



UNIVERSITI PUTRA MALAYSIA

***EFFECTIVENESS OF SIMPLIFIED DIABETES NUTRITION EDUCATION
ON GLYCEMIC CONTROL, AND OTHER DIABETES-RELATED
OUTCOMES IN PATIENTS WITH TYPE 2 DIABETES MELLITUS IN
BASRAH, IRAQ***

ALMALIKI SAMAN AGAD HASHIM

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By

ALMALIKI SAMAN AGAD HASHIM

**Thesis Submitted to the School of Graduate Studies, Universiti Putra
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Doctor of Philosophy**

December 2020

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DEDICATION

I would like to dedicate this thesis to my great late mother "Jameela"; she taught me perseverance and made me face challenges with confidence and modesty. She was an endless motivation for my study life. Although she is not here to give me support and strength, I always sense her presence has been urged me to pursue my goals in life.



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

EFFECTIVENESS OF SIMPLIFIED DIABETES NUTRITION EDUCATION ON GLYCEMIC CONTROL, AND OTHER DIABETES-RELATED OUTCOMES IN PATIENTS WITH TYPE 2 DIABETES MELLITUS IN BASRAH, IRAQ

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December 2020

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Type 2 Diabetes (T2DM) is a global public health concern, with the majority of the patients had inadequate glycemic control. In Basrah, Iraq, one of the factors affecting glycemic control is low health literacy (HL) level. T2DM patients with low HL have limited ability to understand and apply the regimen to their diabetes self-management. Therefore, a simplified diabetes nutrition education (SDNE) may be required to ensure optimum diabetes care. This study evaluates the effectiveness of SDNE on glycemic control and other diabetes-related outcomes in patients with T2DM in Basrah, Iraq.

This study involved three phases based on the Generalized Model for Program Planning conducted at Faiha Specialized Diabetes, Endocrine, and Metabolism Centre (FDEMC), in Basrah, Iraq. Phase I was a cross-sectional study that included 280 participants in determining the factors associated with glycemic control. The factors included socio-demographic status, medical characteristics, nutritional status, lifestyle behavior, and HL level. The results from Phase I informed the content for the Phase II study, which involved developing and assessing nutrition education materials. The developed nutrition education materials were assessed for face validity, readability, and acceptability using a 14-item HL Scale and the Suitability Assessment of Materials (SAM) instrument in 30 participants with T2DM. The experts validated the content of the materials. The effectiveness of the developed nutrition education materials named SDNE was evaluated at Phase III using a randomized controlled trial (RCT) on glycemic control and other diabetes-related outcomes for 22 weeks in patients with T2DM (n = 208). The assessments were performed at baseline (T0), at 12-week of intervention (T1), and at 10-week of follow-up (T2). 208 participants were randomly allocated to either the nutrition education group (NEG, n = 104), or the control group (CG, n = 104). Those in the NEG received the SDNE curriculum

for 12 weeks (12 weekly classes, 1 to 1.5 hours each). Participants in the CG continued with the usual care.

At Phase I, the participants (N = 151) were at their 50s' with the HbA1c, and HL scores were $10.0 \pm 2.6\%$ and 45.7 ± 24.6 . The majority of the participants (76.4%) had either inadequate (55.7%) or marginal HL (20.7%). Factors associated with glycemic control included low HL score, low total income, self-employed, multiple treatments (oral anti-diabetic drugs and insulin therapy), low physical activity level, presence of comorbidities, and low vegetable intake. All of the factors explained 35% of the total variation in HbA1c (adjusted R² = 0.35; p = 0.005).

The modifiable nutrition-related factors that were associated with glycemic control (i.e., HL levels, physical activity, and vegetable intakes) were considered the key nutrition component in the development of nutrition education materials at Phase II. The SDNE curriculum emphasizes the use of the Plate Method and "eating vegetables before carbohydrates." The developed SDNE had the HL scale score of 57.1, indicating it was readable and acceptable among participants. The SAM instruments score was 34 out of 40, indicating the SDNE curriculum's suitability. The dietitians and an endocrinologist confirmed the content validity of the SDNE.

At Phase III, a total of 208 patients aged 20-64 years old with a confirmed diagnosis of T2DM participated in the study. At 22 weeks, the interaction effects were significant and more pronounced in NEG than CG for HbA1c (p < 0.001) and other diabetes-related outcomes including on total cholesterol (p = 0.001), low-density lipoprotein (p = 0.009), high-density lipoprotein (p < 0.001), triglyceride (p = 0.01), waist circumference (p < 0.001), BMI (p = 0.008), total energy (p < 0.001), carbohydrate (p < 0.001), and vegetable (p < 0.001) intakes. Health belief model (HBM) constructs (p = 0.003), diabetes knowledge (DK) (p = 0.004), and HL score (p < 0.001) were also improved. In conclusion, patients with T2DM in Iraq had poor glycemic status, low HL, low vegetable intake, and decreased levels of physical activity. These components were included in the development of a simplified and visual educational material called SDNE. SDNE was demonstrated to be effective in improving HbA1c, metabolic parameters, dietary intake, and physical activity. Likewise, HBM, DK, and HL. SDNE can be used in Clinics as simplified pictorial leaflets that will assist nutritionists in providing appropriate and accessible nutritional education to patients with T2DM.

