminary study that assessed the needs of OHP in Malaysia, the OHP was found to hold a
35 promising framework in building the capacity of the mental health care services in Malaysia(22).
36 Following a process of translation and cultural adaptation, the Malaysian OHP program was
37 developed (henceforth referred to as Pohon Sihat). Being a culturally sensitive tool, Pohon Sihat
38 provides a promising low intensity self-efficacy enhancing psychosocial intervention conducted
39 within the primary care setting.
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46 **Objectives**

47 Pohon Sihat is designed to address the gap in the management of mental health issues in diabetes
48 care within a limited resource setting. This study will examine the effectiveness of this program
49 for diabetes patients within a primary care setting in Malaysia.
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3 The intervention will be offered to patients with diabetes who are currently attending health
4 clinics within the Putrajaya district. Specifically, this study aims to investigate the effectiveness
5 of Pohon Sihat in addition to treatment-as-usual (TAU) as compared to TAU alone. It will also
6 examine the effectiveness of Pohon Sihat in reducing anxiety, depression, diabetes-related
7 distress, and in increasing self-care behaviours and glycemetic control.
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13 **METHODS**

14 **Study design**

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

32 The Federal Territory of Putrajaya is Malaysia's federal administrative center. Based on the
33 National Health and Morbidity survey(8), Putrajaya has high prevalence for diabetes (19.2%)
34 and has the highest prevalence for overweight (37%), obesity (43%) and abdominal obesity
35 (61.3%).
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41 **Participants**

42 *Sampling frame*

43 The sampling frame will be patients with Type 2 Diabetes Mellitus (T2DM) registered at the
44 primary healthcare clinics within the Federal Territory of Putrajaya. With easy accessibility and
45 communal location, approximately 35% of the Malaysian population receives treatment within
46 the government health clinics located in the community(23).
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53 The services and facilities within the clinics differ according to the size of the clinic, which is
54 based on the number of patient visits per day. Health Clinic Presint 9 (KKP9) and Health Clinic
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3 Presint 18 (KKP18) have 500-800 patient visits per day. These health clinics are fully equipped
4 .2with primary health care services, family medicine specialists, laboratory, diagnostic imaging,
5 rehabilitation, dietary, pharmacy, and dental services. Health Clinic Presint 11 (KKP11) and
6 Health Clinic Presint 14 (KKP14) have fewer than 150 patient visits per day. These clinics are
7 limited to outpatient services (non-complex cases and/or stable chronic cases) and pharmacy
8 services.
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15 According to the 2018 National Diabetes Registry, registered diabetes patients (both Type 1 and
16 Type 2) are unevenly distributed in terms of the type of the health clinics, the facilities available
17 and the services provided. The size of the diabetes clinic in each health clinic differ with KKP9
18 having the largest portion of diabetes patients in Putrajaya (64%) and KKP11 having the smallest
19 proportion (2%).
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25 **Eligibility Criteria**

26 *Inclusion criteria*

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28 Eligible patients will have a diagnosis of Diabetes Mellitus Type 2 as assessed by their attending
29 physicians based on the Malaysian Clinical Practice Guidelines for Type 2 Diabetes
30 Mellitus(24); and be aged between 18 to 60 years old; and currently registered to be receiving
31 services in the health clinics in Putrajaya. Patients also need to be able to provide informed
32 consent to participate in the study.
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40 The criteria for diagnosing Diabetes Mellitus Type 2 are based on the Malaysia's Clinical
41 Practice Guidelines for Type 2 Diabetes Mellitus. The guideline defines Diabetes Mellitus Type
42 2 patients as people who have been diagnosed with diabetes mellitus, and have had/have a
43 confirmed glycohemoglobin test (HbA1c) level of $\geq 6.3\%$ (45 mmol/mol) and FPG ≥ 7.0 mmol/L.
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48 *Exclusion Criteria*

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

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

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

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

32 Secondary outcome will include: 1) depression (Patient Health Questionnaire; PHQ-9)(28), 2)
33 anxiety (General Anxiety Disorder scale; GAD-7)(29), 3) diabetes distress (Problem Areas in
34 Diabetes; PAID-5)(30), and 4) general well-being (WHO-5 Wellbeing Index)(31). Self-
35 management behaviors will be measured by the Summary of Diabetes Self-Care Activities
36 (SDSCA) Scale(32,33).
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41 Data on glycaemic control will be collected from patient records while demographic details, co-
42 morbidities, duration, and diabetes complications will be assessed using a standard questionnaire,
43 once participants have been allocated to the treatment or control group.
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50 **Sample size**

51 Considering the study outcomes, the sample size is calculated based on a similar study(34) by
52 using the formula proposed by Zhong(35).
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3 As far as response rate is concerned, in studies using OHP, a 12 months follow up protocol
4 experienced a 14% drop out rate for patients with mental illness(36). Similarly, Moriyama et
5 al.(37) reported a 16% drop out rate for a self-management program in patients with diabetes.
6
7 Other studies showed that a 6 month follow-up, self-management program in T2DM yielded an
8
9 attrition rate that ranged between 10% to 20%(34,38). Within local government settings, the
10
11 attrition rate was 10% for a 12-week follow-up education-based program in patients with
12
13 diabetes(39).
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17 Taking into consideration the duration of follow-ups and a conservative approach, this study will
18
19 estimate a 30% attrition rate for the loss to follow-up at 6 months.
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23 Based on the study by Wu et al.(34), with an expected medium effect size of 0.40 (μ diff =
24 16.19, s.d. =37.01), the sample size required in this study is calculated using a study-wide type I
25
26 error rate (α) of 0.05 and a type II error rate (β) of 0.20 (power of 0.80). The current study will
27
28 require a total of 59 participants for each group. With an expected attrition rate of 30%, the study
29
30 aims to recruit a total of 172 participants, with 86 participants for each group.
31

32 **Recruitment**

33 *Study procedure*

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35 Recruitment will take place at the clinics during a patient's routine check-ups at the diabetes
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37 clinic, over a period of 6 months or until the required number of participants is achieved.
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41 Based on the list of registered patients during a clinic day, patients with diabetes will be screened
42
43 based on age and type of diabetes. Eligible participants will be asked for consent to be
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45 approached by a research assistant. Those who fulfill the criteria and are able to give written
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47 informed consent for participation, will be included in the study.
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51 After enrolment, participants will be given an opaque, sealed and numbered envelope containing
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53 allocation of groups, in numerical sequence. Each participant will be assigned into the
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55 intervention or control group based on the random sequence.
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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.

