QATAR UNIVERSITY

COLLEGE OF MEDICINE

DEVELOPMENT OF A PROBLEM AND ATTRIBUTES BASED DIABETES

SELF-MANAGEMENT (PARADIGM) INTERVENTION

BY

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ABSTRACT

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Title: Development of a Problem and AttRibutes bAsed DIabetes self-manaGeMent (PARADIGM) intervention

Supervisor of Dissertation: Suhail Doi.

Background: Type 2 diabetes mellitus (T2D), is a growing pandemic across the world. T2D requires a comprehensive diabetes self-management (DSM) skills in addition to medications. It is still unclear what interventions can influence intention for DSM and how best these interventions can be delivered.

Aim: To critically evaluate structure of existing diabetes self-management interventions and their impact on different levels of outcomes such as knowledge, physical activity, glycated hemoglobin (HbA1c), and quality of life. Understand perception of T2D patients towards intention to DSM and combine findings to develop problem and attribute-based case scenarios that can be integrated in DSM interventions.

Method: First, a critical evaluation of the recent interventional studies using a concept analysis to clearly define the operational conceptualization and boundaries of existing diabetes self-management interventions programs and eventually provision of tools for further research. Then meta-regression analysis was conducted to classify existing intervention based on the attributes and evaluate the impact of these attributes on different levels of outcomes. Next, a focus group study to explore perspectives of persons with T2D towards DSM performed, followed by tool development using focus group responses to assess intention towards DSM. Finally, Delphi study

included stakeholders in diabetes care was implemented to generate a consensus on case scenarios of attribute and problem-based curriculum for promotion of T2D self-management (PARADIGM).

Results: From concept analysis, the operational conceptualization of interventions were redefined into 5 key core attributes (1) decision making, (2) problem solving, (3) taking action, (4) patient-provider interaction and (5) resource utilization. In meta-regression study consisting of 142 papers, skills related attributes were effective on improving knowledge SMD = 0.80 (0.11, 1.49); P = 0.025. Fear of complications and death was motivators for DSM, whereas food and social customs were demotivators for DSM. The tool developed from focus group study was reliable and a good internal consistency to predict intention towards DSM. In the Delphi, we combined previous findings to generate problems and attributes-based DSM intervention using case scenarios.

Conclusion: This project outlined the importance of developing a robust DSME intervention program. This could result in increasing uptake by PWD of an effective intervention that can help maintain successful DSM with consequent improvements in their quality of life.

DEDICATION

To my parents, my husband, my lovely children

Shahad, Maha, Hassan, Seif, Noor, and Mohamed.

Also

my Loyal Sisters, and Brothers.

Finally

To all People with Diabetes

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3. Othman, M.M., Al-Wattary, N.A., Khudadad, H, Dughmosh, R., Furuya-Kanamori, L., Abou-Samra, A., Doi, S.A.R., Daher-Nashif, S. Perspectives of persons with type 2 diabetes towards diabetes self-management: A qualitative study. Health Education and Behavior, 2021.

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Chapter 1 : Introduction

Diabetes mellitus (DM) is a complex chronic disease that is dramatically increasing in incidence and prevalence and which poses a significant public health challenge to most countries across the globe, DM has not only health implications, but also financial, social, and development consequences especially in low and middle-income countries [1].

Type 2 Diabetes (T2D) among the 20–79 year age groups is currently estimated to affect an estimated 537 million people, and is predicted to rise to 643 million by 2030 and 783 million by 2045 [1]. In the MENA region the prevalence of T2D among those aged 20-79 years old is 16.2%, and this number will be expected to increase to 19.3% by 2045 [1]. In Qatar the prevalence of T2D is 17% [2].

Due to the chronic and complex nature of the disease, the management will not depend on drug use only, but also on different management strategies to ensure good glycemic control. This condition is one of those for which the chronic care model (CCM) was developed and which advocates heavily for patient involvement in care [3] Figure 1.1. The CCM comprises of six components that are interrelated and of these, one is self-management and when applied to diabetes has been called diabetes self-management (DSM). The latter aims to empower patients to be a partner in achieving their glycemic targets [4]. A population-based study evaluating the effectiveness of CCM in managing T2D in primary care suggested that the use of this model of care reduces the incidence of diabetes complications and all cause mortality[5] . The patients who were enrolled in the CCM experienced a reduction in cardiovascular disease by 56.6%, microvascular complications by 11.9%, and mortality rate by 66.1% over five years follow-up[5]. Furthermore, the cost of health care resulted in savings of 7294$ per individual during the five years[6]. The strengths and success of the CCM seem to

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be linked to its team based approach and its focus on empowering patients through self-management [7].

Figure 1.1 Chronic Care Model[3]

1.1 History of Diabetes Self-Management Education (DSME):

In 1918, Joslin identified that tight glucose control leads to fewer and less extreme complications. Recognized pioneer in glucose management, he became a spokesman for the "cause of diabetes". He was the first to advocate for teaching patients to care for their own diabetes, an approach now commonly referred to as DSME. The first formal Joslin Clinic diabetes teaching program was established in the 1930s , and has been the site of many significant developments and has served as a model for other areas of patient education[8]. Figure 1.2 describes the historical review of DSME [9]. The notion of self-management evolved during the 1960s and 1970s influenced by changes in societal values about individuals' responsibility for their health however,

the quality of diabetes education varied considerably. To address this, the National Diabetes Advisory Board (NDAB) in the US, in collaboration with other diabetes-related groups, developed standards to be followed[10].
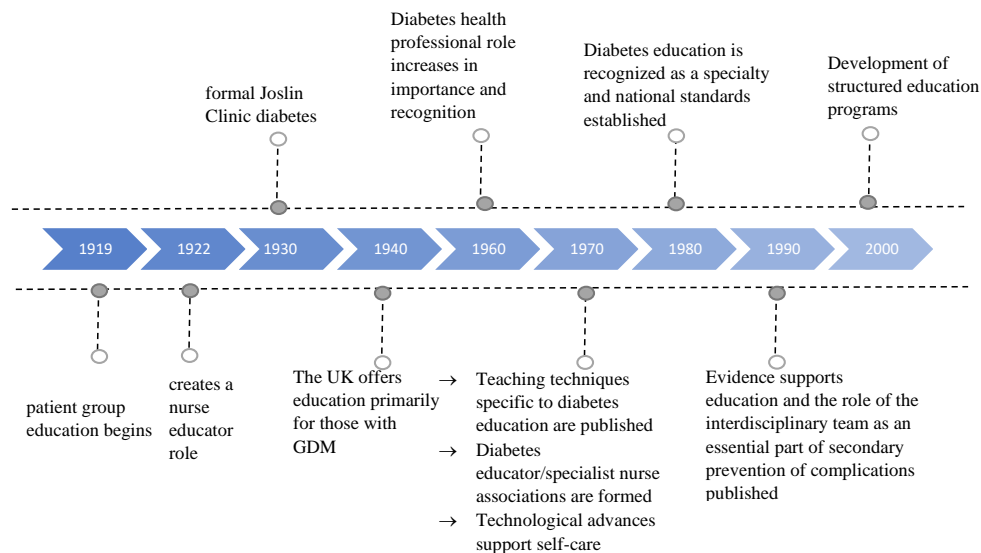
Figure 1.2 History of DSME

In 1983, the National Standards for Diabetes Patient Education Programs was developed as a result of the Diabetes Control and Complications Trial (DCCT) which was conducted from 1983 to 1993[11]. The standards were deliberately designed to be general enough to be implemented in a variety of settings and to deal largely with the processes of developing and maintaining a quality diabetes education program. The original standards consisted of ten components, each divided into elements applicable to the sponsoring institution or the educational program. Review criteria were developed as a method to measure the programs' achievement[12].

The American Diabetes Association (ADA) implemented a process in 1986 to officially recognize programs that attain the National Standards for Diabetes Patient Education Programs. The first program to achieve these standards was recognized by

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the ADA in 1987, and since then over 375 programs have achieved this status [13].

By the 1990s, self-management was firmly established as part of central health care policy through the Wanless reports[14]. Since 1995 several iterations of the guidelines (also called *standards* to be followed) appeared[12, 15-17]. Within the guidelines, teaching techniques for DM education were not specified, but rather deliberately vague, designed to be general enough to be implemented in a variety of settings and to accommodate the processes of developing and maintaining a quality diabetes education program[15].

By 2010, a need for a written curriculum for any diabetes self-management education program was deemed necessary to provide comprehensive instructions in the content areas relevant to the target population's culture, age, type and duration of DM and individual learning abilities. This was identified by a Task Force which was jointly convened by the American Association of Diabetes Educators and the American Diabetes Association [17]. These guidelines consisted of structure-related, process related and outcome related sections. Within the process related guidelines there was reference to the written curriculum with general areas of education outlined such as "incorporating physical activity into lifestyle". Under the direction of these guidelines, self-management programs continued to target a set of daily behaviors that patients should adhere to in order to manage their chronic condition[12, 15].

1.2 Definition of Diabetes Self-Management today and availability of structured intervention programs:

ADA defines DSME as the "process of facilitating knowledge, skills, and abilities necessary for diabetes self-care". Diabetes self-management support (DSMS) is defined as " the support that is required for implementing and sustaining coping skills and behaviors needed to self-manage on an ongoing basis"[16].

The overall objectives of DSME today are to support informed decision-making, self-care behaviors, problem-solving and active collaboration with the health care team and to improve clinical outcomes, health status, and quality of life [17]. Specific benefits were framed in terms of outcomes such as a) improve the knowledge and understanding of the disease for individuals with diabetes, b) empower individuals with diabetes and improve their abilities to live safely with their condition, c) enhance psychological status to living with diabetes, d) motivate diabetes self-management behaviors among individual with diabetes and finally to e) generate better clinical outcomes [18].

There are currently many different structured education programs for different types of DM, for example: X-PERT (Expert Education versus Routine Treatment) is a group based self-management program based on theories of empowerment[19] and DESMOND (Diabetes Education for Ongoing and Newly Diagnosed) is also a group based education program focused on an individual's illness beliefs based on social learning theory[20] . These programs have led to some improvements in clinical and psychosocial outcomes for individuals with T2D compared to one-to-one education[21].

The overall objectives of DSME today include DSM support (DSMS) to support informed decision-making, self-care behaviors, problem-solving and active collaboration with the health care team and to improve clinical outcomes, health status, and quality of life.[22]. Thus, DSME programs are largely focused around outcomes that are audited regularly against consistent criteria by independent assessors for quality assurance. This has resulted in a proliferation of outcomes and the day-to-day tasks or skills patient should learn to achieve those outcomes are left to various healthcare providers to determine based on the advisory structure of the existing guidelines. Some

of these skills taught are purely behavioral and others are a combination of behavioral and psychological aspects while others are management skills, and each provider interprets the delivery of such education in the light of their experience and expertise. This may contribute, in part, to the observation that high participation rates in current DSME programs do not guarantee attainment of clinical outcomes[23].

The first structured diabetes education program delivered for groups of people with diabetes was developed by Michael Berger and his colleagues [24]. It focused on transfer of knowledge and skills around glucose control, insulin use, and preventing acute complications, and was to be delivered by trained nurse educators and, being structured, also allowed the efficacy of such programs to be evaluated. The latter led to a move towards structuring the education program for DM in order for it to be tested in trials and to generate evidence based data [23]. While this was an opportunity to specify what was to be learnt, this did not ultimately change the DSME process as much as would have been expected [23]. One reason was that it lent itself to a broad definition as: "a planned and graded process that facilitates the knowledge, skills and ability for diabetes self-management and empowers individuals to live healthily, to maintain and improve their quality of life and assume an active role in their DM care team [25]". This led to a myriad of interpretations because key elements suggested for a structured education program were process or outcomes based and included [21]:

- A theoretical basis

- A comprehensive and clear structured curriculum

- Delivery by certified educators

- A quality assurance system

- A well-designed auditing processes

This was an attempt to increase benefit from it, but this thinking also led to a proliferation of structured diabetes self-management intervention programs among different institutions worldwide, given the lack of specificity about what was to be taught. Despite the latter, a systematic review conducted in the Gulf Cooperation Council (GCC) states (Saudi Arabia, Qatar and Oman) regarding structured DSME programs reported a positive impact on HbA1c levels, and significant improvement in physical activity(UAE, Saudi Arabia, and Oman) [26]. During the last decade many self-management programs have been developed and delivered by the healthcare sectors, but there has been no consensus over their content and delivery mode [27] and thus all have been developed with different interpretations on content depending on what the health system felt was useful to generate the desired outcomes.

1.3 Rational of the Thesis:

Currently, DSME programs target attainment of aspects within three broad outcome groups: medical outcomes, behavioral outcomes and emotional outcomes [28]. What content and skills are taught to PWD varies widely depending on the providers' interpretation of priorities in these areas. Following Wagner's Chronic Care Model [29], there was a renewed interest in dealing with chronic disease self-management [29] because it subsumed within it efforts to integrate self-management support. Another seminal work was that by Lorig and Holman in 2003, that dealt with the mechanisms underpinning chronic disease self-management [30] which outlined a view-point different from the existing general trend noted for DSME namely that one needs to address three main self-management responsibilities: medical management, role management, and emotional management. However, Lorig and Holman's position was that specific self-management skills patients need to acquire must be defined *a priori* , and thus represented the first attempt to advocate for a skills to be acquired

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approach as opposed to an outcomes to be achieved approach in chronic disease self-management [30]. Unfortunately, Lorig and Holman's much cited paper failed to shift [30], the DSME away from the focus on the attainment of desired outcomes to actual attributes that are desirable to be acquired by patients with DM. Their legacy lay in setting a strong foundation for providers to think of ways in which such skills can be met[30].

Currently, there remains a lack of consensus about what works best to encourage people with T2D to self-manage their condition. Nor is there a clear understanding of how best DSME can be structured for delivery. These questions have been flagged as a research priority in DM by the Diabetes UK–James Lind Alliance Priority Setting Partnership[31]. The National Strategy to Prevent Diabetes in Qatar identifies, patient empowerment as one of the six pillars pertinent to develop a specific tailored self-management intervention program[2]. This program of research therefore was undertaken to examine these gaps locally and propose a framework for structured DSME addressing these issues by shifting from *an outcomes-to-be-achieved* approach towards a *core-attributes-to-be-developed* resolution.

1.4 Aim of the Project:

The main aim of this project is to develop a structured diabetes self-management intervention program which, in future studies, can be assessed against its impact on different levels (immediate, intermediate, post-intermediate and long-term) of outcomes such as knowledge, physical activity, HbA1c, and quality of life.

1.5 Objectives of the Thesis:

Each phase of the integrated project has specific objectives outlined below.

1. Objective 1: To define the boundaries of DSME interventions and resolve ambiguity in its operational conceptualization.

2. Objective 2: To assess the impact of reclassifying existing interventions according to the results in objective 1 and assess the impact of the new classification on the four outcome levels using meta-regression to ensure the key attributes target different outcomes.

3. Objective 3: To understand perceptions of PWD toward diabetes self-management (DSM) to further improve intervention development.

4. Objective 4: To assess the intention of people with T2D toward self-management based on the Triandis model to better tailor intervention development.

5. Objective 5: To use the Delphi process to develop a final diabetes self-management educational intervention using data from objectives 1 – 4.

Chapter 2 : Overview of Methods Used In This Program of Research

2.1 Concept analysis

The project started with literature screening using different databases such as Pubmed, Embase, and Cochrane, and the 50 most recent intervention studies were critically evaluated using a concept analysis approach. Walker and Avant's method was applied because it is a clear and well-structured method that is commonly used in health to develop a clear operational definition of the research concept [34] that integrates the critical attributes and their empirical referents in the real world.

Using concept analysis allows us to clearly define the operational conceptualization and boundaries of existing diabetes self-management interventions programs and eventually provision of tools for further research.

The main outcomes from this approach are:

a) Defining the key attribute of the concept (diabetes self-management intervention)

b) Provision of a model case as an ''absolute example'' of the concept that shows each of the specifying attributes of the concept that emerge through this analysis.

c) A discussion of "antecedents and consequences", and as their names propose, these will either precede or are the result of the concept respectively and clarifying these will help illustrate the evolution of such an intervention.

d) A discussion of the ''empirical referents" which are concrete measures that can be used to measure the defining attributes of the concept itself.

The above outcomes were achieved using the following eight steps based on Walker and Avant's method:

Step 1 "*Select the concept":* The development of structured DSMES programs and the

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best method for the delivery of a structured DSMES intervention is still unclear. A clear operational definition of self-management interventions in T2D was selected as the concept for this analysis.

Step 2 "*Identify analysis aims and purposes":* The main purpose of this analysis is to clarify the definition and conceptualization of self-management interventions for T2D. This would involve a detailed investigation following the steps of a formal concept analysis.

Step 3 "*Recognize concept uses":* The scope of this analysis was exclusively for diabetes self-management interventions and all types of interventions delivered to promote self-management in type 2 diabetes were reviewed. This was done to generate the most inclusive conceptualization of DSME interventions based on those reported in the recent literature. This is especially important since DSME intervention content has been defined ambiguously such that an operational definition is left open to the health system end users. To ensure that our concept analysis was contemporary, we chose the most recent 50 intervention studies from an extensive search reported elsewhere [32]. These 50 intervention studies were limited to those evaluating the efficacy or effectiveness of DSME in T2D, recruited adults 18 years and above, were written in English (or including an abstract in English) and excluded those studies that focused explicitly on special populations (e.g., dementia , Down's syndrome etc.). The search identified 142 studies published between 1990 and April 2020 from which the most recent 50 were selected, published between 2015 and 2020 [32], to ensure the most contemporary data which is essential for concept analysis.

Step 4 "*Determine the defining attributes"*: An organized and focused method was applied to determine the essential attributes of the DSME intervention programs using the most recent 50 studies, by focusing on and re-classifying the selected items

taught in terms of common and essential attributes of the content of the varying diabetes self-management program contents and classifying them based on their putative mechanisms.

Step 5 "*A model case identification":* A model case is one that considers all the defined attributes present in the DSME intervention program applied to the case. The case was identified based on the clinical experience of one of the authors (MO).

Step 6 "*Identify additional cases":* In order to carefully recognize the consequences of the lack of application of the defined attributes, additional cases that did not fully apply or missed all attributes will be considered in the analysis.

Step 7 "*Antecedents and consequences identification":* Antecedents are events or attributes that should be present prior to the to a concept's application. For example, diagnosis with T2D, access to the health care system, and availability of self-management program within the health system are considered antecedents. Impact of DSME programs on the health status for people with T2D, and reduction in the cost of diabetes management on the health system are considered as consequences.

Step 8 "*Describe empirical referents":* Eventually, empirical referents were described for each of the specified attributes to make the attributes of the concept measurable in a more standardized manner.

2.2 Meta-regression analysis

A meta-regression analysis was conducted. PubMed, Embase, Cochrane Central Register of Controlled Trials, Cochrane library, ClinicalTrials.gov, WHO website, PsycINFO, and the grey literature (www.opengrey.eu/) were searched from 1990 to 2020. The search strategy was broad and included several keywords and synonyms (supplement section A). To identify trials that may have been missed through the search strategy, the top 20 similar citations for included studies on PubMed were manually

searched. Simple structured Boolean searches were also constructed as these are efficient and reliable search techniques to assess the completeness of an evidence base consisting of published trials [33]. In addition, all references from the included studies and relevant previous systematic reviews were hand searched to identify possible missed studies.

Study selection:

All interventional studies evaluating the efficacy or effectiveness of DSME in T2D that recruited adults 18 years and above, written in English (or including an abstract in English) published between 1990 and April 2020 were considered further. To be eligible, the studies had to be interventional (RCTs or quasi-experimental study designs) and have reported the outcome of interest which was the impact of a diabetes self- management education program on different levels of outcome (immediate, intermediate, post-intermediate and long-term). One outcome at each level was chosen for analysis – the most commonly reported outcome. These were:

- *knowledge* as the immediate outcome,

- *physical activity* as the intermediate outcome,

- *HbA1c*% as the post-intermediate outcome, and

- *quality of life* as the long-term outcome.

Studies that included people diagnosed with type 1 or other types of diabetes were excluded. Observational studies, study protocols and pilot studies, non-English language publications, studies addressing T2D in special populations (e.g. patients with psychological disorder or with cognitive deficits), or published only in abstract form were excluded.

Data extraction and quality assessment:

Two authors independently assessed the eligibility of the studies using the Rayyan QCRI platform[34] first by title and abstract and then followed by assessment of the eligibility of selected studies by full-text review. Discrepancies were resolved through discussion and consensus after independent evaluation by another author. This process also applied to methodological quality assessment and extraction of key variables (e.g. numbers of events). When reports omitted data that we considered important or seemed inconsistent, the corresponding authors were contacted for clarification and additional information.

The quality of the original studies was assessed using the MethodologicAl STandard for Epidemiological Research (MASTER) quality assessment scale [35], which assesses the studies against 36 bias safeguards across seven standards to be fulfilled. The safeguards present in each study were then counted, and these counts were converted into a relative quality rank between 0 and 1 by dividing the count in each study by the highest in the group [36] . The quality rank was planned to be used for bias adjustment of the pair-wise meta-analysis [37] but due to heterogeneity, a meta-regression analysis was conducted, and quality assessment reported qualitatively.

