UNIVERSITI PUTRA MALAYSIA

FACTORS OF MEDICATION NON-ADHERENCE AMONG TYPE 2 DIABETES MELLITUS PATIENTS IN MALAYSIAN PUBLIC HOSPITALS

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By

NOR FADHILAH BINTI ABDULLAH

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 2020

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Faculty : Medicine and Health Sciences

The prevalence of medications non-adherence (MNA) among type 2 diabetes mellitus (T2DM) patients is high, despite the importance of medications as one of the primary treatments for T2DM. The aim of this study is to explore factors of medication non-adherence among T2DM non-adherence patients.

This study was a triangulation mixed methods design study conducted among T2DM patients in two public hospitals in Klang Valley, Malaysia. A quantitative study involved 427 T2DM patients who were recruited using systematic sampling. A total of 12 participants then participated in qualitative study through a purposive sampling of non-adherence patients revealed from a quantitative study.

The Medication Compliance Questionnaire (MCQ) was used to collect information on socio-demography, clinical profiles and non-adherence to medications. Then, semi-structured in-depth interviews have been conducted to explore factors of medication non-adherence among non-adherence type 2 diabetes patients. Descriptive, bivariate and multivariate analysis was performed using the Statistical Package for Social Science (SPSS 23). The interviews were audio-taped and transcribed verbatim. The data were managed using NVivo 11 and analyzed using constant comparative analysis.

The response rate for this study was 93.4%. Most of the respondents were married (82.0%) and having dyslipidemia (81.7%). A total of 186 (46.6%) of the respondents were not adherence to the medication. Ethnicity, marital status and Haemoglobin A1c (HbA1c) reading have been significantly related with medication non-adherence. Multivariate logistic regression indicated that Malay, with a single, widow, widower or divorced status and poor HbA1c reading, was more likely to become non-adherence.

Five categories evolved from participants' response to MNA factors. The first factor was perceived benefit complementary and alternative medicine (CAM). The second factor was attitude towards drawback of limitation. Third factor was poor health care provider-patient relationship. The fourth factor was an undesirable emotional response to the intake of medications. The last factor was the restraint of daily routine and cognitive function.

In summary, the prevalence of MNA in this study was unsatisfactory and there is a lot of room for improvement. The patients' information on the socio-demographic and clinical profiles should be considered in future intervention in improving MNA. The design of mixed methods in this study allowed the identification of non-adherence patients. The exploration of factors that influence patients' MNA is a key to recommend patient-centred care strategy to improve T2DM patients' non-adherence, which may be a reference for healthcare providers, primarily the nurses to be implemented in improving patients' MNA.

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

FAKTOR KETIDAK-PATUHAN UBATAN DALAM KALANGAN PESAKIT DIABETIS MELITUS JENIS 2 DI HOSPITAL AWAM MALAYSIA

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Prevalens ketidak-patuhan ubatan dalam kalangan pesakit diabetis melitus jenis 2 adalah tinggi, di sebalik kepentingan ubatan sebagai satu rawatan utama bagi diabetis melitus jenis 2. Tujuan kajian ini untuk meneroka faktor ketidak-patuhan ubatan dalam kalangan pesakit diabetis melitus jenis 2.

Kajian ini berbentuk triangulasi campuran yang dijalankan dalam kalangan pesakit diabetis jenis 2 di dua hospital awam di lembah Klang, Malaysia. Kajian kuantitatif melibatkan 427 pesakit diabetis melitus jenis 2, yang dipilih melalui persampelan bersistematik. Sejumlah 12 peserta kemudian telah menyertai kajian kualitatif melalui persampelan bertujuan dari pesakit tidak patuh yang diperolehi dalam kajian kuantitatif.

Soal-selidik Kepatuhan Ubatan (MCQ) telah digunakan untuk mengumpul maklumat sosio-demografi, klinikal profil dan ketidak-patuhan ubatan. Analisis deskriptif, bivariat dan multivariat dibuat menggunakan (SPSS 23). Kemudian, temuramah separa berstruktur dijalankan untuk meneroka factor-faktor ketikpatuhan pada ubatan dalam kalangan pesakit diabetes melitus jenis 2 yang tidak patuh. Temubual telah direkod dan ditranskrip kata demi kata. Data telah diurus menggunakan NVivo 11, dan dianalisis menggunakan analisis perbandingan berterusan.