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5 The panel of reviewers included endocrinologist, family medicine specialists and physicians. The
6 OHP was considered by this review to be a valuable engagement tool to further enhance the
7 primary health care services, and to be more inclusive of mental health needs(22). Following this
8 feedback, the OHP underwent a thorough translation and adaptation process.
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13 The translation and cultural adaptation process involved multiple stages with (1) the
14 development of a panel of experts from Malaysia and Australia, (2) forward and back translation
15 of the program workbook, (3) cultural adaptation through the review and comparison by both
16 content and local experts, including revision and harmonisation of the workbook, (4) pre-testing
17 the program in a group of mental health practitioners, patient support group representatives as
18 well as representatives from the Ministry of Health and finally (5) proofreading and finalising of
19 design.
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25 Based on a thorough translation and adaptation process, the program was assessed as matching
26 the intention and the fidelity of the program
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31 *Training of Diabetes Educators*

32 The facilitator training was modified to include an additional day taking into consideration
33 minimal mental health training for diabetes educators especially psychological strategies for
34 engaging in effective health communication(9). The additional day included more in-depth
35 content, collaborative therapy principles and motivational interviewing based health coaching
36 techniques. This modification was to ensure that the program delivery will maintain fidelity and
37 stay aligned with its intention.
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45 Each group program will be facilitated by a trained mental health practitioner and diabetes care
46 expert to further strengthen the program's fidelity.
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50 *Pilot study*

51 A pilot study was conducted to assess the feasibility and accessibility of the culturally adapted
52 OHP amongst patients with diabetes. Eight participants ($n=8$) were recruited, five completing all
53 5 sessions of the program (three withdrew due to work commitments). Challenges were
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3 identified with: (1) recruitment process, (2) duration of the program and (3) content of the
4 material.
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8 Generally, participants provided valuable feedback on the content of the workbook, structure of
9 the program and ease of delivery. Participants' feedback suggested that the sessions be longer to
10 allow more discussion. This was also echoed by the facilitators, who felt that additional time
11 would allow greater coverage, and improve ease of delivery. An additional information sheet on
12 healthy eating habit and lifestyle tips was also suggested by participants.
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18 The recruitment process was improved based on the feedback provided by participants and
19 facilitators. During recruitment, participants were informed that an official letter and time-slips
20 would be provided to allow time off work to attend the program.
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24 Several groups programs were offered throughout the week to allow people to attend the most
25 convenient sessions. Logistical constraints were also improved by choosing venues with ample
26 parking space. Sessions were extended from 1.5 hours to two hours. Content of the workbook
27 was improved by additional health information such as the food pyramid and the local healthy
28 eating habits. This additional information and some minor language changes improved the
29 overall usability of the OHP Malay workbook.
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36 **ETHICS AND DISSEMINATION**

37 **Consent**

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

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

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

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17
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22 Advisory Board Member for Lu AA21004: Lundbeck; Varenicline: Pfizer; Asenapine:
23 Lundbeck; Bitopertin: Roche Aripiprazole LAI: Lundbeck; Lisdexamfetamine: Shire;
24 Lurasidone: Servier. He has no stocks or shares in any pharmaceutical company.
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30 This study had no other conflict of interest.
31
32

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35
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38 **Data sharing statement**

39 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	<p>What is Optimal Health?</p> <ul style="list-style-type: none"> • Introduction to the Collaborative Therapy Optimal Health 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	<p>The I-Can-Do Model</p> <ul style="list-style-type: none"> • 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	<p>Medication and Metabolic Monitoring</p> <ul style="list-style-type: none"> • 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 <p>Collaborative Partners and Strategies</p> <ul style="list-style-type: none"> • Identify collaborative partners • Introduce TOOL 4: Eco-Mapping • Discussion on role of collaborative partners in maintaining one's optimal health
4	Visioning & Goal Setting	<p>Change Enhancement – Time line activity</p> <ul style="list-style-type: none"> • 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

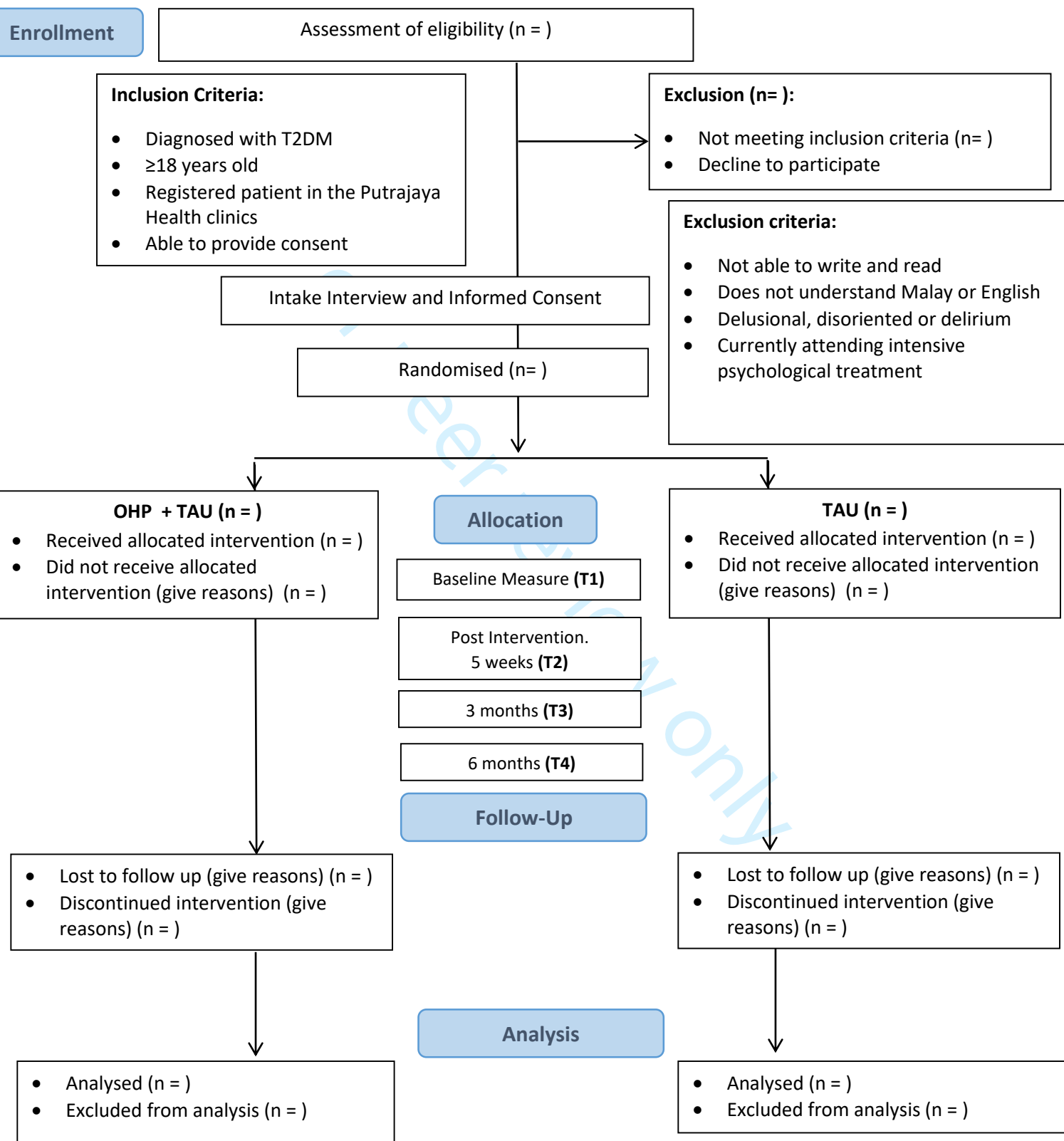
	Visioning & Goal Setting	<p>Visioning and Goal Setting</p> <ul style="list-style-type: none"> • Introduction to creative problem solving and setting SMARTER goals • Introduce TOOL 6: Cost-benefit Table • Discussion on barriers to achieving goals • Identify steps and strategies to achieve future goals
5	Maintain well-being	<p>Maintaining well-being</p> <ul style="list-style-type: none"> • 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	<p>Review of Health Plans</p> <ul style="list-style-type: none"> • 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 assesses 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



