

STUDY PROTOCOL

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Effectiveness and sustainability of a structured group-based educational program (MEDIHEALTH) in improving medication adherence among Malay patients with underlying type 2 diabetes mellitus in Sarawak State of Malaysia: study protocol of a randomized controlled trial

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Abstract

Background: Amidst the high disease burden, non-adherence to medications among patients with type 2 diabetes mellitus (T2DM) has been reported to be common and devastating. Sarawak Pharmaceutical Services Division has formulated a pharmacist-led, multiple-theoretical-grounding, culturally sensitive and structured group-based program, namely "Know Your Medicine – Take it for Health" (MEDIHEALTH), to improve medication adherence among Malay patients with T2DM. However, to date, little is known about the effectiveness and sustainability of the Program.

Methods/design: This is a prospective, parallel-design, two-treatment-group randomized controlled trial to evaluate the effectiveness and sustainability of MEDIHEALTH in improving medication adherence. Malay patients who have underlying T2DM, who obtain medication therapy at Petra Jaya Health Clinic and Kota Samarahan Health Clinic, and who have a moderate to low adherence level (8-item Morisky Medication Adherence Scale, Malaysian specific, score <6) were randomly assigned to the treatment group (MEDIHEALTH) or the control group. The primary outcome of this study is medication adherence level at baseline and 1, 3, 6 and 12 months post-intervention. The secondary outcomes are attitude, subjective norms, perceived behavioural control, intention and knowledge related to medication adherence measured at baseline and 1, 6 and 12 months post-intervention. The effectiveness and sustainability of the Program will be triangulated by findings from semi-structured interviews with five selected participants conducted 1 month after the intervention and in-depth interviews with two main facilitators and two managerial officers in charge of the Program 12 months after the intervention. Statistical analyses of quantitative data were conducted using SPSS version 22 and Stata version 14. Thematic analysis for qualitative data were conducted with the assistance of ATLAS.ti 8.

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