Kadar respon kajian ini adalah 93.4%. Kebanyakan responden adalah berkahwin (82.0%) dan mempunyai tinggi kolestrol (81.7%). Sebanyak 186 (46.6%) responden tidak patuh pada ubatan. Etnik, status perkahwinan dan bacaan HbA1c menunjukkan hubungan signifikan dengan ketidakpatuhan ubatan. Analisis multivariat regresi logistik menunjukkan bahawa Melayu,

mempunyai status bujang, balu, atau bercerai, dan bacaan HbA1c yang tidak baik lebih cenderung untuk tidak patuh.

Lima kategori terhasil daripada respon peserta mengenai faktor ketidak-patuhan ubatan. Faktor pertama adalah merasa faedah Ubatan Komplimentari dan Alternatif (UKA). Faktor kedua ialah sikap terhadap kelemahan Ubatan Barat (UB). Faktor ketiga ialah lemah hubungan pengamal perubatan-pesakit. Faktor keempat adalah tindak balas emosi yang tidak diinginkan dalam pengambilan ubatan. Faktor terakhir ialah kekangan rutin harian dan fungsi kognitif.

Secara ringkasnya, prevalens ketidak-patuhan pada ubatan dalam kajian ini tidak memuaskan dan ada ruang untuk penambahbaikan. Juga, untuk kaitannya dengan ketidak-patuhan pada ubatan, maklumat sosiodemografik dan data klinikal pesakit mesti dimasukkan dalam intervensi memperbaiki ketidakpatuhan pada ubatan. Corak kajian kaedah campuran ini membolehkan untuk mengenal-pasti pesakit yang tidak patuh. Penerokaan faktor mempengaruhi ketidak-patuhan pesakit adalah kunci bagi mencadangkan strategi pelayanan berfokuskan pesakit dalam memperbaiki ketidak-patuhan pesakit diabetes melitus jenis 2. Strategi yang mungkin menjadi rujukan untuk pengamal perubatan, khususnya jururawat untuk diimplemen bagi memperbaiki ketidak-patuhan ubatan pesakit.

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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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This is to confirm that:

- the research conducted and the writing of this thesis was under our supervision;
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LIST OF ABBREVIATIONS

MA	Medication adherence
MNA	Medication non-adherence
T2DM	Type 2 diabetes mellitus
PCC	Patient centred-care
HCP	Healthcare provider
MCQ	Medication compliance questionnaire
DSME	Diabetes self-management education
WHO	World Health Organization
WM	Western medication
CAM	Complementary and alternative medication
MOH	Ministry of Health
ADA	American Diabetes Association
OHA	Oral hypoglycaemic agent
MMAS	Morisky Medication Adherence Scale
TPB	Theory of planned behaviour
SRMI	Self-regulation model of illness
IT	Internet technology

CHAPTER 1

INTRODUCTION

1.1 Background of study

Type 2 diabetes mellitus (T2DM) is a chronic disease that has become a significant global public health issue in the past few decades. Globally, 415 million people have been diagnosed with T2DM, with the incidence quadrupled since 1980 (Schatz, 2016). T2DM patients in Asia alone contributed to more than 60% of the world's diabetic population (Ramachandran, Snehalatha, Shetty, & Nanditha, 2012). In recent years, there has been a steadily increasing trend in T2DM, especially in low- and middle-income countries (LMIC) (World Health Organisation [WHO], 2016). In Malaysia, the National Health and Morbidity Survey (NHMS) showed that the overall prevalence of T2DM (both known and undiagnosed cases) among adults of 18 years old and above had increased from 11.6% in 2006 and 15.2% in 2011 to 17.5% in 2015 (Institute for Public Health (IPH), 2015; Non-communicable Disease Section. Ministry of Health, 2013).

