



UNIVERSITI PUTRA MALAYSIA

***EFFECTIVENESS OF A NURSE-LED DIABETES SELF-MANAGEMENT
EDUCATION ON GLYCOSYLATED HEMOGLOBIN AMONG IRANIAN
ADULTS WITH TYPE 2 DIABETES***

GOLNAZ AZAMI

FPSK(p) 2019 17



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By

GOLNAZ AZAMI

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

April 2019

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Abstract of thesis presented to the Senate of Universiti Putra Malaysia in fulfilment of the requirement for the degree of Doctor of Philosophy

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GOLNAZ AZAMI

April 2019

Chairman : Soh Kim Lam, PhD
Faculty : Medicine and Health Sciences

In recent years, great emphasis has been placed on the role of non-pharmacological self-management in the care of patients with diabetes. Studies have reported that nurses, compared to other healthcare professionals, are more likely to promote preventive healthcare seeking behaviors. The aim of this study was to investigate the effectiveness of a nurse-led diabetes self-management education on glycosylated hemoglobin. A two-arm parallel-group randomized controlled trial with the blinded outcome assessors was designed. One hundred forty-two adults with type 2 diabetes were randomized to receive either usual diabetes care (control group) or usual care plus a nurse-led diabetes self-management education (intervention group). Duration of the intervention was 12 weeks. The primary outcome was glycosylated hemoglobin (HbA1c values). Secondary outcomes were changes in blood pressure, body weight, lipid profiles, self-efficacy (efficacy expectation and outcome expectation), self-management behaviors, quality of life, social support and depression. Outcome measures were assessed at baseline and at 12 and 24 weeks post-randomization. Patients in the intervention group showed significant improvement in HbA1c, blood pressure, body weight, efficacy expectation, outcome expectation and diabetes self-management behaviors. The beneficial effect of a nurse-led intervention continued to accrue beyond the end of the trial resulting in sustained improvements in clinical, lifestyle and psychosocial outcomes.

This study is registered with the Iranian Registry of Clinical Trials number IRCT2016062528627N1.

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

**KEBERKESANAN PENDIDIKAN AHLI BUKAN FARMAKOLOGI
(JURURAWAT) DALAM PENGURUSAN DIRI PENJAGAAN PESAKIT
IRAN DEWASA DIABETES TAHAP 2**

Oleh

GOLNAZ AZAMI

April 2019

Pengerusi : Soh Kim Lam, PhD
Fakulti : Perubatan dan Sains Kesihatan

Dalam beberapa tahun kebelakangan ini, penekanan peranan telah diberikan kepada ahli bukan farmakologi dalam pengurusan diri penjagaan pesakit diabetes. Kajian telah melaporkan bahawa jururawat lebih cenderung untuk menggalakkan pesakit diabetes untuk menjaga kesihatan mereka dengan lebih baik berbanding ahli profesional dalam bidang kesihatan. Tujuan kajian ini adalah untuk mengkaji keberkesanan pendidikan pengurusan diri oleh jururawat terhadap pesakit diabetes “hemoglobin terglukosilat”. Dua kumpulan telah dipilih secara rawak untuk menguji keberkesanan kajian tersebut. Seratus empat puluh dua orang dewasa yang menghidap penyakit diabetes tahap 2 di pilih secara rambang untuk menerima rawatan sama ada penjagaan biasa (kumpulan kawalan) atau penjagaan biasa bersama jururawat untuk mengajar pesakit tentang pengurusan diri mereka dalam mencegah penyakit diabetes (kumpulan intervensi). Tempoh kajian adalah selama 12 minggu. Hasil utama yang akan dilihat adalah nilai perubahan “hemoglobin terglukosilat” (nilai HbA1c) pada pesakit, manakala hasil kedua yang akan di lihat adalah perubahan dalam tekanan darah, berat badan, profil lipid, keberkesanan pengurusan diri sendiri untuk menghidapi diabetes (keberkesanan dalam jangkaan dan hasil jangkaan), tingkah laku pengurusan diri, kualiti hidup, sokongan sosial dan kemurungan pesakit. Kedua-dua hasil di nilai pada ujian asas, dan selepas 12 dan 24 minggu ujian yang di ambil secara rawak. Hasil menunjukkan pesakit dalam kumpulan intervensi jururawat telah menunjukkan peningkatan yang ketara dalam tahap HbA1c, tekanan darah, berat badan, , keberkesanan pengurusan diri sendiri untuk menghidapi diabetes (keberkesanan dalam jangkaan dan hasil jangkaan), dan tingkah laku pengurusan diri. Kesimpulannya, intervensi seorang dalam penjagaan pesakit diabetes telah menghasilkan penambahbaikan yang berterusan dalam bidang klinikal, gaya hidup dan hasil psikososial pesakit. Kajian ini berdaftar dengan Pejabat Pendaftaran Iran daripada Ujian Klinikal IRCT2016062528627N1.

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I certify that a Thesis Examination Committee has met on 4 April 2019 to conduct the final examination of Golnaz Azami on her thesis entitled "Effectiveness of a Nurse-Led Diabetes Self-Management Education on Glycosylated Hemoglobin Among Iranian Adults with Type 2 Diabetes" in accordance with the Universities and University Colleges Act 1971 and the Constitution of the Universiti Putra Malaysia [P.U.(A) 106] 15 March 1998. The Committee recommends that the student be awarded the Doctor of Philosophy.