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

TIMEPOINT	STUDY PERIOD					
	Enrolment	Allocation	Post-allocation			Follow up
	$-t_1$	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:						
<i>Sociodemographic data</i>		X				
<i>DES-SF</i>			X	X	X	X
<i>DMSES</i>			X	X	X	X
<i>GAD-7</i>			X	X	X	X
<i>PHQ-9</i>			X	X	X	X
<i>PAID-20</i>			X	X	X	X
<i>WHO-5</i>			X	X	X	X
<i>SDSCA</i>			X	X	X	X
<i>HbA1C</i>		X				X

Participant Information Sheet SELF-EFFICACY IN DIABETES		 
		Faculty of Medicine and Health Sciences University Putra Malaysia 43400 Serdang Selangor
Study title:	<i>The effectiveness of the Optimal Health Program in improving self-efficacy in patients with diabetes in Putrajaya, Malaysia.</i>	
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).

1
2
3 You will be asked to fill in these questionnaires at four points in time, in the beginning, at 5
4 weeks, 3 months and at 6 months. All questionnaire will require approximately 30 minutes to
5 complete.
6

7 3. Attend either the

8 A) **Treatment as usual**

9 If you are randomly assigned to this group, you will receive treatment as usual. At the end
10 of the study period (one year) we will offer you the chance of participating in the Optimal
11 Health Program.
12

13 *or*

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

15 If you are randomly assigned to the Optimal Health Program, you will receive treatment
16 as usual. In addition, you will be required to attend a group program for 5 sessions, 1.5
17 hours for every week and a booster session after three months.
18
19
20

21 **DO I HAVE TO TAKE PART?**

22
23 Participation in this study is voluntary. It is completely up to you whether or not you participate. If
24 you decide not to participate, it will not affect the treatment you receive now or in the future. You
25 may withdraw from the study at any time and for any reason or no reason. Information that has
26 been collected about you, prior to your withdrawal, will continue to be used in the data analysis. No
27 new information will be collected or used after you have withdrawn from the study.
28
29

30 **WILL MY TAKING PART IN THIS PROJECT BE KEPT CONFIDENTIAL?**

31
32 If you agree to take part in the study you will need to sign and date the Informed Consent Form
33 attached. Your medical records and data will need to be seen by the authorised members of our
34 research team (i.e. treating team in the clinic and the researcher) so they can collect information
35 needed for this research study. Your unique registration number will be used to make sure you
36 cannot be identified outside the study. All information, which is collected, about you during the
37 course of the research will be treated as strictly confidential. The confidentiality of your medical
38 records will be respected at all times.
39
40

41
42 When publishing or presenting the study results, your identity will not be revealed without your
43 expressed consent. No information collected will be shown to anyone apart from the research team.
44 For regulatory purposes, data from the study will be stored securely for at least 3 years following the
45 study and destroyed as confidential waste thereafter.
46
47

48 **WILL I BE INFORMED OF THE STUDY FINDINGS?**

49
50 You will not be informed individually of the study findings. Nonetheless if you are interested to be
51 informed of your personal results at the end of this study, you can express your interest in the
52 Consent form.
53
54

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

56
57 As with any psychosocial intervention, it is possible that discussing about your difficulties may cause
58 you some distress. Similar studies have been conducted in Malaysia and have been shown to have
59
60

1
2
3 minimal to no risk. Nonetheless, if you pose any difficulties or discomfort, please inform the
4 investigator.
5

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

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8
9 The OHP has been shown to be effective in improving one's belief about their capabilities to cope
10 and manage their illness and reduce distress. This study aims to further expand the depth of
11 knowledge in the field of chronic illness specifically in the enhancement of patients' self-
12 management. The study may not directly benefit you but the information we get from the study will
13 help increase the understanding of self-efficacy enhancing program in the management of diabetes.
14
15

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

17
18 Participation in this study will not cost you anything. For sessions and visits that are
19 conducted outside of your routine clinic, you will be reimbursed for your time and
20 reasonable travel.
21
22

23 **WHO IS FUNDING THE RESEARCH?**

24
25 This study is sponsored by a research grant from University Putra Malaysia who will pay for all study
26 procedures except all other medication and procedures that are part of your routine medical care.
27
28

29 **CAN THE RESEARCH OR MY PARTICIPATION BE TERMINATED EARLY?**

30
31 The researcher may stop the study or your participation at any time possibly due to any safety concern.
32 If the study is stopped early for any reason you will be informed and arrangements made for your
33 future care. You may be asked to attend a final follow-up visit.
34
35