Medication is one of the important elements in diabetes self-management worldwide including Malaysia to ensure that the blood glucose is well-controlled among the T2DM patients (Pharmaceutical Serviced Division. Ministry of Health Malaysia, 2014). Diabetes management in Malaysia health setting suggested the empowerment on the patients' assessment for medication issues, documentation actions and plans, provide medication education to patients, and completing follow-ups as the appropriate intervention to improve MNA (Pharmaceutical Serviced Division, Ministry of Health Malaysia, 2014). Therefore, it is vital for the healthcare providers to be fully equipped with knowledge on T2DM management for effective delivery of care for the diabetes patients (Ministry of Health, 2015).

In a recently published multinational study conducted across 28 countries, it was found that suboptimal glycaemic control among T2DM patients is a global issue happening in sync with the T2DM epidemic (Litwak et al., 2013). Suboptimal glycaemic reading casts a big implication as it affects patients' quality of life. Furthermore, it places a huge burden on the society and country due to prolonged hospitalisation, morbidity and mortality, and healthcare resources spent on providing the necessary care to the T2DM patient population (Alqarni, Alrahbeni, Al Qarni, & Al Qarni, 2019; Farhat et al., 2019).

Medication non-adherence (MNA) is important to be improved for T2DM patients to achieve optimal glycaemic control and successful diabetic management (Sontakke, Jadhav, Pimpalkhute, & Jaiswal, 2015). Also, despite the importance

and benefits of adherence to the prescribed medication, patients are still showing poor adherence to their medication (Curkendall, Thomas, Bell, Juneau, & Weiss, 2013). It is important to note that diabetic patients had one of the lowest treatment adherence rates among patients with chronic diseases, such as heart disease and cancer (Bailey & Kodack, 2011). Thus, this emphasises the importance of revamping the available intervention strategies to improve MNA among T2DM patients (Adisa & Fakeye, 2014).

There are various definitions of MNA proposed by different scholars and schools of thought. However, many studies applied the standard definition that was initially established by the WHO (2003). Following this definition, MNA is the extent to which a person's behaviour in taking medication not corresponds with the agreed recommendations from a healthcare provider (HCP). On the other hand, a few other researchers also described MNA either as dose not taken, irregular dosing, or discontinuation of medication (Adams & Stolpe, 2016; Courtenay, Carrier, & Bodman, 2015). Medication non-adherence can be an unintentional or intentional act by the patients. An intentional MNA is when the patient purposely decides not to take the medication. For example, patients with limited financial resources or cognitive problems may struggle and thus, ignore their medication regimens even though they know the importance of adhere to the medication.

Currently, the available literature demonstrates that the reasons for non-adherence are multifactorial in nature and involve both modifiable and non-modifiable factors. Non-modifiable factors include, but are not limited to age, disease duration (Bolarinwa et al., 2016), educational level (Kapawa-Mwale, 2014), while modifiable factors encompass knowledge about the disease and its treatment (Chlebowy, Hood, & Lajoie, 2010), medication complexity (Chung, Chua, Lai, & Morisky, 2015), family support (Tabasi, Madarshahian, Nikoo, Hassanabadi, & Mahmoudirad, 2014), and the severity of side effects (Dibonaventura, Gabriel, Dupclay, Gupta, & Kim, 2012). Taking into consideration the wide spectrum of these factors, WHO (2003) formulated a simplified way and categorised the factors of MNA into five dimensions, namely patient-related, socioeconomic-related, health-related, healthcare system-related, and therapy-related.

Considering the effect of MNA in impeding successful diabetes management, this study was performed among T2DM patients to determine the scenario of and factors associated with MNA in the Malaysian setting. The application of a mixed method approach imparted new ideas about MNA among T2DM patients and identify the factors of MNA. These valuable information added to the existing body of knowledge of this topic and contributed to the recommendation of patient-centred care (PCC) strategies to refine the existing guidelines of T2DM management.

