DEVELOPMENT AND EVALUATION OF A CULTURALLY-SPECIFIC DIABETES SELF-MANAGEMENT EDUCATION AND SUPPORT PROGRAMME FOR TYPE 2 DIABETES MELLITUS PATIENTS IN BAGHDAD, IRAQ: A MIXED-METHOD STUDY

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by

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"Ask, and it will be given to you. Seek, and you will find. Knock, and the door will be opened to you". All praise and thanks to Almighty God, who blessed and guided me during my thesis journey and throughout my life.

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LIST OF ABBREVIATIONS

AADE	American Association of Diabetes Educators
ACR	Albumin to creatinine ratio
ADA	American Diabetes Association
ADCES	Association of Diabetes Care and Education Specialists
BMI	Body Mass index
BP	Blood pressure
CD	Control dominant
CDSMS	Comprehensive Diabetes Self-Management Scale
CG	Control group
CHD	Coronary heart disease
CEA	Cost-effectiveness analysis
CER	Cost effectiveness ratio
CVD	Cardiovascular disease
DBP	Diastolic blood pressure
DM	Diabetes Mellitus
DSM	Diabetes self-management
DSME	Diabetes self-management education
DSME(S)	Diabetes self-management education and support
FBG	Fasting blood glucose
GDP	Gross domestic product
HbA1c	Glycosylated hemoglobin
HDL-C	High density lipoprotein-cholesterol
IADMAS	Iraqi Anti-Diabetic Medication Adherence Scale
ID	Iraqi dinar
IDF	International Diabetes Federation
IG	Intervention group
LDL-C	Low density lipoprotein-cholesterol
MAQ	Medication Adherence Questionnaire
NDC	National Diabetes Center
PPBG	Post-prandial blood glucose
QET	Quasi experimental trial
QRT	Quasi-randomized trial
QOL	Quality of life
QOLSID	Quality of Life Scale for Iraqi Diabetic Patients
RCT	Randomized controlled trial
RDBCL	Randomized double blind controlled clinical trial
ROC	Receiver operating characteristics
SBP	Systolic Blood pressure
SMBG	Self-monitoring of blood glucose
T2DM	Type 2 diabetes mellitus
TC	Total cholesterol
TG	Triglycerides
WHO	World Health Organization

LIST OF APPENDICES

PEMBANGUNAN DAN PENILAIAN PROGRAM PENDIDIKAN DAN SOKONGAN PENGURUSAN DIRI DAN PENDIDIKAN DIABETIS KHUSUS DALAM KALANGAN PESAKIT DIABETIS MELITUS JENIS 2, DI BAGHDAD, IRAQ: KAJIAN KAEDAH CAMPURAN

ABSTRAK

Kebanyakan pesakit Iraq yang menghidapi diabetes jenis 2 (T2DM) tidak mencapai sasaran glisemik kerana kekurangan program pendidikan dan sokongan pengurusan diri diabetes (DSME(S)). Kajian semasa bertujuan untuk meneroka pengetahuan dan amalan pesakit T2DM di Pusat Diabetes Kebangsaan, Baghdad, Iraq terhadap tingkah laku pengurusan diri diabetes (DSM); dan juga menghasilkan alat khusus budaya untuk menilai DSM, pematuhan ubat dan kualiti hidup (secara kolektif, DMAQ) bersama-sama dengan pembangunan program DSME(S) berasaskan budaya dan menilai manfaat dan keberkesanan kos program. Kajian ini menggunakan pendekatan kaedah campuran. Kajian kualitatif telah dilak sanakan melalui temubual separa berstruktur keatas 25 pesakit T2DM. Program DSME(S) dan skala hasil yang dilaporkan pesakit telah dibangunkan dan disahkan pakar. Kajian keratan rentas yang melibatkan sampel 10 peserta setiap item (80-140 peserta) telah dijalankan untuk menilai kebolehpercayaan skala dan kesahan serentak. Program DSME(S) yang disahkan telah dinilai melalui percubaan terkawal buta-tunggal-terawak. Sampel pesakit T2DM dengan HbA1c≥7% distratifikasikan secara rawak kepada blok berdasarkan tahap HbA1c (mereka yang mempunyai HbA1c≥7 dan<8% dan mereka yang mempunyai HbA1c≥8%) kepada sama ada intervensi (39 pesakit) atau kumpulan

kawalan (39 pesakit). Pembolehubah hasil termasuk HbA1c (hasil utama), glukosa darah puasa (FBG), tekanan darah (BP), profil lipid, dan hasil yang dilaporkan oleh pesakit dinilai pada garisdasar, selepas 3 dan 6 bulan. Pada akhir kajian, keberkesanan kos program yang dibangunkan telah dianalisis. Hasil kajian kualitatif menunjukkan bahawa saranan pemakanan sihat dan aktiviti fizikal kurang diamalkan oleh kebanyakan peserta. Kekurangan pengetahuan yang mencukupi merupakan penghalangutama untuk mengamalkan DSM dengan betul. Kebanyakan peserta mempunyai sikap positif terhadapamalan DSM dan program DSME.Semua skala yang dihasilkan menunjukkan konsistensi dalaman yang baik (alfa Cronbach >0.7), kebolehpercayaan uji-uji semula yang stabil (nilaiP<0.05), dan korelasi yang signifikan dengan nilai HbA1c (P<0.001). Pada akhir percubaante rawak, tingkah laku DSM telah meningkat secara signifikan (86.7% dalam kumpulan intervensi Lwn. 56.7% dalam kumpulan kawalan; nilai P = 0.001), manakala HbA1c bertambah baik sebanyak 1.05% dalam kumpulan intervensi, dan 0.29 % dalam kumpulan kawalan (nilai P = 0.073). Program DSME(S) yang dibangunkan mempunyai keberkesanan kos yang tinggi dalam menambahbaik tahap HbA1c, FBG, jumlah kolesterol, BP sistolik dan diastolik, dan trigliserida sebanyak 1 unit, dengan kos tambahan masing-masing sebanyak USD14.08, USD0.94, USD4.05, USD0.95, USD3.85, dan USD14.83. Kesimpulannya, pengetahuan dan amalan semasa tingkah laku DSM adalah lemah manakala sikap terhadap program DSMEdalam kalangan pesakit T2DM yang mengambil bahagian adalah positif.Selainitu, skala yang dihasilkan adalah sah dan boleh dipercayai untuk menilai DMAQ dalam kalangan pesakit T2DM Iraq, dan program DSME(S) khusus budaya yang dibangunkan boleh menambahbaik HbA1c. Penambahbaikan ini adalah kos berkesan dan kebanyakannya ditentukan oleh peningkatan signifikan dalam tingkah laku DSM.