Members of the Thesis Examination Committee were as follows:

Abdah binti Md Akim, PhD

Associate Professor
Faculty of Medicine and Health Sciences
Universiti Putra Malaysia
(Chairman)

Roslida binti Abd Hamid @ Abdul Razak, PhD

Associate Professor
Faculty of Medicine and Health Sciences
Universiti Putra Malaysia
(Internal Examiner)

Khatijah Abdullah @ Lim Geok Khim, PhD

Professor
Faculty of Medicine
University of Malaya
Malaysia
(External Examiner)

Nursalam, PhD

Professor
Faculty of Nursing
Universitas Airlangga
Indonesia
(External Examiner)



RUSLI HAJI ABDULLAH, PhD
Professor and Deputy Dean
School of Graduate Studies
Universiti Putra Malaysia

Date: 26 June 2019

This thesis was submitted to the Senate of the 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:

Soh Kim Lam, PhD

Associate Professor
Faculty of Medicine and Health Sciences
Universiti Putra Malaysia
(Chairman)

Sazlina Shariff Ghazali, PhD

Associate Professor
Faculty of Medicine and Health Sciences
Universiti Putra Malaysia
(Member)

Salmiah Binti Md. Said, PhD

Senior Lecturer
Faculty of Medicine and Health Sciences
Universiti Putra Malaysia
(Member)



ROBIAH BINTI YUNUS, PhD

Professor and Dean
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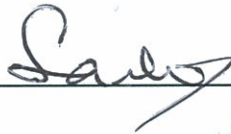
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Committee:



ASSOC. PROF. DR SOH KIM LAN:
PhD (Curtin, AUS) MHS (AUT, NZ), RN
Department of Nursing and Rehabilitation
Faculty of Medicine and Health Sciences
Universiti Putra Malaysia

Signature:
Name of Member
of Supervisory
Committee:



Dr. Sazlina Shariff Ghazali
Associate Professor & Family Medicine Specialist
MBBS (Adelaide) MMed Fam Med (UM), PhD (Monash)
Department of Family Medicine
Faculty of Medicine and Health Science,
University Putra Malaysia

Signature:
Name of Member
of Supervisory
Committee:



DR. SALMIAH BINTI MD. SAID
Medical Lecturer
Public Health Specialist
Full Registration No: 31079
Faculty of Medicine and Health Sciences
Universiti Putra Malaysia
43400 UPM Serdang Selangor

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LIST OF ABBREVIATIONS

T2DM	Type 2 Diabetes Mellitus
DSME	Diabetes Self-Management Education
WHO	World Health Organization
ADA	American Diabetes Associations
AADE	American Association Of Diabetes Educator
EC-SHMKH	Endocrine Clinic of Shahid Mostafa Khomeini
RCT	Randomized Controlled Trial
CONSORT	Consolidated Standards of Reporting Trials
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
FU	Follow-Up
IG	Intervention Group
CG	Control Group
BMI	Body Mass Index
LDL	Low Density Lipoprotein Cholesterol
HDL	High Density Lipoprotein Cholesterol
DMSES	The Diabetes Management Self-Efficacy Scale
PTES	Perceived Therapeutic Efficacy Scale
DSMQ	Diabetes Self-Management Questionnaire
WHOQOL-BREIF	World Health Organization Quality Of Life- Brief Version
MOS	Medical Outcome Study (Mos) Social Support Survey (Sss)
CES-D	Center For Epidemiologic Studies Short Depression Scale

CHAPTER 1

INTRODUCTION

1.1 Background

Type 2 diabetes mellitus (T2DM) is one of the most common endocrine disorders, which affects almost 6% of the adult population worldwide (Adeghate, 2006; De Lusignan, 2005; Gadsby, 2002). According to recent estimates, the total number of patients living with diabetes expected to rise significantly from 176 million in 2000 to 370 million in 2030, with more than four-fifths of them living in developing countries (Wild et al., 2004). Currently, Asia counts for more than 60% of the world's diabetic population. According to the World Health Organization (WHO), the largest relative increase in the prevalence of T2DM will occur in the Middle East, sub-Saharan Africa, and India (Hu, 2011). The Middle East is projected to bear the greatest burden of diabetes in the upcoming decades. In the Middle East, T2DM predominantly affects the economically productive age group (45 to 64 years old), unlike the situation in many developed countries where the mean age of patients with T2DM is generally over 65 years (Hu, 2011; Wild, 2004). The prevalence of diabetes in the Middle East raised significantly from 20,051 in 2000 to 52,794 in 2010 (Hu, 2011).

A major concern about this chronic condition is its negative impact on health. Poorly controlled T2DM often lead to costly complications including chronic cardiovascular diseases, stroke, neuropathy, nephropathy, retinopathy, amputation, severe infection, and poor quality of life (American Association of Diabetes Educators, 2009; Satirapoj, 2013). Diabetes is a costly disease to manage because of the chronic nature and its complications (World Health Organisation, 2015b). In 2013, the global healthcare expenditure for managing diabetes and its complications was estimated to total at least \$US 548 billion. This number is projected to exceed \$US 627 billion by the year 2035 (Lee, 2014). Diabetes patients living in low and middle-income countries pay a larger share of health expenditure than those living in high-income countries. It is possible that this might be due to the poor access to health services, lack of health insurance and expensive medical costs (Aguiree, 2013). The costs related diabetes are not only financial but also social and tangible costs such as missed working days, pain, anxiety, suffering, lower satisfaction and poor quality of life (World Health Organisation, 2015b). As the cost of diabetes management is high, developing and instituting clinically effective and cost-effective programs is essential (Forbes, 2009).