1.2 Problem Statement

Medication has been reported as one of the important aspects of diabetes self-management to maximize blood glucose control among DM patients. However, the literatures found that MNA among diabetes patients was common. Local published study has reported 46.4% of diabetic patients in their study did not adhere towards medication (Chua & Chan, 2011). In a recent study conducted in India, Chatterjee (2006) reported that a large number of diabetic patients did not adhere to all aspects of diabetic care, especially in following the medication regimens prescribed by the doctors (Mathew, 2016). Non-adherence might deprive the T2DM patients of the benefits of the therapeutic regimens being offered to them. The MNA was a serious threat for patients and the society which significantly influences morbidity, mortality and healthcare costs (Brown & Bussell, 2011; Touchette & Sharp, 2019).

This issue is common in developing countries, including those in the Asian region, as highlighted in many studies (Nguyen et al., 2017). However, there are limited studies on MNA in Malaysia. Most of the available studies were confined to primary care clinic settings (Chua & Chan, 2011). Thus, this present study was conducted in a hospital-based setting and aimed to further enhance the exploration of the MNA patterns among T2DM patients who underwent treatment in two public hospitals in the Klang Valley, Malaysia.

Secondly, there is limited study that focused on exploring factors of MNA among non-adherent patients. Previously, the majority of the local studies that measured factors of non-adherence towards anti-diabetic medication were carried out using the quantitative approach (Yun, Hassan, Aziz, Awaisu, & Ghazali, 2007; Tan, Magarey, Chee, Lee, & Tan, 2011). In some instances, researchers who adopted the quantitative approach via questionnaires might be detached from the participants during the data collection. Consequently, an in-depth understanding of how the patients thought and felt about the treatment and the impact on their adherence behaviours were not be obtained by the researchers. Therefore, qualitative studies had been suggested to explore the factors of MNA to recognise the key factors that improve the MNA of patients (Kugbey, Asante, & Adulai, 2017). Furthermore, a study by Alsolami (2016) highlighted that the issue of MNA could be multifactorial. The author emphasised the importance of exploring multiple factors before making any definite conclusions, especially from the patients' perspective (Mukherjee, Sharmasarkar, & Das, 2013). Nevertheless, previous qualitative studies in this area were mainly conducted among the general diabetes population. There was no classification of the study population into adherent or non-adherent patients (Lee, Halimatun, Steven, & Ong, 2012; Jansiraninatarajan, 2013). In order to tackle the MNA issue, it is essential to focus on non-adherent patients. Understanding the reasons for non-adherent is the critical first step in developing strategies to improve MNA (Curkendall et al., 2013).

Apart from the general lack of qualitative studies in this area, there are also limited findings on the associated factors contributing to MNA in Malaysia. Most

of the available studies were conducted using quantitative methods (Chua & Chan, 2011; Lin, Sun, Heng, Chew, & Chong, 2017). Therefore, this mixed method study was conducted to explore the factors of MNA among non-adherent T2DM patients.

In order to comprehend what is lacking from the available quantitative and qualitative studies, this study employed a triangulation mixed method study design. A quantitative component was required to first identify the T2DM patients who did not adhere to the medication regime, followed by a qualitative study to explore the factors of non-adherence among them. This design was more comprehensive as the qualitative phase of the study would fill in the gaps and explore the quantitative findings on non-adherence (Blackmon, Laham, Taylor, & Kemppainen, 2016; Creswell, 2014). Similarly, Aloudah et al. (2018) also employed a mixed method design approach in their study because they felt that an inclusive critical method was better in recognising the barriers of adherence to the treatment.

In addition, MNA could be improved by having a clear understanding of its factors. Kim, Kim, Bowman, & Cho (2016) suggested more studies to be conducted to improve the understanding of how these determinant factors would improve MNA levels so that effective interventions could be developed. Furthermore, Jin, Sklar, Min, & Oh (2008) also recommended researchers and healthcare professionals to focus on the various strategies that could improve the MNA rate. Previous studies have shown that better strategy formulation in countering the MNA problems among T2DM patients was more effective than providing new and costly medical treatment. A comprehensive understanding of factors attributing to non-adherence would help to pinpoint the necessary patient-centred interventions (Psarou, Cooper, & Wilding, 2018). This study agreed that the implementation of more holistic and patient-friendly strategies would be a more cost effective and long-term solution. Such strategies would be able to address the underlying factors of patients' non-adherence to medication and subsequently improve their MNA. In the long term, the prescription of unnecessary medication and healthcare expenditure could be cut down.