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

PEMBENTUKAN DAN KEBERKESANAN PENDIDIKAN PEMAKANAN DIABETES DIPERMUDAHKAN KE ATAS KAWALAN GLISEMIK DAN HASIL LAIN BERKAITAN DIABETES DALAM KALANGAN PESAKIT DIABETES MELLITUS JENIS 2 DI BASRAH, IRAQ

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Diabetes Jenis 2 (T2DM) adalah isu kesihatan awam sedunia dimana majoriti pesakit tidak mencapai kawalan glisemik yang baik. Di Basrah, Iraq, salah satu faktor yang mempengaruhi kawalan glisemik adalah tahap literasi kesihatan (HL) yang rendah. Pesakit T2DM dengan tahap HL yang rendah mempunyai kemampuan terhad untuk memahami aspek pengurusan sendiri diabetes. Oleh itu, pendidikan pemakanan diabetes yang dipermudahkan (SDNE) mungkin diperlukan untuk memastikan penjagaan diabetes yang optima. Kajian ini menilai keberkesanan SDNE ke atas kawalan glisemik dan hasil lain berkaitan diabetes dalam kalangan pesakit T2DM di Basrah, Iraq.

Kajian ini melibatkan tiga fasa berdasarkan model umum untuk perancangan program yang dijalankan di Pusat Khusus Diabetes, Endokrin, dan Metabolisme Faiha (FDEMC), di Basrah, Iraq. Fasa I menggunakan keratan rentas yang merangkumi 280 peserta untuk menentukan faktor-faktor yang berkaitan dengan kawalan glisemik. Faktor-faktor tersebut merangkumi status sosio-demografi, ciri perubatan, status pemakanan, tingkah laku gaya hidup, dan tahap HL. Hasil dapatan dari Fasa I digunakan untuk membentuk kandungan kajian pada Fasa II, yang melibatkan pembentukan dan penilaian bahan pendidikan pemakanan. Bahan pendidikan pemakanan yang dibentuk dinilai untuk kesahan muka, kebolehbacaan, dan penerimaannya menggunakan skala 14-soalan HL dan instrumen Penilaian Kesesuaian Bahan (SAM) dalam kalangan 30 peserta T2DM. Para pakar mengesahkan kandungan bahan. Keberkesanan bahan pendidikan pemakanan yang dibentuk bernama SDNE dinilai pada Fasa III menggunakan percubaan kawalan secara rawak (RCT) pada kawalan glisemik dan hasil lain yang berkaitan dengan diabetes selama 22 minggu. Penilaian dilakukan pada peringkat awal (T₀), pada minggu ke 12

intervensi (T1), dan pada minggu ke 10 rawatan susulan (T2). Sebanyak 208 peserta diagihkan secara rawak kepada Kumpulan Pendidikan Pemakanan (NEG, n = 104), atau Kumpulan Kawalan (CG, n = 104). Mereka yang berada di NEG menerima SDNE selama 12 minggu (12 kelas mingguan, masing-masing 1 hingga 1.5 jam). Peserta dalam CG meneruskan rawatan seperti biasa.

Pada Fasa I, peserta berusia 50 tahun dengan HbA1c, dan skor HL masing-masing $10.0 \pm 2.6\%$ dan 45.7 ± 24.6 . Kebanyakan peserta (76.4%) tidak mempunyai HL yang memuaskan (55.7%) atau HL yang rendah (20.7%). Faktor berkaitan dengan kawalan glisemik termasuk skor HL yang rendah, jumlah pendapatan yang rendah, bekerja sendiri, mempunyai komorbiditi dan pengambilan sayuran yang rendah. Kesemua faktor menjelaskan 35% jumlah variasi bagi HbA1c (pelarasan $R^2 = 0.35$; $p = 0.005$).

Faktor berkaitan pemakanan ini boleh diubah suai berkaitan dengan kawalan glisemik (tahap HL, aktiviti fizikal, dan pengambilan sayur-sayuran) menjadi komponen utama dalam pembentukan bahan pendidikan pemakanan pada Fasa II. Kurikulum SDNE menekankan penggunaan Kaedah Pinggan dan "makan sayur-sayuran sebelum karbohidrat". SDNE yang dibentuk mempunyai skor skala HL 57.1, menunjukkan ia dapat dibaca dan diterima di kalangan peserta. Skor instrumen SAM adalah 34, menunjukkan kesesuaian kurikulum SDNE untuk pelaksanaan di kalangan peserta. Ahli diet dan endokrinologi mengesahkan kesahan kandungan SDNE.

