UNIVERSITI PUTRA MALAYSIA

EFFECTIVENESS OF OPTIMAL HEALTH PROGRAM IN IMPROVING SELF-EFFICACY IN TYPE 2 DIABETES MELLITUS PRIMARY CARE PATIENTS IN PUTRAJAYA, MALAYSIA

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Thesis Submitted to the School of Graduate Studies, Universiti Putra Malaysia, in Fulfilment of the Requirements for the Degree of Doctor of Philosophy

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September 2021

Chair : Prof. Normala binti Ibrahim, PhD
Faculty : Medicine and Health Sciences

Diabetes is seeing an increasing trend globally and locally. Despite advances in medical and healthcare services, Malaysia is still witnessing increased prevalence of disability, co-morbidity, medical complications and poor well-being amongst patients with diabetes. The current approach in diabetes management that is predominantly education and medical focus is no longer adequate to address the complexity of diabetes. Self-efficacy has been found to be fundamental in the process of effective diabetes self-management. The Optimal Health Program (OHP) is a self-management intervention that is wellness-based, person-centred, driven by self-efficacy theory and aimed towards patient empowerment. This study aims to examine the effectiveness of the OHP in improving self-efficacy in Type 2 Diabetes Mellitus (T2DM) patients attending the primary healthcare clinics in Putrajaya.

This study is a single blind randomized controlled trial. This study recruited patients (*n* = 127) diagnosed with T2DM from primary healthcare clinics in Putrajaya. Participants were randomised to either OHP plus treatment-as-usual (OHP plus TAU) or treatment-as usual alone (TAU). The 2-hour weekly sessions conducted over 5 consecutive weeks (i.e., up to Week 5), and 2-hour session at three months post fifth session (i.e., Week 18) were facilitated by trained mental health practitioners and diabetes educators. Primary outcomes were self-efficacy (psychosocial self-efficacy and diabetes management self-efficacy), while secondary outcomes were mental health (depression, anxiety, diabetes-related distress and wellbeing), self-care behaviours and glycaemic control (HbA1c). These outcome measures were assessed at baseline, at Week 5, Week 18 and Week 30. The intention-to-treat analyses were performed with missing values imputed using the LOCF approach

The study's findings provided evidence on the effectiveness of OHP plus TAU when compared to TAU alone in improving self-efficacy (F (2,122) = 8.28, p < 0.001, partial η^2 = 0.12), with effect observed at Week 5 and Week 18. Across time, OHP plus TAU improved both psychosocial self-efficacy (F (3, 122) = 31.74, p < 0.001) and diabetes management self-efficacy (F (3,122) = 13.62, p < 0.001). However, this study did not find significant difference between OHP plus TAU and TAU alone for self-care behaviours and mental health outcomes. Nonetheless, OHP plus TAU showed improvement in self-care behaviours and mental health outcomes over time. This study failed to provide any evidence on the effectiveness of OHP plus TAU in improving glycaemic control.

This study found OHP to be effective as an add-on self-management intervention to the current treatment of T2DM patients in the primary healthcare clinics in improving psychosocial and diabetes management self-efficacy. Beneficial effect on mental health outcomes were limited whilst self-care behaviours yielded a more short-term beneficial effect. There was no beneficial effect on glycaemic control found. Future studies that assess the sustainability of the program at long term and incorporate ongoing support, with frequent contact between sessions and in a longer duration would be beneficial.

Abstrak tesis yang dikemukakan kepada Senat Universiti Putra Malaysia sebagai memenuhi keperluan untuk ijazah Doktor Falsafah

KEBERKESANAN PROGRAM KESIHATAN OPTIMUM DALAM MENINGKATKAN KEBERKESANAN DIRI PESAKIT *TYPE 2 DIABETES MELLITUS* DI KESIHATAN PRIMER PUTRAJAYA, MALAYSIA

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Diabetes adalah penyakit yang memperlihatkan trend meningkat di peringkat global dan tempatan. Walaupun terdapat kemajuan dalam perkhidmatan perubatan dan kesihatan, Malaysia masih menyaksikan peningkatan dalam komorbiditi penyakit, masalah komplikasi perubatan, morbiditi dan mortaliti dan kemerosotoan kesejahteraan diri di kalangan pesakit diabetes. Pendekatan semasa dalam pengendalian diabetes yang bertumpu pada pendidikan dan aspek perubatan sahaja tidak lagi memadai untuk menangani kerumitan penyakit diabetes. Keberkesanan diri didapati menjadi asas dalam proses pengurusan diri diabetes yang berkesan. Program Kesihatan Optimum (OHP) ialah intervensi pengurusan diri yang disokong oleh teori keberkesanan diri, berasaskan kesejahteraan, berfokuskan pada individu dan bertujuan untuk memperkasakan pesakit. Kajian ini bertujuan untuk mengkaji keberkesanan OHP dalam meningkatkan keberkesanan diri dalam pesakit Diabetes Mellitus Type 2 (T2DM) yang menghadiri klinik kesihatan primer di Putrajaya.