1.3 Research questions

1 What is the prevalence of medication non-adherence among T2DM patients?
2. What is the relationship between the sociodemographic and clinical profiles and the medication non-adherence of the patients?
3. What are the factors that can influence non-adherent patients in not adherent with their prescribed medication?
4. What are the PCC strategies that can be recommended to improve patients' medication non-adherence?

1.4 General objective

To explore the factors of MNA among T2DM patients.

1.4.1 Specific objectives

This study was designed to achieve the following specific objectives:

1. To determine the prevalence of medication non-adherence (MNA) among T2DM patients.
2. To identify the relationship of MNA with the selected sociodemographic factors and clinical profiles among T2DM patients.
3. To explore the factors of MNA among non-adherent T2DM patients.
4. To recommend PCC strategies to improve MNA among T2DM patients.

1.5 Justification of the study

This study focused on T2DM patients. T2DM is a highly prevalent chronic disease worldwide, including in Malaysia. Based on a latest report in 2015, the prevalence of T2DM in Malaysia was 17.5% (Tee & Yap, 2017). Medication is the main DM treatment component and thus, represents an essential management aspect of T2DM (Alqarni et al., 2019). With the significant increase in the prevalence of T2DM and the importance of medication in controlling the disease, the issue of MNA has been under scrutiny in recent years. T2DM was reported as one of the chronic diseases with the highest incidence rate of MNA (Adisa & Fakeye, 2014). More worryingly, this non-adherence behaviour often lead to negative impacts and poorer disease prognosis, such as worsening microvascular and macrovascular complications, increase in mortality rate, and eventually, a huge rise the financial burden for both the patients and government (Alqarni et al., 2019; Kleinsinger, 2018; Adisa & Fakeye, 2014).

In 1999, 56% of MNA has been reported among the Malaysian population (Aziz & Ibrahim, 1999). Over a decade, MNA issue showed no greater improvement since its prevalence among Malaysian was 43% to 47% (Ahmad, Ramli, Islahudin, & Paraidathathu, 2013; Chew, Hassan, & Sherina, 2015). The unsatisfactory reduction in the prevalence of MNA among T2DM patients in a local context suggested on the need to conduct a study on non-adherence among T2DM patients to find a suitable solution for better improvement.

Furthermore, PCC is the goal of modern healthcare systems. Currently, many healthcare systems emphasise on providing PCC after patients are informed about the significant benefits of PCC (Freeman-Hildreth, Aron, Cola, & Wang, 2019). Even without the inputs from HCP, patients nowadays are more adept at getting health information, serving as partners for HCP, and collaborating in their treatment plan. Therefore, HCP must strive to understand their patients' preferences and views, besides taking into account their prior knowledge, skills, and experiences (Williams, Walker, Smalls, Hill, & Egede, 2016).

Globally, the term PCC is widely used. It is increasingly viewed as a crucial aspect of modern health and social care services (McCormack et al., 2015). PCC is a concept of care that can benefit healthcare systems overall (Epstein, Fiscella, Lesser, & Stange, 2010). In Malaysia, PCC is still regarded as a Western concept and not fully implemented by local HCP (Puziah, Hamidah, & Al, 2016). Puziah et al. (2016) stressed the importance of the implementation of PCC in the Malaysian healthcare system. However, many patients and HCP are still unfamiliar with PCC practices and their impacts on adherence, particularly among patients with chronic diseases that require long- term treatment.