Glycemic control is considered as the primary therapeutic goal for prevention and management of diabetes-related complications. The main measure of glycemic control is glycosylated hemoglobin (HbA1c), which gives an average of the blood glucose over 12 weeks (Funnell, 2009). An HbA1c level of <7% is considered normal, otherwise, the patient's diabetes was not well controlled. Current estimations suggest that only 14.3% of patients with T2DM achieve and sustain the recommended goals for HbA1c (Ali, 2013). The American Diabetes Association (ADA) recognize diabetes

self-management education (DSME) is a critical element of care for diabetic patients and is necessary in order to improve the overall condition of diabetic patients (American Diabetes Association, 2015a). The DSME has emerged as a powerful resource to help patients inactively participate in the care process and make smart decisions about their own health care (Gucciardi, 2008). Diabetes self-management education (DSME) has been defined as “the ongoing process of facilitating the knowledge, skill, and ability necessary for diabetes self-care” (Funnell, 2009). The goals of DSME are to support informed decision-making, modify lifestyle behaviors, problem-solving, optimize glycemic control, and close collaboration with the healthcare team to maintain and enhance health status, quality of life and clinical outcomes (American Diabetes Association, 2013). Varieties of methods were been used to deliver patient education and teach self-management skills. There is currently no agreement on a single best-known education program that is superior to the rest. A growing body of evidence does indeed suggest that programs incorporating behavioral and psychosocial strategies with or without cross-cultural adaptation have indicated improved patient outcomes (Funnell, 2009; Haas, 2012b). Recently, it has been reported that follow-up studies conducted over a longer period of time are more likely to offer improved patient outcomes (American Diabetes Association, 2013; Piatt, 2010; Polonsky, 2003).

1.2 Problem statement

Given the high prevalence rates and associated complications, T2DM is a major concern for the healthcare system in Iran. T2DM typically affects Iranian patients in the most productive years of their lives. This becomes even more challenging when taking into account that the average age of diabetes patients in developed countries is significantly higher (over 65 years of age) (Esteghamati, 2008). With the prolongation of the average life expectancy, the occurrence of T2DM in the younger age groups will lead to the escalation of the disease-related disability-adjusted life years in Iran (Shaghghi, 2014). Thus, the prevention of serious complications, subsequent development of clinical disabilities, and patient’s quality of life completely depend on early diagnosis and adequate management of diabetes (Shaghghi, 2014).

In the past decades, several studies have shown that depression is common among patients with T2DM, affecting 30% of cases. Depressed patients with T2DM are at increased risk for cardiovascular morbidity and mortality (Pouwer, 2013). The underlying biological mechanisms linking depression to adverse health outcomes have not been completely clarified. One plausible contributing mechanism is the tendency of those with depressive syndromes to experience suboptimal glycemic control (Lustman, 2000), which might be due to less adherence to self-care behaviors (Gonzalez, 2007). Patients with T2DM who have depression are more likely to have distributed eating behaviors, less treatment-related adherence, and lower levels of physical activities (Ciechanowski, 2000; Lustman, 2000; Pouwer, 2013). Up to now, there is limited and somehow controversial information regarding the impact of depression on glycemic control, particularly in Iran. there is a high prevalence of depression in patients with T2DM in Iran (Khamseh, 2007) which negatively impacts their quality of life and worsen their condition.

Over recent decades, significant advances have been achieved in the psychosocial aspects of diabetes. A considerable number of these studies have specifically targeted social support (DiMatteo, 2004; Mayberry & Osborn, 2012; Rosland, 2008). However, the role of social support in glycemic control, especially in the context of self-management and self-efficacy, is not yet completely understood. Social support refers to the support that a patient receives from his/her social network such as family and friends and is generally classified into three major categories: informational, emotional and instrumental support (Lin, 2013). Previous studies showed that Patients from families that are cohesive tend to be more adherent to treatment than those from families live in conflicts (DiMatteo, 2004). Social support plays an important role in improving self-efficacy and diabetes self-management (Maeda, 2013). Self-management behaviors and self-efficacy are two of the most robust factors that have been linked to improved glycemic control in T2DM. According to the previous conducted systematic review in Iran, the status of self-management and social support in patients with diabetes was not favorable (Rad, 2013).

Nowadays, self-management education is considered to be an integral component of diabetes care. The guidelines for diabetes management education has been developed by Iran`s MOH. Despite the availability of national guidelines for diabetes management, there is still limited self-management education program available for patients with T2DM in Iran (Shakibazadeh, 2015). Even though patients with diabetes expressed a need for greater access to culturally appropriate education, there are limited comprehensive self-management education programs (Didarloo, 2012; Mohebi, 2013; Shakibazadeh, 2015; Zareban, 2014). A recent systematic review concludes that, due to the existence of conflicting evidence, it was not possible to reach any definitive conclusions about the effectiveness of DSME in Iranian population (Baradaran, 2010). Therefore, it becomes more and more important to implement clinically effective self-management educations to prevent or delay costly diabetes complications.

A broad search of the published literature in Iran revealed that very few intervention studies have been conducted to improve patient`s self-management in Iran. The literature that does exist has either been generated in the central or Eastern part of Iran. Little information is available about the self-management education in any west Iranian population (Kurdish ethnicity). Iranian adults with T2DM were chosen as the study population because of the high prevalence of T2DM and poor glycemic control compared to other ethnic groups. Rapid changes in the Iranian healthcare system obligate healthcare providers to deliver cost-effective and high-quality care for patients with T2DM. To the best of our knowledge, there is no published data on T2DM self-management education in Ilam. As a related issue, there is a crucial need to develop, implement, and promote efficacious and cost-effective diabetes self-management interventions for adults with T2DM to enhance patient outcomes. Thus, this study was conducted with the aim of filling this gap by developing, implementing and evaluating a theory-based diabetes self-management education suitable for patients with T2DM.

1.3 Significance of study

This study adds to the growing body of evidence on the need for effective diabetes self-management education for adults with T2DM. The researcher expects the findings of the current study to be useful for the context of the Iranian healthcare setting. Those who may have directly or indirectly received benefits from the results of this study are listed as follow.

To patients: Empowering patients to play an active role in self-management is key to achieve desirable diabetes outcomes and quality of life. Well-designed and well-implemented programs are very likely to be cost-effective and should thus be offered to all persons with T2DM.