Pada Fasa III, sejumlah 208 pesakit berusia 20-64 tahun yang disahkan mengidap T2DM mengambil bahagian dalam kajian ini. Pada minggu ke 22, kesan interaksi adalah ketara dan lebih ketara di NEG daripada CG untuk HbA1c ($p < 0.001$) dan hasil berkaitan diabetes lain termasuk pada kolesterol total ($p = 0.001$), lipoprotein berkepadatan rendah ($p = 0.009$), lipoprotein berkepadatan tinggi ($p < 0.001$), trigliserida ($p = 0.01$), ukur lilit pinggang ($p < 0.001$), BMI ($p = 0.008$), jumlah tenaga ($p < 0.001$), karbohidrat ($p < 0.001$), dan pengambilan sayur-sayuran ($p < 0.001$). Konstruk Model Kepercayaan Kesehatan (HBM) ($p = 0.003$), pengetahuan diabetes ($p = 0.004$), dan skor HL ($p < 0.001$) juga bertambah baik. Kesimpulannya, pesakit dengan T2DM di Iraq mempunyai status glisemik yang tidak terkawal, rendah HL, pengambilan sayur yang rendah, dan tahap aktiviti fizikal yang rendah. Komponen-komponen ini dimasukkan dalam pembentukan visual bahan pendidikan yang ringkas yang disebut SDNE. SDNE terbukti efektif dalam mengawal HbA1c, parameter metabolik, pengambilan makanan, dan aktiviti fizikal. Begitu juga, HBM, DK, dan HL. SDNE boleh digunakan di Klinik sebagai risalah bergambar yang mudah yang akan membantu pakar pemakanan dalam memberikan pendidikan pemakanan yang sesuai dan mudah akses kepada pesakit T2DM.

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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:

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LIST OF ABBREVIATIONS

ADA	American Diabetes Association
ANCOVA	Analysis of Covariance
BMI	Body Mass Index
BMR	Basal Metabolic Rate
BP	Blood Pressure
CG	Control group
CHO	Carbohydrates
CONSORT	Consolidated Standards of Reporting Trials
CVD	Cardiovascular Disease
DBP	Diastolic Blood Pressure
DK	Diabetes Knowledge
dL	Deciliter
DM	Diabetes Mellitus
EI	Energy Intake
FBG	Fasting Blood Glucose
FDEMC	Faiha Specialized Diabetes, endocrine, and metabolism Center
HbA1c	Glycated Hemoglobin
HBM	Health Belief Model
HDL-C	High-Density Lipoprotein Cholesterol
HL	Health Literacy
IDF	International Diabetes Federation
IPAQ	International Physical Activity Questionnaire

ITT	Intention-To-Treat
Kcal	Kilocalorie
Kg/m ²	Kilogram/squared meter
LDL-C	Low-Density Lipoprotein Cholesterol
MENA	The Middle East and North Africa
MET	Metabolic Equivalent Task
MOH	Ministry of Health
NEG	Nutrition education group
OADs	Oral Antidiabetic Drugs
PAL	Physical Activity Level
SBP	Systolic Blood Pressure
SDNE	Simplified Diabetes Nutrition Education
S-TOFHLA	Sort Form Test of Functional Health Literacy for Adults
T2DM	Type 2 Diabetes Mellitus
TC	Total Cholesterol
TEE	Total Energy Expenditure
TG	Triglycerides
WC	Waist Circumference

CHAPTER 1

INTRODUCTION

1.1 Background of the Study

Diabetes mellitus is a group of metabolic disorders that lead to hyperglycemia due to the absence or deficiencies in insulin action, insulin secretion, or both (ADA, 2020). The long-lasting hyperglycemia of diabetes is related to dysfunction, long-term impairment, and body organs' failure, mainly the kidneys, eyes, heart, nerves, and blood vessels (ADA, 2020). Type 2 diabetes mellitus (T2DM) is the most common diagnosis of all diabetes cases. While there is no cure, proper intervention leads to improved glycemic control and other diabetes-related outcomes (ADA, 2020).

The prevalence of T2DM is increasing around the world (Williams et al., 2019). In 2019, more than 54.8 million (12.8%) of patients with T2DM aged 20-79 years were living in the Middle East and North Africa region (MENA). The number of patients estimated would be increased to 76.0 million by 2030 and 107.6 million by 2045. The increase in the prevalence is considered the second-highest in 2019 among the IDF Regions (IDF, 2019). Iraq has not been spared from this health issue. In 2006, the prevalence of T2DM in Iraq was 15% (MOH/WHO, 2006). Basrah city in the year 2014 has the highest prevalence of T2DM in Iraq (19.7%) (Mansour, Al-Maliky, Kasem, Jabar, & Mosbeh, 2014).