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ABSTRACT

Most Iraqi patients with type 2 diabetes (T2DM) do not achieve the glycemic target due to the lack of available diabetes self-management education and support (DSME(S)) programs. The current study aimed to explore the knowledge and practice of T2DM patients at the National Diabetes Center, Baghdad, Iraq towards diabetes self-management (DSM) behaviors; besides, developing culturally-specific tools to assess DSM, medication adherence, and quality of life (collectively, DMAQ) along with the development of a culturally-based DSME(S) program and evaluating its benefits and cost-effectiveness. The study utilized the mixed methods approach. A qualitative study was performed by a semi-structured interview on 25 T2DM patients. DSME(S) program and patient-reported outcome scales were developed and expert-validated. A cross-sectional study involving a convenient sample of 10 participants per item (80-140 participants) was conducted to assess the scale's reliability and concurrent validity. The validated DSME(S) program was assessed through a randomized-single-blind controlled trial. A sample of T2DM patients with HbA1c≥7% was randomly stratified into blocks based on the HbA1c level (those with HbA1c≥7 and<8% and those with HbA1c≥8%) to either the intervention (39 patients) or control group (39 patients). Outcome variables including HbA1c (primary outcome), fasting blood

glucose (FBG), blood pressure (BP), lipid profile, and patient-reported outcomes were assessed at the baseline, after 3 and 6 months. At the end of the study, cost-effectiveness of the developed program was analyzed. The results of the qualitative study showed that healthy eating and physical activity recommendations were inadequately practiced by most participants. Lack of sufficient knowledge was the main barrier to practice DSM properly. Most participants had positive attitudes toward DSM practices and DSME programs. All developed scales showed good internal-consistency (Cronbach's alpha >0.7), stable test-retest reliability (P-value<0.05), and significant correlation with HbA1c values (P<0.001). At the end of the randomized-trial, DSM behaviors were significantly improved (86.7% in the intervention group Vs. 56.7% in the control group; P-value= 0.001), while HbA1c improved by 1.05% in the intervention group, and 0.29% in the control group (P-value = 0.073). The developed DSME(S) program was highly cost-effective in improving HbA1c level, FBG, total cholesterol, systolic and diastolic BP, and triglycerides by 1 unit, with an incremental cost of USD14.08, USD0.94, USD4.05, USD0.95, USD3.85, and USD14.83, respectively. In conclusion, the current knowledge and practice of DSM behaviors were poor while the attitudes towards DSME program were positive among participated T2DM patients. Additionally, the developed scales were valid and reliable to assess DMAQ among Iraqi T2DM patients, and the developed culturally-specific DSME(S) program can improve HbA1c. This improvement was cost-effective and mainly attributed to the significant improvement in DSM behaviors.

CHAPTER 1

INTRODUCTION

1.1 Background

Diabetes mellitus (DM) is a chronic and heterogeneous metabolic disorder characterized by the presence of hyperglycemia due to a defect in insulin secretion and/or insulin action (Banday, Sameer, & Nissar, 2020).

Diabetes mellitus is a very common metabolic disease worldwide. According to the International Diabetes Federation (IDF), the global DM prevalence was significantly increased in the last decades. The number of adults, aged older than 18 years, who were living with DM was 151 million in 2000. This number increased dramatically to 463 million in 2019 with a prevalence of 9.3% and expected to continue rising to reach 10.9% at which 700 million adults living with DM in 2045. A similar but more dangerous scenario is seen in the Middle East and North Africa region at which the prevalence of DM in adults (12.5%) was the highest than all other regions in 2019 and expected to continue rising to reach about (14.2%) in 2045 (Saeedi et al., 2019).

There are many types of DM including type 1, type 2, and Gestational DM, besides a group of other rare types that caused by specific genetic defects of beta-cell function or insulin secretion, diseases of the exocrine pancreas, or induced by drugs or chemicals (American Diabetes Association, 2020a). Anyhow, type 2 DM (T2DM) is the most common type that accounts for approximately 90% of all DM cases (Zheng, Ley, & Hu, 2017). T2DM is characterized by hyperglycemia which is mainly caused by a diminished response to insulin (i.e., insulin resistance). This resistance overtime accompanied by inadequate insulin secretion (Galicia-Garcia et al., 2020). Insulin resistance, is attributed to high plasma levels of free fatty acids and pro-inflammatory

cytokines that lead to decreased glucose transport into muscle cells, elevated hepatic glucose production, and increased breakdown of fat (Galicia-Garcia et al., 2020; Khan, Cooper, & Del Prato, 2014).

Type 2 DM can be implicated in causing both acute and chronic complications. Acute T2DM complications include hyperglycemic complications, such as hyperglycemic hyperosmolar non-ketotic coma, and to a lesser extent, hypoglycemia and diabetic ketoacidosis (Negera, Weldegebriel, & Fekadu, 2020). The acute complications especially hyperglycemic crises are associated with increased hospitalization and death rate (Harding, Pavkov, Magliano, Shaw, & Gregg, 2019).

Hyperglycemia and insulin-resistant are the major causes of developing long-term chronic T2DM complications (Defronzo et al., 2015; Balaji, Duraisamy, & Kuma, 2019; Abuyassin & Laher, 2016). These complications are divided into macrovascular (coronary heart, peripheral, and cerebrovascular disease) and microvascular complications (retinopathy, nephropathy and neuropathy) (Zheng, Ley, & Hu, 2017). In this regard, T2DM patients demonstrate 2-4 times greater risks of developing macrovascular complications and they are at 10-20 times greater risks for developing microvascular complications than non-diabetic individuals (Zheng, Ley, & Hu, 2017). Chronic DM complications predispose to various negative consequences. They include increased morbidity (Zimmet, Magliano, Herman, & Shaw, 2014), reduced life expectancy (GBD 2013 Mortality and Causes of Death Collaborators, 2015), and lower individual's quality of life (Makrilakis et al., 2018; Wermeling, Gorter, van Stel, & Rutten, 2012; Verma & Dadarwal, 2017) that can be defined as the degree of an individual physical, psychological and social well being (Chaturvedi & Muliyala, 2016). Thus, DM represents a burden to individuals, families, society, and even to health care systems (Zimmet et al., 2014).