Data synthesis and analysis:

The five identified DSME intervention related attributes from the concept analysis [38], were used to categorize selected intervention studies. The first categorization was those that delivered content on all three skills-related attributes (P, D and A) (henceforth called PDA), or were incomplete (i.e. one or more missing). The second categorization was into those that had all information-related attributes (Res and Rel) or neither present.

The effect size of interest was the standardized mean difference (SMD) for all outcomes

except the post-intermediate (HbA1c) outcome as they were measured across studies on different scales. The weighted mean difference (WMD) was used for the HbA1c outcome. These differences were computed between the intervention and usual care arms in each study. An initial analysis was done synthesizing effects from PDA classified interventions sub-grouped by outcome and the latter was used to explore heterogeneity and small study effects.

Heterogeneity was assessed using the I^2 statistic, and a value between 0-40% was considered as low heterogeneity, 40-60% as moderate heterogeneity and more than 60% as considerable heterogeneity [39]. Small study effects (the tendency for intervention effects estimated in smaller studies to differ from those estimated in larger studies, which can result from reporting or publication biases, methodological or clinical heterogeneity, or other factors) were assessed using Doi plots and the LFK index Doi plots and the LFK index make use of the association between the effect size and the absolute Z score, which is a more reliable approach than funnel plots or Egger regression. A LFK index value greater than 1 or less than −1 indicates minor asymmetry, and a value greater than 2 or less than −2 indicates major asymmetry [40].

Since there was significant heterogeneity across studies, meta regression analysis was only reported, but retained the heterogeneity and publication bias metrics from the initial analysis as an overview. The meta-regression models included two explanatory variables: an indicator for the PDA group (0, incomplete PDA and 1, PDA) and an indicator for the Res-Rel group (0, no Res or Rel and 1, both Res and Rel present) as defined above. A robust error fixed effect meta-regression analysis [41] using these two categorical covariates was performed. In this approach, weighted least squares is used for parameter estimation and (cluster) robust variance estimation is used to

estimate standard errors and conduct hypothesis tests [42].

2.3 Mixed methods analysis

In step 1 a focus group based on Triandis model using qualitative method was designed to understand the perspectives of people with T2D (PWD) towards DSM. [43].

Four focus group interviews with patients attending outpatient diabetes clinic at secondary and tertiary setting were conducted virtually due to COVID-19 gathering restrictions. The inclusion criteria included being an Arabic and English speaker, diagnosed with T2D, have an access and ability to use online platform. The exclusion criteria included, being unable to speak Arabic and/or English, no formal diagnosis of T2D, lack of access and/or ability to use online platform.

A purposive sampling method was used and recruitments continued until we reached saturation [44]. Twenty-nine participants of different nationalities participated in the study. Three participants dropped from the study due to time limitations.

Participants were divided into four groups: two male groups and one female group of Arabic speakers, and one gender-mix group of English speakers. Each group included four to nine participants. The focus group sessions ranged from 60 to 90 minutes and were conducted in either Arabic or English.

Each focus group session was led by two researchers and began with an icebreaker introduction; the researchers were introduced, and participants were asked to share their backgrounds and history of diabetes. The researchers prepared a set of questions that aligned with Triandis' TIB Model, addressing each of the four components in the model [45].

Additional questions emerged from participants' responses to the main questions. The focus group sessions were voice-recorded and transcribed. Discussions in Arabic were translated to English by an expert in translation from Arabic to English.

Two researchers independently analyzed the focus groups transcripts, using structured-deductive content analysis. Furthermore, summative-inductive content analysis was conducted on insights and reflections that did not align with Triandis' themes but contributed to understanding patients' perspectives on T2D self-management. Both researchers compared their final themes of analysis. When consensus could not be reached, a third person adjudicated. Qualitative validation strategies were employed for the findings' validation.

In the next step responses were classified and converted into items within each of the theoretical domains of the Triandis model (intention, social factors, perceived consequences and affect).A questionnaire consisting of 42 such items: 12 in the intention domain (scale s1), 15 in the social factor's domain (scale s2), 9 in the perceived consequences domain (scale s3) and six in the affect domain (scale s4) was developed. All scale items were constructed as five-response Likert-type scales except scale s4 which was a five-point semantic differential scale. Eight items were included for demographic characteristics, including age, sex, nationality, social status, education level, living status and years since diabetes diagnosis. The final pre-coded questionnaire was pre-tested with ten patients in order to assess face validity and duration. Subsequently, minor adjustments were done to the wording of some questions.

Histograms of individual items as well as inter-item correlations within each subscale were reviewed to identify floor or ceiling effects that do not help in discriminating between patients, and thus could be removed from the scale. Those items that had zero or nearly zero variances or average inter-item correlations less than 0.15

were flagged for removal.

Reliability analysis was used to improve the scale derived from the qualitative analysis by selecting out items that largely measure esoteric aspects that can be considered as random error. To do so, the item-test correlation and the Cronbach alpha were calculated. Any item with an item-test correlations <0.2 or any item with a Cronbach's alpha (compares the sum of item variances with the variance of the sum scale) that increased significantly (reaching $0.60 - 0.70$ or higher) when it was excluded were flagged for removal.

The final items that formed each scale were then centered in the middle of the five-point Likert scale (range now -2 through 0 to +2) and averaged into a score for each of the four subscales (s1score to s4score). The s1score (intention subscale average score) was dichotomized into upper tertile (1; higher level intention) and lower two tertiles (0; medium to lower-level intention). Multivariable logistic regression was used to identify the subscale scores independently associated with higher level intention.

Based on the previous findings, a Delphi method was conducted virtually using Microsoft Teams due to COVID-19 restrictions to identify the factors and strategies that can be best employed to develop diabetes self-management educational modules using Problem Based Learning (PBL) addressing the five attributes discussed previously [46].

2.4 Delphi methods

After stakeholder mapping based on their expertise and experience in the field, The Important content to be delivered that was consistent with the five attributes was listed exhaustively and subjected to critical discussion. The following five steps were completed in sequential Delphi rounds: (1) Introduction of the concepts of the five attributes; (2) determination of real examples that mimicked clinical practice related to

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each attribute; (3) scenario building; (4) interaction development and (5) refinement (if required) of the scenarios and interactions.

A total of eleven rounds were carried out with the steering group of key stakeholders. The purpose of the first meeting was to introduce the five attributes that were published previously [38] and to agree on the content of new educational modules for DSME intervention in relation to these attributes. Stakeholders were asked to provide authentic examples of each attribute [46] derived from their daily practice to be discussed in the next round.

In the second meeting, stakeholders identified cases from their practice that exemplified the five attributes. These cases were created based on actual clinical examples witnessed by the educators but subsequently modified to provide a comprehensive teaching case to maximize learning opportunities and target specific learning objectives deemed necessary for people living with diabetes to learn.

The initial cases were discussed after which five educators were tasked with further developing the scenarios to ensure it explored all the facets of the attribute under review. We agreed to start with problem solving, and decision-making attributes for the next round.

The third round comprised of elaboration and content clarification of the two case scenarios. Question prompts and answers were devised to support patient-educator interactions at this time.

In round four, the proposed interactions were finalized and approved. The interactions will help the facilitator to navigate the discussion, focusing on the relevant attributes and engage the learner in productive dialogue that allows learning to procced *ex officio*. The same process was repeated to delineate the learning objectives and develop the PBL scenarios for each of the attributes.

Chapter 3 :Towards A Better Understanding of Self-Management Interventions In Type 2 Diabetes: A Concept Analysis

3.1 Introduction

Diabetes self-management education (DSME) was first developed in the 1930s with the first formal Joslin Clinic Diabetes Mellitus (DM) teaching program [9]. In the mid-eighties to early nineties, the National Standards for Diabetes Patient Education Programs were developed as a result of the Diabetes Control and Complications Trial [47]. Within these programs, most of the diabetes self-management approaches taken were under the direction of the individual's physician and other health care providers, and the emphasis on input from the individual with diabetes was limited [48].

Although patient empowerment was the goal, it was seen more as a vision or philosophy rather than a technique or strategy which could be used by health professionals to help patients to achieve their goals [49]. Therefore, gradually, the focus of such interventions shifted towards patient education deemed necessary for individuals to optimize glycemic control and avoid progression in the face of Type 2 Diabetes (T2D) [50].

Since 1995, over 375 programs have been recognized under the national standards of the American Diabetes Association [8]. The focus continued to be on the individual's responsibilities to avoid outcomes associated with disease progression [50] and the updates made to the DSME guidelines (called *standards* to be followed) [12, 15-17] were deliberately designed to be generic, so that they

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could be implemented in a variety of settings. These guidelines consisted of 10 standards, and each standard was divided into aspects applicable to the sponsoring institution or the educational program [12].

By 2010, a written curriculum was recommended – and this was an attempt to *structure* the self-management education program [17].

This evolution of DSME described above has led guidelines and the standards subsumed within them to be less prescriptive and more general, leading to overall objectives that are generic with ill-defined boundaries. Health professionals are left individually to interpret and decide upon the needs for informed decision-making, self-management behaviors, problem-solving and effective partnership, and to assess how these intervention can be optimally designed such that they result in improvements in clinical outcomes and quality of life [22].

During the last decade many self-management programs have been developed and delivered by the healthcare sector [27] and these have mainly addressed aspects of self-management that are thought to impact three broad outcome groups: medical outcomes, behavioral outcomes, and emotional outcomes. However, the content taught to patients varies widely depending on the providers' interpretation of priorities in these areas.

One reason for this variability in intervention design is that the scholarly literature has not adequately captured the theoretical aspects of self-management interventions in T2D. It is not clear whether the current T2D specific definitions of self-management are based on an adequate operational conceptualization and unraveling of the latter has been flagged as a priority for research [31].

The purpose of this article is therefore to clearly define the boundaries of DSME interventions and resolve ambiguity in its operational conceptualization. We

address this gap through use of Walker and Avant [51] method of concept analysis which will enable us to generate specific attributes desired in an intervention for promoting self-management in T2D .

3.2 Methods

This paper uses a concept analysis as a structured approach to define the boundaries of the chosen concept. Walker and Avant's method was applied in this paper, because it is a clear and well-structured method that is commonly used in health and that can help the development of a clear operational definition of the DSME intervention [51].

The process of completing the analysis will enable a much clearer definition of the boundaries of this concept and what it entails. The end result is expected to be clarification of the DSME intervention's operational conceptualization and eventually provision of tools for further research. The main outcomes from this approach are expected to be:

e) Defining the key attribute of the concept (diabetes self-management intervention)

f) Provision of a model case as an ''absolute example'' of the concept that shows each of the specifying attributes of the concept that emerge through this analysis.

g) A discussion of "antecedents and consequences", and as their names propose, these will either precede or are the result of the concept respectively and clarifying these will help illustrate the evolution of such an intervention.

h) A discussion of the ''empirical referents" which are concrete measures that can be used to measure the defining attributes of the concept itself.

The above outcomes were achieved using the following eight steps:

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Step 1 "*Select the concept*": The development of structured DSMES programs have been tested in trials to generate evidence based data [23] but this has not helped to standardize what should be delivered. While existing programs do indeed achieve some improvements in clinical and psychosocial outcomes for individuals newly diagnosed with T2D compared to one-to-one usual care [21], the best method for the delivery of a structured DSMES intervention is still unclear regardless of who the individual is with diabetes or where they live in the world. This question has been flagged as a research priority in DM by the Diabetes UK–James Lind Alliance Priority Setting Partnership [31]. The James Lind Alliance [31] asked the question "what is the best way to encourage people with type 2 diabetes whoever they are, wherever they live to self-manage their condition and how should it be delivered". An answer to this question requires a clear operational definition of self-management interventions in T2D and hence was selected as the concept for this analysis.

Step 2 "*Identify analysis aims and purposes*": The main purpose of this analysis is to clarify the definition and conceptualization of self-management interventions for T2D. This would involve a detailed investigation following the steps of a formal concept analysis.

Step 3 "*Recognize concept uses*": The scope of this analysis was exclusively for diabetes self-management interventions and all types of interventions delivered to promote self-management in type 2 diabetes were reviewed. This was done to generate the most inclusive conceptualization of DSME interventions based on those reported in the recent literature. This is especially important since DSME intervention content has been defined ambiguously such that an operational definition is left open to the health system end users. To ensure that our concept analysis was contemporary, we chose the most recent 50 intervention studies from an extensive search reported

elsewhere [32]. These 50 intervention studies were limited to those evaluating the efficacy or effectiveness of DSME in T2D, recruited adults 18 years and above, were written in English (or including an abstract in English) and excluded those studies that focused explicitly on special populations (e.g. dementia , Down's syndrome etc.). The search identified 142 studies published between 1990 and April 2020 from which the most recent 50 were selected, published between 2015 and 2020 [32], to ensure the most contemporary data which is essential for concept analysis.

Step 4 "*Determine the defining attributes*": An organized and focused method was applied to determine the essential attributes of the DSME intervention programs using the most recent 50 studies, by focusing on and re-classifying the selected items taught in terms of common and essential attributes of the content of the varying diabetes self-management program contents and classifying them based on their putative mechanisms.

Step 5 "*A model case identification*": A model case is one that considers all the defined attributes present in the DSME intervention program applied to the case. The case was identified based on the clinical experience of one of the authors (MO).

Step 6 "*Identify additional cases*": In order to carefully recognize the consequences of the lack of application of the defined attributes, additional cases that did not fully apply or missed all attributes will be considered in the analysis.

Step 7 "*Antecedents and consequences identification*": Antecedents are events or attributes that should be present prior to the to a concept's application. For example, diagnosis with T2D, access to the health care system, and availability of self-management program within the health system are considered antecedents. Impact of DSME programs on the health status for people with T2D, and reduction in the cost of diabetes management on the health system are considered as consequences.

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Step 8 **"*Describe empirical referents*":** Eventually, empirical referents were described for each of the specified attributes to make the attributes of the concept measurable in a more standardized manner.

3.3 Results

3.3.1 Steps 1 - 3

The initial screening has been reported previously [32], and the 50 most recent studies were used for this concept analysis to evaluate the existing DSME interventions. The analysis of these 50 studies was grounded in their reporting of what was delivered regardless of the delivery mode used in each DSME intervention programs. The average population consisted of subjects from the following countries: US (n=10), Iran (n=8), China (n=4), Spain (n=3),Australia (n=2), Brazil (n=2), Canada (n=2), Indonesia (n=2), Netherlands (n=2), Philippines (n=2), Ethiopia (n=1), Greece (n=1), Hong Kong (n=1), India (n=1), Iraq (n=1), Italy (n=1), Jordan (n=1), Kenya (n=1), Thailand (n=1), and UK (n=1), Turkey (n=1), Mali (n=1), Cyprus (n=1).

3.3.2 Step 4: "Attributes"

Critical evaluation of the different articles using codes and categories on extracted data identified five attributes after discussion within the research team that were consistent with the generic mechanisms of chronic disease self-management previously proposed by Lorig and Holman [30]. Table 9.1(Supplementary file) gives an example of the mapping of the content of the different interventions to the finally chosen attributes. To improve the legibility of the results, the different attributes are organized as follows:

1. Three skills related attributes mainly related to the abilities and skills of the individual with T2D to perform specific tasks that help them to manage and cope with DM.

2. Two information related attributes mainly related to the knowledge and information which should be acquired by an individual with DM to help them to manage and cope with DM.

These five attributes seem to be the core of the intervention programs and cover all aspects from enabling individuals to cope with, manage, and make informed choices about their treatment to discussing these choices with their health care provider [30]. The operational conceptualization of DSME interventions for T2D can therefore be defined in terms of these five attributes.

3.3.2.1 Overview of common delivery items that were classified as skills related attributes:

1. *Attribute 1: Problem solving abilities (P):*

Common delivery items that seemed to be consistent with this attribute include education targeted at flexibility in managing daily life activities impacted by T2D. Examples of intervention content include education around use of insulin injections safely at construction work sites with extreme heat (under the sun) and dealing with work obstacles effectively [52], teaching patients the skills necessary to overcome social barriers such as pressure to eat unhealthy foods on special occasions and festivities or to deal effectively with financial stressors [53] and managing uncertainty around aspects such as medication benefit and herbal alternatives[54].

These items relate to skills and abilities used and learned through experience by persons with T2D to solve any difficulties they may face throughout their life to cope

with and manage their disease. This attribute provides patients with basic information and skills to facilitate effective coping strategies with real-life problems, and to deploy solutions in life outside DM management but brought on by DM. This is different from skills required to solve a specific T2D management problem [55]. It requires critical thinking and planning strategies to generate and implement alternative solutions. These facilitate decision making to prevent undesirable problems in usual life related to DM [55].

The implementation of problem solving skills may affect the individual's emotion and social environment which may require a coping behavioral response that needs support from the surrounding environment such as health care provider, family members, or peers [55]. A key example would be managing DM during special events or festivities.

2. *Attribute 2: Decision making (D):*

Common delivery items that seemed to be consistent with this attribute in the studies reviewed include educational content such as sick day management, for example how to adjust diabetes related treatment if there are common illnesses such as flu [56], decision on treatment changes according to observed blood glucose levels, and management of any immediate event such as what to do with a short acting insulin dose if a meal was skipped [57]. This also includes items such as immediate diet tailoring in response to a recorded blood glucose level, for example if the pre-meal blood glucose level was high, how should a decision be made regarding the next meal [53]. This is an attribute that considers the ability to make informed choices related to personal health, and problem recognition which may have immediate consequences on an individual's health and is usually directly related to medical care of T2D including other related co-morbidities such as hypertension, dyslipidemia, and smoking. This is mainly linked to

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scientific basics learned from health care providers, in what to do or not to do as a consequence of personal judgment [58]. Mostly it requires individual decisions which would not have been possible if there were no initial skills training by healthcare providers.

3. *Attribute 3: Taking action (A):*

Common delivery items that seemed to be consistent with this attribute include educational content that empower the individual to take the right longer term attitude at the right time such as understanding the effect of regular physical activity on improving blood glucose levels and insulin sensitivity that will motivate exercising regularly [59], explaining the relationship between obesity and diabetes control that will improve perceptions about following a healthy diet [60], and the advantages of regular care of the feet that can reduce undesired complications [61]. These are delivery aspects that enable patients to make decisions about long term changes to an aspect of their life which could have long term benefits on the progression of DM and associated co-morbidities that lead to chronic complications. Usually, this skill is associated with individual behavior which requires an effort to understand the benefits and risks of change and modifying individual behavior. The implementation of this skill requires healthcare providers support through tailored and individualized teaching with organizational support by facilitating logistic requirements to implement this change [62].

3.3.2.2 Overview of common delivery items that were classified as information related attributes

4. *Attribute 4: Resource utilization (Res):*

Common delivery items that seemed to be consistent with this attribute across

the interventions included educational content such as recognizing the importance of involvement of surrounding resources such as family and friends based on their needs[63] , access to food resources at participants home and review with them the foods available and how to read nutritional fact label[64] , and providing necessary information that helps promote easy access to available health care resources on various topics when needed[65] .

These all relate to information about resources which are needed to facilitate self-management and can be divided into two aspects: 1) access to the required resources such as medical equipment and materials including correct information resources such as websites, and pamphlets. and 2) the correct way to use and sustain the available resources, considering the economic status of the individual, and support needed such as charities, and insurance to facilitate, and encourage self-management, both of which require input from healthcare providers [30].

5. *Attribute 5: Patient provider relationships (Rel):*

Common delivery items that seemed to be consistent with this attribute across interventions included educational content related to how participation of the health care provider can be helpful during social activities, such as sporting/leisure activities when organized by those with T2D[66], how to maintain collaboration e.g. through reviewing diaries, working on behavioral goals and staying in contact in the period without an intervention meeting [67]. Other aspects included reminders for annual checkup and follow up through different communication channels such as phone calls or patient's log book reviews [68] . These items refer to primary, secondary, or tertiary care level interactions and relate to any relationship or partnership which could provide ongoing self-management support when the patient runs out of options in a new situation or has failed to achieve proficiency in any of the skill-based attributes

previously mentioned. This mainly requires access to providers at different levels including provider to provider interaction and clear organization of care [30].

The delivery methods that existed in the 50 recent interventional studies were classified into the following groups (Table 3.1):

1. Education delivered by traditional educational methods (E) such as lectures, formal presentation (including audio/video) or face to face education in the usual clinical setting as part of routine care for DM (n=1).

2. Structured education (S) which is usually a program with a fixed curriculum over a fixed time period and with trained educators delivered outside of the routine care process (n=49)

Within either of the above strategies, two complementary tools have been utilized and these include:

    a. Technology (T) as a delivery method such as simulated games, computer or mobile technology, apps, or web pages. (n=10)

    b. Extra education materials (X) such as written materials, brochures, pamphlets, booklets, or card messages. (n=29)

Table 3.1 Summary of studies interpreted in the light of the educational strategy

Description	Group	N	References
EDUCATIONAL STRATEGY			
Unstructured education plus extra education materials	EX	1	[52]
Structured education & use of technology	ST	2	[69, 70]
Structured education only	S	18	[56, 57, 59, 64, 71-84]
Structured education plus technology & extra materials	STX	5	[53, 60, 85-87]
Structured education plus extra materials	SX	24	[54, 61, 63, 65, 67, 68, 88-105]

*Traditional educational methods (E), Extra education materials (X), Structured Education (S) & Education Program using Technology (T)

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3.3.3 Step 5: "Determining a model case"

A model case is one in which the 5 attributes are visible and subsequently demonstrates the impact of a good self-management intervention defined through these attributes. An example is given for a fictive case, Moses. He is a male 40 years old diagnosed with T2D which was uncontrolled for a long time leading to coronary artery disease (CAD). As an outcome of the enhanced educational delivery provided during the follow up visit, he was asked about his capacities with respect to the three skills related attributes, for example, asking him how he would deal with common issues encountered in management (e.g. hypoglycemia, dose adjustment) leading on to a conversation about his goals for the next months in one of these areas. Moses chose to work on problem solving and developed more confidence and adhered to his medication regimen and maintained a healthy lifestyle. Moses signed up for further modules that addressed information related attributes in self-management and the diabetes educator worked in partnership with the patient informing him of available resources. In the subsequent programme that was offered to him, another key deficient attribute was targeted, decision making, and he continued to receive further advice on problem solving and resource utilization issues were discussed through enhanced patient-provider interactions. His glycemic targets became easy to maintain and his faith in the system was strengthened.