Kajian ini adalah percubaan terkawal rawak buta tunggal. Kajian ini melibatkan pesakit-pesakit (n = 127) T2DM dari klinik kesihatan primer di Putrajaya. Peserta secara rawak menyertai OHP dan rawatan-seperti-biasa (*OHP plus TAU*) atau rawatan-seperti biasa sahaja (TAU). OHP telah diterjemahkan dan disesuaikan secara budaya, diuji di kalangan fasilitator OHP terlatih di Malaysia, disahkan di kalangan sekumpulan pendidik diabetes dan diuji di kalangan pesakit diabetes di klinik kesihatan primer. Sesi OHP telah dijalankan secara mingguan selamak 2 jam untuk 5 minggu berturut-turut dan sesi 2 jam ada tiga bulan selepas sesi kelima. Sesi difasilitasi oleh pengamal kesihatan mental terlatih dan pendidik diabetes. Hasil utama ialah keberkesanan diri, manakala hasil sekunder ialah kesihatan mental, tingkah laku penjagaan diri dalam diabetes dan kawalan glisemik (HbA1c). Ukuran hasil ini dinilai pada garis dasar (*baseline*), pada

Minggu 5, Minggu 18 dan Minggu 30. Analisis statistik dilakukan menggunakan pendekatan *intention-to-treat analysis* menggunakan pendekatan LOCF.

Penemuan kajian telah membuktikan keberkesanan OHP plus TAU jika dibandingkan dengan TAU sahaja dalam meningkatkan keberkesanan diri ($F(2,122) = 8.28$, $p < 0.001$), dengan kesan diperhatikan pada Minggu 5 dan Minggu 18. OHP *plus* TAU meningkatkan kedua-dua keberkesanan diri dari aspek psikososial ($F(3, 122) = 31.74$, $p < 0.001$) dan pengurusan diabetes ($F(3, 122) = 13.62$, $p < 0.001$). Walaubagaimanapun, kajian ini tidak menemui perbezaan yang signifikan antara OHP *plus* TAU dan TAU sahaja untuk tingkah laku penjagaan diri dalam diabetes dan kesihatan mental. Namun begitu, OHP *plus* TAU menunjukkan peningkatan dalam tingkah laku penjagaan diri diabetes dan kesihatan mental dari semasa ke semasa. Kajian ini gagal memberikan sebarang bukti tentang keberkesanan OHP *plus* TAU dalam meningkatkan kawalan glisemik.

Kajian ini mendapati OHP berkesan sebagai intervensi pengurusan diri bila disepadukan dengan rawatan semasam pesakit T2DM di klinik kesihatan primer dalam meningkatkan keberkesanan diri dalam aspek pengurusan psikososial dan diabetes. Kesan berfaedah ke atas hasil kesihatan mental adalah terhad dan tingkah laku penjagaan diri menghasilkan kesan berfaedah jangka pendek yang lebih. Tiada kesan signifikan terhadap kawalan glisemik ditemui. Kajian masa depan yang menilai keberkesanan program pada jangka panjang dengan menggabungkan sokongan berterusan dan kerap antara sesi dalam tempoh yang lebih lama akan lebih bermanfaat.

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This thesis was submitted to the Senate of Universiti Putra Malaysia and has been accepted as fulfilment of the requirement for the degree of Doctor of Philosophy. The members of the Supervisory Committee were as follows:

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Declaration by Members of Supervisory Committee

This is to confirm that:

- the research conducted and the writing of this thesis was under our supervision;
- supervision responsibilities as stated in the Universiti Putra Malaysia (Graduate Studies) Rules 2003 (Revision 2012-2013) are adhered to.