To healthcare providers: Findings driven from this research can be incorporated into the education of health care professionals to make a widespread impact on health and well-being of patients with T2DM. By incorporating the study intervention into professional practice and staff education, healthcare providers can provide ongoing support to work towards optimal patient self-management behaviors, improve adherence and outcomes.

To the broader community: With the increasing prevalence of T2DM, affected community members must be equipped with the knowledge and skills they need to bring about change in their own lives in order to optimally manage their condition. Advances in knowledge of diabetes management have led to the increased public awareness of the supporting role of family members, friends and other broader community in managing diabetes.

To policymakers: The results of this study can provide up-to-date practical information for policymakers in improving diabetes self-management education. This would enable policymakers to identify priority areas for quality improvement that need to be addressed in line with the efforts for expansion of the diabetes care services. This subsequently leads to improved patients satisfaction with overall diabetes care.

1.4 Research questions

The research project sought to answer the following questions:

Research Question 1: Is the nurse-led DSME effective in improving self-management of patients with T2DM?

Within the Research Question 1 the following further questions will be examined:

Research Question 2: For people with T2DM, following the implementation of the intervention, is there a significant difference in the HbA1c levels between intervention and control groups across the study period (baseline, 3 and 6 months follow up)?

Research Question 3: For people with T2DM, following the implementation of the intervention, is there a significant difference between intervention and control groups across the study period (baseline, 3 and 6 months follow up) on the following measures?

- Lipid Profiles (Triglyceride, Cholesterol, LDL, HDL)
- Blood Pressure,
- BMI,
- Self-efficacy (efficacy expectation and outcome expectation),
- Diabetes self-management behavior
- Quality of life,
- Social support
- Depression

1.5 Objectives

1.5.1 General objective

To develop, implement and evaluate the effect of diabetes self- management education in improving care for people with T2DM

1.5.2 Specific objective

1. To develop a nurse-led diabetes self-management intervention for people with T2DM, based on self-efficacy theory
2. To implement the nurse-led diabetes self-management intervention in addition to the usual diabetes care
3. To determine the effectiveness of a nurse-led DSME intervention, in addition to the usual diabetes on glycosylated hemoglobin (HbA1c) across the study period (baseline, 3 and 6 month follow up).
4. To determine the effectiveness of a nurse-led DSME intervention, in addition to the usual diabetes care across the study period (baseline, 3 and 6 months follow up) on the following measures:
 - Lipid Profiles (Triglyceride, Cholesterol, LDL, HDL),
 - Blood Pressure,
 - BMI,
 - Self-efficacy (efficacy expectation and outcome expectation),
 - Diabetes self-management behaviors,
 - Quality of life,

- Social support
- Depression

1.6 Research hypothesis

The following hypotheses were tested:

1. There is a significant differences in the HbA1c levels between intervention and control groups across the study period (baseline, 3 and 6-month follow up)
2. There is any significant differences in the Lipid Profiles (Triglyceride, Cholesterol, LDL, and HDL), Blood Pressure, BMI, Self-efficacy (efficacy expectation and outcome expectation), Diabetes self-management behavior, quality of life, social support, and depression between intervention and control groups across the study period (baseline, 3 and 6-month follow up).

1.7 Theoretical framework

Intervention studies with a clear theoretical basis and a strong design are more effective than those without an explicit theoretical foundation (Jarvis, 2010; Norris, 2002b; Smith, 2002). Over the past three decades, Bandura`s Social Cognitive theory has been broadly applied in public health intervention as a framework for systematically developing effective interventions to promote health behavior change (Bandura, 1986; Bandura, 1977b). Self-efficacy is a key construct in Social Cognitive Theory and refers to “people`s judgment of their capabilities to organize and execute the course of action which require designated types of performances” (Bandura, 1986). The theory describes how people are more likely to do better and work harder on tasks over which they have high levels of competence. Patients with greater perceived self-efficacy are more likely to actively engage in their own healthcare and seek out additional information and support (Bandura, 1977a). Self-efficacy is the most commonly adopted theoretical framework for promoting self-management behaviors, whereby patients with higher self-efficacy are thought to be able to self-manage (Agema, 2012). Thus, self-efficacy was considered an appropriate theory to underpin the development of the study program of research. It has been hypothesized that self-efficacy plays a crucial role in motivating behavior change (Bandura, 1986; Shortridge-Bagget, 2001). Self-efficacy theory draws a clear connection between self-efficacy and facilitating change in behavior because it refers to the subjective evaluation of one`s ability to perform specific tasks (Bandura, 1982). Bandura outlines the role of self-efficacy in initiating, maintaining health behaviors and compliance to treatment that lead to the adoption of beneficial changes in health behavior (Strecher, 1986). (Refer to Figure 1.1).