1.2 Management of diabetes mellitus

According to the latest report by the American Diabetes Association (ADA) and the European Association for the Study of Diabetes, **optimum control of hyperglycemia cannot be achieved by anti-diabetic medications alone.** Effective control can be accomplished through patient-centered diabetes care, which mainly focuses on prescribing medications after shared decision-making, besides the education of each patient about lifestyle changes (e.g., diet, physical activity, and self-monitoring of blood glucose) (Davies et al., 2018). This means that patient education is one of the essential elements of diabetes care (Siminerio et al., 2018). Meanwhile, any educational program can't be effective for diabetes care unless it is based on improving knowledge "Knowledge is a highly valued state in which a person is in cognitive contact with reality (Zagzebski, 2017)", increasing DM awareness, and supporting behavioral changes (Siminerio et al., 2018). Therefore, ADA considers diabetes self-management education and support (DSME(S)) programs as a cornerstone part of diabetes care and management (Powers et al., 2016; Stephani, Opoku, & Beran, 2018; American Diabetes Association, 2018e). These programs can be defined as "the ongoing process of facilitating the knowledge, skills, and ability necessary for diabetes self-care, as well as activities that assist a person in implementing and sustaining the behaviors needed to manage his or her condition on an ongoing basis, beyond or outside of formal self-management training", (Beck et al., 2017).

In this regard, the Association of Diabetes Care & Education Specialists (ADCES) 7 self-care behaviors ™ can be considered as a useful framework for DSME(S) programs (Beck et al., 2017). ADCES self-care behaviors consist of seven points essential for DSM including: healthy eating, physical activity, taking medications, blood glucose monitoring, problem solving (including hypoglycemia and

management of DM during sick days), reducing DM risks, and healthy coping with stress (American Association of Diabetes Educators, 2009). For achieving maximum benefits from an educational program, these self-care behaviors should be delivered to the patient through a patient-centered approach rather than a didactic education approach (Windrum, García-Goñi, & Coad, 2016).

1.3 Economic burden of diabetes

Diabetic patients need higher medical expenditure compared with the general population (American Diabetes Association, 2018a). For example in 2019, the IDF estimated that US$760 billion was spent on DM treatment, and this expenditure is anticipated to further increase and become $845 billion by 2045 (R, Williams et al., 2020). Meanwhile, the majority of this medical expenditure is directed toward treating DM complications especially renal and cardiac problems (Zimmet et al., 2014).

The economic burden for having T2DM is not limited to the cost of treating DM and its complications; it also involves costs attributed to the low quality of life, disability, and loss of productivity (American Diabetes Association, 2018a).

Achievement of glycemic control can reduce the overall cost of DM treatment (Herman, 2013) through prevention or at least delaying the development of DM complications (Simó & Hernández, 2002; American Diabetes Association, 2018c), thus reducing the direct costs resulting from treating these complications and the indirect costs by improving the patient quality of life (Simó & Hernández, 2002; Hirsch & Morello, 2017). However, glycemic targets cannot be achieved by pharmacological therapies without practicing self-care by the patients (Tegegne et

al., 2014). In this regard, it has been found that DSME(S) is a cost-effective method of DM management and care (Powers et al., 2016; Siegel et al., 2020).

1.4 Problem statement

The prevalence of DM in Iraq is 7.6% according to the reports of the IDF (International Diabetes Federation, 2019). On the other hand, DM prevalence may be higher, approaching 19.7%, after taking into account the number of individuals previously undiagnosed with DM along with those already diagnosed with it (Mansour, Al-Maliky, Kasem, Jabar, & Khalid, 2014). Moreover, this prevalence is significantly increased (~4 times) in the last four decades. It will continue to rise in the future (Mansour & Al Douri, 2015). The significant increase in DM prevalence among Iraqi people may be related to aging and obesity that is caused by the shift towards a western sedentary lifestyle (i.e., a dramatic decrease in physical activity and the consumption of an unhealthy diet such as fast food, French fries, sweets, and soft drinks). Additionally, the excessive and irrational use of nonprescription corticosteroids (e.g., in management of common cold symptoms) may be another factor for this dramatic increase in the prevalence of DM (Mansour & Al Douri, 2015; Hwang & Weiss, 2014).

Type 2 DM is implicated in lowering quality of life (QOL) of Iraqi patients at which most of them have moderate QOL (Al-Tukmagi & Moussa, 2014; W. Mostafa & Almkhtar, 2012). Moreover, the QOL among Iraqi T2DM patients are lower than those living in other countries due to the difference in socio-economic condition and health services between Iraq and other developed countries (Shakor etal., 2015). Additionally, T2DM is associated with the development of macrovascular such as cardiac diseases and stroke, and microvascular complications such as retinopathy,

nephropathy, and neuropathy. The prevalence of such complications is significantly higher among T2DM patients living in Middle East countries (Litwak et al., 2013) especially in Iraq (Almayahi, 2015; Mansour, 2009) than those living in other regions of the world (Litwak et al., 2013). This high prevalence of DM complications was seen in different regions of Iraq (Northern, middle and southern governorates) (Almayahi, 2015; Mansour, 2009; Al-Ani, 2011; Ali, Allela, Salih, & Ahmed, 2019). It is mainly attributed to poor glycemic control among Iraqi T2DM patients (Fasil, Biadgo, & Abebe, 2018). Furthermore, the opportunities for preventing and treating DM complications are limited in Iraq (Ministry of health, 2004). Hence, DM is the 5^{th} cause of morbidity and the 8^{th} cause of death for Iraqi individuals (Al-Mosawi, 2020).

Accordingly, DM is associated with a devastating economic burden in Iraq at which a huge part of the Iraqi estimated gross domestic product (GDP) is spent on DM patients (Zhang et al., 2010; Kadum, Lafta, & Burnham, 2013). Meanwhile, the average diabetes-related expenditure per Iraqi DM person was increased from just 96$ in 2010 (Zhang et al., 2010) to $544 in 2017 (Al Busaidi, Shanmugam, & Manoharan, 2019). Most of this expenditure is directed toward controlling blood glucose level and treatment of DM complications (Zimmet et al., 2014).

Controlling blood glucose level and achieving the glycemic target (HbA1c <7%) is one of the commonest problems among Iraqi T2DM patients, at which ≥76% of the patients couldn't reach their glycemic target (Yaseen & Atyia, 2018; Sattar, 2015; Mansour, 2008). The main reason for this poor glycemic control is the lack of adherence to anti-diabetic medications (H. Khan, Lasker, & Chowdhury, 2011; Polonsky & Henry, 2016; Raheem, 2010; AL-Khfajy, Aboddy, & Arif, 2018). In Iraq, adherence to antidiabetic medications was poor by most patients and ranged

from 55% (AL-Khfajy, Aboddy, & Arif, 2018) to 98.5% in other studies (Abbas, Al-Tukmagi, & Al-Auqbi, 2015a); this wide range for poor medication adherence may be attributed to the usage of different assessment tools, in which all of these tools were used without confirming their reliability and validity among Iraqi T2DM patients (AL-Khfajy, etal., 2018; Abbas, etal., 2015a).