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LIST OF ABBREVIATIONS

AGI	alpha-glucosidase inhibitors
ANOVA	Analysis of Variance
ANCOVA	Analysis of covariance
CPG	Clinical Practice Guidelines
CC	Complete Case
CDSES	Adapted Standford Chronic Disease Self-Efficacy Scale
DES	Diabetes Empowerment Scale
DES-SF	Diabetes Empowerment Scale – Short form
DM	Diabetes Mellitus
DMSES	Diabetes Management Self-Efficacy
DPP-4	dipeptidyl Peptidase-4
DSEQ	Diabetes Self-Efficacy Outcomes Expectancies Questionnaire
DSM-5	Diagnostic and Statistical Manual of Mental Disorders, 5th ed.
GAD-7	Generalised Anxiety Disorder-7
GLP-1	glucagon-like Peptide-1
GSE	Generalized Self-efficacy Scale
HbA1c	Glycated Haemoglobin
ICD-10	International Classification of Diseases, tenth edition
KK	Healthcare Clinic *(Klinik Kesihatan)*
KKP9	Healthcare Clinic *(Klinik Kesihatan)* Putrajaya Presint 9
KKP11	Healthcare Clinic *(Klinik Kesihatan)* Putrajaya Presint 11
KKP14	Healthcare Clinic *(Klinik Kesihatan)* Putrajaya Presint 14
KKP18	Healthcare Clinic *(Klinik Kesihatan)* Putrajaya Presint 18
LOCF	Last Observed Response Carried Forward

MANOVA	Multivariate Analysis of Variance
MANCOVA	Multivariate Analysis of Covariance
MI	Multiple Imputation
OAD	oral anti-diabetes
OHP	Optimal Health Program [POHON SIHAT]
OGTT	oral glucose tolerance test
RCT	Randomised Controlled Trial
SDSCA	Summary of Diabetes Self-Care Activities
SGLT2	sodium-glucose cotransporter 2
SOI	salutogenic-oriented intervention
TAU	Treatment-as-usual
T1DM	Type 1 Diabetes Mellitus
T2DM	Type 2 Diabetes Mellitus
PAID	Problem Areas in Diabetes
PHQ-9	Patient Health Questionnaire-9
PST	Problem Solving Therapy
PTES	Perceived Therapeutic Efficacy Scale
TZD	thiazolidinediones
WHO-5	WHO-5 Well-being Index

CHAPTER 1

INTRODUCTION

This introduction chapter provides an overview of the research study. It starts with a background of diabetes prevalence; the advancement seen in the management of diabetes and further illustrates how diabetes is beyond just a medical problem. It then describes a person-centred self-management intervention towards empowerment as a way forward in the management of diabetes and further explain the most used theory in diabetes self-management i.e. theory of self-efficacy. The introduction follows with a description of the current scenario on Malaysia's diabetes care and illustrates how Optimal Health Program may benefit in in the integration in the current diabetes care. This chapter follows the significance of the study and wraps up with the research objectives and research hypothesis.

1.1 Background

1.1.1 Diabetes Prevalence

Diabetes is an endemic globally with increasing trend globally and locally. Type 2 Diabetes Mellitus (T2DM) comprises the majority of cases representing up to 90% of diabetes cases worldwide (Cho et al., 2018). Despite it being considered a lifestyle disease that is highly preventable, T2DM dominates the global diabetes landscape and has become a major public health concern. The global prevalence of diabetes in 2019 amongst 20 to 79 years old adults is currently at 9.3% (International Diabetes Federation, 2019). Whilst Malaysia reported an almost two-fold prevalence of overall raised blood glucose of 18.3% in 2019 amongst adults 18 years and above(Institute for Public Health (IPH), National Institutes of Health Malaysia, & Ministry of Health Malaysia, 2020). Whilst for Putrajaya, which is the area of interest in the current study, found prevalence of overall raised blood glucose in 2019 amongst adults 18 years and above was above the national prevalence [22.9% (95% CI: 18.8, 27.5)], with high prevalence for obesity and highest for overweight in the country (Institute for Public Health (IPH) et al., 2020). Thus, puts Putrajaya at an even more vulnerable state with risk factors evidently contributing towards increased associated health complications and premature mortality in patients with diabetes (Toplak, Hoppichler, Wascher, Schindler, & Ludvik, 2016).

1.1.2 Advancement in Management of Diabetes

The increasing prevalence of diabetes have driven the advancement in the clinical management of diabetes. Research has expanded in the technological,

biological and especially pharmacological treatments in diabetes and remarkable progress has been made (Sattar, 2019; Shomali, 2012). Malaysia too has shown great improvement in efforts of prevention, treatment and control of diabetes (Hussein, Taher, Gilcharan Singh, & Chee Siew Swee, 2015). There has been a promising growth towards human resources, with more specialised services and integrated multidisciplinary care (Chan, 2015; Hussein, Taher, Kaur, et al., 2015; Malaysian Healthcare Performance Unit, 2017; Ministry of Health Malaysia, 2015). Additionally, the percentage of patients with diabetes receiving standard care has also shown a promising annual increment (Kuo, Lin, & Tsai, 2014; Malaysian Healthcare Performance Unit, 2017; Tai, 2018).