3.3.4 Step 6 "Determining borderline and contrary cases"

1. Borderline case:

Our borderline case is one in which attributes are lacking and an example is

Noora, also a fictive case. She is a 55-years old woman diagnosed with T2D for the past 25 years. Noora was started on insulin, and she attended an educational session about insulin injection techniques but had not received structured education around the attributes identified in this paper. The main focus of her conversation with the provider was on decision making and she developed good decision-making skills when it came to deciding on insulin doses and took the necessary action to follow lifestyle advice. However, problem solving was not her strength and recently when she travelled to Oman, she missed out on planning to ensure enough insulin with needles for the period she was away from home, and she missed her insulin doses in the last two days of her holiday as she did not know from where to get the insulin and needles.

2. *Contrary case*

Our contrary case is a clear example of 'not the operational concept of the intervention'. An example of a fictive contrary case is Alaa. Alaa never made efforts to take responsibility as he generally takes advice from doctors and educators on his clinic visit only and never made an effort to come for any extra sessions. He had limited knowledge, was not actively involved in the care process, and was unable to act autonomously in the right way because he was dependent on the therapist. No specific skills could be recognized, and he did not consider managing his condition a personal lifetime task and expected the health system to take care of his needs at each visit. As soon as he leaves the clinic, his care process deteriorates with the result that he is frequently admitted for complication management.

The above-described cases show the diversity of DSME interventions and the probability to assess interventions clearly linked to the key attributes described above. When assessing the needs for a person with T2D in daily practice in the healthcare setting, these cases are examples of how the decision making may proceed to targeting

those attributes that are deficient, and what should be prioritized amongst the five attributes for each individual.

3.3.5 Step 7 "Determining antecedents and consequences"

Antecedents:

As described above, "antecedents are incidents or features that must arise prior to the occurrence of self-management". The research group agreed to classify teamwork and continuity of care as the two main antecedents after extensive discussion. This would result in referral of people with T2D to different specialties within a multidisciplinary team and a holistic approach for diabetes management with patient and provider agreeing on the medical management plan and follow up.

Consequences:

The consequences are those events or incidents that arise after successful DSME intervention following all attributes and these include immediate, intermediate, post-intermediate and long-term consequences. Immediate consequences stand for any immediate improvement of knowledge and skills that are acquired by the people with diabetes after attending an educational session [106]. Intermediate consequences are improvement in knowledge and skills leading to behavior change of people with T2D, so they will start to follow specific regimens such as diet or physical activity, that will lead to improved clinical outcomes. Post-intermediate consequences include improvements in clinical parameters such as HbA1C and lipid profiles [106]. Finally, long-term consequences include the improvement in the quality of life, general health status, and reduction in absenteeism from work [106].

3.3.6 Step 8 "Describing the empirical referents of the concept".

"Empirical referents are quantifiable ways of explaining the potential use of

self-management by confirming whether the attributes can be measured" [51]. These have been detailed in Table 9.2 (Supplementary file).

3.4 Discussion

This study has demonstrated that the optimal delivery attributes, while addressed somewhat by the current DSMES interventions, have mostly not been the intervention targets and thus have been implemented in an ad hoc manner. This is because the lack of concrete boundaries for the concept allowed the focus to dwell upon various clinical outcomes which may be short-term or long-term outcomes and resulted in inconsistent delivery of key attributes within the evaluated interventions. The skills-related attributes appeared to be the most implemented using different educational strategies, but this was inefficient because the latter were not the target of the intervention development. There is therefore a need to define the operational boundaries of a DSME intervention when designing it for implementation in a healthcare system. Making the attributes the focus of the implementation will facilitate better outcomes for patients. Although many desired goals of such interventions have been described in the literature, there has been no such study in T2D, and this study fills this gap. In other chronic diseases there has been some literature that support the findings of this study, for example, in musculoskeletal diseases self-management delivery [30] thus strengthening our findings.

The implementation of DSMES programs require a complex interaction between the individual, socio-cultural, physical environment, health systems, and other factors such as individual interest, financial , availability of resources etc [107, 108]. A comprehensive DSMES delivery framework must standardize the implementation of DSMES interventions. This can be achieved by considering the delivery attributes uncovered in this concept analysis, with the educational delivery method tailored to the

needs of individual attributes. A structured education program should therefore be tailored to fulfil the different attributes that are a priority for an individual and have content tailored to match the empirical referents related to these attributes (for example by determining a priori which attribute to address first in each patient). Furthermore, structured DSMES needs well trained educators to deliver the program and a well-designed quality assurance program with annual auditing. Currently, a clear understanding of the operational conceptualization of a structured program is lacking and the proposed attributes can provide a useful guide.

The current diabetes education curricula appear to be "glucose-centric". Current evidence from intervention studies have shown that treating glucose to target (without managing hypertension, dyslipidemia or smoking problems), may have little impact on mortality [109]. DSMES should evolve to teaching skills and knowledge about "comprehensive" self-management of both diabetes and associated risk factors such as hypertension, dyslipidemia, smoking, and sedentary behavior. These should be considered a key aspect of the attribute *taking action*, tailored to the patient's needs. To maintain successful self-management, identifying the exact status of each attribute vis a vis the patient is therefore essential. In addition, within these delivery standards, the empirical referents need to be developed further to define a basic-referent and referent items for more proficient DSMES. The priority for future research should be to enable an understanding of how the attributes and educational strategy rank in terms of achievement of optimal outcomes.

What also needs more attention is the fact that current intervention programs may neglect individual needs such as adherence to blood sugar monitoring, taking medications, following meals and physical activity regimens, and circumstantial factors that support or inhibit effective diabetes self-management [108]. Consequently, this

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lack of emphasis on information related attributes may result in patients becoming demotivated and less inclined to sustain the self-management strategies they have learned from these interventions. Human behavior is extremely complex and remains unpredictable and therefore academic research within the field of psychology is trying to understand the influential factors related to forming intentions and performing actions [110]. The reasoned action and planned behavior theories recognize that individuals' intentions can change before behavior accomplishment (e.g., as a result of new information), and subsequently the initial intention measure may not offer precise estimate of behavior [111]. In other words when the skills will be performed is equally as important as where and how they will take place. This phenomenon is known as implementation intention [112] and needs to be considered in more depth in the future.

In conclusion, we recommend that future DSME intervention programs define the intervention based on the five attributes and focus their attention on what is needed as opposed to those driven by changes in the desired outcomes. In addition, these attributes can be used to individualize delivery of DSME to patients as it is expected that their needs will differ with respect to the attributes and DSME specialists can focus on those that need prioritization based on individual patient needs.

Chapter 4 : Towards A Better Understanding of Self-Management Interventions

In Type 2 Diabetes: A Meta-Regression Analysis

4.1 Introduction

Diabetes mellitus (DM), particularly type 2 DM (T2D), is a growing pandemic that poses a significant health burden on most countries around the globe, and has financial, social, and developmental consequences especially in low and middle-income countries [1]. Due to the chronic and complex nature of the disease, T2D management does not depend on pharmacotherapy alone, but requires a comprehensive management strategy that includes diabetes self-management (DSM) skills to ensure good glycemic control and effective management of associated atherosclerotic risk factors[113] . Early detection and proper management could reduce the burden of the disease on the health care systems [114]. One of the vital strategies to achieve good glycemic control is to teach and train patients on diabetes self-management (DSM) skills to empower them to be a partner in their medical management[115] .

Diabetes self-management education (DSME) started in the mid-1920s by Joslin, who took the lead as the world spokesman for the "cause of diabetes"; he was the first to advocate for teaching patients to care for their own diabetes. He is also a recognized pioneer in glucose management, who emphasized that tight glucose control leads to fewer and less severe complications.

In the early 1990s, in response to the global increasing prevalence of chronic diseases including T2D, a chronic care model (CCM) was developed. The CCM relies heavily on patient's involvement in their care and self-management is an essential component of it [3]. The education and support program for DSM eventually became

an established part of care in T2D and is now known as diabetes self-management education and support (DSMES). The aim of such programs is to inculcate within patients the necessary knowledge, skills,

and abilities to empower them to achieve their self-management goals [116]. DSME has been delivered through a wide variety of education methods, delivered to individuals, groups, or a combination of both. The overall objectives of DSME today are to support informed decision-making, self-care behaviors, problem-solving and active collaboration with the health care team and to improve clinical outcomes, health status, and quality of life [17].

There have traditionally been many different DSME programs created across different health systems. One example is X-PERT (Expert Education versus Routine Treatment), where adults with T2D were invited to attend DSME program for six weekly group sessions each lasting two hours. This program showed an improvement in clinical outcomes (HbA1c, cholesterol levels, BMI)[19] . Another example is DESMOND (Diabetes Education for Ongoing and Newly Diagnosed), which is a structured group education program for patients with newly diagnosed T2D. The program which delivers a six to eight hour session, showed improvement in weight loss, smoking cessation, and beliefs about illness, but no difference in HbA1c levels up to 12 months after diagnosis[20]. Other programs have shown some improvements in both clinical and psychosocial outcomes for individuals with new or ongoing T2D [104, 117, 118]. However, the best method for the delivery of a structured DSME program is still unclear regardless of who the individual is with diabetes or where they live in the world.

One of the problems has been that DSME programs have mainly focused on outcomes, and each provider interprets the delivery of such educational program in the light of their experience and expertise [50]. The impact of structured DSME programs

have been tested in trials to generate evidence-based data [23] and their impact on health outcomes have largely been assessed through the results of heterogenous DSME programs that are difficult to synthesize given the heterogeneity of their content and educational strategy. We have previously undertaken a concept analysis to define the key attributes that such an intervention program should include and were able to demonstrate that five key attributes (i.e. problem solving abilities, decision making, taking action, resource utilization, and patient provider relationship) were necessary for the operational conceptualization of an ideal program [38]. This paper now aims at classifying existing interventions based on these five key attributes [38] and assessing the impact on four levels of outcomes that we have predefined. The hypothesis was that application of these attributes may lead to better outcomes, despite the heterogeneity of delivery across the programs studied, if these attributes were indeed well chosen.

4.2 Methods

This synthesis of experimental data is reported according to PRISMA guidelines [119]. We did not initiate PROSPERO registration given its disputed benefit for the research community[120] However a study protocol was prespecified and made available to the local Institutional Review Board (QU-IRB 1440-EA/20).

4.2.1 Data sources and searches:

PubMed, Embase, Cochrane Central Register of Controlled Trials, Cochrane library, ClinicalTrials.gov, WHO website (International Clinical Trials Registry Platform (ICTRP)), PsycINFO, and the grey literature (www.opengrey.eu/) were searched from 1990 to 2020. The search strategy was broad and included several keywords and synonyms (supplement section A). To identify trials that may have been missed through the search strategy, the top 20 similar citations for included studies on

PubMed were manually searched. Simple structured Boolean searches were also constructed as these are efficient and reliable search techniques to assess the completeness of an evidence base consisting of published

trials [33]. In addition, all references from the included studies and relevant previous systematic reviews were hand searched to identify possible missed studies.

4.2.2 Study selection:

All interventional studies evaluating the efficacy or effectiveness of DSME in T2D that recruited adults 18 years and above, written in English (or including an abstract in English) published between 1990 and April 2020 were considered further. To be eligible, the studies had to be interventional (RCTs or quasi-experimental study designs) and have reported the outcome of interest which was the impact of a diabetes self- management education program on different levels of outcome (immediate, intermediate, post-intermediate and long-term). One outcome at each level was chosen for analysis – the most commonly reported outcome. These were:

- *knowledge* as the immediate outcome,

- *physical activity* as the intermediate outcome,

- *HbA1c*% as the post-intermediate outcome, and

- *quality of life* as the long-term outcome.

Studies that included people diagnosed with type 1 or other types of diabetes were excluded. Observational studies, study protocols and pilot studies, non-English language publications, studies addressing T2D in special populations (e.g. patients with psychological disorder or with cognitive deficits), or published only in abstract form were excluded.

4.2.3 Data extraction and quality assessment:

Two authors independently assessed the eligibility of the studies using the Rayyan QCRI platform[34] first by title and abstract and then followed by assessment of the eligibility of selected studies by full-text review. Discrepancies were resolved through discussion and consensus after independent evaluation by another author. This process also applied to methodological quality assessment and extraction of key variables (e.g. numbers of events). When reports omitted data that we considered important or seemed inconsistent, the corresponding authors were contacted for clarification and additional information.

The data were extracted in Excel spreadsheets. In the first spreadsheet about general study information, the following data were extracted from the studies: study name, tool used, type of tool (knowledge, behavioral or psychological tool), duration of the program in weeks, hours per session, total sessions, session attributes considered in the program (problem solving, decision making, taking action, resource utilization, & patient provider relationship), control description, type of educators, study design, study population, type of outcome, country, health care setting and year of publication. The second spreadsheet contained information about the outcomes, and it was divided into four sections, each reflecting one level of outcome (immediate, intermediate, post-intermediate and long-term outcomes) with the same study identifiers as the previous sheet.

The quality of the original studies was assessed using the MethodologicAl STandard for Epidemiological Research (MASTER) quality assessment scale because it is comprehensive and well-structured tool that can assess the quality of studies for different study designs [35], which assesses the studies against 36 bias safeguards across seven standards to be fulfilled. The safeguards present in each study were then

counted, and these counts were converted into a relative quality rank between 0 and 1 by dividing the count in each study by the highest in the group [36] . The quality rank was planned to be used for bias adjustment of the pair-wise meta-analysis [37] but due to heterogeneity, a meta-regression analysis was conducted, and quality assessment reported qualitatively.

4.2.4 Data synthesis and analysis:

In our concept analysis [38], we had identified five DSME intervention related attributes to be fulfilled:

- Three of them were related to the skills-related attributes that patients must acquire - problem solving abilities (P), decision making (D), taking action (A)

- Two of them were related to information-related attributes needed by the patient - resource utilization (Res) and patient provider relationship (Rel).

We utilized these proposed T2D specific intervention delivery attributes to categorize selected intervention studies. The first categorization was those that delivered content on all three skills-related attributes (P, D and A) (henceforth called PDA), or were incomplete (i.e. one or more missing). The second categorization was into those that had all information-related attributes (Res and Rel) or neither present.

The effect size of interest was the standardized mean difference (SMD) for all outcomes except the post-intermediate (HbA1c) outcome as they were measured across studies on different scales. The weighted mean difference (WMD) was used for the HbA1c outcome. These differences were computed between the intervention and usual care arms in each study. An initial analysis was done synthesizing effects from PDA classified interventions sub-grouped by outcome and the latter was used to explore heterogeneity and small study effects.

Heterogeneity was assessed using the I^2 statistic, and a value between 0-40% was considered as low heterogeneity, 40-60% as moderate heterogeneity and more than 60% as considerable heterogeneity [39]. Small study effects (the tendency for intervention effects estimated in smaller studies to differ from those estimated in larger studies, which can result from reporting or publication biases, methodological or clinical heterogeneity, or other factors) were assessed using Doi plots and the LFK index Doi plots and the LFK index make use of the association between the effect size and the absolute Z score, which is a more reliable approach than funnel plots or Egger regression. A LFK index value greater than 1 or less than −1 indicates minor asymmetry, and a value greater than 2 or less than −2 indicates major asymmetry [40].

Since there was significant heterogeneity across studies, we only reported a meta-regression analysis, but retained the heterogeneity and publication bias metrics from the initial analysis as an overview. The meta-regression models included two explanatory variables: an indicator for the PDA group (0, incomplete PDA and 1, PDA) and an indicator for the Res-Rel group (0, no Res or Rel and 1, both Res and Rel present) as defined above. A robust error fixed effect meta-regression analysis [41] using these two categorical covariates was performed. In this approach, weighted least squares is used for parameter estimation and (cluster) robust variance estimation is used to estimate standard errors and conduct hypothesis tests [42].

We used Stata version 15 (College Station, TX, USA) for all analyses making use of the *metan* package for the initial meta-analysis and exact p-values were reported throughout.

4.3 Results

4.3.1 Identified studies:

The search strategy identified 3565 publications which were then imported in to the Rayyan QCRI software[34], and duplication was removed followed by a title, and abstracts screening. Following exclusion of 2671 irrelevant titles/abstracts the full texts of the remaining 894 articles were reviewed, of which 125 studies met the inclusion criteria. All references of included articles were downloaded for reference screening as well as similar citation screening (top 20) [52, 59, 64, 66, 73, 96, 102, 121-133], and 17 new studies were identified. A total of 142 studies were finally included (Figure 4.1).
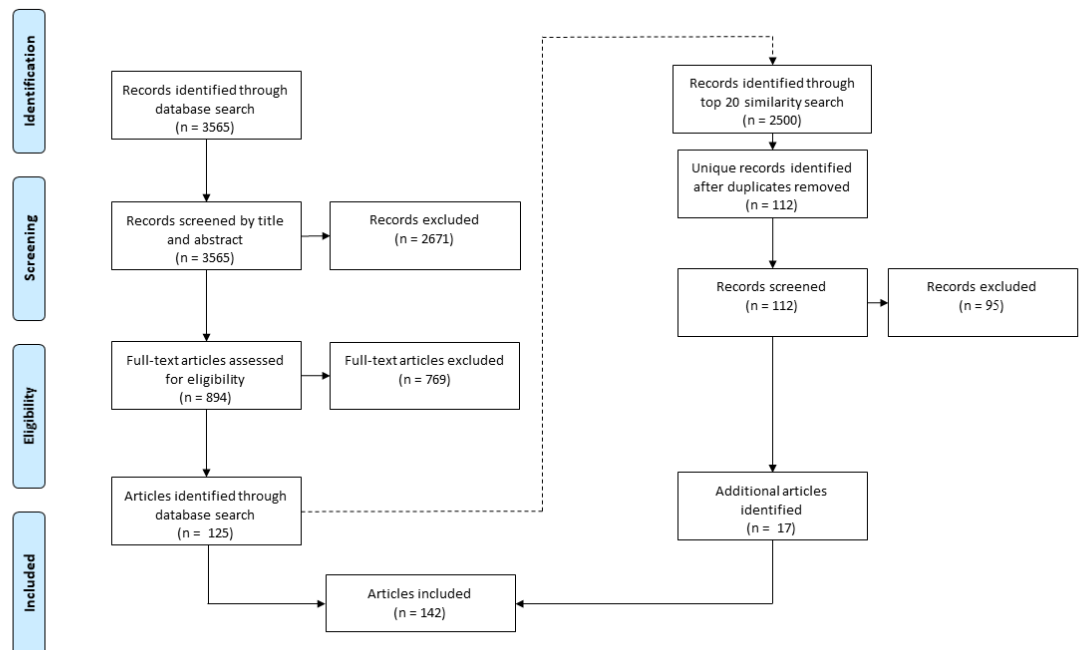
Figure 4.1 Flowchart of the selection of studies

This systematic review and meta-regression analysis included 142 interventional studies (115 RCTs and 27 quasi experimental studies) which examined the effectiveness of DSME intervention programs on different levels of outcome in relation to the implementation of the five defined attributes [38].

4.3.2 Origin of the studies:

The interventional studies were conducted in 39 different countries: Sixty from North America (USA [52, 53, 64-66, 78, 82, 90, 103, 117, 122, 126, 127, 129, 130, 132-171], Canada [71, 80, 172], Mexico [173]), twenty nine were from Europe (UK [19, 86, 174-178], Netherlands [67, 70, 179, 180], Spain [88, 96, 125, 181], Norway [182, 183], Sweden [184, 185], Turkey [89, 186], Belgium [187], Cyprus [93], Finland [188], Germany [189], Greece [105] , Iceland [190], Georgia [123], Italy [104]), twenty seven were from the Western Pacific (Australia [63, 87, 131, 191], China [54, 72, 74, 98, 192-195], Korea [196-199], Hong Kong [75, 200], Indonesia [69, 83], Japan [201], Philippines [94, 101], Taiwan[118, 121], Thailand [99, 202]), seventeen were from the Middle East and North Africa (Qatar [203], Saudi Arabia[204], Jordan [102, 205], Iran [57, 59, 61, 76, 77, 84, 95, 206-210], Iraq [73]), four were from Africa (Kenya [91], Mali [92], Ethiopia[68] , South Africa [211]), four were from South America (Brazil [79, 97, 212, 213]), and one was from South- East Asia (India [56]).Tables 9.3 & 9.4 (Supplementary file).