The main causes for such low medication adherence include the lack of sufficient knowledge, patient health beliefs, forgetfulness, high cost of medications, complex regimen, and medications side effects (Fadheel & Mohammed, 2016). Unfortunately, the effect of the Iraqi culture on the patient health beliefs and medication adherence (Chia, Schlenk, & Dunbar-Jacob, 2006) was not measured in the above studies. Anyhow, most of the causes of medication non-adherence are interrelated and attributed to low patient awareness and knowledge about diabetes and the importance of its treatment (Brunton & Polonsky, 2017). The proper adherence to anti-diabetic medications can improve glycemic control; however, optimum glycemic control cannot be achieved unless medication adherence is accompanied by proper self-management behaviors (Khattab, Khader, Al-Khawaldeh, & Ajlouni, 2010; Shrivastava, Shrivastava, & Ramasamy, 2013).

Meanwhile, the adherence to self-management behaviors (e.g., lifestyle modifications) was also found to be low among Iraqi T2DM patients since only 1/3 and 1/10 of them adhere to diet and physical activity recommendations, respectively (Aladhab & Alabbood, 2019). Unfortunately, other DSM behaviors like SMBG, solving DM problems, reducing DM risks, and health coping with stress were not studied among Iraqi T2DM patients (Aladhab & Alabbood, 2019). The low adherence to healthy diet may be linked with the fact that most traditional foods in the Iraqi cuisine are high in fat and added sugars with low amounts of fibers

(**University of New England Applied Nutrition Program**, 2019). On the other hand, physical (hot weather and unfriendly built environment) and social (cycling, jogging and running are unconventional activities) barriers resulted in poor physical activity among most Iraqi adults (Sharara, etal., 2018). These cultural issues along with the lack of awareness and knowledge about the importance of lifestyle modification in DM management (Aladhab & Alabbood, 2019) were the main factors in such low adherence to these DSM measures among Iraqi DM patients.

Therefore, the low level of patient knowledge about DM and its management can be directly linked with poor glycemic control (Bukhsh et al., 2019). In this regard, many studies conducted in Iraq found that the knowledge about DM and its management is good (high) only among the minority (27% or even less) of DM patients, especially middle age (40-60 years old) men with higher educational level (BSc or more) (Saad, 2019; Khurshid & Othman, 2018; Abbas, Al-Tukmagi, & Al-Auqbi, 2015b). Reasons for this poor knowledge among Iraqi DM patients are widely heterogeneous and conflicting in the literature (including age, formal education, gender, duration of DM, and type of medication); however, all studies agreed that lacking of sufficient education about DM and its management is the main cause for such poor knowledge (Saad, 2019; Khurshid & Othman, 2018; Abbas, Al-Tukmagi, & Al-Auqbi, 2015b).

1.5 Rational of study

American Diabetes Association (ADA) mentioned that all DM patients are in need to receive DSME(S) to ensure optimum glycemic control (American Diabetes Association, 2020b). In line with the above recommendation, the Iraqi Ministry of Health is highly convinced of the importance of practicing DSM to prevent or at least postpone DM complications, rate of hospitalization, and hence, the burden on health

institutions (Steering Committee for Prevention and Control of Noncommunicable Diseases, 2013). However, the current quality of care provided to Iraqi DM patients in both private and public sectors is less than the desired level (Ministry of Health, 2016; Abdulameer, 2018), at which Iraqi DM patients receive only short periods of education (Alsamarai & Bashir, 2018) with limited information that focus mainly on diet restriction and medication adherence (Lafta, Faiq, & Al-Kaseer, 2009) during the diagnosis stage and may be when DM complication occurs. In addition to that, no any comprehensive DSME(S) program is adopted in Iraq yet (Zabetian, et al., 2013; Abbas et al., 2015b; Fadhil & Khalifa, 2018). Although many DSME(S) programs are developed and tested with positive outcomes in different countries (Krebs et al., 2013; Gamboa Moreno et al., 2013; Moghadam, Najafi, & Yektatalab, 2018; Zareban et al., 2014), no one can be directly adopted because they are evaluated in countries in which patients have different health beliefs, practices, social and ethnic structures from Iraqi DM patients (Beck et al., 2017). Hence, the development and evaluation of an Iraqi culturally-specific DSME(S) program is crucial. The first step in developing such a program is based on identifying the effect of the Iraqi culture on the practice and attitudes of Iraqi T2DM patients toward DSM. Unfortunately, such information is absent in previous literature. Therefore, the knowledge, practice, and barriers to DSM among Iraqi T2DM patients must be studied and explored clearly. On the other hand, lacking of comprehensive valid and specific tools to assess the benefit of DSME(S) program on DSM (Lu, Xu, Zhao, & Han, 2016), QOL (Trikkalinou, Papazafiropoulou, & Melidonis, 2017; Mostafa & Almkhtar, 2012), and medication adherence (Abbas, Al-Tikmagi, & Al-Auqbi, 2015b; AL-Khfajy, Aboddy, & Arif, 2018;Nguyen, Caze, & Cottrell, 2014) among Iraqi T2DM patients necessitate developing of such tools to evaluate the effectiveness of the developed

culturally-specific DSME(S) program. Since, it is well known that personal and cultural beliefs can affect patient medication adherence (Chia, Schlenk, & Dunbar-Jacob, 2006), DSM (Abdulrehman et al., 2016), and even QOL (Scott, et al., 2008); this means that all of the currently available scales may not be suitable for assessing DSM, medication adherence, and QOL among Iraqi patients even after a valid translation process because the culture and patients' beliefs at which these scales were developed is somewhat different from that in Iraq.

1.6 Conceptual framework

The present conceptual framework will emphasize on the DSM behaviors that affect on outcomes of the DSME(S) program, and also influence the success of such program. The DSME(S) can be defined as enduring process to assist DM patients to acquire knowledge, skills, and motivation to perform DSM behaviors. This means that the DSME(S) program aims to improve the practice of self-management among DM patients through eating a healthy diet, performing physical activity, proper medication consumption, monitoring of blood glucose level, solving diabetes-related problems (particularly hyperglycemia, hypoglycemia and sick-days management), reducing the risk of DM complications and healthy coping with stress. Patients can be motivated to practice DSM by using a health belief model. Practicing DSM can improve short-term (clinical) outcomes (glycosylated hemoglobin (HbA1c), blood pressure (BP), lipid profile and body weight). The improvement in clinical outcomes can ultimately lead to improvements in long-term (health status) outcomes through reducing the risk of developing DM complications, enhancing individual quality of life (QOL) and thus eventually reduce the economic burden of DM on individuals and even on society (Figure 1.1).