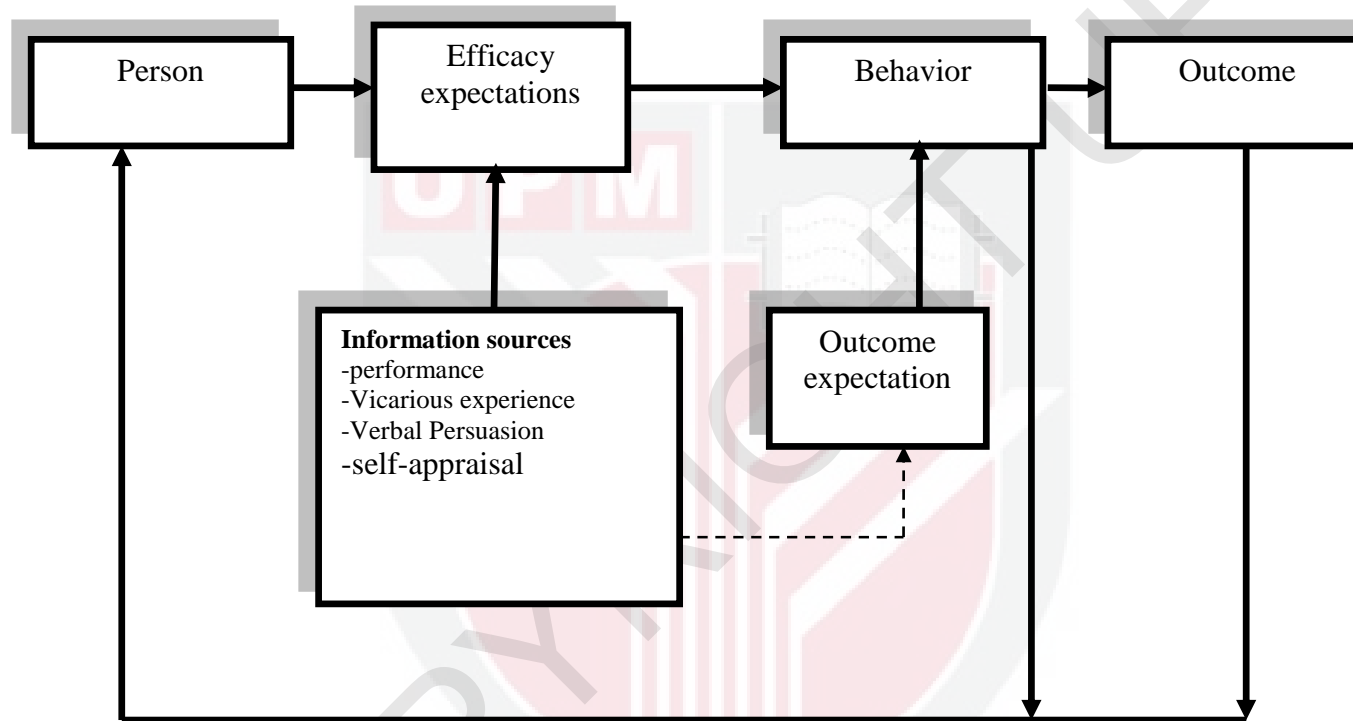


Figure 1.1 : Self-efficacy theory- structural path of influence
(Adapted from Bandura, 1977, 2004; Shortridge-Baggett & Van Der Bijl, 1996)

According to the above-mentioned paradigm (Figure 1.1), behavior change and maintenance are a function of efficacy expectation and outcome expectation. Efficacy expectation refers to beliefs in one's ability to successfully perform a specific behavior. Outcome expectation refers to beliefs about the consequence of a given behavior leading to the specific outcome. People are motivated to engage in tasks if they believe that they are capable of producing desired outcomes. Outcome expectation extremely depends on the efficacy expectation. As a result, efficacy expectation seemed to be more important than outcome expectation in predicting the performance (Bandura, 1986).

1.7.1 Self-efficacy theory components

The development of self-efficacy beliefs requires four main sources of information including performance accomplishments, vicarious experience, verbal persuasion and self-evaluation (Bandura, 1977a; van de Laar & van der Bijl, 2001).

1.7.1.1 Mastery experiences: practicing and earlier experiences

Mastery experience, also known as performance accomplishment, is the most powerful source of self-efficacy (Bandura, 1977a; van de Laar & van der Bijl, 2001). Smith (2002) stated two reasons for this. First, it is based on experiences that are direct and personal. Second, successful performance of a specific task is usually attributed to one's own effort and abilities (Smith, 2002). The patient experience of success may lead to improved self-efficacy, while regular failure may result in decreased self-efficacy particularly when the failure takes place early in the learning process. "Positive and negative experience can influence the ability of an individual to perform a given task. If one has performed well at a task previously, he or she is more likely to feel competent and perform well at a similarly associated task" (Bandura, 1997). Mastery experience is the strongest source of information for the development of self-efficacy beliefs. In turn, Self-efficacy beliefs contribute significantly to motivation to change and performance improvements (Bandura, 1986).

1.7.1.2 Vicarious experience: observation of others

The second source of self-efficacy is vicarious experience (observation of people around us). "people can develop high or low self-efficacy vicariously through other people's performance. A person can watch another perform and then compare their own competence with the other individuals' competence" (Bandura, 1997). Seeing other people successfully perform a task, helped people to believe that they too could successfully perform. These persons can serve as excellent examples (role models) for providing information about the level of difficulties experienced when performing specific tasks (Lenz, 2002).

1.7.1.3 Verbal persuasion

Verbal persuasion is the most common and easy to use sources of self-efficacy. “Verbal persuasion implies that people who are convinced verbally that they have the ability to accomplish a specific task are more likely to put in the effort and sustain it when problems arise. Self-efficacy is influenced by encouragement and discouragement pertaining to an individuals’ performance or ability to perform” (Bandura, 1997).

1.7.1.4 Physiological information: self-evaluation of physiological and emotional states

People experience sensation from their body and how they perceive this emotional arousal influences their beliefs of efficacy. Depression, for example, can decrease confidence in our capabilities. Positive emotions can boost our confidence in our skills whereas tension or stress reaction is interpreted as a sign of vulnerability to poor performance (Bandura, 1997).

Clearly, a concerted hierarchy exists among the four sources of self-efficacy. Mastery experience, the repeated performance of a task, is believed to be the most powerful sources because it is based on the direct information. This may result in success or failure. The other sources are based on indirect information. Vicarious experiences, observing how other people performing the desired behavior, can provide important information influencing self-efficacy but it is not based on one’s own experiences. Verbal persuasion, being convinced verbally that you have the ability to accomplish a task, is a weaker source of information and should be combined with any of the other three sources. Physiological information, people rely on their physiological and emotional responses to the activity to judge their ability, influences self-efficacy via positive or negative moods (Lenz, 2002).