Despite advances in diabetes care, most T2DM patients cannot achieve optimal glycemic control (Moghissi et al., 2009). In Saudi Arabia, almost 80% had inadequate glycemic control (Azab, 2001). In Basrah, Iraq, poor glycemic control (HbA1c) was evident, reported by almost 90% of patients with T2DM (Mansour et al., 2020).

In the literature, studies reported various factors contributing to poor glycemic control among T2DM patients, including diabetes duration, diabetes treatment, medical background, and numerous other factors (Ali, Allela, Salih, & Ahmed, 2019; Dauod, 2018; Mansour et al., 2014). Although different studies have been conducted in this area, the results are inconsistent and vary across countries and between different ethnic groups (Alramadan et al., 2018; Al-Rasheedi, 2015a). Poor glycemic control is commonly due to an unhealthy lifestyle such as physical inactivity, high carbohydrate, and fewer fiber intakes leading to obesity and diabetes-related complications (Janghorbani & Amini, 2012). In Iraq, the nutritional status is not optimal, and an unhealthy lifestyle among patients with T2DM leads to an increase in Body Mass Index (BMI) (Abdul-Hasan & Yassin, 2018). The mean BMI among Iraqi patients with T2DM ranged from 27.4-28.2

kg/m², which were categorized as overweight. with almost 90% of patients with T2DM were either obese or overweight (Hasnawi, Nisak, Hazizi, & Rafi, 2015; Mansour & Ajeel, 2009; Al-Marroof & Al-Sharbatti, 2006).

Furthermore, the non-clinical factors, in particularly the concept of health literacy (HL) has emerged as an influential factor in the health outcomes for patients with complex chronic diseases including T2DM (N'Goran et al., 2018). HL is principally defined as 'the degree to which individuals can obtain, process, understand, and communicate about health-related information needed to make informed health decisions' (Nutbeam, 2008). In other words, HL requires individuals with T2DM to have specific skills to understand the printed information, oral communication, and numeracy to practice self-diabetes care (Ishikawa, Takeuchi, & Yano, 2008). A low HL level is typically reported worldwide, in developing countries was ranging from 40% to 70%, lowest in Saudi Arabia (Abdel-Latif & Saad, 2019), and the highest in Iran (Mohammadi et al., 2015).

The same phenomenon is also observed in Iraq. A study by Abdul-Hasan & Yassin 2018 identified that Iraqi T2DM patients had inadequate HL levels with a mean score of 43.3. In this study, HL scores were significantly associated with poor glycemic control and the presence of diabetes complications (Abdul-Hasan & Yassin, 2018). However, the mentioned study used different instruments that the author self-developed, which was not adequately validated and has not covered the whole spectrum of HL measures. The short-form Test of Functional Health Literacy in Adults (S-TOFHLA) is considered the best (Kim, Love, Quistberg, & Shea, 2004; Schillinger et al., 2002).

A study using S-TOFHLA was conducted among the customers who attended pharmacies in two cities in Iraq. The study identified that about 17% had low HL levels which was lower as compared to the studies in Western countries (Al-Jumaili, Al-Rekabi, & Sorofman, 2015). The data indicate the critical need of having the assessments of HL among patients with T2DM and its association with glycemic control.

Medical Nutrition Therapy (MNT) plays an essential role in diabetes management (ADA, 2020). MNT intervention is delivered via a provision of structured diabetes nutrition education to improve the food-and-nutrition knowledge deficit in facilitating positive dietary practices and lifestyle modifications in patients with T2DM (Coppoolse, Seidell, & Dijkstra, 2020). The provision of structured diabetes nutrition education in T2DM has been proven effective in achieving optimal glycemic control with a 0.6 - 1.9% reduction in HbA1c (Mottalib et al., 2018; Franz et al., 2017). In Oman, a diabetes nutrition education improved HbA1c by 1.8% compared to the minimal care among T2DM. Other improvements included the nutritional status and increased physical activity levels (Al-Shookri, 2013).

Patients with T2DM are expected to follow a complex set of regimens to effectively self-manage their diabetes, including engaging in appropriate lifestyle practices and adhering to a meal plan (Shrivastava, Shrivastava, & Ramasamy, 2013). A fundamental nutrition strategy in diabetes nutrition is carbohydrate management, either using exchanges or counting methods. Both methods have been associated with improved clinical outcomes (Mohamed, Staite, Ismail, & Winkley, 2019). Nonetheless, the methods require adequate diabetes literacy and numeracy skills. Due to the nutrition regimen's complexity, most patients still identify that adopting diabetes nutrition into their daily routine is the most challenging aspect of self-care (Han et al., 2020).