1.7 Study objectives

1.7.1 General objective

To develop and evaluate the effectiveness of a structured, culturally-based DSME(S) program in improving DSM behaviors, clinical outcomes, and QOL for T2DM patients at the National Diabetes Center, Baghdad, Iraq.

1.7.2 Specific objectives

1. To explore T2DM patients' knowledge about DM and DSM, besides the extent and barriers of practicing DSM; besides exploring T2DM patients' attitudes "a psychological tendency that is expressed by evaluating a particular entity with some degree of favor or disfavor (Gawronski,2007)" and perspectives about DSME(S) programs.
2. To develop and validate comprehensive and culturally specific tools to assess patient-reported outcomes such as DSM practices, medication adherence, and QOL among Iraqi T2DM patients.
3. To develop and validate culturally-based DSME(S) program for Iraqi T2DM patients.
4. To measure the impact of the developed DSME(S) program on patient-reported outcomes such as DSM practices, medication adherence, and QOL.
5. To evaluate the effect of the developed DSME(S) program on clinical outcomes such as HbA1c, fasting blood glucose (FBG), BP, lipid profile, and body weight.
6. To evaluate the cost-effectiveness of the developed DSME(S) program.

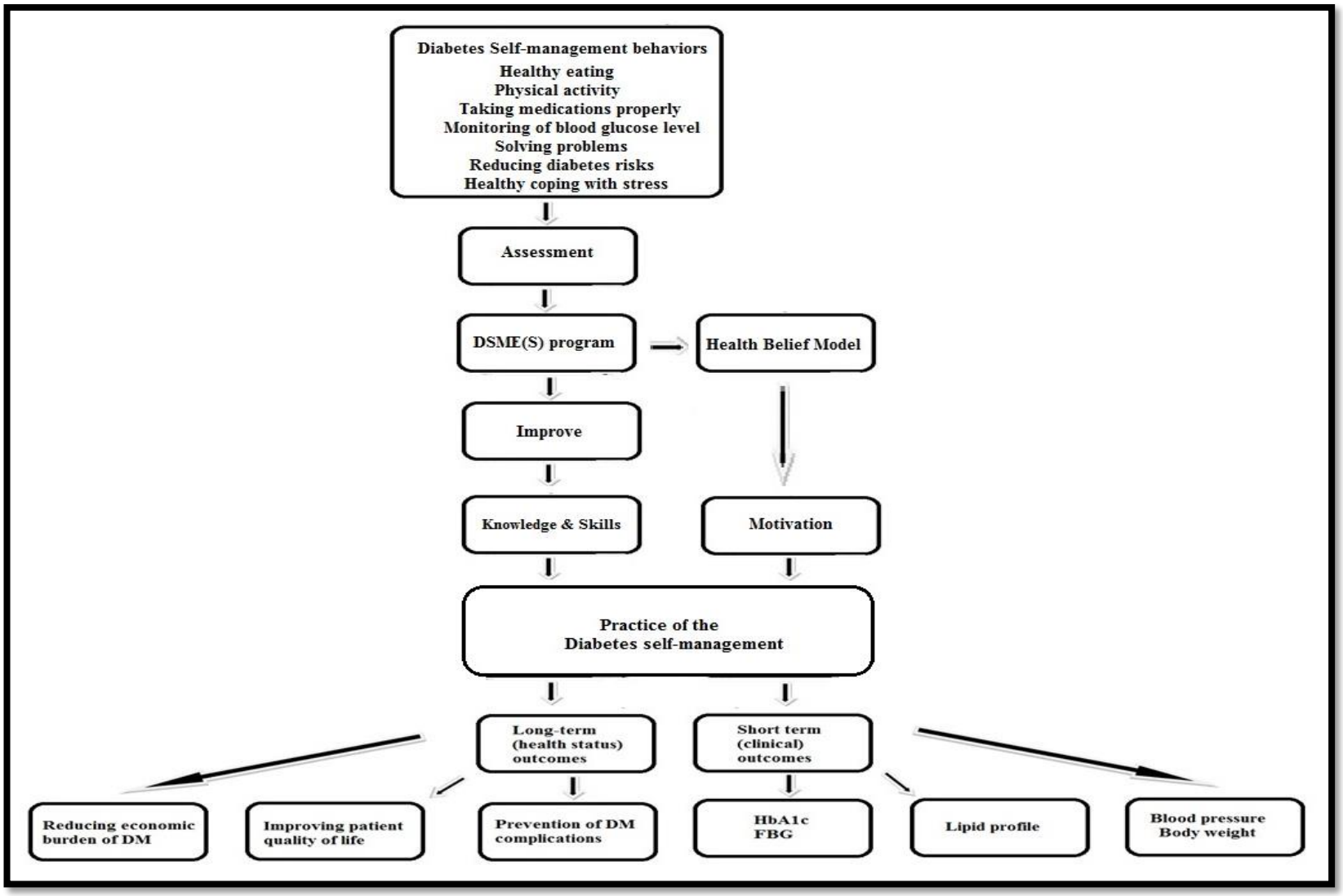

Figure 1.1: Conceptual framework

1.8 Study hypothesis

A. **Null Hypothesis:** The developed patient reported outcomes assessment scales are valid and reliable; and the developed DSME(S) program is effective to improve HbA1c, FBG, lipid profile, BP, body weight, DSM behaviors, medication adherence, and QOL.

B. **Alternative hypothesis:** The developed patient reported outcomes assessment scales are not valid and/or reliable; and the developed DSME(S) program is not effective to improve HbA1c, FBG, lipid profile, BP, body weight, DSM behaviors, medication adherence, and QOL.

1.9 Significance of the study

1. Identify barriers for practicing self-management among Iraqi T2DM patients and working to overcome these barriers through the development of a structured, culturally-based and patient centered DSME(S) program.

2. Identify perceptions and attitudes of Iraqi T2DM patients about DSME(S) program and design the program accordingly.

3. Help to provide Iraqi health care professionals with a basic guideline for educating DM patients about DSM behaviors.

4. Help to improve DM management through providing a patient-centered education.

5. Help to decrease the economic burden of DM in Iraq through ensuring the rational use of medications and resources.

1.10 Expected Outcomes

The developed DSME(S) program can be adopted by the Committee for Prevention and Control of Non-communicable Diseases at the Iraqi Ministry of Health as a guideline to train healthcare workers to promote and implement a national action plan to provide all DM patients with the required DSME(S).