4.3.3 Interventions and outcomes:

1. *Immediate outcome:*

The most commonly reported outcome in this category was *knowledge* as assessed by several scales (e.g. DKQ [95], DKT[143], SKILL-D [169]. Of the 39 interventional studies that reported knowledge as the immediate outcome, 31 (79.5%) studies included aspects of all three skills-related attributes (PDA) while 8 (20.5%) studies had deficits in one or more of these attributes. Of the 39 studies 16 (41%) studies also included aspects of both information-related attributes (Res-Rel), 11 (28.2%) studies implemented one type of information related attributes and 12 (30.8%) studies

utilized neither Table 9.4 (Supplementary file).

2. *Intermediate outcome:*

The most commonly reported outcome in this category was *physical activity* as assessed by several scales (e.g. IPAQ[73], BRFSS [132], RAPA[127]). Of the 39 interventional studies that reported physical activity as the intermediate outcome, 27 (69.2%) studies included aspects of all three skills-related attributes (PDA) while 12 (30.8%) studies had deficits in one or more of these attributes. Of the 39 studies, 18 (46.2%) included both information-related attributes (Res-Rel), 12 (30.8%) studies implemented one type of information related attribute and 9 (23%) utilized neither Table 9.4 (Supplementary file).

3. *Post-intermediate outcome:*

The most commonly reported outcome in this category was *HbA1c* as reported on the percentage scale. Of the 99 interventional studies that reported HbA1c as the post-intermediate outcome, 79 (79.8%) studies included aspects of all three skills-related attributes (PDA) while 20 (25.3%) studies had deficits in one or more of these attributes. Of the 99 studies, 43 (43.4%) studies utilized both information-related attributes (Res-Rel), 34 (34.4%) studies implemented one type of information related attribute and 22 (22.2%) utilized neither Table 9.4 (Supplementary file).

4. *Long-term outcome:*

The most commonly reported outcome in this category was *quality of life* as reported by several scales (e.g. HRQoL[126], DQOL[76], PCS-12[118]. Of the 24 interventional studies that reported quality of life as the post-intermediate outcome, 18 (75%) studies included aspects of all three skills-related attributes (PDA) while 6 (25%) studies had deficits in one or more of these attributes. Of the 24 studies, 12 (50%)

included both information-related attributes (Res-Rel) and 7 (29.2%) studies implemented one type of information related attribute and 5(20.8%) utilized neither Table 9.4 (Supplementary file).

4.3.4 Quality of the studies

Quality assessment of the 142 studies was done against the 36 safeguards within seven broad standards. The assessment was done for each of the four main outcomes: immediate (supplement section C), intermediate (supplement section C), post-intermediate (Figures 10.1 to 10.11- Supplementary file), and long-term outcomes (supplement section C). The least deficient standards across studies were equal recruitment, and equal implementation. The most deficient standards found across studies were equal ascertainment, and equal prognosis.

4.3.5 Meta-regression results

At baseline (without PDA and Res-Rel interventions) there were clinically important effects seen for physical activity, HbA1c and quality of life, but not knowledge (SMD 0.07; P=0.811; Table 4.1).

PDA interventions were associated with further improvements in knowledge (SMD increase of 0.80; P=0.025) with moderate evidence against the model hypothesis at this sample size. PDA interventions were not associated with increase in intervention effects for the other outcomes over and above that seen at baseline (Table 4.1).

Res-Rel interventions were associated with further increases in quality of life over baseline (SMD increase of 0.96; P=0.405), but with little evidence against the model hypothesis at this sample size. There were also smaller improvements in knowledge over baseline with Res-Rel interventions (SMD 0.31; P=0.307) also with little evidence against the model hypothesis at this sample size. There were no

improvements seen in the estimated effects for other outcomes (Table 4.1).

While there was no improvement in HbA1c over baseline with either PDA or Res-Rel interventions, both together had a sub-additive interaction effect (difference in WMD 0.21; P=0.402) though with little evidence against the model hypothesis at this sample size. There was also a sub-additive interaction seen for knowledge (difference in SMD -0.61; P=0.126) with some evidence against the model hypothesis at this sample size.

4.3.6 Heterogeneity and small study effects (PDA studies only)

For knowledge, the effect sizes reported among PDA studies were heterogeneous $I^2 = 94.5$ and the Doi plot demonstrated minor asymmetry (LFK index= 1.12). For physical activity, the heterogeneity of the effect sizes reported among PDA studies was substantial with $I^2 = 87.8\%$ and the Doi plot suggested minor asymmetry (LFK index= 1.28). For HbA1c, there was moderate heterogeneity ($I^2 = 63.2\%$) and no Doi plot asymmetry (LFK=-0.89). Finally, for quality of life, heterogeneity of the effect sizes among PDA studies was high at $I^2 = 85.9$ with the Doi plot demonstrating no asymmetry (LFK=0.88) (supplement section D).

Table 4.1 Results of meta-regression analysis based by outcomes

	No. of participants; No. of studies	Meta-regression results	R^2	I^2 (%)	LFK index
Knowledge					
Incomplete PDA	922 participants;	Res-Rel: 0.31 (-0.30, 0.92); P=0.307	0.10	91.3	1.12(minor asymmetry)
	8 studies	PDA: 0.80 (0.11, 1.49); P=0.025			
PDA	4682 participants;			94.5	1.12(minor asymmetry)

	No. of participants; No. of studies	Meta-regression results	R^2	I^2 (%)	LFK index
	31 studies	Interaction: -0.61 (-1.41, 0.18); P=0.126			
		Baseline: 0.07 (-0.52, 0.66); P=0.811			
Physical activity					
Incomplete PDA	1808 participants;	Res-Rel: -0.03 (-0.50, 0.44); P=0.895	0.10	83.1	5.7(major asymmetry)
	12 studies	PDA: -0.26 (-0.73, 0.22); P=0.272			
PDA	6470 participants;	Interaction: 0.23 (-0.29, 0.75); P=0.368		87.8	1.28(minor asymmetry)
	27 studies	Baseline: 0.30 (-0.14, 0.75); P=0.168			
HbA1c					
Incomplete PDA	2861 participants;	Res-Rel: 0.08 (-0.32, 0.48); P=0.679	0.14	58	- 0.65(no asymmetry)
	20 studies	PDA: 0.01 (-0.41, 0.42); P=0.981			
PDA	15172 participants;	Interaction: 0.21 (-0.28, 0.69); P=0.402		70.5	- 0.89 (no asymmetry)
	79 studies	Baseline: -0.49 (-0.83, -0.14); P=0.006			
Quality of life					
Incomplete PDA	1272 participants.	Res-Rel: 0.96 (-1.46, 3.38) ; P=0.405	0.31	98	1.13 (minor asymmetry)
	6 studies	PDA: -0.38 (-1.03, 0.26); P=0.223			
PDA	3883 participants; 18 studies	Interaction: -0.65 (-3.09, 1.80); P=0.577		85.9	0.88 (no asymmetry)

No. of participants; No. of studies	Meta-regression results	R^2	I^2 (%)	LFK index
	Baseline: 0.35 (-0.25, 0.96); P=0.230			

*Taking Action (A), Decision Making (D), Problem Solving (P); Patient Provider Relationship (Rel), Resource Utilization (Res)
Baseline: Without PDA and Res-Rel interventions

4.4 Discussion

This study evaluated existing interventions based on five key attributes of DSME programs which we have previously defined [38]. We then assessed the impact of the programs within these attributes on four pre-defined outcomes. We were able to demonstrate that PDA interventions increased knowledge, while Res-Rel interventions improved quality of life. Interestingly, interventions that delivered neither PDA nor Res &Rel fully were able to improve HbA1c suggesting that one of the attributes, perhaps, drives this outcome and since the diet and physical activity agenda seems common across interventions, taking action may be this attribute. There was insufficient data to confirm the latter. Different attributes facilitate different outcomes, and it would be reasonable to infer that the *a priori* consideration of these attributes in intervention development may lead to more effective interventions and less heterogeneity of outcomes between studies.

In this synthesis, we also found that the implementation of all three skills-related attributes and the information-related attributes were variable, there was no standardized strategy for delivering these attributes within the DSME intervention programs across 142 studies reporting different outcomes (immediate, intermediate, post-intermediate, and long-term). There was a deficit of implementation for the

information-related attributes (resource utilization and patient provider relationship), however many of the studies implemented some aspects of the three skills-related attributes (problem solving, decision making, and taking action) in DSME programs, but we could not judge to what extent each was implemented thus contributing to the heterogeneity seen across studies.

We demonstrate that there is a considerable literature existing that have tested the impact of these DSME programs on different levels of outcomes. Part of the heterogeneity in results we describe are also due to the considerable heterogeneity of intervention delivery methods other than content (the attributes we defined) [153, 214, 215]. The delivery variations found in most of the reported interventions include length, duration, and number of sessions, method of delivery (i.e., in-person and technology-based, individual, or group-based), and moderators (i.e., self-directed, health care professional, peer). These heterogeneities certainly will dilute our assessment of the impact of the attributes within intervention programs on the measured outcomes. Despite the latter we could determine specific directions and magnitudes of effect suggesting that well-chosen attributes are important and what is delivered may not improve the different levels of outcome without explicitly thinking in terms of the attributes *a priori*. Different health care systems have developed different DSME programs and the literature has many examples of the heterogeneity of such interventions [23]. The latter is a major disadvantage because it means there is an absence of a standardized holistic delivery approach with clear mechanism and principles for DSME intervention design. This has driven DSME programs towards a focus on planned outcomes by the health care provider in lieu of directly addressing the patient's needs. It is anticipated that considering the five attributes [38] during program design and delivery may resolve some of these issues.

Systematic reviews and meta-analyses have regularly been carried out to examine DSME intervention programs in relation to various outcomes. A PubMed search in April 2021 spanning the previous five years identified 44 meta-analyses of which 14 targeted apps and tele-medicine support, 8 looked at effectiveness in general and 4 were protocols or miscellaneous. Many of the syntheses just investigated general efficacy while some looked at the efficacy of specific types of interventions such as theory based interventions [216] , use of interactive strategies [217] or personal health coaching [218], Others looked at sub-groups by certain characteristics. One example is group-based versus individual based interventions looking at clinical, lifestyle and psychological outcomes in T2D patients [219]. The study findings were greater reductions in HbA1C in group-based compared with individual based sub-groups at 6-10 months [219]. There have not been any syntheses however looking at the impact of sub-groups by *content* of the DSME intervention on outcomes except this study. Based on the attributes defined through our concept analysis [38] and the results of this synthesis, it is likely that DSME would benefit from a problem-based approach centered around the five core attributes (problem solving, decision making, taking action, resource utilization and patient provider relationship). This would then avoid DSME programs lacking some of these attributes and introduce a standardized strategy that ensures the implementation of all these attributes to a basic standard.

We acknowledge that a limitation of this synthesis was that the implementation of these five attributes have not been well described in the extant literature, and thus the classification was broad rather than specific. The strengths of this meta-regression analysis were that it provided a high-level overview of evidence for informing decision makers and changing policies within the health system, and all four outcomes were of direct relevance to clinical practice. In addition, it included only interventional studies,

using a comprehensive search strategy developed with a research librarian.

In conclusion, the study findings suggest that there are gains form DSME intervention programs in addressing these five attributes in the implementation of an intervention. There were significant improvements in immediate (knowledge) and long-term (quality of life) outcomes, but not intermediate (physical activity) and post-intermediate (HbA1c) outcomes. The latter may be because specific attributes modulate intermediate and post-intermediate outcomes (e.g. taking action for HbA1c) and many programs prioritize aspects related to the attribute most commonly delivered - decision making. Implementation of DSME intervention programs through the lens of the five attributes has the potential to help in standardizing the delivery strategy across these programs. Monitoring the implementation of the five attributes in the DSME intervention programs may therefore improve the quality and impact of these DSME intervention programs. These finding will help to develop a standardized, quality assured curriculum for DSME. Also, we recommend studying the DSME from different perspective starting from patient, health system and community to develop a holistic picture of understanding for DSME.

Chapter 5 : Perspectives of Persons With Type 2 Diabetes Towards Diabetes Self-Management: A Qualitative Study

5.1 Introduction

Despite advances in technology and awareness, (T2D) continues to be on the rise all over the world. [1]. In addition to its health implications, T2D has financial, social, and developmental consequences, especially in low- and middle-income countries[220]. Early detection and proper management could save lives and reduce health care expenditures. Due to the chronic and complex nature of the disease, management does not depend on pharmacotherapy alone; rather, a comprehensive medical and self-management plan is required[113]. One of the main strategies for controlling T2D is diabetes self-management (DSM), which empowers patients with diabetes to become active partners in managing their health[115]. DSM education (DSME) offers patients the knowledge and skills to perform daily self-care tasks[115]. DSM comprises three distinct sets of management activities: (1) medical, e.g., adhering to medication and dietary advice; (2) behavioral, e.g., adopting and maintaining new behaviors, such as physical activity; and (3) emotional, e.g., navigating frustration and despair[28]. Low socioeconomic status and characteristics of diabetes may challenge patients' ability to maintain DSM[221]. DSME programs should address diabetes-specific behaviors and be grounded in patients' perceptions of their disease and its consequences[30, 222]. In the past decade, healthcare organizations have developed and delivered many DSME programs [27]. The Association of Diabetes Care & Education Specialists (ADCES) suggested seven behaviors that should be included and promoted to achieve patient-centered diabetes education, including eating healthy foods, remaining active, monitoring blood sugar, self-administering medications, problem solving independently, being able to successfully reducing risk, and using

healthy coping methods[106]. Another example is the 6-week Spanish Diabetes Self-Management Program (SDSMP) developed by Stanford University, which helps patients with diabetes learn to eat, sleep, and manage daily activities more effectively, thus assisting them in navigating the symptoms of diabetes, including tiredness, pain, and emotional issues[223].

Differences between programs can be explained by varying program contexts and the lack of evidence regarding the practical accuracy of current T2D-specific definitions of self-management[31]. A culturally tailored diabetes education interventions granted greater improvements in glycemic control than usual care for multiethnic population with diabetes[224]. For example, Chinese immigrants have identified social support as integral part of a proper diabetes management[225].

In their concept analysis, Othman et al. (2021) used Walker and Avant method of analysis and clearly defined five specific attributes that should be addressed in any DSME intervention programs. These five attributes seem to be the core of the intervention programs and cover all aspects of DSM including enabling individuals to cope with diabetes, managing diabetes, and making informed choices about their treatment preferences[46].

A common interpretation of poorly self-managed diabetes is low motivation caused by lack of knowledge[224]. However, effective DSM does not depend on knowledge alone; it also involves factors such as intention to complete actions related to specific goals[221]. Health-related motivations depend on psychosocial factors, knowledge, beliefs, and attitudes towards health and health care, sociodemographic factors, and culture. Similarly, intentions are also influenced by people's lifelong attitudes arising from level of education, socioeconomic status, cultural values, personal experiences, and existing health policies. They can be intrinsic (what we want and can do) or

extrinsic (what others expect us to do and what conditions enable us to do). Intentions can lead to actions and can be used to explain them[221].

Harry Triandis developed a tri-level Theory of Interpersonal Behavior (TIB), identifying habits and facilitating conditions that enable or hinder the performance of particular behaviors [45]. He counts every variable and considers every factor as socially important for understanding human's behavior. Triandis' interpersonal behavior (TIB) Model frames behavior as a multifaceted and complex phenomenon. His model has been applied in the study of health-related behaviors and has helped to predict and understand patients' behaviors[226]. Robinson (2010) refer to Triandis' TIB Model as more complex and effective compared to other psychosocial models of health-related behavior[227]. Although other models provide frameworks for understanding health-related behavior, they employ simpler structures tailored to specific contexts to predict individuals' probability and intention of engaging in health-risking behavior[228].

The first level of Triandis' TIB Model includes beliefs about and evaluations of outcomes, norms, roles, self-concepts, and emotions. The second level is shaped by these components and includes perceived consequences (shaped by beliefs about and evaluations of outcomes), social factors (shaped by norms, roles, and self-concepts), and affect (shaped by emotions). The third level includes intention, which is shaped by the three components of the second level, and the habits that are produced through the frequency of past behavior[229]. In this study we use Triandis TIB Model to examine perceptions, intentions and DSM behaviors (Habits) among people with T2D living in Qatar, from patients' perspectives.

Qatar's population includes 94 nationalities, incorporating various cultures and religious identities. Two-thirds of the population are expatriates who live either alone

or with their nuclear families, mostly far from extended family. The prevalence of diabetes in Qatar is 15.5% [1].

Although the healthcare system in Qatar is public, the varying salaries and work conditions among expatriates are reflected on their living conditions and access to healthy food[1] suitable to people with diabetes. These and other factors such as marital status, living status, cultural customs, and values, are expected to affect individuals' ability to manage both their general health and their diabetes. The purpose of this study is to understand how T2D patients' perspectives and their sociodemographic factors, influence their intention to manage their diabetes.

5.2 Method and Design

This study employed a qualitative phenomenological research method, aiming to understand perspectives of people with T2D towards their DSM. Phenomenological research aims to examine how individuals make meaning of their life experiences [43].

To collect data, four focus group interviews with patients attending a diabetes clinic at Hamad General Hospital in Doha, Qatar, were conducted virtually due to COVID-19 gathering restrictions. Focus group interviews can capture insights into patients' personal experiences, beliefs, perceptions, and attitudes through discussion directed towards a specific topic and its sub-themes, maximizing the diversity of perspectives, experiences, and opinions on a specific subject[231]. The inclusion criteria included being an Arabic and English speaker, diagnosed with T2D, have an access and ability to use online platform. The exclusion criteria included, being unable to speak Arabic

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[1] According ADA standards healthy food for people with diabetes includes Mediterranean-style ,low-carbohydrate, and vegetarianor plant-based eating patterns are all examples of healthful eating patterns230.	*5. Facilitating Behavior Change and Well-being to Improve Health Outcomes: Standards of Medical Care in Diabetes-2021.* Diabetes Care, 2021. **44**(Suppl 1): p. S53-s72.

and/or English, no formal diagnosis of T2D, lack of access and/or ability to use online platform.

A purposive sampling method was used to recruit T2D patients from diabetes clinics at HMC. Recruitments continued until no new themes exist and we reached saturation[44]. Twenty-nine participants of different nationalities participated in the study. Three participants dropped from the study due to time limitations.

Participants were divided into four groups: two male groups and one female group of Arabic speakers, and one gender-mix group of English speakers. Each group included four to nine participants. Gender-segregated focus groups were conducted to comply with Arabic cultural and traditional values prohibiting gender-integrated discussion of bodily and private health issues among strangers. The focus group sessions ranged from 60 to 90 minutes and were conducted in either Arabic or English.

Each focus group session was led by two researchers and began with an icebreaker introduction; the researchers were introduced, and participants were asked to share their backgrounds and history of diabetes. The researchers prepared a set of questions that aligned with Triandis' TIB Model, addressing each of the four components in the model [45] (See appendix A).

Additional questions emerged from participants' responses to the main questions. The focus group sessions were voice-recorded and transcribed. Discussions in Arabic were translated to English by an expert in translation from Arabic to English.

Two researchers independently analyzed the focus groups transcripts, using structured-deductive content analysis. Structured-deductive content analysis is an analytical method that aims to examine existing categories and concepts from models and theories in a document. Furthermore, summative-inductive content analysis was conducted on insights and reflections that did not align with Triandis' themes but

contributed to understanding patients' perspectives on T2D self-management (Table 5.1). Summative-Inductive analysis aims to identify new themes that emerge from the document's content only, and involves counting and comparisons, usually of keywords or content, followed by the interpretation of the underlying context [232]. Both researchers compared their final themes of analysis. When consensus could not be reached, a third person adjudicated. Qualitative validation strategies were employed for the findings' validation. First, participants were asked to support their statements with examples. Second, two researchers read all the interviews, conducted the content analysis separately, discussed the results, and agreed upon the findings. Third, the results were presented and discussed with a DSM expert.

This study was approved by HMC's Institutional Review Board (HMC-IRB NO.:MRC-01-20-963) and Qatar University Institutional Review Board (QU-IRB 1440-EA/20). Informed written consent was obtained from participants before the focus group sessions. Participants were informed about the study aims, procedures, research team, their voluntary participation in the study, and their right to withdraw at any time. Participants were ensured that all information collected would remain confidential, and all identifiable information was coded.

Table 5.1 Main Categories and Subcategories

Categories	Subcategories
Perceived consequences	Harm to the body
	Negative consequences on life style
	Factors influence perceived consequences
Social factors	Human factors
	Environmental factors
Affect	Negative affect (Emotional)
	Coping strategies
	Positive affects
	Factors that shape the affect
Intention	Motivating factors for their intention to manage
	Demotivating factors

5.3 Results

The content analysis resulted in revealing perceptions of T2D patients on DSM, social factors that modify or prevent them from managing their diabetes, effect of having T2D on their mental state and behaviors, their intentions, their personal approaches to DSM, and their recommendations for better DSM.

5.3.1 Perceived Consequences:

Participants reported different perceived consequences that might negatively affect their health conditions and overall lifestyles if they stopped DSM. For instance, a 67-year-old Bangladeshi man diagnosed with T2D 25 years ago stated, "We will develop diabetes complications and it will affect our retina, kidney, and limbs; it is the complication that harm the whole body."