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

37
38 If you have any questions, concerns or complaints about the study at any stage, you can contact:


39
40
41 **Prof Madya Normala Ibrahim**

42 *Consultant Psychiatrist*
43 *Faculty of Medicine and Health Sciences*
44 *University Putra Malaysia*
45 *43400 Serdang Selangor*
46 **normala_ib@upm.edu.my**

41
42 **Aida Farhana Suhaimi**

43 **Clinical Psychologist**
44 **PhD Psychological Medicine Candidate**
45 *Department of Medicine and Health Sciences*
46 *University Putra Malaysia*
47 *43400 Serdang Selangor*
48 **aida.hjsuhaimi@gmail.com**

49
50
51 If you have any questions about your rights as a participant in this study, please contact: The Secretary,
52 Medical Research & Ethics Committee, Ministry of Health Malaysia, at telephone number 03-2287
53 4032.
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<p>Consent Form</p> <p>SELF-EFFICACY IN DIABETES</p>	
	<p>Faculty of Medicine and Health Sciences University Putra Malaysia 43400 Serdang Selangor</p>

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 SPIRIT reporting 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

1	Roles and	#5a	Names, affiliations, and roles of protocol contributors	1-2
2	responsibilities:			
3	contributorship			
4				
5				
6	Roles and	#5b	Name and contact information for the trial sponsor	n/a
7	responsibilities:			
8	sponsor contact			
9	information			
10				
11				
12				
13	Roles and	#5c	Role of study sponsor and funders, if any, in study	n/a
14	responsibilities:		design; collection, management, analysis, and	
15	sponsor and funder		interpretation of data; writing of the report; and the	
16			decision to submit the report for publication, including	
17			whether they will have ultimate authority over any of	
18			these activities	
19				
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21				
22				
23	Roles and	#5d	Composition, roles, and responsibilities of the	n/a
24	responsibilities:		coordinating centre, steering committee, endpoint	
25	committees		adjudication committee, data management team, and	
26			other individuals or groups overseeing the trial, if	
27			applicable (see Item 21a for data monitoring committee)	
28				
29				
30				
31	Introduction			
32				
33	Background and	#6a	Description of research question and justification for	5
34	rationale		undertaking the trial, including summary of relevant	
35			studies (published and unpublished) examining benefits	
36			and harms for each intervention	
37				
38				
39				
40	Background and	#6b	Explanation for choice of comparators	6
41	rationale: choice of			
42	comparators			
43				
44				
45	Objectives	#7	Specific objectives or hypotheses	6
46				
47				
48	Trial design	#8	Description of trial design including type of trial (eg,	7
49			parallel group, crossover, factorial, single group),	
50			allocation ratio, and framework (eg, superiority,	
51			equivalence, non-inferiority, exploratory)	
52				
53				

54
55 **Methods:**
56 **Participants,**
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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: adherence	#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

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8	Data collection plan:	#18b	Plans to promote participant retention and complete
9	retention		follow-up, including list of any outcome data to be
10			collected for participants who discontinue or deviate from
11			intervention protocols
12			
13			
14			
15	Data management	#19	Plans for data entry, coding, security, and storage,
16			including any related processes to promote data quality
17			(eg, double data entry; range checks for data values).
18			Reference to where details of data management
19			procedures can be found, if not in the protocol
20			
21			
22			
23	Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary
24			outcomes. Reference to where other details of the
25			statistical analysis plan can be found, if not in the
26			protocol
27			
28			
29			
30	Statistics: additional	#20b	Methods for any additional analyses (eg, subgroup and
31	analyses		adjusted analyses)
32			
33			
34	Statistics: analysis	#20c	Definition of analysis population relating to protocol non-
35	population and		adherence (eg, as randomised analysis), and any
36	missing data		statistical methods to handle missing data (eg, multiple
37			imputation)
38			
39			
40			
41	Methods: Monitoring		
42			
43	Data monitoring:	#21a	Composition of data monitoring committee (DMC);
44	formal committee		summary of its role and reporting structure; statement of
45			whether it is independent from the sponsor and
46			competing interests; and reference to where further
47			details about its charter can be found, if not in the
48			protocol. Alternatively, an explanation of why a DMC is
49			not needed
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54	Data monitoring:	#21b	Description of any interim analyses and stopping
55	interim analysis		guidelines, including who will have access to these
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interim results and make the final decision to terminate the trial

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4	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
5			
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11	Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor
12			
13			
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15			
16	Ethics and dissemination		
17			
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19			
20	Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval
21			
22			
23			
24	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)
25			
26			
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31			
32	Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)
33			
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36			
37	Consent or assent: ancillary studies	#26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable
38			
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43	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
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49	Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site
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53	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
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1	Ancillary and post trial	#30	Provisions, if any, for ancillary and post-trial care, and for	n/a
2	care		compensation to those who suffer harm from trial	
3			participation	
4				
5				
6	Dissemination policy:	#31a	Plans for investigators and sponsor to communicate trial	16
7	trial results		results to participants, healthcare professionals, the	
8			public, and other relevant groups (eg, via publication,	
9			reporting in results databases, or other data sharing	
10			arrangements), including any publication restrictions	
11				
12				
13				
14	Dissemination policy:	#31b	Authorship eligibility guidelines and any intended use of	16
15	authorship		professional writers	
16				
17				
18	Dissemination policy:	#31c	Plans, if any, for granting public access to the full	16
19	reproducible research		protocol, participant-level dataset, and statistical code	
20				
21				
22	Appendices			
23				
24	Informed consent	#32	Model consent form and other related documentation	Sup. 1
25	materials		given to participants and authorised surrogates	
26				
27				
28	Biological specimens	#33	Plans for collection, laboratory evaluation, and storage of	n/a
29			biological specimens for genetic or molecular analysis in	
30			the current trial and for future use in ancillary studies, if	
31			applicable	
32				
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34				

35 None The SPIRIT checklist is distributed under the terms of the Creative Commons Attribution
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 37 tool made by the [EQUATOR Network](#) in collaboration with [Penelope.ai](#)
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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.