1.11 Thesis overview

Thesis overview is shown in figure 1.2.

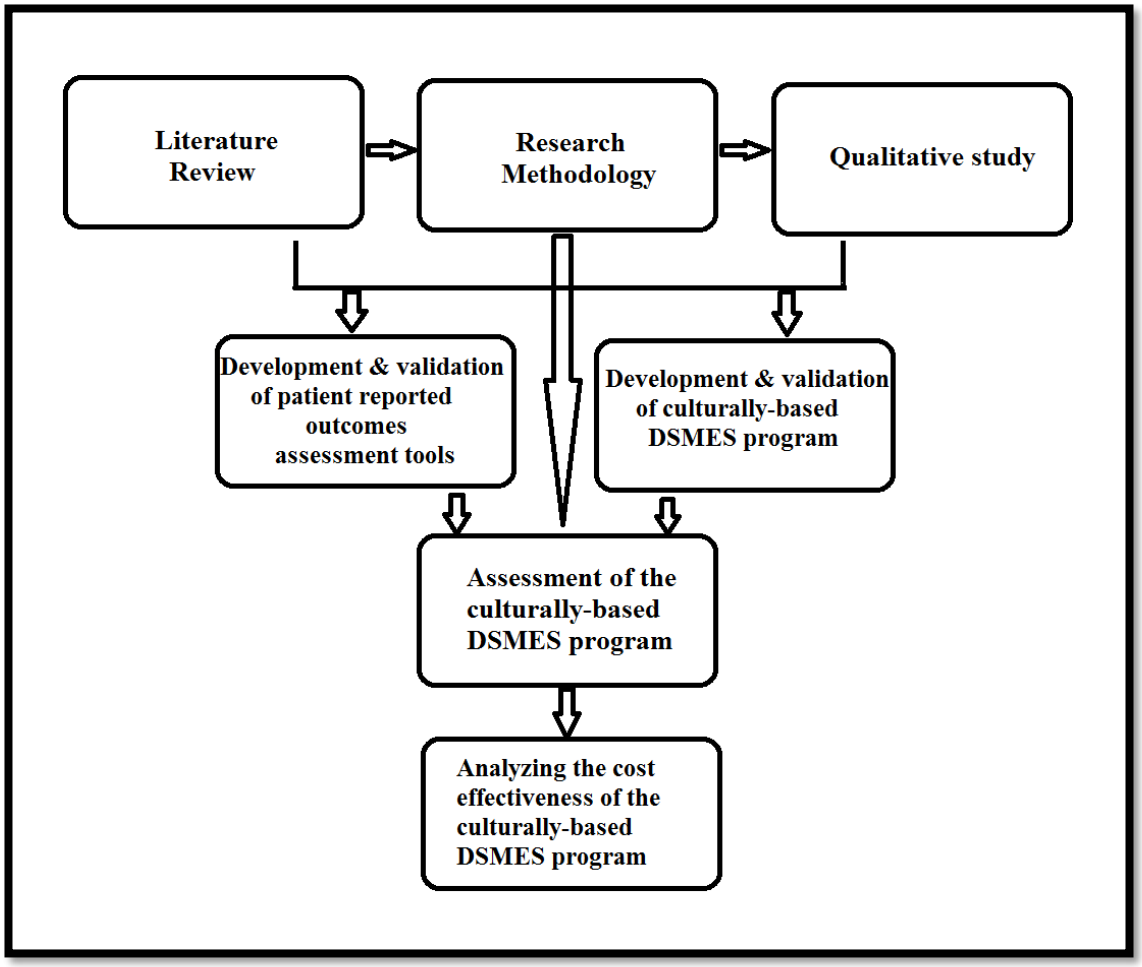

Figure 1.2: Thesis overview

CHAPTER 2

LITERATURE REVIEW

2.1 Introduction

Many reviews were conducted to evaluate the benefits of DSME programs for T2DM patients in developed (Gucciardi, Chan, Manuel, & Sidani, 2013; Norris, Lau, Smith, Schmid, & Engelgau, 2002) and developing countries (Dube, Van den Broucke, Housiaux, Dhoore, & Rendall-Mkosi, 2015). Unfortunately, and despite the fact that people living in Middle East countries have some cultural, historical, economic, and even physiographic similarities (Culcasi, 2010), only one review study was conducted specifically to assess the benefits of such programs for patients living in ME countries and was focusing on type 1 DM patients (Gagliardino et al., 2019) while no review study was conducted on T2DM patients.

Therefore, this study aimed to review the effectiveness and factors affecting the success of DSME programs in T2DM patients living in ME countries.

2.2 Methods for literature review

2.2.1 Search strategy

An extended literature review using the electronic databases of Google Scholar and PubMed was conducted for 2 months starting from the end days of August 2017 based on the following sets of keywords: " diabetes self-management education", "diabetes self-management educational program evaluation", "diabetes self-care education", "pharmacist-led diabetes self-management education" and " nurse-led diabetes self management education".

2.2.2 Inclusion criteria and study selection

Articles published in English during the last 10 years between 1st January 2007 and 1st September 2017, which focus on the effect of DSME among adult (18–99 years) patients with T2DM who live in any Middle East country were included in this review study. Only interventional studies (randomized and non-randomized) were included, while reviews, qualitative and observational studies were excluded.

2.2.3 Review method

All titles during the database search were manually reviewed. Relevant articles at which their titles imply the presence of DSME through their inclusion of certain words such as education, care, support, and management were retrieved and reviewed. On the other hand, articles were not reviewed if their titles indicate that they had been conducted in a non-Middle East country (Figure 1.3).

2.2.4 Extraction and summarizing methods

Information from the included studies was summarized in relation to the country where study conducted, description of study population, sample size, duration of follow up, details about DSME program (mode of delivery, education provider, theoretical bases, frequency and duration of the educational sessions), and the follow-up time, besides the parameters used during assessment, results, and conclusions. For this review, all data about the clinical outcome were presented as mean±standard deviation. Some studies present their results using a mean and confidence interval, for these studies the standard deviation was calculated from the confidence interval based on the Cochrane method (Higgins & Green, 2019).