1.7.1.5 Behavior

Many researchers have argued that people make decisions about what to pursue and what to avoid every day based on their level of self-efficacy. Self-efficacy is a strong predictor of behaviour; people engage in activities that they believe they competent to perform and avoid activities that they believe they cannot carry out (Bandura, 1986; Bandura, 1977b). For example, diabetes patients with lack of self-efficacy are likely to shy away from difficult tasks, such as sticking to a healthy diet or regular monitoring of blood sugar, which were perceived as a personal threat (Hockmeyer, 1990). On the other hand, diabetes patients with the strong sense of self-efficacy are likely to view the difficult task as challenges to be mastered rather than threats to be avoided (Lenz, 2002).

Bandura (1997) proposed that adaptive behaviors depend on a person's perception of three critical areas: risk perception, efficacy expectation (they believe that their behavior will decrease the risk), and outcome expectation (they believe they have the ability to change their behavior) (Bandura, 1977b). These three perceptions can influence individual's behavioral intention. Furthermore, these perceptions together can influence behaviour adoption from early initiation of the disease to long-term maintenance of healthy behaviours (Bandura, 1986).

1.8 Conceptual framework

Patients with chronic disease play an important role in the management of their condition. Diabetes is a chronic disease that requires long-term management. Low sense of self-efficacy is known as a key barrier to facilitate optimal patient's self-management (Glasgow, 2001). The model of self-efficacy adopted from Shorridge-Baggett & Van Der Bijl, (1996) was used as a conceptual framework for the present study (Refer to Figure 1.2). Key concepts in this model include personal characteristics, behavior, and patient outcomes. The basic idea underlying this theory is that expectation of personal mastery (efficacy expectation), and success (outcome expectation) predict whether a person will engage in a specific behavior, a hypothesized by Bandura (1977, 1986). The key aspects of the self-efficacy theory incorporated in the intervention are the efficacy and outcome expectation. Although efficacy expectation and outcome expectation are viewed as different mechanisms, their influence on behavior change is synergistic. Both self-efficacy (confidence in ability) and outcome expectation (belief that the behavior will have the desired effect) are required for any given outcome. The four main sources of the self-efficacy theory (performance accomplishment, vicarious experiences, verbal persuasion, and emotional arousal) were used as effective strategies to build the patient's confidence and prepare them for adapting healthy behaviors. The study intervention plays an important role in fostering self-efficacy and changing behavior of the patients to achieve optimal outcome. The primary outcome of this study was HbA1c. The secondary outcomes were blood pressure, lipid profiles, BMI, self-efficacy (efficacy expectation and outcome expectation), self-management behaviors, quality of life, social support, and depression.

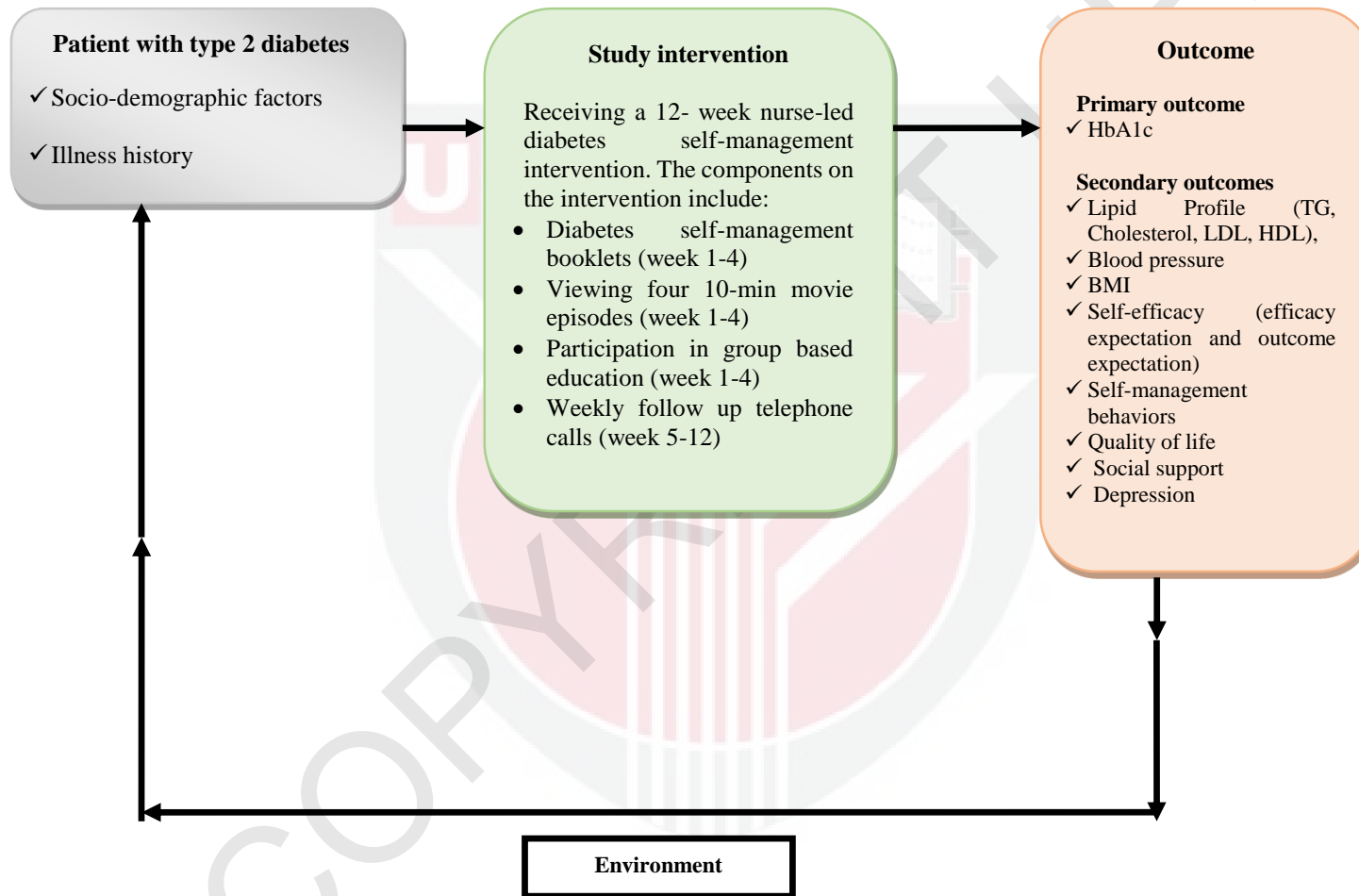


Figure 1.2 : Conceptual framework of study

1.9 Definition of terms

Here, a glossary of key terms used in this study clearly defines both conceptually and operationally as follow:

1.9.1 Type 2 diabetes

Conceptual definition: Type 2 diabetes (also known as type II, none-insulin-dependent diabetes mellitus) is characterized by insulin resistance and progressive decline in beta cell function (**Gavin III, 1997**).

Operational definition: patients were eligible if they had been diagnosed with type 2 diabetes for at least 6 months.

1.9.2 Glycosylated hemoglobin test

Conceptual definition: glycosylated hemoglobin (also known as hemoglobin A1C) is a blood test that can be used to follow-up the average blood sugar levels over the last 3 months. this can indicate that how well a person`s diabetes is controlled. The normal level for HbA1c is less than 7%. Individuals with diabetes rarely achieve an ideal level of HbA1c, but tight glycemic control aims to come close to it (Online Medical Dictionary, 2017).

Operational definition: HbA1c is the primary outcome of this study as measured by testing the differences between groups in the mean of HbA1c. for patient with diabetes, The goal of glycemic control is not achieved if HbA1c is $\geq 8\%$ as recommended by American diabetes association (American Diabetes Association, 2015b). Thus, in this study the researcher only consider those patients with baseline HbA1c $\geq 8\%$.

1.9.3 Triglyceride test

Conceptual definition: Triglyceride refer to the fatty acids that are normally found in our body. The levels of serum triglyceride less than 150 mg/dL (1.7 mmol/L) are considered in the healthy, normal range (American Association for Clinical Chemistry, 2014).

Operational definition: Triglyceride is one of the secondary outcomes of the study as measured by testing the differences between groups in the mean of Triglyceride.

1.9.4 Total cholesterol test

Conceptual definition: Total cholesterol test measures the amount of cholesterol in the blood. The levels of serum cholesterol less than 200 mg/dL (5.18 mmol/L) are considered in the healthy, normal range (American Diabetes Association, 2013).

Operational definition: Total cholesterol is one of the secondary outcomes of the study as measured by testing the differences between groups in the mean of cholesterol.

1.9.5 Low density lipoprotein cholesterol test (LDL)

Conceptual definition: LDL is known as bad cholesterol. The levels of serum LDL less than 100 mg/dL (2.6 mmol/L) are considered in the healthy, normal range (American Diabetes Association, 2013).

Operational definition: LDL is one of the secondary outcomes of the study as measured by testing the differences between groups in the mean of LDL.

1.9.6 High-density lipoprotein cholesterol test (HDL)

Conceptual definition: HDL is known as good cholesterol. The levels of serum HDL greater than 40 mg/dL (1.0 mmol/L) in men and greater than 50 mg/dL (1.3 mmol/L) in women are considered in the healthy, normal range (American Diabetes Association, 2013).

Operational definition: HDL is one of the secondary outcomes of the study as measured by testing the differences between groups in the mean of HDL.

1.9.7 Blood pressure

Conceptual definition: Blood pressure is the force of blood against the walls of the arteries. For individuals with diabetes a blood pressure reading of 135/80 is considered to be within normal range (Jovinelly, 2012).

Operational definition: Blood pressure is one of the secondary outcomes of the study as measured by testing the differences between groups in the mean of systolic and diastolic blood pressure.

1.9.8 Body mass index (BMI)

Conceptual definition: BMI is a simple index of weight and height that is commonly used to classify underweight, overweight and obesity in adults. It is defined as the weight in kilograms divided by the square of the height in meters (kg/m^2). The International Classification of adult underweight, overweight and obesity according to BMI ranges (kg/m^2) are as follow: sever thinness (<16), moderate thinness (16-17), mild thinness (1-18.5), normal (18.5-25), overweight (25-30), obese class I (30-35), obese class II (35-40), and obese class III (>40) (World Health Organisation, 2015a).

Operational definition: BMI is one of the secondary outcomes of the study as measured by testing the differences between groups in the mean of BMI.

1.9.9 Self-efficacy

Conceptual definition: self-efficacy is “people’s judgment of their capabilities to organize and execute the course of action which require designated types of performances” (Bandura, 1986). Self-efficacy theory posits there are two main constructs including efficacy expectation and outcome expectation. Efficacy expectation refers to the beliefs that an individual can successfully perform a specific task. Outcome expectation refers to the beliefs that certain kind of behavior may result in certain outcomes (Bandura, 1986).

Operational definition: Key concepts of Bandura’s self-efficacy theory (efficacy expectation and outcome expectation) were measured. Efficacy expectation measured using the Diabetes Management Self-Efficacy Scale (DMSES). Outcome expectation measured using the Perceived Therapeutic Efficacy Scale (PTES).

1.9.10 Diabetes self-management

Conceptual definition: Self-management is recognized as an essential aspect of care, particularly for patients with chronic diseases. The main goal of diabetes self-management is to monitor blood glucose levels and guide patients in making adjustments to lifestyle or treatment to achieve optimal glycemic control (Chen, 2013).

Operational definition: Diabetes self-management behavior is one of the secondary outcomes and as measured using the Diabetes Self-Management Questionnaire (DSMQ).

1.9.11 Quality of life

Conceptual definition: Quality of life has been defined as “a concept encompassing a broad range of physical and psychological characteristics and limitations, which describe an individual’s ability to function and to derive satisfaction from doing so” (Walker, 1988).