The main source of these perceived consequences was family, friends, and celebrities who suffered from T2D consequences. A 41-year-old Qatari man diagnosed with T2D 10 years ago mentioned the deaths of his relative and a Qatari celebrity as examples:

The cases around us, for example Hamad bin 'Eid, a champion of rally, who had a low blood sugar and he died . . .The complications for angriness and for the unhealed wounds like what happened with my sister-in-law, and they were about to cut her hand, so I need to cope with.

Personal experience was also a source of these perceived consequences. For example, a 56-year-old Qatari woman diagnosed with T2D 17 years ago shared, "I

almost lost my visions […] My eyes were damaged [by the disease], and I did two operations so I felt that I should not work, and I need to sit at home, because it had an impact on how I manage my sugar."

Participants' reflections indicate that their past personal and familial experiences have created negative perceptions of T2D. Perceived consequences were found to be major factors in effective DSM.

5.3.2 Social Factors in the community:

Participants in this study reported on two types of social factors that affect their DSM. The first is human factors such as family and peer support, and cultural behaviors, the second is environmental factors such as access to healthy food and physical activity.

For example, a 57-year-old Jordanian woman diagnosed with T2D 19 years ago described her family and peer support as modifiers to her DSM:

The family is the main supportive factor. They help by not bringing sweets and they don't eat in front of me. This supports me not to eat things that might cause harm to me, so we are all eating healthy food now at home . . . also, the good friends can support when we eat the same cake together when we go out together.

In contrast, a 41-year-old Qatari man diagnosed with T2D 10 years ago viewed his family and friend relationships as barriers preventing him from managing his diabetes. He explained, "We are invited to fatty dinners and [culturally] we can't say no. The community needs to understand the importance of diabetes management." The Qatari cultural code requires accepting invitations and introduced food from the host; an individual's rejection of an invitation or introduced food, is perceived as rude. Hence,

people with diabetes face a conflict between managing their disease and meeting sociocultural expectations.

Environmental factors included work-related stress and lifestyle circumstances. For example, a 41-year-old Sudanese man diagnosed with T2D 10 years ago explained,

I think that the work stress is also a factor, there is a need for all the departments to understand that the diabetic person needs some relaxation for his body and mind and thanks for them during corona we work from home. The workplace can help by reducing working hours and having some sports equipment

Similarly, a 69-year-old retired Qatari man who had lived with T2D for 36 years viewed his retirement as an opportunity to improve his health and diabetes management, as it allowed him more time to exercise: "I am retired so I have time to walk and to do so the time is flexible I can walk in the morning or at night."

Three participants also mentioned the impact of the COVID-19 pandemic on reducing their work-related stress. A 42-year-old Qatari man who had lived with diabetes for two years reported, "We had the opportunity to work from home during the pandemic, which reduced work stress and facilitated me to manage my diabetes."

Other environmental factors mentioned by participants included the weather in Qatar, the healthcare system, and the availability of resources such as advanced types of medications and drugs and diabetes supplies that facilitate self-management. For instance, a 56-year-old Qatari woman mentioned Qatar's seven annual months of heat as a barrier to exercise. A 69-year-old Qatari man mentioned walking in the malls to combat the heat. Another participant, a 42-year-old Jordanian man, mentioned that the sports area at his job site facilitated his ability to exercise regularly: "We have a sports area in our building, I take breaks sometimes to exercise and manage my diabetes."

These reflections indicate the role of workload and labor conditions in enhancing or deteriorating workers' health. A 41-year-old Sudanese man explained, "One time I have a site work in Halool, and it was the industrial area from 6 am to 6 pm and there was nothing available except the water. This was difficult for me."

Participants mentioned that the metro service in Doha and the ability to walk instead of driving supported their health. They also mentioned helpful health care policies, including medication deliveries to their homes due to COVID, free access to the public health system, and support from health care providers. Costs were mentioned by others as barriers. For example, a 47-year-old Pakistani participant mentioned the high cost of test strips as a barrier: "The test strips are so expensive, and many non-Qatari diabetic persons cannot afford to buy strips to measure their diabetes levels."

These insights reflect that, even if patients understand the importance of DSM and wish to manage their diabetes, some factors are not within their control. These factors include environmental conditions, work-related conditions, and health care system factors. Issues of access related to availability, time, and cost are important to consider when constructing any DSM program.

5.3.3 Affect

Participants reported various impacts of diabetes on their lives. The main effects were emotional, including acceptance and coping, frustration, sadness, depression, and reconciliation with diabetes. Most participants reported acceptance of their condition and active coping with its different challenges. These effects were evident in a 57-year-old Qatari woman who had lived with T2D for seven years. She stated, "It's a routine for me now and I feel happy that the sugar level is good. It is part of my life that makes me unique."

Similarly, a 60-year-old Sudanese male who had lived with T2D for 24 years explained how diabetes had positively impacted his self-discipline levels: "It makes our life beautiful. At home, they start making more salad and vegetables and eat less sweets. It changes my whole family's lifestyle."

An additional example came from a 67-year-old Bangladeshi man who described his acceptance and coping after living with T2D for 15 years: "I was frustrated at the beginning, then I realized that we have a lot of blessings and alhamdullah [Thanks to God] in Qatar they provide the required care."

Recently diagnosed patients were more likely to experience fears, sadness, and frustration than those who had lived with diabetes for over five years. For example, a 44-year-old Palestinian woman who had lived with T2D for two years described diabetes as a cause of frustration and sadness: "I always thought that it is the end of life and there is no life with it. I refuse to believe that I have diabetes." This feedback was similar to that of a 42-year-old Indian woman recently diagnosed with diabetes: "Sometimes I do not think that I have a problem, I challenge this disease and try to eat less sweets, which causes me depression."

In addition, a 51-year-old Qatari woman who has had diabetes for three years explained that "I was shocked at the beginning, I had fear because I had clot before, and was afraid from complications of the diabetes. I thought what will happen in 10 years and how can I protect myself." Another 33-year-old Jordanian participant recently diagnosed with diabetes described her mood swings: "Sometimes I feel satisfied, while other times I feel down and not normal."

These responses suggest that the more experience patients have with diabetes, the better they become at adapting to control, accept, and effectively manage it. Time living with diabetes can be viewed as a modifier for DSM, providing a phase to process

and reconcile with the disease. Two of the participants even referred to diabetes as their "friend."

5.3.4 Intention

Participants reported two main intention-related factors relevant to managing their diabetes: motivating and demotivating factors. Most participants highlighted fear from health complications as a major motivator that arose from witnessing complications faced by family members and friends with diabetes. For instance, a 42-year-old Jordanian man diagnosed with T2D nine years ago explained,

> [What motivates me] is what I saw in my family experience. My uncle died young from diabetes […] his legs were amputated. Recently my aunt's legs were also amputated, so diabetes is not a joke. We have to take care. I remember my uncle—he was taking the medication but not controlling his food.

Another 48-year-old Qatari woman diagnosed with T2D 21 years ago noted, "When my father died from diabetes, I thought that I need to try to avoid the consequences related to the diabetes [..] diabetes will not go so at least we need to control it and live with it."

They also worried about the complications of their health deterioration on their families. They expressed fear related to their roles as breadwinners; therefore, they managed their diabetes more effectively with the intention of maintaining their health so they could continue working. For example, a 56-year-old British man who was recently diagnosed with diabetes stated, "I need definitely to take care of my health so I can support my family and maintain my job responsibilities."

Another motivating factor was satisfaction from effective self-management. For example, a 69-year-old Qatari man diagnosed with T2D 36 years ago stated, "I feel

happy and satisfied when my sugar levels are low and that I was able to manage my diabetes effectively." Managing diabetes while being able to "escape" it occasionally without negative consequences was a motivator for some participants. A 42-year Qatari woman who was diagnosed with diabetes two years ago explained, "I usually give myself a break, by eating a chocolate, a sweet or something that I would like to eat so I can contribute to effectively manage my diabetes."

Some participants reported food temptation and mental state as demotivating factors for effective DSM. A 47-year Pakistani man who had lived with diabetes for almost 15 years mentioned food temptation as a barrier, stating, "I want to manage my diabetes, however, eating healthy food is sometimes challenging with all the temptations around us."

Patients also mentioned psychological state as a demotivating factor. A 42-year-old Jordanian man diagnosed with T2D nine years ago reported stopping medication due to feelings of uselessness and frustration: "Before 5 or 6 months I had a psychological problem and stopped taking the medication for 2 or 3 months although I was eating little food and I did not monitor my blood sugar or anything else."

The patients' descriptions indicate that their DSM intentions are influenced by various motivators and demotivators, including inner-personal, mental, sociodemographic, familial, cultural, and past experiences.

5.3.5 Approaches to DSM and recommendations:

In addition to Triandis' themes, two additional themes emerged after analyzing the focus groups transcripts: management approaches and recommendations for patients.

Participants reported several approaches and strategies for managing their diabetes. For instance, a 57-year-old Jordanian woman described the importance of maintaining her mealtimes: "I have specific times for my meals so I can have accurate readings of my sugar levels." Another 42-year-old Qatari participant mentioned the role alternative medicine played in her DSM: "I think that herbals and checking sugar on daily basis can improve [the conditions of] my diabetes."

Within this theme, most participants mentioned the importance of obtaining the correct information to support their DSM. These sources of information could include relatives who had experienced diabetes, health professionals (endocrinologists, nutritionists, and health educators), and the internet (websites and social media). For example, a 69-year-old Qatari participant diagnosed with diabetes 36 years ago explained that different information sources supported his DSM: "I read a lot, I go to the internet to learn how to manage my diabetes, and I follow the doctor's and the diabetes educators' advice to effectively manage my sugar levels." A 48-year-old Qatari participant suggested that a structured awareness campaign in TV and media could be a useful source of information: "The awareness we need more within TV and social media."

Participants also offered recommendations for managing T2D; many mentioned the importance of avoiding stress, exercising more, checking their retinas every 6 months, fasting, controlling bad habits such as smoking, and drinking copious amounts of water. For instance, a 48-year-old Qatari woman highlighted regular check-ups as important to improving the health of people with diabetes and preventing serious illness:

This is a joined responsibility between the patient and the doctor that should be supported by the doctor and the family, thus, there is a need to book regular follow-up

appointments for us, and more awareness campaigns to understand the impact of diabetes on our health and our society in general.

This insight summarizes the importance of the collaboration between the patient, the family, and the healthcare system in managing diabetes and general health. Rather than placing responsibility on the patient alone, this patient-centered approach calls for the collaborative responsibility of personal, sociocultural, and institutional bodies.

5.4 Discussion

The participants' experiences and perspectives illuminated the factors influencing T2D patients' DSM intentions. Our study found that fear of health complications was a motivator for DSM, which is consistent with the findings of previous research. For example, Kuniss et al.[233] found that one third of 104 participants reported intense fear of diabetes-related complications. Similarly, Arend et al. [234] assessed the fear and expectations of diabetes complications in people with T1D and T2D, and found elevated fear of complications in both groups, with higher rates in T2D taking insulin. In their study on the most-feared diabetes complications in a cohort of patients with DM, Wukich et al.[235] explored those patients with diabetic foot pathology reported lower limb amputation as their greatest fear, ranking it above their fear of death. Patients feared not only health complications but also how they might affect family members; they also feared dying and leaving family members behind. These fears were the main DSM motivators reported in this study. In Qatar, such fears are expected, as most families are expatriates who came to Qatar for work purposes with no extended family nearby to offer support if harm befalls the family breadwinner. This can explain that Qatari participants did not mention this fear, because they have their extended families around them. They also do not have fear of losing their job in case their disease deteriorates, compared to the non-Qataris who expressed

their concern regarding losing their financial resources and having no alternative to support their families.

Another motivator in this study is DSM's positive results. In previous studies, perceived personal experience with blood glucose monitoring has been considered a valuable factor to enhance and motivate DSM [236]. Other studies found additional motivators for DSM; for example, Polzer & Miles [237] found that the spirituality of African Americans affects their DSM.

We found that cultural factors such as food and social customs can contribute to demotivating patients from DSM. For example. the local cultural code requires accepting invitations and introduced food from the host during social and family gatherings. An individual's rejection of such invitation or introduced food, is perceived as rude. Hence, people with diabetes face a conflict between managing their diabetes and meeting sociocultural expectations. Similarly, in a qualitative study involving 23 Pakistanis and nine Indians with T2D, Lawton et al.[238] found that most interviewees continued to consume South Asian foods, especially in the evenings, despite their concerns that these foods could be "dangerous" and detrimental to their diabetes control. One could argue that when patients do not perceive the life-threatening nature of diabetes or its long-term complications, they are less strict with managing the disease. The Health Belief Model (HBM) refers to perceived severity and threat as major factors influencing individuals' health management. Several studies highlighted found fear of hypoglycemia as barrier to manage diabetes and taking medications [239-241].

When asked about perceived consequences, participants in this study cited health complications as the main negative result of failing to properly manage their diabetes. This response suggests their negative perception of diabetes as a chronic

disease that needs to be managed. Their main source of knowledge on the consequences of stopping DSM came from the complications they witnessed in family members. Some participants mentioned their own experiences of past deterioration as a source of knowledge. Such findings can be supported by the Health Belief Model (HBM) that describes internal and external cues as factors that positively affect patients' health self-management[242]. Several studies have found that educational programs based on HBM improve self-management amongst patients with diabetes. Observing 120 T2D patients in Iran, Jalilian et al. [243] reported significant improvement in the intervention group where the HBM was employed for diabetes education. When planning and structuring DSM programs, health care providers and health policymakers should consider HBM components, especially that the HBM describes sociodemographic factors as modifiers of health management.

Participants in this study highlighted family support as the main factor supporting their DSM. Similar findings were presented by most past studies examining the role of families in DSM. Rosland et al.[244] state that 75% of respondents reported supportive family involvement in self-care; however, 25% reported frequent family-related barriers to self-care. In a systematic review of 22 intervention studies, Pamungkas et al.[245] found that family support was linked to a healthier diet, increased perceived support, higher self-efficacy, improved psychological well-being, and better glycemic control.

Our participants mentioned social customs such as evening gatherings, Ramadan fast-breaking meals, and holiday meals as a barrier to DSM. They explained that cultural expectations such as respecting and accepting what people serve made it more difficult for them to manage their diabetes. Similarly, Lawton et al.[238] highlighted a cultural expectation to participate in meals with family/community

members that forced respondents with diabetes to eat unhealthy food despite knowing its negative impact. Therefore, empowering patients with diabetes to stand for their health and raising awareness within the community, may help in reducing feelings of shame and disrespectful.

In addition to social-environmental influences, our participants reported physical-environmental factors as modifiers and barriers to effective DSM. These factors included the weather in Qatar (from October to March), the availability of resources and healthy food at work, access to medications, and retirement and pandemic-related remote work, both of which created time for exercise. Almutairi's [224] literature review of 11 studies found that factors affecting DSM could be categorized into patient factors (including adherence, attitudes, beliefs, knowledge, financial resources, and co-morbidities) and healthcare provider factors (including patient-provider interactions and communication). Furthermore, Adu et al. [246] interviewed 217 participants from Europe, Australia, Asia, and America, and found that the common modifiers for DSM included (1) the will to prevent the development of diabetes complications, and (2) the use of technological devices. Issues including financial constraints, unrealistic expectations, frustration with the variable and chronic nature of diabetes, and work- and environment-related factors limited patients' effective self-management of diabetes. Similarities and differences among the different contexts result from specific socio-cultural contexts, environments, family structures, and health systems. One element missing from our and other studies is the deep examination of health policies' role in DSM. Unfortunately, most studies tend to position patients and families as the main people responsible for DSM. We argue that even if patients intend to maintain DSM, factors outside their control related to the physical environment, labor conditions, and health policies impact their ability to do

so. Our participants' insights somewhat supported this idea, as they mentioned work-related stress, working hours, and expensive test strips as barriers to DSM.

Diabetes was found to have emotional and behavioral impacts on our participants. Most male participants expressed acceptance and positive attitudes towards diabetes, while most female participants expressed depression and described negative impacts on their mental health. Such findings are supported by studies on depressive symptoms among patients with T2D in Qatar[247, 248]. Several studies in other societies also found that women with T2D are more likely to be diagnosed with depression than men[249-251]. These findings can be explained by mental health stigma and perceptions that masculine mental health issues are a sign of weakness. Many male participants in this study mentioned the importance of accepting and reconciling themselves with T2D; prior studies have also highlighted acceptance as a factor improving self-management[138, 252]. Furthermore, time was found to be a factor in helping patients to process and accept the diagnosis. Long-term patients reported fewer mental health issues compared to those recently diagnosed. These responses suggest that an individual's ability to cope with and self-manage diabetes can increase as they develop knowledge and experience over time. This result contradicts studies that have reported higher levels of depression in previously diagnosed patients with diabetes than in newly diagnosed patients[253]. This difference can be explained by the contribution of other factors such as family support, socioeconomic status, access to health, and others that affect the mental state of T2D patients and their ability to physically and emotionally manage their diabetes.

5.5 Conclusion

This study highlights the importance of understanding how individuals with T2D in a multicultural population perceive DSM; this understanding can help

healthcare providers develop culturally competent and evidence-based DSM programs. We found that cultural, environmental, institutional, and familial factors can improve DSM. Healthcare providers are encouraged to understand each patient's motives and barriers to DSM to build effective and patient-centered programs. Empowering patients also means enabling them to resist social customs, state their needs within workplaces, and express their emotions without shame.

This study has several limitations. Although we used a comprehensive theory of social behavior (the Triandis model), this approach could have precluded a more thorough discussion that incorporated additional insights and perspectives. Furthermore, we could not include all nationalities, and we included only Arabic and English speakers. As a result, the study may exclude blue-collar workers who do not speak these languages and who also may experience distinct financial challenges in managing their diabetes. We expect this population to experience other barriers to DSM, mainly associated with labor conditions, access to healthy food, time, and ability to exercise. Another limitation is that the focus group sessions were conducted virtually due to the COVID-19 pandemic. This might have positively impacted the comfort level of the participants, leading to more openness in their responses, but it could have also negatively impacted the process by preventing interviewers from reading the participants' body language. In the future, we wish to surmount these limitations by conducting a continuous study that utilizes face-to-face, individual in-depth interviews and incorporates additional languages to include participants from the diverse classes and races of Qatar.

Chapter 6 : Factors Associated With The Intention To Self-Manage In Type 2 Diabetes

6.1 Introduction

Diabetes is a chronic disease that contributes significantly to public health burden around the globe exacting a heavy toll on individuals, families, and communities[1]. The prevalence of type 2 diabetes (T2D) among the 20–79 year age groups is 537 million, a number predicted to rise to 643 million by 2030 and 783 million by 2045[1].

Over time, individuals with T2D are at risk of developing serious life-threatening health issues, resulting in higher medical care costs especially if inadequately supported or have delayed treatment. Consequently, early detection and proper management will save lives and reduce health costs [1]. The chronic and complex nature of diabetes, requires patients to acquire knowledge and skills extending across medical, behavioral, and emotional domains in order to self-manage this condition [9]. Good glycemic control and effective management of associated atherosclerotic risk factors requires careful self-management decisions to be made daily by the patient[113] .

Diabetes self-management education and support (DSMES) can address a constellation of clinical, educational, psychosocial, and behavioral features of care, and empowers persons with T2D to be partners in their medical management [115, 254]. There remains much scope to actively engage persons with T2D in self-management and to encourage its wide-spread adoption [255]. Studies have shown that knowledge itself does not prompt persons with T2D to maintain effective self-management [256] thus a comprehensive understanding of the factors that lead to an intention to self-manage is necessary. Individual's beliefs and other psychosocial factors also have a

role in enhancing self-management [257] and indeed intention was the most predictive construct for diabetes self-care behaviors (18% – 76% of explained variance) [258].

Behavioural scientists have developed a number of tools to explore health-seeking behaviours including the Health Belief Model [259], the Theory of Planned Behavior [260], Social Learning theory [261], the Transtheoretical Model [262] and Triandis' Social Behavior Theory [45]. These behavioral models are predicated on the notion that a person's intention to perform a specific health behavior is key to performance of a specific task and is rooted in attitude, subjective norms, and other related factors [263]. The Triandis theory of interpersonal behavior can be employed effectively to explain behavioral intention pertaining to health [228, 264]. According to the Triandis perspective, intention toward a specific behavior is a function of social factors, affect toward performing the act and the perceived consequences of performing the behavior. This theory is used to gain an understanding of health-related behaviors and helps to predict people's behaviors based on its components [226]. In this paper, the Triandis Model was used to develop a questionnaire that could be used to assess the intention of people with T2D toward self-management to better understand the important modulators of such intention in a diverse ethnic population.

6.2 Methods

6.2.1 Survey instrument

A group of twenty-nine participants of different nationalities with T2D from the same pool as the persons recruited in the survey at Hamad General Hospital were interviewed using open ended questions. The interview consisted of six open ended questions inquiring about interviewee's beliefs and experiences in relation to constructs of the Triandis model of interpersonal behavior as it pertained to any intention to self-

manage their diabetes. Responses were classified and converted into items within each of the theoretical domains of the Triandis model (intention, social factors, perceived consequences and affect).The final questionnaire consisted of 42 such items: 12 in the intention domain (scale s1), 15 in the social factor's domain (scale s2), 9 in the perceived consequences domain (scale s3) and six in the affect domain (scale s4). All scale items were constructed as five-response Likert-type scales except scale s4 which was a five-point semantic differential scale. Eight items were included for demographic characteristics, including age, sex, nationality, social status, education level, living status and years since diabetes diagnosis. The final pre-coded questionnaire was pre-tested with ten patients in order to assess face validity and duration. Subsequently, minor adjustments were done to the wording of some questions (Appendix B).