Simplified education refers to attractive and straightforward education that may help patients apply changes leading to glycemic and diabetes-related outcomes control (Imai et al., 2011; Ziemer et al., 2003; Brown et al., 2001). Hence, it is recommended to provide a simplified diabetes nutrition education (SDNE) that is attractive and straightforward education which may help patients to apply changes leading to improvement of glycemic control and diabetes-related outcomes (Imai et al., 2011; Ziemer et al., 2003; Brown, Lackey, Miller, & Priest, 2001). One of the simplified approaches in SDNE is using the Idaho Plate Method. This method visualized the estimated serving of major food groups on one's plate. The approach is easy to use when eating out, particularly for patients at a low literacy level, have cognitive difficulties, and the elderly (Raidl et al., 2007). Besides, it does not require math skills or a high reading level (Brown et al. 1998). The Plate Method produced comparable improvement in HbA1c as those using the carbohydrate counting than the general education for T2DM patients (Bowen et al., 2016).

Improving the overall dietary quality is also the main nutrition goal in diabetes. One of the recommended eating patterns for diabetes is to include a non-starchy vegetable, which may help achieve dietary fiber needs (Evert et al., 2019). The regular intake of sufficient dietary fiber improved other diabetes metabolic outcomes, including lipid profiles and blood pressures (Jiang et al., 2012; McIntosh & Miller, 2001). Besides, the retrospective observational study that advocates eating vegetables before carbohydrates versus the exchange method among elderly Japanese with T2DM found sustainable improvement in HbA1c and glucose excursion in the acute study. The educational approaches have also reduced starchy consumption and unhealthy food (Imai, Fukui, & Kajiyama, 2014). Therefore, choosing a specific food group may further simplify nutrition education in diabetes.

1.2 Problem Statement

Inadequate glycemic control among Iraqi T2DM is highly prevalent. About 86.2% had poor glycemic control indicated by HbA1c of > 7% (Mansour et al., 2020). The prevalence of T2DM in Iraq increases and causes diabetes-related complications (Ali et al., 2019). This is pertinent in the present context as about

72% of Iraqi patients with T2DM are without self-care skills toward glycemic control (Razzaq, 2013). T2DM patients with poor glycemic control could be contributed by physical inactivity, low education, obesity, unhealthy diet, and nutritional advice (Faik & Lami, 2016), which warrant further investigation.

Besides, most of the studies conducted in Basrah City, South of Iraq, have focused on several other medical associated factors such as treatment modalities, diabetes complications, diabetes duration, and comorbidities (Mansour, 2012). None of them has focused on nutrition education, nutritional status, HL level, and dietary management among Iraqi patients with T2DM. Besides, low HL is considered the main barrier to usual self-management practices among Iraqi patients with T2DM (Mikhael, Hassali, Hussain, & Shawky, 2019). The data indicate the critical needs of assessing HL among patients with T2DM and its association with glycemic control.

In Iraq, nutritional education is provided using an internal brochure that contains only general nutrition advice for the public such as healthy food and a source of vitamins and minerals that provide somewhat challenging and targeted information to the general public (Abdulah, Hassan, Saadi, & Mohammed, 2018). Nevertheless, until today, the role of plate model intervention or "eating vegetables before carbohydrates" approaches has not been assessed in the Iraqi context. The lack of information about diabetes nutrition education highlighted the need for the current study. In diabetes nutrition, the Plate model is known for its practicability, simplicity, and flexibility. It has been presented to be fruitful in all diabetic populations (Ziemer et al., 2003), but not tested among Iraqi T2DM.

Eating vegetables first before carbohydrate was also considered the beneficial approach in diabetes nutrition education among Japanese T2DM (Imai et al., 2014). Besides, no study has combined the concept of eating vegetables before carbohydrates with the Plate Method concept. Combining both ideas could have a meaningful effect on diabetes management and that lead to optimal glycemic control. However, the application of the combined method among Iraqi patients with T2DM is unknown.

Together with the impact of the gulf war and internal conflicts on the health care system (Hussain & Lafta, 2019), the requirement for a structured SDNE is exact. Since most T2DM patients had inadequate health literacy and hyperglycemia (Abdulah et al., 2018), diabetes nutrition education should be modified and simplified, tailoring to the cultural needs of T2DM patients. At present, the provision of education usually delivers by giving in-house brochures that cover general nutrition advice (Abdulah et al., 2018). Thus, this study determined the effectiveness of SDNE on glycemic control and other diabetes-related outcomes in Iraqi patients with T2DM.