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2019-033920.R2
Article Type:	Protocol
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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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For peer review only

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,

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3 depression, and anxiety has also been reported(13,17). Therefore, an intervention that enhances
4 self-efficacy would be expected to improve depression, diabetes distress, as well as enhance self-
5 management behaviours. The inclusion of self-efficacy as a treatment outcome in a diabetes
6 intervention program is crucial, as this allows researchers to evaluate the effectiveness of the
7 program accurately(4).
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13 **POHON SIHAT – Cross-culturally adapted Malay Optimal Health Program (OHP)**

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15 The Optimal Health Program (OHP) is a biopsychosocial program that promotes patients to be
16 actively involved in their own healthcare and overall well-being. The aim of OHP is to improve
17 individual self-efficacy and to build on strengths and values which in turn serves to enhance
18 overall wellbeing. Initially developed to integrate physical and mental health, the OHP has been
19 found to be effective in mental health care settings(18,19), and has been extended to managing
20 physical health and chronic illnesses(20,21). Having a platform to discuss the multiple areas of a
21 person's life and associated psychosocial barriers creates tremendous potential in the
22 management of DM.
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31 In a preliminary study that assessed the needs of OHP in Malaysia, the OHP was found to
32 provide a promising framework for building the capacity of the local mental health care services
33 (22). Following a process of translation and cultural adaptation, the Malaysian OHP program
34 was developed (henceforth referred to as Pohon Sihat). Being a culturally sensitive tool, Pohon
35 Sihat is suited to use in local Malaysian clinical settings.
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41 **Objectives**

42 Pohon Sihat is designed to address gaps in the management of mental health issues in diabetes
43 care within a limited resource context. This study will examine the effectiveness of this program
44 for diabetes patients within a primary care setting in Malaysia.
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50 The intervention will be offered to patients with DM who are currently attending health clinics
51 within the Putrajaya district. Specifically, this study aims to investigate the effectiveness of
52 Pohon Sihat in addition to treatment-as-usual (TAU) as compared to TAU alone. It will examine
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3 the effectiveness of Pohon Sihat in reducing anxiety, depression, diabetes-related distress, and in
4 increasing self-care behaviours and glycaemic control.
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8 **METHODS**

9 **Study design**

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

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

37 *Sampling frame*

38 The sampling frame will be patients with Type 2 Diabetes Mellitus (T2DM) registered at the
39 primary healthcare clinics within the Federal Territory of Putrajaya. With easy accessibility and
40 communal location, approximately 35% of the Malaysian population receives treatment within
41 the government health clinics located in the community(23).
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48 The services and facilities within the clinics differ according to the size of the clinic, which is
49 based on the number of patient visits per day. Health Clinic Presint 9 (KKP9) and Health Clinic
50 Presint 18 (KKP18) have 500-800 patient visits per day. These health clinics are fully equipped
51 with primary health care services, family medicine specialists, laboratory, diagnostic imaging,
52 rehabilitation, dietary, pharmacy and dental services. Health Clinic Presint 11 (KKP11) and
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3 Health Clinic Presint 14 (KKP14) have fewer than 150 patient visits per day. These clinics are
4 limited to outpatient services (non-complex cases and/or stable chronic cases) and pharmacy
5 services.
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10 According to the 2018 National Diabetes Registry, registered patients with DM (both Type 1 and
11 Type 2) are unevenly distributed in terms of the type of the health clinics, the facilities available
12 and the services provided. The size of the diabetes clinic in each health clinic differ, with KKP9
13 having the largest portion of patients with DM in Putrajaya (64%), and KKP11 having the
14 smallest proportion (2%).
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20 **Eligibility Criteria**

21 *Inclusion criteria*

22 Eligible patients will have a diagnosis of T2DM as assessed by their attending physicians based
23 on the Malaysian Clinical Practice Guidelines for T2DM (24); be aged between 18 and 60 years;
24 and currently registered to receive services in the health clinics in Putrajaya. Patients also need to
25 be able to provide informed consent to participate in the study.
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32 The criteria for diagnosing T2DM are based on the Malaysia's Clinical Practice Guidelines,
33 namely being diagnosed with DM and having had/having a confirmed glycohemoglobin test
34 (HbA1c) level of $\geq 6.3\%$ (45 mmol/mol) and FPG ≥ 7.0 mmol/L.
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39 *Exclusion Criteria*

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

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

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3 The four health clinics will first be stratified by the size of the clinic. To ensure a balanced
4 representation of patients with DM within each clinic, randomisation will be conducted based on
5 the size of the diabetes clinic as reported in the National Diabetes Registry. KKP9 with the
6 largest portion of registered patients with DM (64%) will be allocated 110 participants (64% of
7 172 participants), followed by KKP18 (31%) allocated 53 participants, KKP 14 (3%) allocated 5
8 participants and KKP11 (2%) with an allocation of 4 participants.
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14 15 *Allocation concealment mechanism and implementation of random allocation*

16 To ensure that clinics are assigned with a balanced number of allocated intervention and control,
17 two lists of randomisation sequences will be made 1) clinics with 500-800 patient visits per day –
18 KKP9 and KKP18, and 2) clinics with fewer than 150 visits per day – KKP11 and KKP14.
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24 Research assistants involved in the recruitment will be blinded to the sequence allocation. Sealed
25 envelopes will only be opened after eligible participants provide and sign the informed consent
26 form.
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30 31 *Contamination Bias*

32 To minimise contamination bias, the OHP plus TAU sessions will take place outside of the
33 participating health clinics. Intervention sessions will be conducted in either a community-based
34 rehabilitation center or a central health district center situated within Putrajaya. Participants will
35 also be informed of the study parameters, with directives not to discuss the content of the
36 materials or to exchange materials with other diabetes patients outside of the group.
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42 43 *Blinding*

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

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3 The intention-to-treat principle and per-protocol analyses will be performed. Any deviations
4 from the random allocation and missing data will be fully reported as outlined in the
5 Consolidated Standards of Reporting Trials (CONSORT) statement(40).
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10 Any differences between individuals in the intervention and control conditions at baseline (socio-
11 demographics, clinical details, psychosocial self-efficacy, diabetes management self-efficacy,
12 anxiety, depression, diabetes-related distress, well-being, self-care behaviours and HbA1C) will
13 be assessed using one-way analysis of variance ANOVA or chi-square test as appropriate.
14 Assumptions of normality and homogeneity of variance will be assessed and adjusted
15 accordingly.
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22 A Mixed model ANOVA will be used to investigate the effectiveness of Pohon Sihat (OHP plus
23 TAU) vs Treatment as usual (TAU) on all continuous variables at four points (i.e. baseline, 5
24 weeks, 3 months and 6 months). For all analysis of mixed effect, repeated measures, condition
25 and time will be specified as fixed effects. A one-way analysis of covariance (ANCOVA) will be
26 used to assess the effectiveness of the intervention compared with the control group, when
27 covariates included duration of diabetes and diabetes complication are expected to impact on
28 outcome measures.
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36 **Program assessment, treatment fidelity and cultural adaptation**