In the literature, PCC was able to significantly improve patients' experience regarding their treatment (Baird, 2014). When patients were empowered to be actively involved in their health-related decision making, they were more likely to comply with their treatment plans and medication intake as agreed together with their doctors (Royal College of General Practitioners, 2014). This also meant that patients were more likely to adhere to their medication through PCC practice. The available evidence suggested that PCC improved the patient's level of satisfaction and would improve their adherence to the treatment plans (Epstein et al., 2010). Following that, proper implementation of PCC strategies is needed to achieve the full benefits of PCC in the field of patient care. PCC strategies can act as a written tool that represents patients' voices and emotions in terms of their decision making in health treatment. With this, patients will feel respected by HCP as PCC promotes the consideration of individuals' experience of life and disease. PCC also encourages HCP to respect the emotions, morals, and values of the patients. Jansiraninatarajan (2013) revealed in her qualitative study that T2DM patients believed their emotions to play a vital role in making them adhered to the therapeutic regimen.

Besides this, PCC strategies are constructed based on reliable sources from the patients themselves when it comes to the issue of non-adherence. Thus, PCC strategies may offer potential solutions to the issue of non-adherence at hand. Using PCC strategies, HCP can review the various non-adherence issues related to the emotions of the patients. This aspect is frequently overlooked by HCP during consultation. PCC may offer suitable health recommendations and interventions to be implemented by HCP based on the patients' needs and preferences. Previous studies have indicated that suitable interventions would contribute to a positive impact on the improvement of non-adherence levels (Johston, 2013).

1.6 Significance of the study

Apart from providing knowledge for future studies on the MNA of T2DM in Malaysia, the results from this study also served as references for the Ministry of Health Malaysia (MOH) to incorporate patients' views for future guideline development on disease management.

Moreover, the mixed methods approach with sequential explanatory design in this study could provide a better understanding of patients' point of view for the reference of future studies. This mixed methods design approach rendered an advantage over other published studies as it enabled the assessment of patients' experience towards MNA. This design revealed the underlying reasons for non-adherence among T2DM patients. Peeters, Tongelen, Duran, and Yüksel (2015) expressed a similar opinion that an extensive exploration of patients' perspectives on diabetes treatment was a useful starting point for the promotion of MA.

On top of that, this study provided positive implications to clinical practices, especially for nurses. It would help them to identify patients with a higher likelihood to be non-adherent to the medication. Based on the identification, relevant strategies could be planned to overcome the non-adherence issue. A previous study conducted in United Arab Emirates (UAE) reported that the contributing factors of non-adherence towards diabetes treatment must be identified before the planning of appropriate interventions to overcome this issue (Mohammed et al., 2014). The recognition of the factors would also enable nurses to select suitable nursing interventions in promoting patients' adherence to prescribed medication in their diabetes management programmes.

Lastly, the formulation of PCC strategies could contribute to the existing knowledge and insights of HCP, especially nurses. The delivery of effective and holistic care would lead to an improvement in the MNA of the T2DM patients through their involvement in the diabetes management care programmes.

1.7 Scope of the study

The scope of this study was on the prevalence of MNA, sociodemographic and clinical factors associated with the MNA, exploration of the factors of non-adherence, and recommendation of PCC strategies to improve MNA among T2DM patients in two public hospitals in the Klang Valley, Malaysia.

1.8 Organisation of the thesis

This thesis was presented in the following research chapters:

Chapter 1: Introduction.

This chapter comprised a brief background of research on MA to diabetes medication, followed by the problem statement, research questions, objectives of the study, justification of the study, significance of the study, scope of the study, and the operational definitions used in this study.

Chapter 2: Literature Review.

This chapter included an overview of the theoretical framework that underpinned this study and the conceptual framework used in the study. It was followed by a review on T2DM, adherence, type of medications, the prevalence of MNA, factors influencing MNA, and PCC.

Chapter 3: Methods.

A review of the research philosophy of the study was outlined. It consisted of two parts that presented the information about the methodological approach of the two phases of quantitative and qualitative study. The chapter also included information on the research design, the procedures and instruments used to collect and analyze data for this study.

Chapter 4: Results.

This chapter presented the results of both quantitative and qualitative study to answer the objectives of the study.

Chapter 5: Discussion.

This chapter discussed the findings for both quantitative and qualitative findings.

Chapter 6. Conclusion.

In this chapter, a description of the research strengths and limitations, implications for clinical practice, and recommendations for future practice was provided.

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