1.3 Research Questions

1. What is the association of socio-demographic status, medical characteristics, nutritional status, lifestyle characteristics, and health literacy level with HbA1c among patients with T2DM in Basrah, Iraq?
2. What are the significant predictors that can explain variations in HbA1c?
3. How can nutrition education materials be developed, what are the components, and how to assess them?
4. Does the SDNE improves glycemic control (HbA1c and FBG) at baseline (T0), after 12 weeks of intervention (T1), and after 10 weeks of follow-up (T2) among the nutrition education group (NEG) compared to those in the control group (CG)?
5. Does the SDNE improves nutritional status, physical activity, health belief model (HBM) constructs, diabetes knowledge (DK), and health literacy level at T0, after T1, and after T2 among NEG compared to those in NEG?

1.4 Objectives of the Study

1.4.1 General Objective:

To determine the effectiveness of an SDNE on glycemic control and other diabetes-related outcomes in patients with T2DM in Basrah, Iraq.

1.4.2 Specific Objectives:

1. To determine the predictors that explain variations in glycemic control.
2. To develop the SDNE for patients with T2DM in Basrah, Iraq.
3. To determine the effectiveness of SDNE on glycemic control at T0, after T1, and after T2 among NEG compared to those in CG.
4. To determine the effectiveness of SDNE on other diabetes-related outcomes at T0, after T1, and after T2 among NEG compared to those in CG.

Phase I: Needs Assessment

The main objective was to determine the predictors that explain variations in glycemic control among patients with T2DM in Basrah, Iraq.

Specific Objectives:

1. To determine the glycemic control (HbA1c) among patients with T2DM.
2. To determine the socio-demographic status, nutritional status, lifestyle practices, medical characteristics, and HL level in patients with T2DM.
3. To determine associations of socio-demographic status, nutritional status, lifestyle characteristics, medical characteristics, and HL with HbA1c.
4. To determine the predictors that explain variations in glycemic control among patients with T2DM in Basrah, Iraq.

Phase II: Development

The main objective is to develop and assess the SDNE materials for patients with T2DM in Basrah, Iraq.

Specific Objectives

1. To develop the SDNE materials for patients with T2DM in Basrah, Iraq.
2. To assess the validity, readability, and acceptability of SDNE materials for patients with T2DM in Basrah, Iraq.

Phase III: Evaluation of the SDNE

The main objective is to determine the effectiveness of the SDNE on glycemic control (HbA1c and FBG), and diabetes-related outcomes in patients with T2DM in Basrah, Iraq.

Specific Objectives

1. To determine and compare the glycemic control, socio-demographic status, medical characteristics, nutritional status, lifestyle practices, HBM constructs, DK, and HL between NEG and CG at T0.
2. To determine and compare the effects of SDNE on glycemic control within and between NEG and CG, after T1, and after T2 from T0.

3. To determine and compare effects of SDNE on diabetes-related outcomes including nutritional status, lifestyle practice, HBM constructs, DK, and HL, within and between NEG and CG, after T1, and after T2 from T0.
4. To determine the differences in glycemic control and other diabetes-related outcomes at T1 from T0 and T2 from T0 within and between NEG and CG.

1.5 Hypotheses

1. There are significant associations of socio-demographic status, medical characteristics, nutritional status, lifestyle characteristics, and HL level with HbA1c in patients with T2DM.
2. Socio-demographic status, medical characteristics, nutritional status, lifestyle characteristics, and HL contribute to HbA1c in patients with T2DM.
3. The SDNE would significantly improve the HbA1c in NEG compared to CG over the study period.
4. The SDNE would significantly improve the other diabetes-related outcomes including, nutritional status, blood pressure, physical activity level, HBM constructs, DK, and HL in the NEG compared to the CG over the study period.

1.6 Operational Definitions

Glycated Haemoglobin (HbA1c)

Provides evidence about a person's average blood glucose during the last two to three months, which is the expected half-life of red blood cells (Khan, Weinstock, Mcpherson, & Pincus, 2011). It is suggested as a standard of care for diabetes monitoring (WHO, 2011b). An HbA1c of 6.0% represents the typical plasma glucose of equal to 6.7 mmol/l. Overall; each 1% rise in HbA1c is a consideration of an increase of average glucose levels of similar 1.7 mmol/l (ADA, 2020).

Poor Glycemic Control

In the current study, "poor glycemic control" is defined, when the HbA1c value is $\geq 7\%$ for the past three months, according to ADA (ADA, 2020).

Good Glycemic Control

In the current study, "good glycemic control" is defined when the HbA1c value is equal or less than 6.9% for the past three months, according to ADA (ADA, 2020).

Plate Method

The Plate Method is a meal planning method that works mainly well for patients who consume three meals per day, are with a low level of literacy, have cognitive troubles, have T2DM, and want to lose weight, or are hospitalized and need information for survival. It does not involve calculation skills or a high level of reading (Brown et al., 2001).