37 *Program assessment*

38 The adaptation of the OHP for the Malaysian community was informed by: (1) review by
39 Malaysia's primary and mental health care professionals, (2) structured translation and (3)
40 cultural adaptation of the program.
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46 The panel of reviewers included endocrinologist, family medicine specialists and physicians. The
47 OHP was considered by this review to be a valuable engagement tool to further enhance the
48 primary health care services, and to be more inclusive of mental health needs(22). Following this
49 feedback, the OHP underwent a thorough translation and adaptation process.
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55 *Translation and cultural adaptation*

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

19 The facilitator training has been modified to include an additional day, taking into consideration
20 minimal prior mental health training for diabetes educators, especially psychological strategies
21 for engaging in effective health communication(9). The additional day includes collaborative
22 therapy principles and motivational interviewing-based health coaching techniques. This
23 modification ensures that the program delivery will maintain fidelity and stay aligned with its
24 intention.
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32 Each group program will be facilitated by a trained mental health practitioner and a diabetes care
33 expert to further strengthen the program's fidelity.
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38 **Pilot study**

39 A pilot study was conducted to assess the feasibility and accessibility of the culturally adapted
40 OHP amongst patients with T2DM. Eight participants ($n=8$) were recruited, five completing all 5
41 sessions of the program (three withdrew due to work commitments). Challenges were identified
42 with: (1) recruitment process, (2) duration of the program and (3) content of the material.
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48 Generally, participants provided valuable feedback on the content of the workbook, structure of
49 the program and ease of delivery. Participants' feedback suggested that the sessions be longer to
50 allow more discussion. This was also echoed by the facilitators, who felt that additional time
51 would allow greater coverage, and improve ease of delivery. An additional information sheet on
52 healthy eating habit and lifestyle tips was also suggested by participants.
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5 The recruitment process was improved based on the feedback provided by participants and
6 facilitators. During recruitment, participants were informed that an official letter and time-slips
7 would be provided to allow time off work to attend the program.
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10 Several groups programs were offered throughout the week to allow people to attend the most
11 convenient sessions. Logistical constraints were also improved by choosing venues with ample
12 parking space. Sessions were extended from 1.5 hours to two hours. Content of the workbook
13 was improved by additional health information such as the food pyramid and the local healthy
14 eating habits. This additional information and some minor language changes improved the
15 overall usability of the OHP Malay workbook.
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22 **Patient involvement**

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

40 **Consent**

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

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5 The OHP is a self-efficacy enhancing psychological intervention that is low-intensity, structured
6 and can be delivered by trained facilitators. The recovery-based approach emphasises the
7 language of hope and well-being rather than illness and disease, and is suitable for a primary
8 health care setting. Through a patient centered, collaborative approach, the OHP may offer a
9 platform for a wide range of primary health care providers to engage in a discussion with patients
10 regarding their well-being. As a psychological intervention program for primary health care
11 providers, OHP can address mental health concerns and promote overall wellbeing for people
12 experiencing chronic illness. The OHP will be the first engagement tool in Malaysia with
13 potential to act in a curative and preventative role
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22 In addition to providing further understanding in the effectiveness of an add-on psychological
23 intervention, the study will also provide information on the effectiveness of the current standard
24 of practice within the primary health care as guided by the Malaysian Clinical Practice
25 Guidelines in the Management of Type 2 Diabetes Mellitus.
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31 **Trial Status**

32 Patient recruitment commenced October 2018 and data collection will continue until August
33 2020. ClinicalTrials.gov NCT03601884
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38 **Acknowledgements**

39 The OHP was developed at the Mental Health Research Institute of Victoria and St Vincent's
40 Hospital Melbourne. We would like to thank the Director General of Health Malaysia for his
41 permission to publish this article.
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50 **Figure**

51 **Figure 1.** Flow chart of participants

52 **Figure 2.** Schedule of enrolment, interventions, and assessments.
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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, Allergan, 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.

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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	<p>What is Optimal Health?</p> <ul style="list-style-type: none"> • Introduction to the Collaborative Therapy Optimal Health 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	<p>The I-Can-Do Model</p> <ul style="list-style-type: none"> • 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	<p>Medication and Metabolic Monitoring</p> <ul style="list-style-type: none"> • 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