1.1.3 Diabetes beyond just a medical problem

Unfortunately, despite advancements in the clinical management of diabetes, diabetes prevalance continues to rise with increasing burden of illness. A person with diabetes are continuously faced with challenges in coping with the demands of treatment regime, engaging in lifestyle modifications, preventing further complications, sustaining social relationships and achieving optimal well-being (Tirumalesh & Chandraiah, 2017). A person with diabetes have been consistently shown to experience several psychosocial issues including poor mental health, diabetes-related psychological problems, poor psychological support, mental disorder comorbidities and poor overall quality of life (Nicolucci, Kovacs Burns, Holt, Comaschi, Hermanns, Ishii, Kokoszka, Pouwer, Skovlund, Stuckey, Tarkun, Vallis, Wens, & Peyrot, 2013; Peyrot et al., 2005; Vallis, Burns, Hollahan, Ross, & Hahn, 2016). These psychosocial issues have further led to poor diabetes control and hold barriers to effective management (Capoccia, Odegard & Letassy, 2016; Gonzales et al., 2008; Sumlin et al., 2014). In short, diabetes was impacting a person to its entirety and management solely on the medical aspect of illness were no longer sufficient. Thus, over the years, management in diabetes has seen a shift towards a more holistic approach to management with greater emphasis on the role of the diabetes person in managing their health (American Diabetes Association (ADA), 2016).

1.1.4 Person centred self-management intervention towards patient empowerment

In order to achieve optimal medical outcomes and optimal well-being, recommendations have moved towards medical care that integrates a more holistic, person centred approach in self-management interventions that enhances patient empowerment (American Diabetes Association, 2015; Kalra, Balhara, & Das, 2013). The shift called upon a focus that goes beyond just treating the physical illness, but also on optimising a person's overall health. Self-management interventions are developed to involve (1) diabetes education (2) psychological strategies and (3) social and lifestyle support (Captieux et al., 2018). A person-centred approach considers patient's needs, preferences and values to guide clinical management (Young-Hyman et al., 2016). The approach involves paying attention to all factors that may impact a person in their ability to

manage their diabetes and overall health (Rutten, Van Vugt, & De Koning, 2020). While, patient empowerment shifts the focus from a paternalistic model to a collaborative framewok that facilitates patient active participation in management (Anderson & Funnell, 2010; Asimakopoulou, Gilbert, Newton, & Scambler, 2012). Patient empowerment is closely grounded on the theory of self-efficacy and has become the most widely used theoretical framework in self-management interventions (McAllister, Dunn, Payne, Davies, & Todd, 2012; Zhao, Suhonen, Koskinen, & Leino-Kilpi, 2017).

1.1.5 Theory of self-efficacy and diabetes self-management

Self-management interventions facilitate a behavioural change process. Theory of self-efficacy has been found to be the most well-developed behaviour change theory and provides a strong framework in informing diabetes self-management interventions (Smith & Liehr, 2018; Zhao et al., 2017). The use of the self-efficacy theory in self-management interventions has shown beneficial effect as a psychological construct and resource (Zhao et al., 2017). Self-efficacy theory relates to one's beliefs of their own capabilities to perform specific behaviours in particular situations (Bandura, 1998). Self-efficacy has been shown to consistently correlate with diabetes self-care behaviours and psychosocial outcomes (Devarajooh & Chinna, 2017; Gao et al., 2013; Lin et al., 2018; Tharek et al., 2018; Xu, Leung, & Chau, 2018; Yao et al., 2019) as well as a strong predictor for diabetes self-care behaviours (Yee, Said, & Manaf, 2018). Additionally, self-efficacy is one of the most fundamental psychosocial indicator that provides accurate evaluation on the effectiveness of a diabetes self-management program (Anderson, Fitzgerald, Funnell, & Oh, 2003; Lin et al., 2018; Vas et al., 2017; Young-Hyman et al., 2016). Thus, not only is self-efficacy fundamental in the process of effective diabetes self-management, it is also a reliable key outcome measure in assessing the effectiveness of a self-management intervention towards patient empowerment.