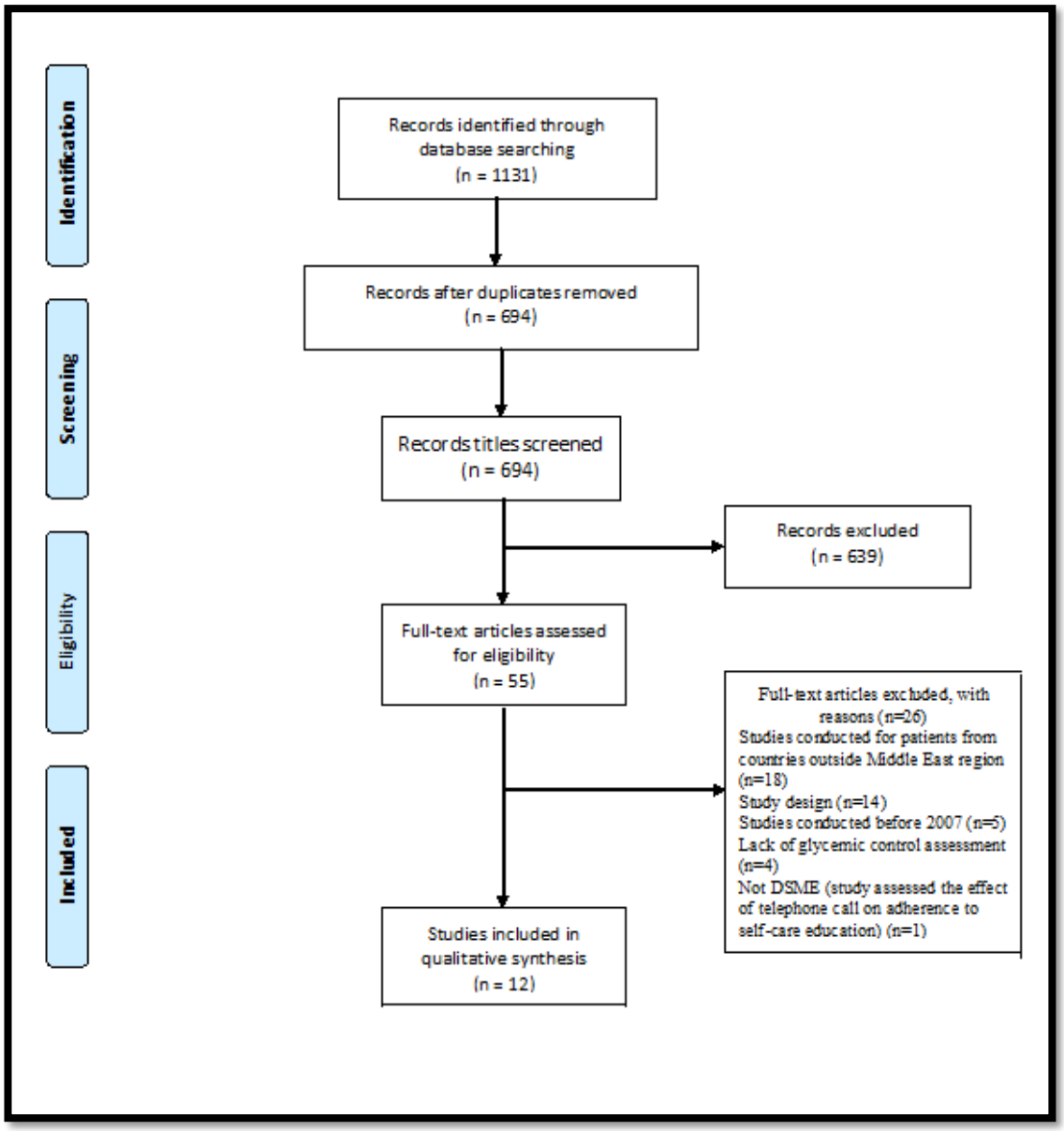

Figure 2.1: The PRISMA flow chart of included and excluded studies

2.2.5 Risk of bias assessment

All the included studies were assessed for the presence of any risk of bias using the Cochrane Risk of Bias tool (Higgins & Green, 2019).

2.2.6 Sample size

The DSME studies were categorized according to the number of enrolled patients into small sample size studies (with a sample of less than 100), intermediate (100-200) and large (greater than 200).

2.2.7 Characteristics of the DSME program

2.2.7(a) The provider of DSME

DSME was provided by a variety of healthcare professions including pharmacists, physicians, dietitians, nurses, and DM educators and in some cases by a non-healthcare professional (e.g., interested DM patients). To achieve the aim of this study and to know which DSME provider is the best, DSME was classified as being delivered by a team (i.e., two or more individuals were involved with the provision of DSME to the study participants), a pharmacist or other single provider (a nurse or trained DM educator).

2.2.7(b) Mode of delivering DSME

During face-to-face contact, delivery of DSME was categorized into 3 distinct types: (1) education for a group of patients, (2) education to each patient individually, and (3) a combined education which consists of group education followed by individual education.

Additionally, the DSME programs were also categorized as supported (e.g., phone contact and/or written material) and non-supported programs.

2.2.7(c) Contents and duration of the DSME program

The duration of the DSME program was measured based on the number (frequency) of the provided educational sessions and the contact time of each educational session. For this review, the number of educational sessions was categorized into DSME with many sessions (more than 5 educational sessions) and DSME with few sessions (less than 5 educational sessions) (Steinsbekk, Rygg, Lisulo, Rise, & Fretheim, 2012). The total contact time was calculated by multiplying the frequency of educational

sessions with the contact time of each educational session. DSME was categorized based on total contact time as short (less than 4 hours) or long (more than 4 hours) (Johnson, Richards, & Churilla, 2015).

Regarding the covered self-management topics, the American Association of Diabetes Educators [Currently known as Association of Diabetes Care and Education Specialists (ADCES)] 7 self-care behaviors (healthy eating, medication consumption, exercise, healthy coping with stress, self-monitoring of blood glucose (SMBG), resolving problems (such as hypoglycemia and sick days management), and reducing diabetes risks were covered either completely or partially by the included studies; the studies were categorized based on the percent of covered topics into either poor with coverage of less than 50% of ADCES 7 self-care topics (i.e., 3 topics or less) or good with coverage of at least 50% of ADCES 7 self-care topics (i.e., 4 topics or more) (Farrar, Dworkin, & Max, 2006).

2.2.7(d) Follow up period

DSME programs had a wide range of follow up periods; for this review, DSME studies were categorized according to follow-up period as short (3 months or less), intermediate (>3– 6 months) and long (> 6 months) (Fan & Sidani, 2009). This categorization was based on the fact that the benefits of DSME usually start to fade out after 6-12 months (Tshiananga et al., 2012; Harris, Harris, and Mertlich, 2005).

Some studies had more than one follow-up assessment; however, in this review, the effect of the DSME program based on the assessments of the last follow up period.