6.2.2 Survey delivery

Participants in this study were recruited from the national diabetes centre outpatient department at one secondary and one tertiary care setting. Eligible participants were patients with T2D, aged 18 to 65 years who had attended at least one diabetes education clinic, had no physical or mental disability, and were willing to participate. All patients with other types of diabetes and having any major complication were excluded.

Informed written consent was obtained from participants prior to administration of the survey. Participants were informed about the study aims, procedures, research team, their voluntary participation in the study, and their right to withdraw at any time. Participants were assured that all data would remain confidential, and all identifiable information was coded.

6.2.3 Survey analysis

Histograms of individual items as well as inter-item correlations within each subscale were reviewed to identify floor or ceiling effects that do not help in discriminating between patients, and thus could be removed from the scale. Those items that had zero or nearly zero variances or average inter-item correlations less than 0.15 were flagged for removal.

Reliability analysis was used to improve the scale derived from the qualitative analysis by selecting out items that largely measure esoteric aspects that can be considered as random error. To do so, the item-test correlation and the Cronbach alpha were calculated. Any item with an item-test correlations <0.2 or any item with a Cronbach's alpha (compares the sum of item variances with the variance of the sum scale) that increased significantly (reaching 0.60 – 0.70 or higher) when it was excluded were flagged for removal.

The final items that formed each scale were then centered in the middle of the five-point Likert scale (range now -2 through 0 to +2) and averaged into a score for each of the four subscales (s1score to s4score). The s1score (intention subscale average score) was dichotomized into upper tertile (1; higher level intention) and lower two tertiles (0; medium to lower-level intention). Multivariable logistic regression was used to identify the subscale scores independently associated with higher level intention. Stata version 15 software (StataCorp, College Station, TX, USA) was used for all analyses and exact P values were reported.

6.2.4 Ethics

This study was approved by HMC's Institutional Review Board (HMC-IRB NO.:MRC-01-20-963) and Qatar University Institutional Review Board (QU-IRB 1440-EA/20).

6.3 Results

The questionnaire was administered to 300 participants all of whom returned the questionnaire, details of which are in the supplementary material. The participant's number was selected based on outcome variables, we have five variables, each variable to do logistic regression, we expected to have 20 outcomes related to each item. So 20 multiply by 5 equal 100 and based on the focus group responses we expected one third of participants have higher intention toward DSM, so we divided 100 by one third and got 300 participants. The questionnaire took approximately 15 minutes to complete. Based on the results of item and reliability analyses there were no items excluded. Table 9.5 to Table 9.8 (Supplementary file). and the subscales had good internal consistency.

Of the participants, the majority were married (250; 83.3%) or lived with family (272; 90.6%). About half were female (153; 51%), were over 55 years-old (129, 43%) and were diagnosed with diabetes for 10 years or more (132; 44%). There was a diversity of educational levels with half having a bachelor's degree (173; 57.6%). About a third were Qatari nationals (106; 35.3%). A third also were diagnosed with diabetes for less than five years (110; 36.7%) and a third were aged between 45 to 54 years old (82; 27.3%) (Table 6.1). Demographic variables did not demonstrate a consistent pattern with respect to intention (Table 6.1).

Table 6.1 Sociodemographic Characteristics

| | | | Level of intention | |
		All Participants Count(%)	Low to moderate Intention Count(%)	High Intention Count(%)
		300	203(67.7)	97(32.3)
Age				
	<25	5(1.7)	5(2.46)	0(0.0)
	25-34	24(8)	18(8.87)	6(6.19)

	All Participants Count(%)	Level of intention	
		Low to moderate Intention Count(%)	High Intention Count(%)
	300	203(67.7)	97(32.3)
35-44	60(20)	44(21.67)	16(16.49)
45-54	82(27.3)	58(28.57)	24(24.74)
≥55	129(43)	78(38.42)	51(52.58)
Sex			
M	147(49)	102(50.25)	45(46.39)
F	153(51)	101(49.75)	52(53.61)
Nationality			
Qatari	106(35.3)	70(34.48)	36(37.11)
Asian	61(20.3)	43(21.18)	18(18.56)
Arab	113(37.7)	75(36.95)	38(39.18)
Other	20(6.7)	15(7.39)	5(5.15)
Marital Status			
Single	23(7.7)	14(6.90)	9(9.28)
Married	250(83.3)	169(83.25)	81(83.51)
Divorced	13(4.3)	9(4.43)	4(4.12)
Widow	14(4.7)	11(5.42)	3(3.09)
Education level			
Primary (or less)	15(5)	14(6.90)	1(1.03)
Elementary/Secondary	50(16.7)	35(17.24)	15(15.46)
Bachelors	173(57.7)	111(54.68)	62(63.92)
Master/MD/PhD or Equivalent	62(20.7)	43(21.18)	19(19.59)
Living Status			
With Family	272(90.7)	184(90.64)	88(90.72)
Alone	17(5.7)	12(5.91)	5(5.15)
Shared Accommodation	11(3.7)	7(3.45)	4(4.12)
Working Status			
Government	148(49.3)	108(53.20)	40(41.24)
Private	72(24)	42(20.69)	30(30.93)
None/retired	74(24.7)	48(23.65)	26(26.80)
Others Specify	6(2)	5(2.46)	1(1.03)
Years with diagnosis			
<5	110(36.7)	73(35.96)	37(38.14)
5-9	58(19.3)	48(23.65)	10(10.31)
≥10	132(44)	82(40.39)	50(51.55)

A one unit increase in all three subscales was associated with an increased odds

of higher-level intention to self-manage but the social factors scale was clearly more important and had double the effect seen with the other two scales (Table 6.2). When the average score was zero (neutral) on all three sub-scales the baseline odds of higher-level intention was 0.13 (Pr=11.7%) and when it was 1 on all three subscales, the odds increased to 1.54 (Pr=60.6%). Adjusting for the demographic variables did not improve prediction because they contributed very little to the intention to self-manage independent of the subscale scores (Table 6.2). The statistical model demonstrated goodness of fit as indicated by the AUC of 0.762 for the model with all three scales (Table 6.2). The link test in Stata also suggested goodness of link. Addition of demographic variables did not result in significantly higher AUCs (Table 6.2)

Table 6.2 Odds ratios* for the different models of Triandis variables against the variable 'Intention to self-manage their T2D'

Model	OR (95% CI)	AUC
Intention – social factors	5.17 (3.12, 8.58)	0.741
Intention – perceived consequences	2.36 (1.43, 3.89)	0.600
Intention – affect	2.86 (1.92, 4.25)	0.677
Multivariable model 1		
Intention –		0.762
social factors +	4.03 (2.33, 6.97)	
perceived consequences +	1.78 (1.01, 3.14)	
affect	1.60 (1.01, 2.55)	
Multivariable model 2		
Intention –		0.790
social factors +	3.98 (2.26, 7.01)	
perceived consequences +	1.89 (1.05, 3.40)	
affect	1.67 (1.02, 2.71)	
(+ *work status + years with DM*)		

*The odds ratios are for the odds of higher-level intention in those with a one unit lower compared to a one-unit higher score on the three Triandis variables.

6.4 Discussion

Generally, the questionnaire sections had good internal consistency and could

predict intention to self-manage in persons with T2D from a diverse multi-cultural population. The results highlight that while higher levels of intention are associated with factors within the three Triandis domains, neither the demographic status nor duration of diagnosis with diabetes were important for intention. Previous studies suggest that education level has a direct association towards intention to self-manage diabetes [265, 266] and that education level greatly influences the understanding of self-management concepts such as healthy diet, physical activity improvement, monitoring blood glucose level, diabetic treatment adherence, and foot care [258]. In addition to health literacy, it may be that higher education also imbues individuals with the confidence and belief in self-efficacy underpinning their high rates of self-management. The findings of this study suggest that education levels (and other demographic factors) just modulate the scores of persons with diabetes on the Triandis domains and have no independent role supporting one's intention to self-manage their diabetes. While previous results found diabetes knowledge to be predictive of self-management [267-269],significantly affecting overall diabetes self-care [270], this probably also translates to changes in the patients understanding of perceived consequences or affect in relation to self-management.

The result of this study shows that social factors are the most important domain predicting intention and more important than perceived consequences or affect. Thinking of family, having peer support or having group support can have a strong positive impact on intention towards self-management, and this is consistent with other studies reporting that patients rely on a combination of formal and informal support for diabetes self-management [271]. A study from India reported that people who had greater family support for diabetes had better self-management behaviors [272]. Families can be a major source of support as well as a major stressor, since thinking of

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taking care of family members is driven by religious and cultural obligations in this setting and failure to comply with such obligations results in social stigma. This led to increase in intention, and it was one of the major elements participants identified as a motive to stay healthy and care for their diabetes. However this finding was inconsistent with other studies as T2D persons have been reported to neglect their own diabetes self-management to care for family members [271]. While lack of food enjoyment during family gatherings negatively impacts the intention to self-manage, there is also pressure from social norms and expectations. Some individuals with T2D report eating high carbohydrate foods during social events to avoid offending their invitees [271]. This is significant as these social gathering occur regularly and therefore pose a routine adverse threat to one's intention to self-manage.

Perceived consequences were also associated with intention to self-manage diabetes. Fears associated with diabetic complications positively fuels an intention to self-manage. Research has indicated that fear of losing one's role due to diabetes complications such as amputation or visual loss motivated self-management [273].

Affect was as important as perceived consequences in this study and feelings of insecurity or depression can be a barrier to self-management. The literature suggests that frustration and helplessness with success in achieving optimal levels of glycemic control, may lead to a feeling of depression in some patients and consequently result in people neglecting to care for their diabetes [274-276]. People with diabetes, therefore, have been reported to more frequently develop anxiety and depression than others [277-279]. Diabetes self-management requires consideration of behaviors that people with diabetes should adopt to achieve the minimum goals of self-management, conversely, recognizing factors that overwhelms the person may lead to emotional distress such as anxiety, depression, and frustration and should be consciously avoided [280].

Although the study results provide important information about the relationships between intention to self-manage diabetes and the three Triandis domains, some limitations should be considered. The data of this study were collected using a self-reported questionnaire. Participants may underestimate or overestimate their self-management behaviors, which may affect the findings. The strength of this research lies in the fact that it employs the Triandis model as a theoretical framework to better understand intentions towards a specific behavior. Second, results can be generalized beyond the study sample and therefore can be generalized to other populations given that the findings were more or less independent of the patient demographics.

In conclusion, we demonstrate that the main predictor of intention to self-manage were social factors, while perceived consequences and affect were less important. Foregrounding social factors may prove a useful strategy in the design of future structured diabetes self-management programs that can the contribute to a greater uptake of patient self-management. Current work is underway on an attribute based [38] structured self-management program where problem solving related to these social factors will be given an important emphasis.

Chapter 7 : A Delphi Consensus Study Introducing A Problem and Attributes Based Diabetes Self-Management (PARADIGM) Intervention for Patients With Type 2 Diabetes

7.1 Introduction

Diabetes Mellitus (DM) is a growing pandemic that poses a significant public health challenge to countries across the globe. It is estimated that the number of people with diabetes in the region will double by 2045 [1], generating significant financial, social and development implications especially in low and middle-income countries [281]. The management of T2D is a chronic and complex condition requiring different management strategies with disease-specific knowledge and self-management skills being essential to achieve optimal glycemic control and better health outcomes [282]. Diabetes self-management (DSM) is defined as "the ongoing process of facilitating knowledge, skills and abilities necessary for diabetes self-care, delivered by specialized healthcare professionals"[283]. Encouraging those with diabetes to self-manage, empowers patients to be a partner in achieving their glycemic targets[115]. Several studies have demonstrated the effectiveness of diabetes self-management education and support (DSMES) interventions in improving health outcomes, particularly glycemic control and the prevention of diabetes complications [284]. Although the goals of DSME programs are clearly defined, there is little consensus regarding which strategies should be adopted to achieve them, resulting in a heterogenous approach to T2D interventions [7, 8].

We have recently defined the operational boundaries of an intervention in terms of five core attributes, three of which were skills related attributes while two were information related attributes [46]. These five attributes cover all major aspects of self-management education including enabling individuals to cope with, manage,

and make informed choices about their treatment. This study now aims to use the identified attributes to develop diabetes self-management educational modules using PBL and we now report on a novel intervention based on these attributes and its development process.

7.2 Methods

The study took place between January and June 2021. The Delphi method was used to identify the factors and strategies that can best be employed to develop diabetes self-management educational modules using PBL addressing the five aforementioned attributes discussed previously [46]. These attributes consist of three skills related attributes: Problem solving (P), Decision Making (D), and Taking Action (A) and two information related attributes: Resource utilization (Res), and Patient Provider Relationship (Rel) [46]. The PBL approach is a form of inquiry-based learning and a technique that encourages learners to apply relevant skills and strategies to solve self-identified problems in a simulated "real-world" environment. It has also been used effectively in empowerment-based training in diabetes patient education programs [285].

The Delphi method is a technique that collects the opinion of relevant stakeholders. This usually involves consensus development on content with respect to a particular issue with related examples from practice discussed in different discussion rounds [286]. The process terminates when an acceptable degree of consensus is reached [286]. In this study we had two main stages: stakeholder mapping and engagement, followed by a Delphi study. This study was approved by HMC's Institutional Review Board (HMC-IRB NO.:MRC-01-20-963) and Qatar University Institutional Review Board (QU-IRB 1440-EA/20).

7.2.1 Stage 1: Stakeholder mapping and engagement

The steering group consisted of stakeholders in diabetes patient education at Hamad General Hospital, the main health organization in the State of Qatar. The team consisted of diabetes educators, endocrinologists, clinical epidemiologists, and clinical researchers. The consensus development group was led by the chair of the advisory group (first author) for diabetes self-management. Members of the diabetes self-management education group were selected based on their expertise and experience in the field.

7.2.2 Stage 2 Delphi Study:

This was structured around the five attributes considered key for a diabetes self-management intervention defined in our previous concept analysis [46]. Important content to be delivered that was consistent with the five attributes was listed exhaustively and subjected to critical discussion. Discussion centered around the baseline content to be conveyed in an intervention related to a specific attribute. Each Delphi round attempted to reach consensus on what information could be dispensed with and what pertinent information was essential. Consensus was considered reached when no changes were made in a particular discussion round. The following five steps were completed in sequential Delphi rounds: (1) Introduction of the concepts of the five attributes; (2) determination of real examples that mimicked clinical practice related to each attribute; (3) scenario building; (4) interaction development and (5) refinement (if required) of the scenarios and interactions.

The Delphi study was conducted virtually using Microsoft Teams due to COVID-19 restrictions. The discussion was led by the senior educator (first author) and a clinical epidemiologist and endocrinologist (senior author) to maximize participant's

engagement in each round.

7.2.3 Summary of Delphi meetings

Eleven rounds were carried out with the steering group of key stakeholders. The purpose of the first meeting was to introduce the five attributes that were published previously [38] and to agree on the content of new educational modules for DSME intervention in relation to these attributes. Stakeholders were asked to provide authentic examples of each attribute [46] derived from their daily practice to be discussed in the next round.

In the second meeting, stakeholders identified cases from their practice that exemplified the five attributes. These cases were created based on actual clinical examples witnessed by the educators but subsequently modified to provide a comprehensive teaching case to maximize learning opportunities and target specific learning objectives deemed necessary for people living with diabetes to learn. The initial cases were discussed after which five educators were tasked with further developing the scenarios to ensure it explored all the facets of the attribute under review. We agreed to start with problem solving, and decision-making attributes for the next round.

The third round comprised of elaboration and content clarification of the two case scenarios. Question prompts and answers were devised to support patient-educator interactions at this time. In round four, the proposed interactions were finalized and approved. The interactions will help the facilitator to navigate the discussion, focusing on the relevant attributes and engage the learner in productive dialogue that allows learning to procced *ex officio*. The same process was repeated to delineate the learning objectives and develop the

PBL scenarios for each of the attributes.

A summary of each of the five case scenarios is included in Table 7.1. Detailed case scenarios are available in the Table 9.9 (Supplementary file). and the complete cases are available in Table 9.10 (Supplementary file).

7.3 Results

7.3.1 Participants

A total of 10 stakeholders from the National Diabetes Center at Hamad General Hospital participated in the different Delphi rounds discussing in depth the best-case scenarios from their clinical experience based on the five attributes that had been identified in the previous concept analysis [38].

At the end of this process, five case modules were developed and are summarized in Table 7.1.

Table 7.1 Summary of the case modules

Case Module Title	Case Module Summary
Case module 1: Problem solving	Female 48 yrs old, married lives with her family, has four kids, working as a teacher. Diagnosed with T2D for 10 years, with arthritis and neuropathy. HbA_{1c}: 9.5% (80 mmol/mol), BMI 35 Kg/M^2 Rx: Metformin 1000 mg BID, Gliclazide 90 mg OD, and Dapagliflozin 10 mg OD. ✓ Overwhelmed daily life due to family and work burden. She used to skip meals, medication, and monitoring. In the last medical appointment, her physician added another medication.
Case module 2 Decision Making	Male 50 yrs old, married lives with his family, doing office work. Diagnosed with T2D for 20 years with dyslipidemia, HTN, and recurrent hypoglycemia episodes. HbA_{1c}: 10% (86 mmol/mol), BMI 30 Kg/M^2 Rx: on Insulin Degludec (Tresiba) 30 unit pm and Novo Rapid 10-unit lunch time, Metformin 1000 mg BID, Empagliflozin 10 mg OD, Dulaglutide 1.5 unit

Case Module Title	Case Module Summary
	weekly, Valsartan 80 mg OD, and Atorvastatin 10 mg OD. ✓ Uncontrol diet, unaware of differentiation between hypo and hyperglycemia signs and symptoms, unfamiliar with the blood glucose target, and facing difficulty in interpretation of blood glucose reading and how to adjust the medications accordingly.
Case module 3 Taking Action	Female 42 yrs, divorced living alone, working as secretary. Diagnosed with type 2 diabetes for 5 years HbA$_{1c}$: 9% (75 mmol/mol), weight 85 kg (*gained 5 kg since she started the medication*). Rx: On Metformin 1000 mg BID and Glimepiride 4 mg OD. ✓ Uncontrolled diet, frequently snacks at night, facing difficulty in reducing the weight despite diet, no motivation to make physical activity. Decided to stop Glimepiride without physician consultation.
Case module 4 Resource Utilization	Male 55 yrs, married living alone, worked as civil engineer. Diagnosed with type 2 diabetes for 7 years. HbA$_{1c}$: 11.5 % (102 mmol/mol), BMI 28 Kg/M^2 Rx: On Metformin 1000 mg BID, Lantus 15 units OD pm and Empagliflozin 10 mg OD. ✓ Lost his job, no insurance, stopped all medication and monitoring of blood sugar due to financial problems. He adopted an unhealthy habit (smoking) due to stress.
Case module 5 Patient Provider Relationship	Female 45 yrs old, married Diagnosed with type 2 diabetes for 12 years, feeling numbness and heat in her foot mainly at night. HbA$_{1c}$: 10% (86 mmol/mol), BMI 33 Kg/M^2 Rx: Empagliflozin 25 mg OD, Sitagliptin/Metformin 50/1000 mg BID, and recently started Glargine 15 units (bedtime). ✓ Uncontrolled blood sugar stopped taking insulin due to misinformation about insulin that it may cause death. No physical activity nor diet control. Unaware of available diabetes services.

7.3.2 Interactions (Questions and Possible Answers)

The Delphi process allowed us to develop the best interactions related to each case scenario reflecting each attribute. That will help in determining the most effective flow of the educational strategies delivered to people with diabetes using PBL. A summary of the natures of the interactions are depicted in Figure 7.1.
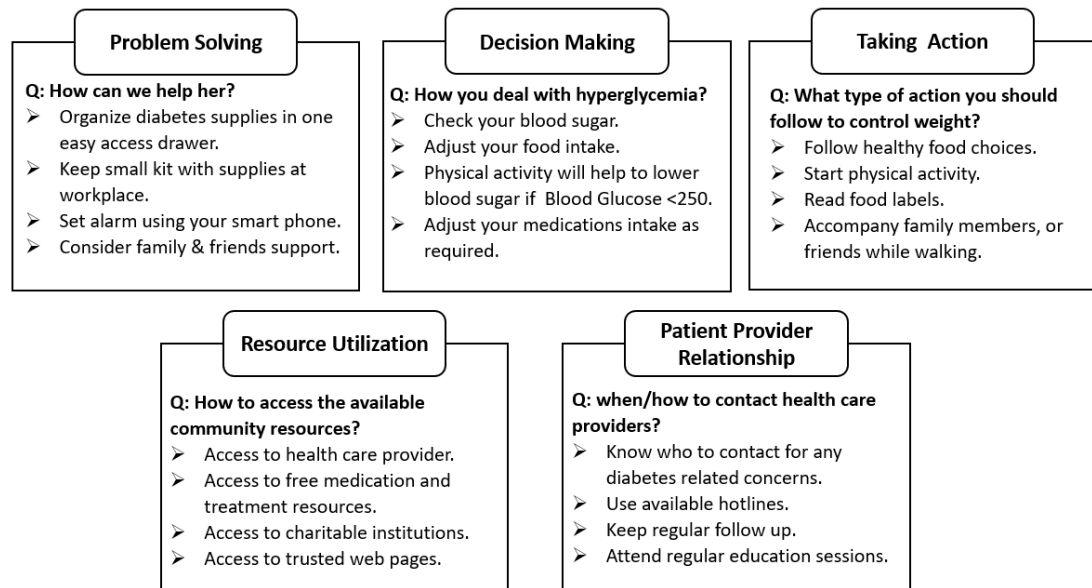
Figure 7.1 Example of interaction questions and possible answers

7.4 Discussion

Currently, DSME is largely focused around outcomes that are audited regularly against consistent criteria by independent assessors for quality assurance. For this reason, there has been a proliferation of outcomes and the day-to-day tasks or skills patients should learn to achieve them are left to various health care providers to determine. Some skills taught are purely behavioral, others are a combination of behavioral and psychological aspects, while some are management skills. Each provider interprets the delivery of such education based on their experience and expertise. Thus, there exists a plethora of interventions that meet the criteria for DSME, yet it is unclear what the best approach is. Encouraging people with T2D to self-manage

their condition and deciding on the best delivery style has been flagged as a research priority in diabetes by the Diabetes UK–James Lind Alliance Priority Setting Partnership [31]. This study constitutes a response to this research priority through development of this novel program using a scientific and structured approach that has the potential to help people with diabetes to understand in-depth their current condition, develop realistic goals, and enable self-directed behavior changes [163].