1.1.6 Current Scenario in Malaysia's Diabetes care

In spite of medical advances, expansion of healthcare services and increasing provision of diabetes education and resources, Malaysia is still witnessing increased prevalence of disability, co-morbidity, medical complications and poor well-being amongst patients with diabetes (Institute for Public Health (IPH) et al., 2020; Ministry of Health Malaysia, 2015). Self-management interventions have mainly focussed on the provision of diabetes education (Hussein, Taher, Kaur, et al., 2015). Such self-management interventions is the diabetes self-management education (DSME) programs that are currently practiced sporadically in diabetes clinics. However, comparatively, psychological strategies and social support components in these self-management interventions are given a much lesser focus. Though diabetes self-management education have been found to improve self-efficacy and improve patient empowerment, the delivery of the program and the components of the program may contribute towards inconsistent findings (Odgers-Jewell et al., 2017).

Despite local guidelines recommending a more holistic person-centred approach that facilitates patient empowerment, primary healthcare providers were still consistently found promoting self-care behaviours through scare tactics and "patient blaming", lacking skills in addressing psychosocial issues and having inadequate training in patient-centred care that promotes patient empowerment (Kragelund et al., 2020; Lim, Aagaard-Hansen, Mustapha, & Bjerre-Christensen, 2018; Saidi, Milnes, & Griffiths, 2018). The current practice in Malaysia is still mainly aimed in achieving satisfactory biomarkers and is still predominantly paternalistic, education based and medical focussed with limited psychosocial integration, and little consideration on patient's role (Ang, Leo, George, & Chan, 2018; Saidi, Milnes, & Griffiths, 2019). The implementation of the diabetes management may not be as effective when it does not involve managing diabetes to its entirety.

Nonetheless, a person-centred self-management that integrates the medical, emotional and social aspect of health of the individual patients may not be easily practiced within the realities and limitation within the primary care settings (Kusnanto, Agustian, & Hilmanto, 2018). Thus, rather than treating it as different components in management, integrating psychosocial care to the current clinical management of diabetes can be a practical way forward towards the continuous application of a holistic person centred approach (Hatala, 2012; Patel & Chatterji, 2015a). The existing medical routine care within primary healthcare setting can further be enhanced by integrating a holistic, person-centred self-management intervention that improves self-efficacy and aimed towards patient empowerment.

1.1.7 Optimal Health Program

The Optimal Health Program (OHP) is a wellness-based, person-centred, self-management program that promotes patient empowerment. The Optimal Health Program or formerly known as Collaborative Therapy was developed by the Mental Health Research Institute of Victoria Melbourne (Gilbert, Miller, Berk, Ho, & Castle, 2003). Since its development, St Vincent's Hospital Melbourne and in collaboration with Within Australia has been involved in the delivering of OHP across Australia and outside of Australia. Initially developed for the psychiatric population, the program has over the years expanded beyond just psychiatry. Moving away from illness focus towards a holistic wellness-based approach, OHP focusses on the promotion of a person's overall well-being through a person-centred approach that is delivered using health coaching and motivational interviewing techniques. It covers the common elements of self-management programs (i.e., education, psychological strategies, social and lifestyle support) that is low-intensity, structured, and can be delivered by a broad category of health professionals. Evidently, OHP has shown to be effective in improving health and social functioning in mental health patients (Gilbert et. al., 2012), substance use and psychotic disorders (James et al., 2004). The OHP has slowly expanded towards managing physical health and chronic illnesses (O'Brien et al., 2016). In 2018, the OHP was tested amongst Malaysia's mental heathcare services and was found to be a promising framework in supporting

the mental health services (Silim, Suhaimi, Moore, Ryan, & Castle, 2019). Following the translation and cultural adaptation of the program, OHP has been used within the mental health clinics, mental health peer support groups, amongst a sample of obese and overweight participants, COVID-19 patients and COVID-19 frontliners,

Self-efficacy is central to the program and is enhanced in a systematic approach where facilitators and participants work collaboratively through the OHP materials. Self-efficacy has been continuously found to have a positive relationship with diabetes self-management behaviours and glycaemic control within Malaysia's patients with diabetes which are central to diabetes management (Sharoni & Wu, 2012; Tharek et al., 2018). The enhanced believed that they have the ability essential in conducting diabetes self-management behaviours including tasks related to blood glucose monitoring leads to better glycaemic control (Sharoni & Wu, 2012). Enhancing self-efficacy beyond just diabetes education, but also through developing skills in psychological strategies to overcome psychological barriers and enhancing social support to identify and engage resources in their environment further enhances the patient's ability to commit to self-management behaviours. Thus, OHP which is aimed towards enhancing self-efficacy, through a holistic approach that includes components of education, psychological strategies and social support would enhance patients with diabetes' believes in their ability to commit to self-management behaviours, leading to better diabetes care and glycaemic control,