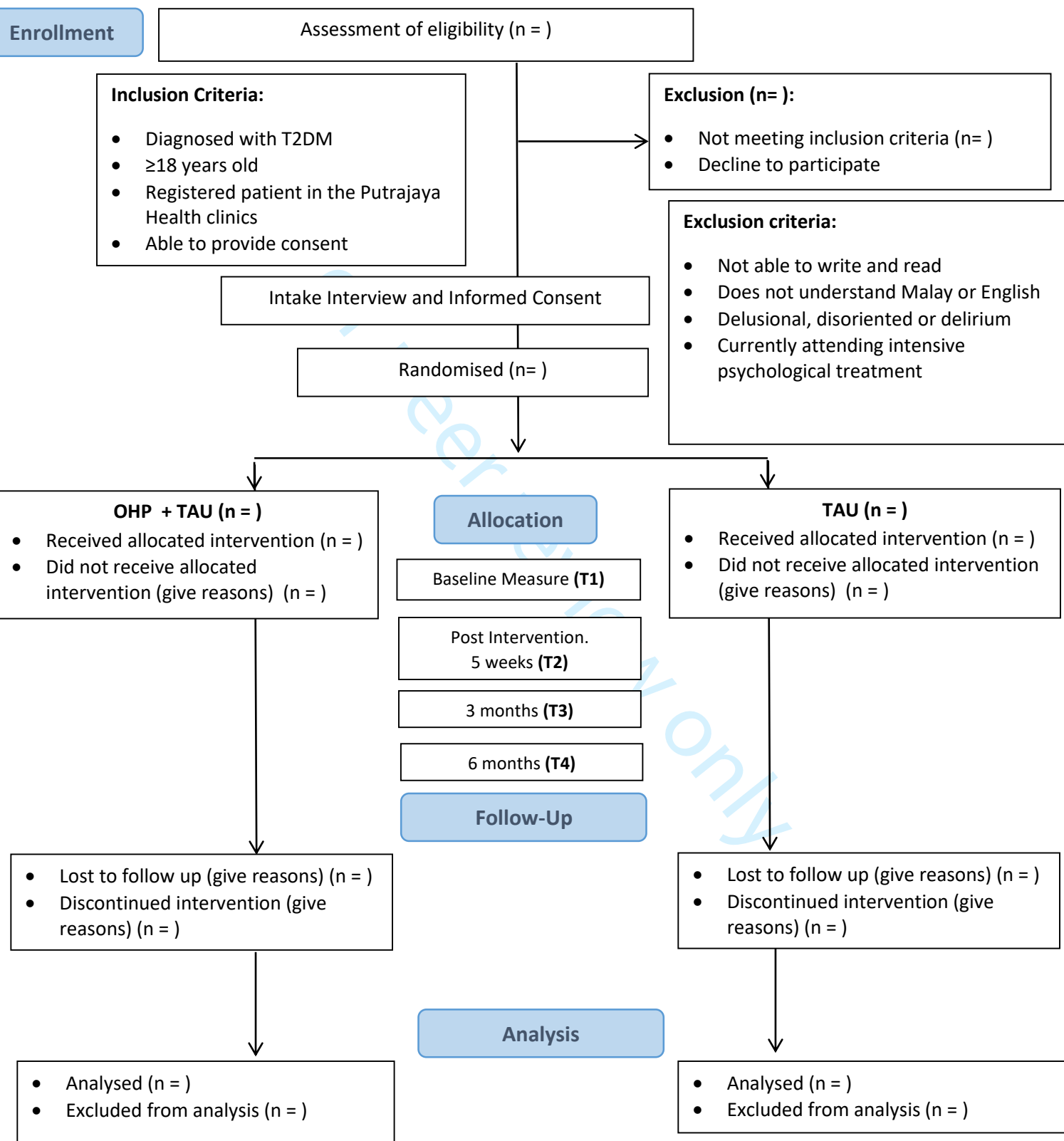
		<ul style="list-style-type: none"> • Addressing common myths amongst diabetes patients • Further emphasis on healthy lifestyle and eating habits <p>Collaborative Partners and Strategies</p> <ul style="list-style-type: none"> • Identify collaborative partners • Introduce TOOL 4: Eco-Mapping • Discussion on role of collaborative partners in maintaining one's optimal health
4	Visioning & Goal Setting	<p>Change Enhancement – Time line activity</p> <ul style="list-style-type: none"> • 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 <p>Visioning and Goal Setting</p> <ul style="list-style-type: none"> • 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	<p>Maintaining well-being</p> <ul style="list-style-type: none"> • 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	<p>Review of Health Plans</p> <ul style="list-style-type: none"> • 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 assesses 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



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

TIMEPOINT	STUDY PERIOD					
	Enrolment	Allocation	Post-allocation			Follow up
	$-t_1$	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:						
<i>Sociodemographic data</i>		X				
<i>DES-SF</i>			X	X	X	X
<i>DMSES</i>			X	X	X	X
<i>GAD-7</i>			X	X	X	X
<i>PHQ-9</i>			X	X	X	X
<i>PAID-20</i>			X	X	X	X
<i>WHO-5</i>			X	X	X	X
<i>SDSCA</i>			X	X	X	X
<i>HbA1C</i>		X				X

Participant Information Sheet SELF-EFFICACY IN DIABETES		 
		Faculty of Medicine and Health Sciences University Putra Malaysia 43400 Serdang Selangor
Study title:	<i>The effectiveness of the Optimal Health Program in improving self-efficacy in patients with diabetes in Putrajaya, Malaysia.</i>	
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).

1
2
3 You will be asked to fill in these questionnaires at four points in time, in the beginning, at 5
4 weeks, 3 months and at 6 months. All questionnaire will require approximately 30 minutes to
5 complete.
6

7 3. Attend either the

8 A) **Treatment as usual**

9 If you are randomly assigned to this group, you will receive treatment as usual. At the end
10 of the study period (one year) we will offer you the chance of participating in the Optimal
11 Health Program.
12

13 *or*

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

15 If you are randomly assigned to the Optimal Health Program, you will receive treatment
16 as usual. In addition, you will be required to attend a group program for 5 sessions, 1.5
17 hours for every week and a booster session after three months.
18
19
20

21 **DO I HAVE TO TAKE PART?**

22
23 Participation in this study is voluntary. It is completely up to you whether or not you participate. If
24 you decide not to participate, it will not affect the treatment you receive now or in the future. You
25 may withdraw from the study at any time and for any reason or no reason. Information that has
26 been collected about you, prior to your withdrawal, will continue to be used in the data analysis. No
27 new information will be collected or used after you have withdrawn from the study.
28
29

30 **WILL MY TAKING PART IN THIS PROJECT BE KEPT CONFIDENTIAL?**

31
32 If you agree to take part in the study you will need to sign and date the Informed Consent Form
33 attached. Your medical records and data will need to be seen by the authorised members of our
34 research team (i.e. treating team in the clinic and the researcher) so they can collect information
35 needed for this research study. Your unique registration number will be used to make sure you
36 cannot be identified outside the study. All information, which is collected, about you during the
37 course of the research will be treated as strictly confidential. The confidentiality of your medical
38 records will be respected at all times.
39
40

41
42 When publishing or presenting the study results, your identity will not be revealed without your
43 expressed consent. No information collected will be shown to anyone apart from the research team.
44 For regulatory purposes, data from the study will be stored securely for at least 3 years following the
45 study and destroyed as confidential waste thereafter.
46
47

48 **WILL I BE INFORMED OF THE STUDY FINDINGS?**

49
50 You will not be informed individually of the study findings. Nonetheless if you are interested to be
51 informed of your personal results at the end of this study, you can express your interest in the
52 Consent form.
53
54

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

56
57 As with any psychosocial intervention, it is possible that discussing about your difficulties may cause
58 you some distress. Similar studies have been conducted in Malaysia and have been shown to have
59
60

1
2
3 minimal to no risk. Nonetheless, if you pose any difficulties or discomfort, please inform the
4 investigator.
5

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

7
8
9 The OHP has been shown to be effective in improving one's belief about their capabilities to cope
10 and manage their illness and reduce distress. This study aims to further expand the depth of
11 knowledge in the field of chronic illness specifically in the enhancement of patients' self-
12 management. The study may not directly benefit you but the information we get from the study will
13 help increase the understanding of self-efficacy enhancing program in the management of diabetes.
14
15