The case scenarios were developed to facilitate interactive group discussions using a PBL approach, which has been used previously in diabetes patient education programs with demonstrable effectiveness [163, 184, 287]. This PBL strategy is consistent with adult learning and empowerment theories and is expected to facilitate needs identification, problem solving, skills and resource understanding and relationship building with the health care provider. The expectation is that this will enable persons with diabetes to be in control of their own lives with the ability to make informed diabetes-related decisions [287]. These case scenarios were aligned with interactions that help to provide people with diabetes with an effective avenue for "intentionally" practicing needed skills in a safe environment and to engage in a learning process that mimics reality [288]. The intervention can be delivered as group sessions in a problem-based setting and can be sequenced according to the needs of a patient. Thus, if a patient needs more of problem solving or decision-making these cases can be scheduled first.

In conclusion, we have developed a novel problem-based intervention for DSME that makes use of the conceptual definition of such an intervention [38]. There is evidence in the literature for the benefit of such a PBL approach in diabetes patient education with reported gains in clinical outcomes [184] as well as durability of empowerment outcomes for at least one year [163]. In a subsequent study that will start soon, we will test this intervention using a quasi-experimental trial on people with T2D.

Chapter 8 : Summary of The Research Outcomes and Their Integration

Diabetes is a serious and chronic condition that is increasing at an alarming rate causing a significant burden on global health systems. It requires continuous medical management and support targeting multifactorial risk-reduction strategies beyond glycemic control [4]. Management thus goes beyond pharmacotherapy and one of these is to encourage diabetes self-management (DSM). The latter focuses on supporting patient empowerment by teaching PWD the necessary skills to make informed self-management decisions and to be a partner in achieving their glycemic targets, aiming to maintain good health, preventing acute complications, and reducing the risk of long-term complications.

DSMES is defined as "the ongoing process of facilitating knowledge, skills and abilities necessary for diabetes self-care, delivered by specialized healthcare professionals"[283]. During the last decade many self-management programs have been developed and delivered by the health-care sector [27]. Mostly, these programs address three broad goals: medical outcomes, behavioral outcomes, and emotional outcomes. Lorig and Holman had attempted, very early on, to classify the mechanisms through which self-management benefits patients with chronic disease but unfortunately this classification has not been utilized well [30]. Therefore, what is taught to patients varies widely depending on the providers' interpretation of priorities they consider important. While this has led to some improvement for PWD at different levels of outcomes (knowledge, physical activity, clinical outcome, and general health status), there had not yet been an adequate capture of the theoretical aspects of the self-management intervention for DSM. Thus, the current DSM programs will benefit from a better operational definition whose boundaries are clearly defined.

Despite over 375 DSME programs that have been recognized by the ADA since

1987 [13], there still remains controversy about what is the best DSME program and, in 2017, it was flagged as a priority for diabetes research by the Diabetes UK–James Lind Alliance Priority Setting Partnership [31] who asked the question "what is the best way to encourage people with type 2 diabetes whoever they are, and wherever they live to self-manage their condition and how should it be delivered?". This program of research was designed to answer this question through multiple studies details of which are summarized in Figure 8.1.

Phase 1 — Building Attributes: Define operational attributes for DSME

Phase 2 — Evaluating Attributes: Assess the possible impact of these attributes against different outcomes

Phase 3 — Understanding Intention: Assess correlates of patient's intention toward self-management

Phase 4 — Building the intervention: Generate a core curriculum based on attributes and stakeholder consensus (PARADIGM)

Phase 5 — Testing the Intervention: Evaluate the intervention in a quasi-experiment (clinical trial)

Figure 8.1 PARADIGM Development Process

The main aim of the 1st paper was to define the boundaries of and resolve ambiguity in the operational conceptualization of the intervention. A structured approach using concept analysis based on Walker and Avant's method [51] and a critical evaluation of 50 recent interventional studies clearly identified five attributes that seems to be at the core of the intervention programs that cover all aspects from enabling PWD to cope with, manage, and make informed decision about their

treatment. Also, this study has demonstrated that the optimal delivery attributes, while addressed somewhat by the current DSMES interventions, have mostly not been the intervention targets and thus have been implemented in an ad hoc manner. This is because the lack of concrete boundaries for the concept allowed the focus to dwell upon various clinical outcomes which may be short-term or long-term outcomes and resulted in inconsistent delivery of key attributes within the evaluated interventions.

The skills-related attributes appeared to be the most implemented using different educational strategies, but this was inefficient because the latter were not the target of the intervention development. Making the identified attributes the focus of the implementation will facilitate better outcomes for patients. These attributes are classified into skills related attributes (problem solving, decision making, taking action) and Information related attributes (resource utilization, and patient provider relationship) [38]. A structured education program should therefore be tailored to fulfill the different attributes that are a priority for an individual and have content tailored to match the empirical referents related to these attributes.

Following that a meta-regression analysis was performed to evaluate the impact of existing interventions classified by their delivery of skills or information related attributes on different levels of DSM outcomes immediate (knowledge), intermediate (physical activity), post-intermediate (HbA1c), and long-term (quality of life) outcomes in PWD. The findings demonstrate that the skills and information related attributes contribute to different outcomes for people with T2D [289]. The PDA interventions were associated with further improvements in knowledge (SMD increase of 0.80; $P = 0.025$) with moderate evidence against the model hypothesis at this sample size. The Res-Rel interventions were associated with further increases in

quality of life over baseline (SMD increase of 0.96; P = 0.405), but with little

evidence against the model hypothesis at this sample size. While there was no

improvement in HbA1c over baseline with either PDA or Res-Rel interventions, both

together had a sub-additive interaction effect (difference in WMD 0.21; P = 0.402)

though with little evidence against the model hypothesis at this sample size. There

was also a sub-additive interaction seen for knowledge (difference in SMD −0.61; P =

0.126) with some evidence against the model hypothesis at this sample size.

Interestingly, interventions that delivered neither PDA nor Res & Rel fully

were able to improve HbA1c suggesting that one of the attributes, perhaps, drives this

outcome and since the diet and physical activity agenda seems common across

interventions, taking action may be this attribute. Moreover, in this synthesis, the

implementation of all three skills-related attributes and the information-related

attributes were variable, there was no standardized strategy for delivering these

attributes within the DSME intervention programs across 142 studies reporting

different outcomes.

Subsequently, mixed methods analysis was implemented using a focus group

interview of 29 participants of different nationalities with T2D using open ended

questions based on the Triandis Model of Interpersonal Behavior (TIB), to explore the

factors influencing the intention of PWD toward self-management. Participant's

responses suggested different perceived consequences that might negatively affect

their health condition and overall lifestyle if they stopped DSM. There were also two

types of social factors that affected their DSM - The first was human factors such as

family, peer support and cultural behaviors while the second was environmental

factors such as access to healthy food and physical activity. In addition, Participants

reported various impacts of diabetes on their lives. The main effects were emotional, including acceptance and coping, frustration, sadness, depression, and reconciliation with diabetes. However, most participants reported acceptance of their condition and active coping with its different challenges. These responses were classified into theoretical domains of the Triandis Model of Interpersonal Behavior (Intention, social factors, perceived consequences and affect), and used for development of an assessment tool to evaluate the intention of PWD towards self-management. Results demonstrated that a higher level of intention was associated with factors within all three Triandis domains, but neither the demographic status, nor duration of diagnosis with diabetes were important for intention [290, 291]. The social factors were the main drivers of intention such as thinking of family, having peer support or having group support which can have a strong positive impact on intention towards self-management, while perceived consequences and affect were less important. Foregrounding social factors may prove a useful strategy in the design of future structured diabetes self-management programs that can then contribute to a greater uptake of patient self-management. Current work is underway on an attribute based [38] structured self-management program where problem solving related to these social factors will be given an important emphasis.

Using the previous findings, a Delphi process for consensus achievement was used to design and build the intervention. A total of eleven rounds were carried out with the steering group of key stakeholders in DSM resulting in development of five model cases and associated interactions and learning outcomes. These case scenarios will help to facilitate interactive group discussions using a PBL approach.

After completion of the project, the only major limitation is that the model developed is yet to be tested in a clinical trial due to COVID 19 constrains. The strengths of this project were critical evaluation of 142 existing clinical trials which examined the effectiveness of the DSME intervention for T2D. The novelty of this project was that different research methods and approaches were used to evaluate the existing DSM intervention and identify the core attributes of self-management. These included a concept analysis, meta-regression, qualitative methods, mixed methods, use of the Triandis Theory of Interpersonal Behavior and Delphi consensus all serving to enable the eventual development of a proposed model curriculum and delivery mode and made this a unique approach.

A future direction of this project is the testing of the proposed intervention in a clinical trial that will help to establish its clinical utility conclusively. The approaches outlined in this program of work are of great importance to anyone wishing to develop a robust DSME intervention program. Wide-spread adoption of this approach could result in increasing uptake by PWD of an effective intervention that can help maintain successful DSM with consequent improvements in the quality of life and outcomes for PWD.

Chapter 3 Supplementary File:

Note these required judgments to be made by the team and should not be construed in absolute terms)

Table 9.1 Examples of mapping of intervention content to the five attributes

Study name	Intervention	Skill's related attributes (PDA)Examples			Information's related attributes (Res-Rel) Examples	
		Problem Solving (P)	Decision Making(D)	Taking Action(A)	Resource utilization (Res)	Patient provider relationship (Rel)
Coria2020 [88]	Structured group education program	Basic knowledge of diabetes	Self-monitoring of blood glucose	Physical activity	Self-management booklet was provided to the participants	Goal setting and motivational interviewing techniques
Guner2020 [89]	Structured group education program	General Information about Diabetes/Physi opathology of Diabetes	Regulatory Drugs other than Insulin in Diabetes	Medical Nutritional Treatment	Education Booklet for Patients with Type 2 DM	Weekly smss reminder based on the education module
Kusnanto2019 [69]	Structured group education program	Basic concepts of DM	Monitoring that needed to be done	Nutritional therapy and physical activity	Access to healthcare facilities	DM-calendar application master to be installed on their mobile phone

Study name	Intervention	Skill's related attributes (PDA)Examples			Information's related attributes (Res-Rel) Examples	
		Problem Solving (P)	Decision Making(D)	Taking Action(A)	Resource utilization (Res)	Patient provider relationship (Rel)
Lynch2019 [53]	Structured group education program	Informal problem solving focused on overcoming barriers to behavior change, such as social pressure to eat unhealthily and financial stressors.	Self-monitoring of blood glucose	Culturally tailored diabetes nutrition education	Social support	Group discussion about goals, progress, and barriers to behavior change.
McElfish2019 [90]	Structured group education program	Reducing risks and healthy coping	Taking medications	Healthy eating	X	Goal setting
Pon2019 [70]	Proactive interdisciplinary self-management (PRISMA)	Acknowledged that nearly all day-to-day, minute-by-minute decisions	Medication taking	Food choices	X	Ensuring individuals with diabetes are supported in processing and understanding the information provided to them
Abdulla2018 [204]	Structured group education program	X	Glycemic control	Foot ulcer testing	X	X

Study name	Intervention	Skill's related attributes (PDA)Examples			Information's related attributes (Res-Rel) Examples	
		Problem Solving (P)	Decision Making(D)	Taking Action(A)	Resource utilization (Res)	Patient provider relationship (Rel)
Azar2018 [59]	Group diabetes education program based on PRECEDE PROCEED model combined with self-management theory.	X	Blood Glucose Monitoring	Diet	X	X
Chapman2018 [72]	Structured group education program	X	Monitor blood glucose	Addressing other cardiovascular disease risk factors and improving lifestyle	X	Participants received two telephone and two face-to-face coaching sessions
Cheng2018 [54]	Structured group education program	Establishing self-efficacy: culturally tailored knowledge acquisition	Strategies to interpret the SMBG	Healthy cooking	Social resources to facilitate the continuity of self-care	Providing informative and emotional support to help patients solve problems in a collaborative manner

Study name	Intervention	Skill's related attributes (PDA)Examples			Information's related attributes (Res-Rel) Examples	
		Problem Solving (P)	Decision Making(D)	Taking Action(A)	Resource utilization (Res)	Patient provider relationship (Rel)
Debussche2018[92]	Structured group education program	Understanding of diabetes and treatment	Challenges of insulin therapy	Prevention of foot lesions	X	On-going SME support
defeudis2018 [104]	Conversation Map program	Living with diabetes,	Starting insulin	Healthy eating		
gathu2018 [91]	Empowerment based diabetes education programme	Problem-solving	Adherence to medication	Monitoring blood glucose	Hotline number	Goal-setting
Hailu2018 [68]	Structured group education program	Patient experience in diabetes management	What to do on sick day	Monitoring of weight		Participants were reminded of upcoming sessions by phone
Moreno2018 [181]	Structured group education program	Acquire knowledge and skills related to the disease	Medication adherence	Improvements in diet	Educational material	Communicate more effectively, with their relatives and healthcare professionals
Reid2018 [71]	Structured group education program	Diabetes education	X	Delay or prevent onset of complications of diabetes.	X	Individual and caregiver engagement.
Rusdiana2018 [83]	Structured group	X	Monitoring	Management diet and Healthy eating		

Study name	Intervention	Skill's related attributes (PDA)Examples			Information's related attributes (Res-Rel) Examples	
		Problem Solving (P)	Decision Making(D)	Taking Action(A)	Resource utilization (Res)	Patient provider relationship (Rel)
	education program					
sarayani2018 [57]	Phone calls consultation	X	Solved drug therapy problems	X		
Aponte2017 [64]	Group diabetes education using the National Diabetes Educational Program (NDEP)	Diabetes Knowledge	Monitoring	Read a nutritional facts label	Home visits were conducted to address any questions the participants	Follow up calls
Cheung2017 [75]	Patient empowerment programme (PEP)	Disease-specific knowledge	Self-monitoring of blood glucose	Healthy diet	X	X
Azar2017 [76]	Group diabetes education program based on PRECEDE PROCEED model.	X	X	Healthy eating, exercise and medication		

Study name	Intervention	Skill's related attributes (PDA)Examples			Information's related attributes (Res-Rel) Examples	
		Problem Solving (P)	Decision Making(D)	Taking Action(A)	Resource utilization (Res)	Patient provider relationship (Rel)
Habibzadeh2017 [77]	Group Discussion-based Education on Self-management	X	Measurement of blood sugar and other parameters as well as interpretation of the results	Nutrition management	X	Continuous communication with the health care team
Korcegez2017 [93]	Structured group education program	Diabetes knowledge,	Discussed recommendations for changes to medication regimens	Smoking cessation	X	Clinical goals
McEwen2017 [78]	Structured group education program	Stress management.	Managing diabetes to improve glycemic control	Food consumed	X	Telephone calls
Murray2017 [86]	Structured group education program	Unusual situations like parties, holidays, travelling or shift work and what lifestyle modifications will improve health.	How diabetes is treated possible complications	Moderating alcohol consumption	X	Reminder text messages or emails

Study name	Intervention	Skill's related attributes (PDA)Examples			Information's related attributes (Res-Rel) Examples	
		Problem Solving (P)	Decision Making(D)	Taking Action(A)	Resource utilization (Res)	Patient provider relationship (Rel)
Paz-Pacheco 2017 [94]	Structured group education program		Pharmacologic treatment of diabetes	Foot care.	Those without a personal private physician were referred to the municipal health office after the study for continuity of diabetes care.	Medications for hyperglycemia, hypertension, and Participants were encouraged to follow-up with their personal physicians if they have one.
Peimani2017 [207]	Structured group education program	Patients' fears, worries, and concerns about the future and living with diabetes	X	Complying with diabetic diet and perceptions about their obesity risk and weight control	Family relationships and patients' expectations regarding compassion and support	Regular scheduled telephone contacts weekly
shabibi2017 [61]	Educational intervention based on the Health Belief Model	Introduction on diabetes	Testing blood sugar	Quitting smoking	Family member was asked to take part in the sessions	X
Shao2017 [74]	Structured group education program	Basic knowledge of T2DM	Proper use and precautions of oral antidiabetics and insulin,	Signs or symptoms of hypoglycemia and self-management	X	Telephone follow-up

Study name	Intervention	Skill's related attributes (PDA)Examples			Information's related attributes (Res-Rel) Examples	
		Problem Solving (P)	Decision Making(D)	Taking Action(A)	Resource utilization (Res)	Patient provider relationship (Rel)
Vissenberg2017 [67]	Structured group education program	Coping strategies	Medication adherence	Seeking adequate food and physical activity alternatives	Social support	Behavioral goal, making it specific, determining who could help with this goal and thinking of a reward when achieving this goal.
Albikawi2016 [102]	Diabetes self-efficacy enhancing intervention package (dseeip)	Dm education regarding knowledge on how to maintain a low glucose diet	Insulin injection	Diet control,	X	Self-goal setting
Grillo2016 [79]	Structured group education program	Identification of modifiable risk factors for type 2 diabetes mellitus	Mechanism of action and side effects of glucose-lowering medications	Emphasizing diet and exercise,	X	Reinforcement meetings
Lima2016 [96]	Diabetes self-management record sheet (DSMRS)	X	Impact on glycemic control and in turn on diabetes-related complications	Discussions/reflections about the importance of adequate diabetes self-management	X	X

Study name	Intervention	Skill's related attributes (PDA)Examples			Information's related attributes (Res-Rel) Examples	
		Problem Solving (P)	Decision Making(D)	Taking Action(A)	Resource utilization (Res)	Patient provider relationship (Rel)
Pauley2016 [80]	Home-based diabetes self-management coaching	X	Treatment (e.g., testing blood sugars, insulin administration)	Skin care	X	Frame the goal
Sadeghian2016 [56]	Structured group education program	Managing diabetes when traveling.	Taking diabetic medication	Meal planning	X	Self-management goal
Shayeghian2016 [84]	Structured group education program based on acceptance and commitment therapy (ACT)	Nature of the disease	Blood-glucose testing,	Behavioral change	X	X
shakibazadeh2016 [95]	Persian Diabetes Self-Management Education (PDSME) program	Healthy coping	Taking medication	Healthy eating	Invited a family member to enhance the self-efficacy of the patients and improve family support	Set goals for each patient

Study name	Intervention	Skill's related attributes (PDA)Examples			Information's related attributes (Res-Rel) Examples	
		Problem Solving (P)	Decision Making(D)	Taking Action(A)	Resource utilization (Res)	Patient provider relationship (Rel)
Anderson-Loftin2005 [103]	Group diabetes education program	Problem solving	Making informed choices	Meal preparation	Emotional support from peers and family	Weekly telephone follow-up by the nurse case manager
Ayala2015 [52]	Group diabetes education program	Diabetes management in daily living such as problem-solving	Diabetes and medical management	Checking feet	Communicate effectively with family members about one's needs	Ongoing support over time
Campbell2015 [63]	Structured group education program	Diagnosis	Insulin and medication	Healthy eating and exercise	Family and friends Support	X
Cani2015 [97]	Individualized pharmacother apeutic care plan (PCP)	X	Importance of home blood glucose monitoring	Foot inspections,	Pill organizers were given to each patient along with verbal directions	Written guidance on prescriptions was provided at each consult.
Chao2015 [98]	Integrated health management model	Group lectures on health and diabetes	long-term diabetes drug monitoring	Tailor-made exercise program	Distribution of health promoting materials	Individual telephone consultation
Escamilla2015 [171]	Structured group education program	Individual tailoring was determined based on the	Medication adherence	Skills, and support in the areas of nutrition	Family members present at home during home sessions were	Patient jointly developed a T2D self-management plan

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Study name	Intervention	Skill's related attributes (PDA)Examples			Information's related attributes (Res-Rel) Examples	
		Problem Solving (P)	Decision Making(D)	Taking Action(A)	Resource utilization (Res)	Patient provider relationship (Rel)
		patient's stage of change, level of motivation, health literacy			allowed to participate	
Jaipakdee2015 [99]	Computer-assisted instruction (CAI)	Knowledge of diabetes	Self-monitoring of clinical indicators	Foods for diabetes	X	Goals of diabetes control
Kim2015 [65]	Structured group education program	Knowledge and skills about DM and its management	Diabetes treatment	Ongoing self-monitoring of glucose	Encouraging better healthcare utilization	Better communication with their healthcare providers
Merakou2015 [105]	Structured group education program	Living with diabetes' which constitutes a review of diabetes and includes a description of what the disease	Discuss the myths about diabetes	Healthy diet and physical exercise	X	X
steinhardt2015 [143]	Resilience-based diabetes self-	General information about diabetes	Self-monitoring blood glucose	Healthy eating	Community connections and support systems	Creating a sick day plan

Study name	Intervention	Skill's related attributes (PDA)Examples			Information's related attributes (Res-Rel) Examples	
		Problem Solving (P)	Decision Making(D)	Taking Action(A)	Resource utilization (Res)	Patient provider relationship (Rel)
	management education (RB-DSME)	and its management				
Ku2014 [101]	Community-based diabetes self-management support (DSMS)	Gaining control over the condition through problem solving skills	Diabetes Medication	Adoption of self-care behavior	Written materials on healthy eating, exercise and glycemic goals were given out during the sessions	Goal setting
Naccashian2014 [82]	Structured group education program	Taking Care of Your Diabetes	Medication Management	Mastering the Meal Plan	X	X
Jennings2014 [87]	Structured group education program	Just being diagnosed, living with diabetes	Diabetes and medications	Physical activity	Social support	Messages were designed to be perceived as personally relevant and encourage continued use of the logbooks

X= attributes was not addressed in the study.