Additionally, the OHP materials have undergone a thorough translation and cultural adaptation process to suit the Malaysian population. The OHP consists of five weekly sessions plus one session three months after the fifth session. The sessions encompass a wellness-based approach that builds strategies towards achieving and maintaining overall well-being such as skills in behaviour change, interagency collaboration, goal setting, problem solving, understanding and managing stress and identifying social support and health collaborators. These are all in which central skills towards patient empowerment in diabetes. Thus, the OHP is a promising self-management intervention that could fill in the current gap in management within the healthcare system.

1.2 Problem Statement

Despite advances in medical and healthcare services in the country, outcomes of care including glycaemic control and proportions of patients with complications and comorbidities remains unchanged, with increasing number of patients with diabetes showing increasing burden of illness (Institute for Public Health (IPH) et al., 2020; Ministry of Health Malaysia, 2015, 2020).

Up to 75% patients with diabetes in Malaysia reported combined microvascular complications and 29% reported macrovascular complications and 25% reported severe late complications such as legal blindness, end-stage kidney disease and

leg amputation (Mafauzy, Hussein, & Chan, 2011). Whilst, disability adjusted life year (DALYs) for diabetes mellitus in Malaysia doubled from the year 2000 (3.6%) to year 2008 (6.6%), and continued to increase in 2014 (7.8%) with no indication of slowing down (Institute for Public Health, 2015; Ministry of Health Malaysia, 2016). For the management of diabetes and its complications, it is estimated that it will cost the country approximately RM 2.04 billion, with approximately RM 1.04 billion being borne annually by government alone (Mustapha et al., 2017). Treatment of these complications is the major contributor to the total medical cost and health care utilization as well as increasing mental health and emotional distress in these patients (Ogurtsova, et al., 2017).

Self-management is crucial in the optimal management of diabetes with the patient predominantly holds the key to cope living with diabetes. The way forward in managing diabetes puts a greater emphasis on self-management intervention that enhances patient empowerment (Young-Hyman et al., 2016). Patient empowerment is embedded in patient's self-efficacy. Self-efficacy holds an important role as part of a process in enhancing self-management aimed towards patient empowerment as well as a reliable outcome measurement of a self-management intervention (Lin et al., 2018; Young-Hyman et al., 2016). Due to its significant role in self-care behaviours, self-efficacy has been shown to be one of the most fundamental psychosocial indicator in self-management outcomes and allows accurate evaluation on the effectiveness of a self-management program (Anderson et al., 2003; Lin et al., 2018; Vas et al., 2017; Young-Hyman et al., 2016). Continuously, self-efficacy in patients with diabetes in Malaysia has been found to be associated with better diabetes self-care behaviours and glycaemic control (Sharoni & Wu, 2012; Tharek et al., 2018). Additionally, self-management interventions that emphasizes the role of self-efficacy in enhancing patient empowerment has been found to be effective in improving diabetes self-care behaviours (Ahmad Sharoni, Abdul Rahman, Minhat, Shariff-Ghazali, & Azman Ong, 2018; Tan, Magarey, Chee, Lee, & Tan, 2011).

In line with this, there have been greater focus on patient empowerment and the role of psychosocial aspect in diabetes management in Malaysia. In the latest national guideline, the role of the patient was emphasised and a section on mental disorder and diabetes was added (Ministry of Health Malaysia, 2015). Nonetheless, initiatives towards patient empowerment has mainly focussed on diabetes education through the development of health education modules and peer support group educational initiatives (Chan, 2015; Hussein, Taher, Gilcharan Singh, et al., 2015). However, despite increasing efforts in diabetes education and health literacy as well as specially assigned diabetes educators in health clinics and hospitals (Hussein et al., 2015), improvement in diabetes care has been marginal (MOH, 2015). The current approach that is predominantly education and medical focus in diabetes management is no longer adequate to address the complex interplay of the biological, psychological and social determinants of the lifelong chronic illness (Schinckus, Dangoisse, Van den Broucke, & Mikolajczak, 2017).

