

**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**

ABSTRACT

**Introduction** People with diabetes are often associated with multifaceted factors and comorbidities. Diabetes management frameworks need to integrate a biopsychosocial, patient-centred 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 Programme (OHP) 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 OHP was developed under the name 'Pohon Sihat' (OHP). The study aims to evaluate the effectiveness of the mental health-based selfmanagement and wellness programme 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. The 2-hour weekly sessions over five consecutive weeks, and 2-hour booster session post 3months 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. Outcome measures will be assessed at baseline, immediately postintervention, as well as at 3 months and 6 months postintervention. Where appropriate, intention-to-treat analyses will be performed. **Ethics and dissemination** This study has ethics approval from the Medical Research and Ethics Committee, Ministry of Health Malaysia (NMRR-17-3426-38212). Study findings will be shared with the Ministry of Health Malaysia and participating healthcare clinics. Outcomes will also be shared through publication, conference presentations and publication in a peer-reviewed journal.