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

17
18 Participation in this study will not cost you anything. For sessions and visits that are
19 conducted outside of your routine clinic, you will be reimbursed for your time and
20 reasonable travel.
21
22

23 **WHO IS FUNDING THE RESEARCH?**

24
25 This study is sponsored by a research grant from University Putra Malaysia who will pay for all study
26 procedures except all other medication and procedures that are part of your routine medical care.
27
28

29 **CAN THE RESEARCH OR MY PARTICIPATION BE TERMINATED EARLY?**

30
31 The researcher may stop the study or your participation at any time possibly due to any safety concern.
32 If the study is stopped early for any reason you will be informed and arrangements made for your
33 future care. You may be asked to attend a final follow-up visit.
34
35

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

37
38 If you have any questions, concerns or complaints about the study at any stage, you can contact:



39
40
41 **Prof Madya Normala Ibrahim**

42 *Consultant Psychiatrist*
43 *Faculty of Medicine and Health Sciences*
44 *University Putra Malaysia*
45 *43400 Serdang Selangor*
46 **normala_ib@upm.edu.my**

41
42 **Aida Farhana Suhaimi**

43 **Clinical Psychologist**
44 **PhD Psychological Medicine Candidate**
45 *Department of Medicine and Health Sciences*
46 *University Putra Malaysia*
47 *43400 Serdang Selangor*
48 **aida.hjsuhaimi@gmail.com**

49
50
51 If you have any questions about your rights as a participant in this study, please contact: The Secretary,
52 Medical Research & Ethics Committee, Ministry of Health Malaysia, at telephone number 03-2287
53 4032.
54
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60

Consent Form SELF-EFFICACY IN DIABETES	  UNIVERSITI PUTRA MALAYSIA BERILMU BERBAKTI
	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 SPIRIT reporting 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

1	Roles and	#5a	Names, affiliations, and roles of protocol contributors	1-2
2	responsibilities:			
3	contributorship			
4				
5				
6	Roles and	#5b	Name and contact information for the trial sponsor	n/a
7	responsibilities:			
8	sponsor contact			
9	information			
10				
11				
12				
13	Roles and	#5c	Role of study sponsor and funders, if any, in study	n/a
14	responsibilities:		design; collection, management, analysis, and	
15	sponsor and funder		interpretation of data; writing of the report; and the	
16			decision to submit the report for publication, including	
17			whether they will have ultimate authority over any of	
18			these activities	
19				
20				
21				
22				
23	Roles and	#5d	Composition, roles, and responsibilities of the	n/a
24	responsibilities:		coordinating centre, steering committee, endpoint	
25	committees		adjudication committee, data management team, and	
26			other individuals or groups overseeing the trial, if	
27			applicable (see Item 21a for data monitoring committee)	
28				
29				
30				
31	Introduction			
32				
33	Background and	#6a	Description of research question and justification for	5
34	rationale		undertaking the trial, including summary of relevant	
35			studies (published and unpublished) examining benefits	
36			and harms for each intervention	
37				
38				
39				
40	Background and	#6b	Explanation for choice of comparators	6
41	rationale: choice of			
42	comparators			
43				
44				
45	Objectives	#7	Specific objectives or hypotheses	6
46				
47				
48	Trial design	#8	Description of trial design including type of trial (eg,	7
49			parallel group, crossover, factorial, single group),	
50			allocation ratio, and framework (eg, superiority,	
51			equivalence, non-inferiority, exploratory)	
52				
53				

54
55 **Methods:**
56 **Participants,**
57

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: adherence	#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

1			
2			
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5			
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7			
8			
9	Data collection plan:	#18b	Plans to promote participant retention and complete 13
10	retention		follow-up, including list of any outcome data to be
11			collected for participants who discontinue or deviate from
12			intervention protocols
13			
14			
15	Data management	#19	Plans for data entry, coding, security, and storage, 15
16			including any related processes to promote data quality
17			(eg, double data entry; range checks for data values).
18			Reference to where details of data management
19			procedures can be found, if not in the protocol
20			
21			
22			
23	Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary 13
24			outcomes. Reference to where other details of the
25			statistical analysis plan can be found, if not in the
26			protocol
27			
28			
29			
30	Statistics: additional	#20b	Methods for any additional analyses (eg, subgroup and 13
31	analyses		adjusted analyses)
32			
33			
34	Statistics: analysis	#20c	Definition of analysis population relating to protocol non- 13
35	population and		adherence (eg, as randomised analysis), and any
36	missing data		statistical methods to handle missing data (eg, multiple
37			imputation)
38			
39			
40			
41	Methods: Monitoring		
42			
43	Data monitoring:	#21a	Composition of data monitoring committee (DMC); n/a
44	formal committee		summary of its role and reporting structure; statement of
45			whether it is independent from the sponsor and
46			competing interests; and reference to where further
47			details about its charter can be found, if not in the
48			protocol. Alternatively, an explanation of why a DMC is
49			not needed
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54	Data monitoring:	#21b	Description of any interim analyses and stopping n/a
55	interim analysis		guidelines, including who will have access to these
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interim results and make the final decision to terminate the trial

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4	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
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11	Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor
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16	Ethics and dissemination		
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20	Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval
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24	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)
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32	Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)
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37	Consent or assent: ancillary studies	#26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable
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43	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
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49	Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site
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53	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
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1	Ancillary and post trial	#30	Provisions, if any, for ancillary and post-trial care, and for	n/a
2	care		compensation to those who suffer harm from trial	
3			participation	
4				
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6	Dissemination policy:	#31a	Plans for investigators and sponsor to communicate trial	16
7	trial results		results to participants, healthcare professionals, the	
8			public, and other relevant groups (eg, via publication,	
9			reporting in results databases, or other data sharing	
10			arrangements), including any publication restrictions	
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14	Dissemination policy:	#31b	Authorship eligibility guidelines and any intended use of	16
15	authorship		professional writers	
16				
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18	Dissemination policy:	#31c	Plans, if any, for granting public access to the full	16
19	reproducible research		protocol, participant-level dataset, and statistical code	
20				
21				
22	Appendices			
23				
24	Informed consent	#32	Model consent form and other related documentation	Sup. 1
25	materials		given to participants and authorised surrogates	
26				
27				
28	Biological specimens	#33	Plans for collection, laboratory evaluation, and storage of	n/a
29			biological specimens for genetic or molecular analysis in	
30			the current trial and for future use in ancillary studies, if	
31			applicable	
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