In the 2015 National Morbidity Health survey, Putrajaya recorded the 2nd highest prevalence for overall diabetes (19.2%) amongst adults age 18 and above (Institute for Public Health, 2015). It also recorded highest prevalence of overweight (37%), obesity (43%) and abdominal obesity (61.3%) in the same population (Institute for Public Health, 2015). Consecutively, Putrajaya still continued to show high prevalence overall raised blood glucose in adults age 18 years and above (22.9%) which was above the national prevalence of 18.3% in the latest National Health Morbidity Survey 2019 (Institute for Public Health (IPH) et al., 2020). However, to the contrary, Putrajaya also recorded 2nd highest prevalence for adequate health literacy amongst adults age 18 and above in the National Health Morbidity Survey in 2015 and highest respondents having sufficient health literacy amongst all other states in a similar survey in 2019 (54.9%). This is despite increase in assigned diabetes educators in the Putrajaya health clinics and efforts in the provision of diabetes education, with up to 82% of patients with diabetes in Putrajaya reported to have had diabetes education exposure (Zhu, Mooi, & Shamsuddin, 2019). Education alone was no longer enough in the management of diabetes where desired adherence to optimal diabetes care can be achieved without good level of diabetes knowledge (Samsudin et al., 2015). In line with this, the WHO non-communicable disease report 2015 also echoed that knowledge and awareness were not sufficient to address the raising trend in non-communicable disease (WHO, 2015). Thus, challenging the effectiveness of the existing education and medical focus approach in diabetes self-management.

Going beyond just education, movement towards good diabetes care have shifted towards a more holistic approach that addresses includes psychosocial care that is person centred with greater emphasis on patient empowerment. The national guideline has raised concerns on possible inadequacy of health practitioners to manage psychological problems suggesting limitations in skills and resources within Malaysia's healthcare system in addressing psychosocial issues and mental health disorders in patients with diabetes. (Ministry of Health Malaysia, 2015). This raise concerns as efforts are amiss when management neglects the psychosocial and overall well-being of the diabetes person and disregards their central role in diabetes management. Thus, there is a need to enhance the current management of diabetes and healthcare services through integrating a self-management program that is more holistic, integrated psychosocial intervention, using a person-centred approach that enhances self-efficacy to empower patients to be proactive in preventative strategies, self-management skills and lifestyle changes towards optimal well-being.

1.3 Significance of the Study

This study identifies gaps in prior literature within the current management of diabetes in Malaysia. First, significance of this study lies in OHP filling in the current management gap with an add-on person-centred, self-management intervention that incorporates education with a greater focus on the psychosocial aspect of care. It is time-limited, flexible and easily facilitated using a workbook

that can be integrated into the existing clinical management of diabetes within the primary healthcare setting. Thus, potentially providing a platform to enhance the limited skills of diabetes educators within the primary care setting in managing psychosocial issues in patients with diabetes through a person-centred approach that utilizes health coaching and motivational interviewing. Secondly, OHP is a wellness-based intervention that shifts the focus from discussion on just illness to a more holistic approach to their health and overall well-being. Thus, it is broadly applicable across a wide range of individuals (with or without a psychiatric illness) and across different phases of their illness (e.g., any duration of diabetes years). Thirdly, as managing diabetes requires commitment to self-care behaviours, OHP aims to enhance self-efficacy and empowerment which in turn can improve self-care behaviours and ultimately achieve optimal diabetes management. Fourthly, the OHP has undergone a thorough translation and cultural adaptation process for the Malaysian population. Thus, this study presents a self-management intervention that is culturally adapted to best suit and readily available to be used within the current sample. Finally, the results of the study would provide evidence to several levels of stakeholders on the current diabetes management within the primary care. The results of the study can further inform the effectiveness of an integrated wellness based, person-centred approach for patients with diabetes in the primary healthcare clinics, and further enhance the existing skills of the healthcare practitioners in the primary care. Healthcare system will be better informed on the feasibility and effectiveness of such programs within the primary healthcare setting in which could further advice policymakers.

1.4 Research Questions

1. Is OHP in addition to treatment-as-usual (TAU) more effective than the current treatment-as-usual (TAU) in improving self-efficacy, mental health outcomes, self-care behaviours and glycaemic control in patients with Type 2 Diabetes Mellitus attending the primary healthcare clinics within the Putrajaya district?
2. Is OHP in addition to treatment-as-usual (TAU) effective in improving self-efficacy, mental health outcomes, self-care behaviours and glycaemic control in patients with Type 2 Diabetes Mellitus attending the primary healthcare clinics within the Putrajaya district across time?
3. Is OHP in addition to treatment-as-usual (TAU) effective in improving self-efficacy, mental health outcomes, self-care behaviours and glycaemic control in patients with Type 2 Diabetes Mellitus attending the primary healthcare clinics within the Putrajaya district more effective than treatment-as-usual (TAU) across time?