Operational definition: Quality of life is one of the secondary outcomes and as measured using the World Health Organization Quality of Life brief version scale (WHOQOL-BRIEF).

1.9.12 Social support

Conceptual definition: social support refers to the sense of support that people receive from others. Social support is generally classified into three categories: emotional, instrumental, and informational support. Emotional support refers to “the things that people do that make us feel loved and cared for, that bolster our sense of self-worth (e.g., talking over a problem, providing encouragement/positive feedback)”. Instrumental support refers to “the various types of tangible help that others may provide (e.g., help with childcare/housekeeping, provision of transportation or money”. Informational support refers to “the help that others may offer through the provision of information” (Seeman, 2008).

Operational definition: social support is one of the secondary outcomes and as measured using the Medical Outcomes Study (MOS) Social Support Survey (SSS) tool.

1.9.13 Depression

Conceptual definition: Depression is a common and serious disorder that results in a variety of emotional and physical problems and can decline in functioning ability and impairment to quality of life (Murray, 1996).

Operational definition: *Depression* is one of the secondary outcomes and as measured using the Centre for Epidemiology Studies Short Depression Scale (CES-D).

1.10 Thesis structure

Chapter 1 has outlined the background, problem statement, significance of this study, presenting research questions, objectives, hypotheses and outcomes. The framework of the study is described in chapter one as well.

In chapter 2, literature review was conducted.

Chapter 3 is divided into four sections. Section 1 presents the study method for the systematic review and meta-analysis. Section 2 presents the study method for translation and pre-testing of the existing validated diabetes-related instruments in Iranian population. Section 3 discusses the study method for developing the intervention component based on self-efficacy theory and pre-testing the intervention. Section 4 presents the study methods including study setting, design, sampling, ethical consideration, data management and data analysis of the main randomized control trial.

Chapter 4 outlines the results of the systematic review and meta-analysis. it followed by the result of the pilot testing of the instruments, the result of validating the intervention, and the main study results, participants' characteristics and retention. Chapter 5 outlines the discussion on the findings of the study. Chapter 6 outlines the summary, conclusion and future recommendation.

1.11 Summary

In summary, the motivation for exploring this study is based on the increasing trend of diabetes prevalence, low self-management abilities, poor glyceemic control, and lack of Randomized Controlled Trials (RCT) for diabetes management in Iran, particularly in Kurdish population. The purpose of this study was to assess whether a nurse-led diabetes self-management education based on the self-efficacy theory can improve glyceemic control and other efficacy parameters in Iranian adults with T2DM.

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BIODATA OF STUDENT

Name: Golnaz Azami

Father`s name: Javad Azami

Date of Birth: 07.05.1985

Contact Number: +601135425065 & +989183446450

Email Address: golnaz.azami64@gmail.com

Nationality: Iranian

Language Known: Persian, Kurdish, English

Carrier objective

Soon-to-graduate honors PhD in nursing student, fluent in Persian and with three years of experience working as a staff nurse/lecturer, seeks a position as a lecturer or post-doc fellowship.

Education

Bachelor of Nursing science at Ilam University of Medical Sciences (year obtained: 2009)

Master of nursing Science at University Malaya (year obtained: 2014)

PhD in nursing at University Putra Malaysia (expected date of graduation: October 2019).

My academic training and three years of experience working as a staff nurse/lecturer prepare me to be an effective researcher in the future. I have a passion for providing quality care to patients, and the necessary leadership skills to inspire other staff members to strive to provide above standard levels of service. I have a wide knowledge base in the field of nursing and am enthusiastic about sharing personal insight with you. I have the ability to work independently and as a member of a team. I have a strong problem-solving ability, communication skills, and adaptability.

LIST OF PUBLICATIONS

The following manuscript has been published:

G Azami, K. L. Soh, S. G. Sazlina, M. S. Salmiah, S Aazami, M Mozafari, H Taghinejad (2018). Effect of a Nurse-Led Diabetes Self-Management Education Program on Glycosylated Hemoglobin among Adults with Type 2 Diabetes. *Journal of diabetes research*. Volume 2018, Article ID 4930157.

G Azami, K. L. Soh, S. G. Sazlina, M. S. Salmiah, S Aazami, M Mozafari, H Taghinejad (2018). Validation of the Iranian/Persian Version of the Perceived Therapeutic Efficacy Scale for Type 2 Diabetes. *Archives of Iranian Medicine*. Vol. 21 Issue 8, p356-361.

Azami, G., Soh, K. L., Sazlina, S. G., Salmiah, M. S., & Aazami, S. (2018). Behavioral interventions to improve self-management in Iranian adults with type 2 diabetes: a systematic review and meta-analysis. *Journal of Diabetes & Metabolic Disorders*, 1-16.

Developing and validating the educational materials for a nurse-led self-management education in adults with type 2 diabetes (2018). *International Journal Of Diabetes And Metabolism*.

List of proceeding:

Predictors of diabetes self-management behaviors among adults with type 2 diabetes In Iran (2018). Submitted in the *Iranian Journal of diabetes and obesity*.

The mediating roles of self-efficacy and diabetes self-management behaviors on the association between social support and glycemic control (2018). Submitted in the *Archives of Iranian Medicine*.

The Effect of Depression on Glycemic Control in Adults with Type 2 Diabetes: The Mediating Roles of Self-Efficacy and Self-Management Behaviors (2018). Submitted in the *international journal of diabetes and metabolism*.

Social support, depression and quality of life: mediating roles of self-efficacy, self-management behaviors, and glycemic control (2018). Under preparation

Letter to the editor: Alarming prevalence of Comorbid conditions in adults with type 2 diabetes in Iran . Submitted in the *Journal of Diabetes & Metabolic Disorders*.



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