Carbohydrate Counting

Carbohydrate counting is a meal planning method ranges from an awareness of foods that have carbohydrate and their outcome on glycemic control, over counting the number of 15 g carbohydrate exchanges, or grams of carbohydrate consumed (Gillespie, Kulkarni, & Daly, 1998).

Anthropometric Measurements

Weight, height, WC, are the measurement which helps to calculate the body mass index and central obesity. It provides detailed information on the different components of the human body structure and helps evaluate nutritional status (Baumgartner, 1993).

Body Mass Index (BMI)

BMI is calculated using weight and height. Weight in kilogram divided by height in meter squared. for normal BMI < 18.5 - 24.9 kg/m², overweight and obese if BMIs were 25–29.9 kg/m², and ≥ 30 kg/m² (WHO, 2004).

Metabolic Equivalents (METs)

Metabolic equivalents are multiples of resting metabolic rates, and a MET-minute is computed by multiplying the MET score of activity by the minutes performed (Craig et al., 2003).

Crowding Index

The crowding index is a whole number of co-occupants per household, without the newborn infant, divided by the whole number of rooms, without bathrooms and kitchen. The overcrowding standard for persons per room most often reported is a standard of more than 1.5 (Blake, Kellerson, & Simic, 2007).

Type of House

This term refers to the state of the house, whether complete or not (Abdul-Hasan & Yassin, 2018).

Type of Family

This term refers to family status, is it extended (living with another family (s)) or separated (living alone) (Abdul-Hasan & Yassin, 2018).

1.7 Conceptual Framework

Figure 1.1 visualizes the study's conceptual framework based on the Generalized Model for Program Planning conducted in 3 phases (McKenzie, Neiger, & Thackeray, 2009). The Phase I study involved the needs assessment in collecting the preliminary data on the basic needs of Iraqi patients with T2DM and in prioritizing them. Their demands were based on the factors determined to be associated with glycemic control. This phase is intended to investigate the extent to which the need assessment could be helpful to detect the actual needs among patients with T2DM to develop the nutrition education materials tailored to their needs. Therefore, Phase II was to develop the nutrition educational materials supported by phase I. In this context, diabetes nutrition education materials were named SDNE.

The SDNE was developed according to the HBM and utilized the Phase I findings to support content development. The HBM constructs (Glanz, 2005) were measured to determine the beliefs about severity, barriers, and the benefits of the intervention. As well as HBM theory was used as a theoretical framework to guide this intervention and improve its effectiveness. HBM is the most common theoretical framework applied to diabetes and nutrition education (Muchiri, Gericke, & Rheeder, 2009). Therefore, the intervention's focus was to create knowledge among patients and help them develop an accurate perception of their unhealthy diet and physical inactivity.

Phase III determined the effectiveness of the SDNE among the targeted population, i.e., patients with T2DM on glycemic control and diabetes-related outcomes. The evaluation process was conducted to assess whether the SDNE was delivered as planned (Young et al., 2008). The findings were used to evaluate the intervention in terms of reliability and completeness. The study was initially planned for 24 weeks. Still, it was conducted for 22 weeks due to some conflicts in Iraq at the beginning of December 2019 between the Iraqi people and the government to change some legislation that did not achieve justice between the Iraqi people at that time. Thus, the study was shortened to 22 weeks due to fear of worsening the situation and imposing a Curfew, which prevents study participants from accessing the study site.