1.5 Research Objectives

1.5.1 General Objectives

To examine the effectiveness of OHP in addition to treatment-as-usual (TAU) in improving self-efficacy, mental health outcomes, self-care behaviours and glycaemic control in patients with Type 2 Diabetes Mellitus attending the primary healthcare clinics within the Putrajaya district.

1.5.2 Specific Objectives

1. To compare sociodemographic details and clinical characteristics between the OHP plus TAU (intervention) and TAU alone (control) at baseline (T1).

2. To examine the effectiveness (condition, time, and interaction) of OHP on self-efficacy (psychosocial self-efficacy and diabetes management self-efficacy) between OHP plus TAU (intervention) and TAU alone (control) at baseline (T1), Week 5 (T2), Week 18 (T3), and Week 30 (T4).

3. To examine the effectiveness (condition, time, and interaction) of OHP on mental health outcomes (depression, anxiety, diabetes-related distress and well-being) between OHP plus TAU (intervention) and TAU alone (control) at baseline (T1), Week 5 (T2), Week 18 (T3) and Week 30 (T4).

4. To examine the effectiveness (condition, time and interaction) of OHP on self-care behaviours between OHP plus TAU (intervention) and TAU alone (control) at baseline (T1), Week 5 (T2), Week 18 (T3) and Week 30 (T4).

5. To examine the effectiveness (condition, time and interaction) of OHP on glycaemic control between OHP plus TAU (intervention) and TAU alone (control) at baseline (T1), Week 5 (T2), Week 18 (T3) and Week 30 (T4).

1.6 Research Hypotheses

H1: There would be significant difference between sociodemographic details (i.e., age, gender, race, religion, education, employment, marital, smoking) and clinical characteristics (i.e., major medical illness, neurological disorder, psychiatric disorder, time since diagnosis, family history, treatment and diabetes related complications) between the OHP plus TAU (intervention) and TAU alone (control) at baseline (T1).

Self-efficacy

H2a: There would be a significant difference in self-efficacy (psychosocial self-efficacy and diabetes management self-efficacy) between OHP plus TAU (intervention) and TAU alone (control).

H2b: There would be a significant difference in self-efficacy (psychosocial self-efficacy and diabetes management self-efficacy) across baseline (T1), Week 5 (T2), Week 18 (T3), and Week 30 (T4) in OHP plus TAU (intervention).

H2c: There would be a significant condition by time interaction in self-efficacy (psychosocial self-efficacy and diabetes management self-efficacy) between OHP plus TAU (intervention) and TAU alone (control) across baseline (T1), Week 5 (T2), Week 18 (T3), and Week 30 (T4).

Mental Health Outcomes

H3a: There would be a significant difference in mental health outcomes (depression, anxiety, diabetes-related distress, and well-being) between OHP plus TAU (intervention) and TAU alone (control).

H3b: There would be a significant difference in mental health outcomes (depression, anxiety, diabetes-related distress and well-being) across baseline (T1), Week 5 (T2), Week 18 (T3), and Week 30 (T4) in OHP plus TAU (intervention).

H3c: There would be a significant condition by time interaction in mental health outcomes (depression, anxiety, diabetes-related distress and well-being) between OHP plus TAU (intervention) and TAU alone (control) across baseline (T1), Week 5 (T2), Week 18 (T3), and Week 30 (T4).

Self-care behaviours

H4a: There would be a significant difference in self-care behaviours between OHP plus TAU (intervention) and TAU alone (control).

H4b: There would be a significant difference in self-care behaviours across baseline (T1), Week 5 (T2), Week 18 (T3), and Week 30 (T4) in OHP plus TAU (intervention).

H4c: There would be a significant condition by time interaction in self-care behaviours between OHP plus TAU (intervention) and TAU alone (control) across baseline (T1), Week 5 (T2), Week 18 (T3), and Week 30 (T4).

Glycaemic control

H5a: There would be a significant difference in glycaemic control between OHP plus TAU (intervention) and TAU alone (control).

H5b: There would be a significant difference in glycaemic control between baseline (T1) and Week 30 (T4) in OHP plus TAU (intervention).

H5c: There would be a significant condition by time interaction in glycaemic control between OHP plus TAU (intervention) and TAU alone (control) across baseline (T1) and Week 30 (T4).

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