UNIVERSITI TEKNOLOGI MARA

A PRAGMATIC CLUSTER
RANDOMISED CONTROLLED TRIAL
TO EVALUATE THE
EFFECTIVENESS OF THE
EMPOWER-PAR INTERVENTION IN
IMPROVING PRIMARY CARE
PROVIDERS' ADHERENCE TO T2DM
CPG AND MEDICATION
ADHERENCE IN T2DM PATIENTS

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Thesis submitted in fulfillment of the requirements of the degree of **Master of Science**

March 2016

CONFIRMATION BY PANEL OF EXAMINERS

I certify that the Panel of Examiners has met on the 11th November 2015 to conduct the final examination of Maryam Hannah Daud, on her Master of Science (Medicine) thesis entitled "A Pragmatic Cluster Randomised Controlled Trial To Evaluate The Effectiveness Of The Empower-PAR Intervention On Medication Adherence And Primary Care Providers' Adherence To T2DM CPG in T2DM patients" in accordance with Universiti Teknologi MARA Act 1976 (Akta 173). The Panel of Examiners recommends that the student be awarded the relevant degree. The Panel of Examiners were as follows:

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I declare that that work in this thesis was carried out in accordance with the regulations in Universiti Teknologi MARA. It is original and is the result of my own work, unless otherwise indicated or acknowledged as referenced work. This thesis has not been submitted to any other academic institution or non-academic institution for any degree or qualification.

I, hereby, acknowledge that I have been supplied with the Academic Rules and Regulations for Post Graduate, Universiti Teknologi MARA, regulating the conduct of my study and research.

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ABSTRACT

Background: Numerous local studies have shown that there were poor adherence to T2DM clinical practice guideline (CPG) recommendations among primary care providers (PCP) and poor medication adherence among T2DM patients in primary care. The Chronic Care Model (CCM) had been proven to be effective in improving providers' adherence to CPG and medication adherence among T2DM patients in developed countries. However, evidence in developing countries is still lacking. Objectives: The first objective of this study was to design a pragmatic intervention based on the CCM i.e. EMPOWER-PAR intervention. The second objective was to evaluate the effectiveness of this intervention in improving the PCPs' adherence to T2DM CPG, medication adherence level and clinical outcomes among T2DM patients in the Malaysian public primary care setting. Methods: This is a sub study of a larger pragmatic cluster randomized controlled trial - participatory action research which was conducted in 10 public primary care clinics in Selangor and Kuala Lumpur. Five clinics were randomly selected to provide the EMPOWER-PAR intervention for 1 year and another 5 clinics continued with usual care. The PCPs' adherence to T2DM CPG was measured using the 'Process of Care Questionnaire', which includes the indicators of care as recommended by the Malaysian CPG on the Management of T2DM. Data were collected from the patients' medical records, retrospectively at baseline and at 1-year follow-up. Medication adherence levels among T2DM patients were measured using the previously validated Malay version of the Morisky Medication Adherence Scale – 8 (MMAS-8). Data were collected using face-to-face interview by trained interviewers, at baseline and at 1-year follow-up. Clinical outcome data were collected at baseline and at 1-year follow-up. Intention to treat analysis was performed for all outcome measures. A generalised estimating equation method was used to account for the baseline differences and the clustering effect. Results: A total of 888 patients were recruited at baseline; 471 were in the intervention and 417 in the control group. There was no significant demographic difference between the two groups at baseline except for ethnicity. At 1-year, 455 (96.6%) and 406 (97.3%) patients in the intervention and control groups completed the study, respectively. There were significant improvements in the percent change of the level of PCPs' adherence in the intervention compared to the control group at 1-year follow-up in several indicators of care. The intervention improved medication adherence levels twice more likely compared to usual care (adjusted OR 2.18, 95% CI 1.55 – 3.06, p-value<0.001). The proportion of patients achieving HbA1c target in the intervention group was significantly higher compared to the control groups (18.0% vs. 12.5%, p-value=0.022). The intervention also improved the proportion of T2DM patients achieving HbA1c target twice more likely compared to usual care (adjusted OR 2.34, 95% CI 1.22 – 4.51, p-value<0.011). Conclusions: The EMPOWER-PAR intervention has been proven to be effective in improving the PCPs' adherence to T2DM CPG in several indicators of care, patients' medication adherence levels and the proportion of patients achieving HbA1c target. Findings from this study provided objective evidence of the effectiveness of this intervention in the Malaysian public primary care setting.

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