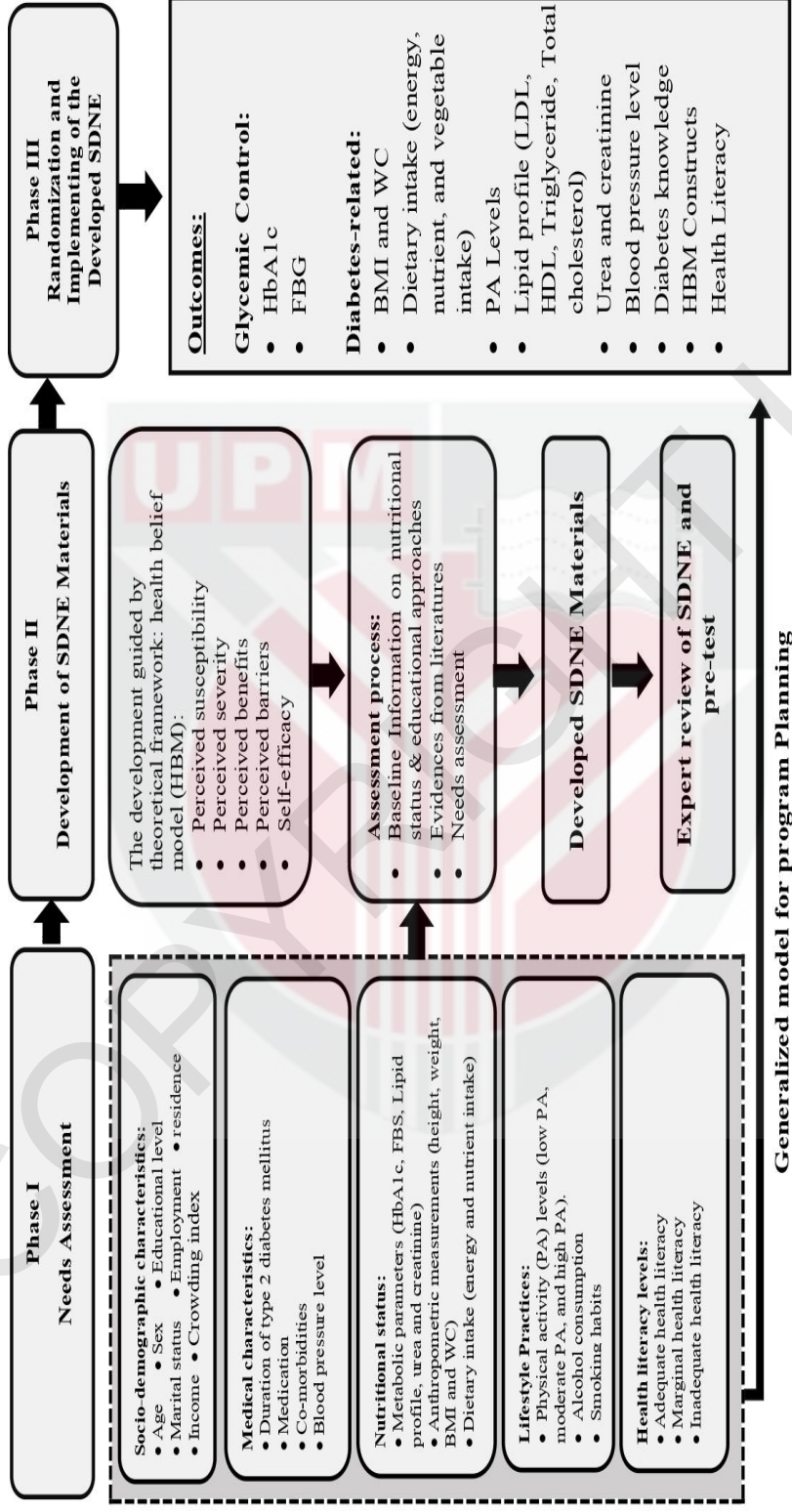


Figure 1.1 : Conceptual Framework of the whole study based on the generalized model for program planning. HbA1c = Glycated hemoglobin, FBG = fasting blood glucose, LDL= low-density lipoprotein, HDL = high-density lipoprotein, BMI = body mass index, WC = waist circumferences, simplified diabetes nutrition education= SDNE.

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BIODATA OF STUDENT

Saman Agad Hashim was born on 11th April 1979 in Najaf, Iraq. He started primary school at Al-Thaora school in Erbil. Later, he continued his secondary school at Al-Farazdak School in Basrah. He had finished his high school at Al-Shaab School in Basrah. In 2000, he did his university education at the medical institute, Southern Technical University, in Basrah, and graduated in 2003 with a Diploma in community health. After graduated, he was offered as a medical assistant at Al-Sader Teaching Hospital in Basrah before persuading his Bachelor and master's degrees. In 2008, he completed his Bachelor of Science (Community Health) at the faculty of medical technology, Middle Technical University, in Baghdad. Almost three years before persuading his Master, he had involved as a health educator in the public health clinic in Al-Sader Teaching Hospital in Basrah City. In 2011, he received his master's degree in Medical Sciences (Community Health) at the faculty of medical technology, Middle Technical University, in Baghdad with a thesis entitled "Risk Factors of Low birthweight Neonates in Governmental Hospitals in Basrah City." Almost six years before persuading his Ph. D, he was involved in the nutrition clinic as a nutritionist at Al-Sader Teaching Hospital in Basrah. He improved and gained more knowledge and experience in managing weight and dietary planning. He persuaded his Ph.D. in the year 2017 – 2020. He continues his Ph.D. due to his interest in Clinical Nutrition in Universiti Putra Malaysia (UPM).

LIST OF PUBLICATIONS

Journals:

Hashim, S. A., Barakatun-Nisak, M. Y., Abu Saad, H., Ismail, S., Hamdy, O., & Mansour, A. A. (2020). Association of Health Literacy and Nutritional Status Assessment with Glycemic Control in Adults with Type 2 Diabetes Mellitus. . *Nutrients* 2020, 12, 3152.

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