Retention rate was categorized based on Cochrane Collaboration criteria into: good (retention rate ≥80%) and poor (retention rate <80%) (Higgins & Green, 2019).

2.2.7 (e) Effect of DSME on the clinical outcomes

The included studies expressed the changes in clinical outcomes (those that can be measured clinically such as glycosylated hemoglobin (HbA1c), blood glucose level, lipid profile, blood pressure (BP), and body weight) by different ways, including the change between pre- and post-intervention in each study arm, compare post-intervention values between an intervention group (IG) and control group (CG) (after taking into account non-significantly different baseline level), or compare the mean difference between IG and CG. In this review, we evaluated the changes in the clinical outcomes by 2 methods. First, we calculated the percentage of DSME studies that produce a significant improvement in the clinical outcome by including only studies that directly compare follow-up results between IG and CG. Second, we examined the absolute effect (absolute improvement) in clinical outcomes for all the included studies; the absolute change was calculated by measuring the difference in the change (post-study value – baseline value) between the IG and CG (Tripepi, Jager, Dekker, Wanner, & Zoccali, 2007). Furthermore, we examined the influence of different factors such as the enrolled sample, characteristics of the DSME, and the follow-up period on the absolute effect of DSME on glycemic control.

2.2.7 (f) Effect of DSME on the patient-reported outcomes

The included studies expressed the changes in the patient-reported outcomes (directly reported by the patient who experienced it such as quality of life (QOL), medication adherence, health beliefs, self-efficacy, self-management behavior, knowledge and attitude towards diabetes) by different ways, including the difference between pre and post-intervention in each study arm, comparison of post-intervention (absolute value or proportion of participants achieving the outcome)

values between IG and CG, or comparison of the mean difference between IG and CG. Additionally, Patient-reported outcomes are usually assessed by a wide variety of questionnaires; therefore, we evaluated the changes in patient-reported outcomes by just calculating the percentage of DSME programs that produce a significant improvement in a patient-reported outcome.

2.3 Results

Twelve studies (Mollaoğlu & Beyazıt, 2009; Al Mazroui et al., 2009; Faresi, Sabzghabaee, Zargarzadeh, & Amini, 2011; Jarab, Alqudah, Mukattash, Shattat, & Al-Qirim, 2012; Aliha et al., 2013; Zareban et al., 2013; Mohamed, Al-Lenjawi, Amuna, Zotor, & Elmahdi, 2013; Jahangard-Rafsanjani et al., 2014; Shakibazadeh, Bartholomew, Rashidian, & Larijani, 2016; Ebrahimi, Sadeghi, Amanpour, & Vahedi, 2016; Reisi et al., 2017; Surucu, Kizilci, & Ergor, 2017) were found to be eligible and thus included in this review.

The included studies were conducted in five ME countries, 7 in Iran (Faresi et al., 2011; Aliha et al., 2013; Zareban et al., 2013; Jahangard-Rafsanjani et al., 2014; Shakibazadeh et al., 2016; Ebrahimi et al., 2016; Reisi et al., 2017), two in Turkey (Mollaoğlu & Beyazıt, 2009; Surucu et al., 2017), one in UAE (Al Mazroui et al., 2009), one in Jordan (Jarab et al., 2012) and one in Qatar (Mohamed et al., 2013).

Heterogeneity was found among the included studies in terms of: 1) DSME program characteristics (mode of delivery whether group based or individual based, delivering person whether a pharmacist, nurse, or group of healthcare experts); 2) the enrolled patients (with uncontrolled hyperglycemia or without regard to glycemic control); 3) duration of follow up (ranged from 1-24 months); 4) assessment methods (different laboratory tests, different assessment tools for patients reported outcomes, and different statistical analysis methods) and 5) obtained outcomes (Table 2.1). Because

of this excessive heterogeneity (heterogeneity in 5 study domains), it was not possible to conduct a meta-analysis (Chrvala, Sherr, & Lipman, 2016).

Table 2.1: Characteristics of the included studies

Study Details	Study Design	Enrolled patients	Demographic characteristics	No. of enrolled patients (IG/CG)	No. of patients completed the study (IG/CG): Overall retention rate	Follow up period (months)	DSME characteristics					Assessed parameters (N)
							Frequency & duration of educational sessions	Covered self-care topics (N)	DSME provider/ Mode of delivering DSME	Supporting strategy	Theory -based	
Mollaoğlu & Beyazıt, 2007; Turkey	RCT	T2DM aged 18-65 years who are able to read	Non-significant difference between patients in IG and CG regarding age, gender, marital status, and educational level	50 (25/25)*	50 (25/25): 100%	2	3 sessions (30-40) min each session	Diet, exercise, medication, and SMBG (4)	Nurse/ Individual-based	Education-al brochure	None	HbA1c, PPBG, FBG, T-Chol, LDL-C, HDL-C, TG (7)
Al Mazroui et al., 2009; UAE	RCT	T2DM patients on oral anti-diabetic agents	Non-significant difference between patients in IG & CG regarding age, gender, duration of DM & family	240 (120/ 120)*	234 (117/117) : 97.5%	12	1 session (unknown period)	Medications, exercise, SMBG, and reducing risk (smoking cessation)	Pharmacist / Individual-based	Printed leaflet	None	HbA1c, FBG, SBP, DBP, T-chol, LDL-c, HDL-C, TG, BMI, CHD risk, Medication adherence, knowledge, & quality of life

			history of DM					(4)				(13)
Faresi et al., 2011; Iran	RCT	T2DM patients with uncontrolled hyperglycemia (HbA1c > 7%) and the ability to read and write	Non-significant differences between patients in IG and CG regarding age, gender, duration of DM, type of DM treatment, educational level, and in presence of co-morbid diseases.	174 (87/87)*	174 (87/87): 100%	3	2 sessions (unknown period)	Diet, exercise, and medications (3)	Pharmacist /Individual-based	Phone call	None	HbA1c and FBG (2)
Jarab et al., 2012; Jordan	RCT	T2DM patients already on treatment but with uncontrolled hyperglycemia (HbA1c >7.5%)	Non-significant differences between patients in IG and CG regarding age, gender, duration of DM, marital status, monthly income, and educational	171 (85/86)*	156 (77/79): 91.23%	6	1 session (unknown period)	Diet, medication, exercise, SMBG and reducing DM risks (smoking cessation) (5)	Pharmacist /Individual-based	A phone call and educational booklet (combined)	Motivational interviewing	HbA1c, FBG, SBP, DBP, T-chol, LDL-c, HDL-C, TG, BMI, Medication adherence, DSM activity, and behavior (11)