Table 9.2 Empirical referents of the concept

	Skills			Information	
	Attribute 1: Problem Solving	Attribute 2: Decision Making	Attribute 3: Taking Action	Attribute 4: Resource utilization	Attribute 5: Patient provider relationship
Description of what can be measured against this attribute	Skills and abilities that are used and learned by experience by persons with diabetes to solve or face any difficulties they may face throughout life to cope and manage with the disease. This skill does not entail dictating certain resolutions for a particular challenge, but rather the learning of skills to implement solutions. It requires critical thinking and planning strategies to navigate life situations related to diabetes whenever they occur, but it does not require an immediate action. Mainly it requires inputs from either the	Skills and abilities to make informed choices related to personal health which may have immediate outcomes, and usually its directly related to the current medical condition. It is mainly linked to scientific basics which are learned from health care providers. Mostly it requires collaboration from the person and the health care providers with final individual decisions.	Decisions made about long term changes to an aspect of persons life that has long term benefit on their health for example: It is skills and abilities of individual of making a plan to follow and maintain specific regimen that enhance self-management and improve long term outcomes Mainly it requires inputs from individual, with supports of health care providers, and organizations.	Resources that needed to facilitate the self-management and can be divided to two aspects: 1. access for the required resources such as medical equipment and materials in addition to access for the right information resources. 2. Correct way to use and sustain the available resources, in order to facilitate the	It could be primary, secondary and tertiary or It could be HCP to the patient. Patient provider relationship: Stands for any relationship or partnership could affect and enhance self-management skills such as individual to health care provider, health care providers among them self, health organization among themselves and with other organizations. Mainly It requires inputs from different levels and aspects from individuals to organizations.

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	Skills			Information	
	Attribute 1: Problem Solving	Attribute 2: Decision Making	Attribute 3: Taking Action	Attribute 4: Resource utilization	Attribute 5: Patient provider relationship
	individual alone or with supports from the health care provides or family members.			self-management Mainly It requires inputs from individuals and health care providers	
Example of specific areas of measurement	1. Knowledge about the disease that helps in coping with usual life such as storage and transport of insulin? 2. Coping with diabetes, at work, street, school, home 3. How to manage stress related to diabetes 4. Special occasion (how to manage diabetes during	1. Sign and symptoms of high and low blood sugar 2. Decision making regarding medical targets (glycemic, BP, lipids etc) and what to do when not met 3. Medication type, action, and side effect 4. Monitoring (how to test blood sugar, interpret results, other parameters such as BP, Cholesterol, weight, renal function test, retina screening, dental care) 5. Taking insulin injection	1. Meal planning 2. Weight management 3. Preventing acute and chronic complications 4. Sleeping patterns 5. acute and chronic complications 6. Healthy shopping 7. Reading food labels	1. Access to the health care when needed 2. Access to Insulin syringe, needle, meters, blood glucose strips, 3. Access to shoes choosing, and comfortable socks 4. Any support from your work 5. Family or friends involvement	1. When and where to contact the provider 2. How to access providers e.g. educators, nurses, pharmacists etc 3. Goal setting 4. Treatment planning 5. Premarital counselling 6. Preconception counselling

Skills			Information	
Attribute 1: Problem Solving	Attribute 2: Decision Making	Attribute 3: Taking Action	Attribute 4: Resource utilization	Attribute 5: Patient provider relationship
Eid, Hajj, travelling)	6. Storing insulin 7. Sick day management (other diseases can affect blood sugar level) 8. Disposing needles and other sharps 9. When to seek for help 10. When to contact health care provider 11. Use of alternative medicine (e.g. herbal) 12. Vaccination type. When and how 13. Medication management (when to take and when to stop) 14. How to detect fungal infection	8. Physical activity 9. Healthy eating 10. Healthy cooking 11. Maintaining a healthy lifestyle 12. Meal planning 13. Medication adherence 14. Foot care (feet hygiene, cutting nails, moisturizing heels	through education? 6. using community resources such as charity	

Chapter 4 Supplementary File

SUPPLEMENTARY MATERIAL

A. Search criteria
B. Study Characteristics
C. Quality breakdown
D. Publication bias assessment

Section A Search criteria

A1: Detailed search string

PubMed

(self -manage[All Fields] OR self- manageable[All Fields] OR self- management[All Fields] OR self- manage[All Fields] OR self- manageable[All Fields] OR self- managed[All Fields] OR self- management[All Fields] OR self- management's[All Fields] OR self- management for[All Fields] OR self-management of[All Fields] OR self- managements[All Fields] OR self- management were[All Fields] OR self- manager[All Fields] OR self -managerial[All Fields] OR self- managers[All Fields] OR self manages[All Fields] OR self- managing[All Fields] OR self- management[All Fields]) AND (("policy"[MeSH Terms] OR "policy"[All Fields]) OR ("policy"[MeSH Terms] OR "policy"[All Fields] OR "policies"[All Fields]) OR framework[All Fields] OR ("guideline"[Publication Type] OR "guidelines as topic"[MeSH Terms] OR "guideline"[All Fields]) OR model[All Fields] OR strategy[All Fields] OR strategies[All Fields] OR standard[All Fields])

AND

(("diabetes mellitus"[MeSH Terms] OR ("diabetes"[All Fields] AND "mellitus"[All Fields]) OR "diabetes mellitus"[All Fields] OR "diabetes"[All Fields]) OR ("glucose

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intolerance"[MeSH Terms] OR ("glucose"[All Fields] AND "intolerance"[All Fields]) OR "glucose intolerance"[All Fields] OR ("impaired"[All Fields] AND "glucose"[All Fields] AND "tolerance"[All Fields]) OR "impaired glucose tolerance"[All Fields]) OR ("prediabetic state"[MeSH Terms] OR ("prediabetic"[All Fields] AND "state"[All Fields]) OR "prediabetic state"[All Fields] OR "prediabetes"[All Fields]) OR (early[All Fields] AND ("diabetes mellitus"[MeSH Terms] OR ("diabetes"[All Fields] AND "mellitus"[All Fields]) OR "diabetes mellitus"[All Fields] OR "diabetes"[All Fields])))

Embase

("self -manage" OR "self- manageable" OR "self- management" OR "self- manage" OR "self- manageable" OR "self- managed" OR "self- management" OR "self- managements" OR "self- management for" OR "self-management of" OR "self- managements" OR "self- management were" OR "self- manager" OR "self - managerial" OR "self- managers" OR "self manages" OR "self- managing" OR "self- management")

AND

('policy'/exp OR policy OR 'policy'/exp OR policy OR policies OR framework OR 'practice guideline'/exp OR guideline OR model OR strategy OR strategies OR standard)

AND

('diabetes mellitus'/exp OR (diabetes AND mellitus) OR "diabetes mellitus" OR 'glucose intolerance'/exp OR (glucose AND intolerance) OR "glucose intolerance" OR (impaired AND glucose AND tolerance) OR 'impaired glucose tolerance'/exp OR 'prediabetic state'/exp OR (prediabetic AND state) OR "prediabetic state" OR prediabetes OR (early AND diabetes))

PsycINFO

("self -manage" OR "self- manageable" OR "self- management" OR "self- manage" OR "self- manageable" OR "self- managed" OR "self- management" OR "self-management's" OR "self- management for" OR "self-management of" OR "self-managements" OR "self- management were" OR "self- manager" OR "self -managerial" OR "self- managers" OR "self manages" OR "self- managing" OR "self-management")

AND

(exp Health Care Policy/ OR policy OR exp Health Care Policy/ OR policy OR policies OR framework OR "guidelines as topic" OR guideline OR model OR strategy OR strategies OR standard)

AND

(exp Diabetes Mellitus/ OR (diabetes AND mellitus) OR "diabetes mellitus" OR "glucose intolerance" OR (glucose AND intolerance) OR "glucose intolerance" OR (impaired AND glucose AND tolerance) OR "impaired glucose tolerance" OR "prediabetic state" OR (prediabetic AND state) OR "prediabetic state" OR prediabetes OR (early AND diabetes))

Cochrane Library/Cochrane CENTRAL

("self -manage" OR "self- manageable" OR "self- management" OR "self- manage" OR "self- manageable" OR "self- managed" OR "self- management" OR "self-management's" OR "self- management for" OR "self-management of" OR "self-managements" OR "self- management were" OR "self- manager" OR "self -managerial" OR "self- managers" OR "self manages" OR "self- managing" OR "self-

management")

AND

([mh policy] OR policy OR [mh policy] OR policy OR policies OR framework OR [mh "guidelines as topic"] OR guideline OR model OR strategy OR strategies OR standard)

AND

([mh "diabetes mellitus"] OR (diabetes AND mellitus) OR "diabetes mellitus" OR [mh "glucose intolerance"] OR (glucose AND intolerance) OR "glucose intolerance" OR (impaired AND glucose AND tolerance) OR "impaired glucose tolerance" OR [mh "prediabetic state"] OR (prediabetic AND state) OR "prediabetic state" OR prediabetes OR (early AND diabetes))

Section B Study Characteristics

Table 9.3 Characteristics of studies included in this synthesis: Populations.

Study (Year)	Country	HealthCare Setting	Study population	Study Design	Sample Size (n)
Abdulah2018 [73]	Iraq	tertiary	Patients with T2D age ≥ 25 Years	RCT	39
wu2011 [121]	Taiwan	tertiary	Patients with T2D age ≥ 30 Years	RCT	145
Mitchell2011 [131]	Australia	others	Patients with T2D HbA1C>7	PPOG	346
albikawi2016 [102]	Jordan	tertiary	Patients with T2D age 25 Years	PPOG	149
Gold2008 [122]	US	tertiary	Patients with T2D HbA1C≥ 9.5	RCT	35
Ruggiero2014 [66]	US	primary	Patients with T2D age ≥18 Years	PPOG	77
Speer2008 [123]	Georgia	primary	Patients with T2D age 60-74 Years	PPOG	48
Lima 2016 [96]	Spain	primary	Patients with T2D age ≥18 years HbA1C>7	RCT	184
Hillen2013 [132]	US	primary	Patients with T2D HbA1C ≥7% in last 6 months	RCT	377
Sturt2006 [174]	UK	primary	Patients with T2D age ≥ 65 Years HbA1C>7	PPOG	16
Torre2013 [125]	Spain	tertiary	Patients with T2D	RCT	130
Trief 2012 [292]	US	primary	Patients with T2D age ≥55 Years	RCT	1665
Adepoju2014 [126]	US	tertiary	Patients with T2D age ≥18 Years	RCT	196
Anderson2010 [127]	US	others	Patients with T2D age ≥18 Years	RCT	209
Aponte2017 [64]	US	tertiary	Patients with T2D HbA1C ≥8.	RCT	106
Anderson-Loftin2005 [103]	US	primary	Patients with T2D, High risk African American adults age ≥18 Years	PPNEC	86
Ayala2015 [52]	US	primary	Patients with T2D who had received services during the previous 3-month HbA1C ≥7	RCT	263
Azar2018 [59]	Iran	secondary	Patients with T2D for more than one year	RCT	86
Boehm1993 [129]	US	tertiary	Patients with T2D age ≥18 Years HbA1C>8	RCT	69
Adepoju2014 [130]	US	tertiary	Patients with T2D age ≥18 Years	RCT	101

Study (Year)	Country	HealthCare Setting	Study population	Study Design	Sample Size (n)
brun2009 [189]	Germany	tertiary	Patients with T2D on insulin at least one geriatric syndrome (such as incontinence, reduced mobility requiring the use of assistive devices, a history of falls during the previous 2 years or cognitive dysfunction), multi-morbidity (more than two chronic diseases besides T2D) and age >65 years	RCT	119
Brown2007 [168]	US	.	Patients with T2D, age 35 to 70 years	RCT	216
Dizaji2014 [210]	Iran	tertiary	Patients with T2D	PPOG	78
depue2013 [134]	US	primary, others	Patients with T2D age ≥18 Years , mentally competent and able to consent; unlikely to leave AS for .4 months; and no serious comorbid conditions (e.g., end-stage renal disease, cancer).	RCT	268
defeudis2018 [104]	Italy	tertiary	Patients with T2D and overweight or obesity(BMI > 25 kg/m^2) treated only with metformin	RCT	66
davis2010 [135]	US	primary	Patients with T2D, HbA1C>7%, age 35 years and above, willing to participate in a 1-year clinical trial.	RCT	43
estabrooks2005 [136]	US	tertiary	Patients with T2D, age (≥ 25 years), language (English)	RCT	204
estey1990 [172]	Canada	tertiary	Patients with T2D, not using insulin, willing to practice SMBG, and to give consent, accessible by telephone	RCT	53
Farbodebadifardazar2017 [76]	Iran	tertiary	Patients with T2D, mean age 55 years, mean BMI 28.7	PPNEC	86
Forjuoh2014 [137]	US	tertiary	Patients with T2D age ≥18 years HbA1C ≥7.5%	open-label-RCT	194
Sadeghian2016 [56]	India	tertiary	Patients with T2D, HbA1C%	RCT	306
gathu2018 [91]	Kenya	tertiary	Patients with T2D, age 18- 65 years, HbA1C ≥8%	non-blinded-	96

Study (Year)	Country	HealthCare Setting	Study population	Study Design	Sample Size (n)
				RCT	
goudswaard2004 [179]	Netherlands	primary	Patients with T2D age < 76 Years , HbA1C ≥7%, taking the maximum feasible dosages of two different oral hypoglycemic agents	RCT	50
gregg2007 [138]	US	primary	Patients with T2D	RCT	73
anderson1995 [139]	US	tertiary	Patients with T2D	RCT	122
glasgow2006 [140]	US	primary	Patients with T2D	RCT	217
miller2002 [141]	US	tertiary	Patients with T2D, age ≥65, no impaired cognitive function	PPOG	93
aliha2013 [206]	Iran	tertiary	Patients with T2D	RCT	62
Cani2015 [97]	Brazil	tertiary	Patients with T2D age ≥45 Years, HbA1C>8% , on insulin	RCT	70
Cheung 2017 [75]	Hong Kong, China	primary	Patients with T2D age ≥18 Years,	PPOG	353
Chao2015 [98]	China	tertiary	Patients with T2D age ≥60 Years who are locally permanent residents.	RCT	100
Samuel-hodge2009 [142]	US	others	Patients with T2D age ≥20 Years,	RCT	170
Campbell2015 [63]	Australia	others	Patients with T2D age 30-70	RCT	595
steinhardt2015 [143]	US	others	Patients with T2D, age 30-85	PPOG	61
Chapman2018 [72]	China	primary	Patients with T2D, age ≥50	RCT	544
Cheng2018 [54]	China	tertiary	Patients with T2D HbA1C>7.5, age > 18 Years	RCT	242
Jaipakdee2015 [99]	Thailand	primary	Patients with T2D, age ≥20 Years, HbA1C ≥7%	RCT	378
Jennings2014 [87]	Australia	others	Patients with T2D, age > 18 Years, access to internet and email,	RCT	397
sarayani2018 [57]	Iran	others	Patients with T2D, HbA1C>7, use oral hypoglycemia agent	RCT	84

Study (Year)	Country	HealthCare Setting	Study population	Study Design	Sample Size (n)
sarkadi2004 [184]	Sweden	others	Patients with T2D, on insulin treatment for not more than 2 years	RCT	64
schillinger2009 [144]	US	tertiary	Patients with T2D, HbA1C ≥8	RCT	215
shabibi2017 [61]	Iran	primary	Patients with T2D, age 30 to 60	PPOG	70
shakibazadeh2016 [95]	Iran	tertiary	Patients with T2D, age > 18 Years	RCT	176
Shayeghian2016 [84]	Iran	tertiary	Patients with T2D, age 40 to 60 Years	RCT	106
amoako2008 [145]	US	primary	Patients with T2D, age between 49 to 83 Years	RCT	126
sperl-hillen2011 [146]	US	.	Patients with T2D HbA1C≥ 7%	RCT	377
khan 2011 [169]	US	tertiary	Patients with T2D age ≥18 Years,	RCT	100
Hailu2018 [68]	Ethiopia	primary	Patients with T2D, age > 30 Years, overweight or obese,	PPNEC	220
Reid2018 [71]	Canada	primary	Patients with T2D, age ≥65	RCT	139
Murray2017 [86]	UK	primary	Patients with T2D age ≥18 Years,	RCT	374
Peimani2017 [207]	Iran	tertiary	Patients with T2D age between 25 to 75 Years,	RCT	200
McElfish2019 [90]	US	primary	Patients with T2D age ≥18 Years,	RCT	173
Rusdiana2018 [83]	Indonesia	primary	Patients with T2D, age > 40 Years	PPOG	158
Vissenberg2017 [67]	Netherlands	tertiary	Patients with T2D, age ≥35 Years, HbA1C> 3%	PPOG	69
Paz-Pacheco 2017 [94]	Philippines	primary	Patients with T2D	RCT	155
Escamilla2015 [171]	US	primary	Patients with T2D, age ≥21 Years, HbA1C≥ 7%	RCT	211
Merakou2015 [105]	Greece	primary	Patients with T2D age ≥18 Years,	RCt	193
Pauley2016 [80]	Canada	primary	Patients with T2D age ≥18 Years, on insulin	RCT	94
Kim2015 [65]	US	primary	Patients with T2D, age ≥35 Years, HbA1C≥ 7%	RCT	209
Lynch2019 [53]	US	primary	Patients with T2D age ≥18 years HbA1C ≥7%	RCT	196
Ruggiero2014 [293]	US	primary	Patients with T2D age ≥18 years HbA1C≥ 6.5%	RCT	126
Varney2014 [191]	Australia	tertiary	Patients with T2D, HbA1C>7	RCT	94
Yuan2014 [192]	China	others	Patients with T2D, age > 18 Years	RCT	88

Study (Year)	Country	HealthCare Setting	Study population	Study Design	Sample Size (n)
Ledford2013 [147]	US	tertiary	Patients with T2D, age between 40 to 80 Years	PPOG	126
Liu2012 [148]	China	primary	Patients with T2D age 35-80	RCT	176
nishita2012 [149]	US	primary	Patients with T2D age 18 to 62 years HbA1C≥ 6.5%	RCT	190
vanderwulp2012 [175]	UK	primary	Patients with T2D for less than 12 months	RCT	238
Ko2011 [196]	Korea	primary	Patients with T2D newly diagnosis	PPOG	96
Landim2011 [212]	Brazil	primary	Patients with T2D	PPOG	43
Lee2011 [200]	Hong Kong	tertiary	Patients with T2D, HbA1C≥ 7%	RCT	117
Naik2011 [170]	US	primary	Patients with T2D, age 50-90 Years, HbA1C> 7.5%	RCT	85
Philis-Tsimikas2011 [150]	US	primary	Patients with T2D, age 21-75 Years, HbA1C> 8 %	RCT	145
Quinn2011 [151]	US	primary	Patients with T2D ≥ 6-month, age 18- 64 years HbA1C ≥7.5 %	RCT	57
Rosal2011 [152]	US	primary	Patients with T2D , age ≥18 years HbA1C ≥7.5 %	RCT	252
Welch2011 [153]	US	tertiary	Patients with T2D , age 30-70 years HbA1C ≥7.5 %	RCT	184
Wu2011 [121]	Taiwan	tertiary	Patients with T2D , age ≥30 years, on oral Medication	PPOG	145
Walker2010 [154]	US	Primary	Patients with T2D , age ≥ 40 years	PPOG	145
Torbjornsen2014 [182]	Norway	Primary	Patients with T2D , age ≥18 years HbA1C ≥7.1 %	RCT	78
Noh2010 [197]	Korea	tertiary	Patients with T2D , age ≥18 years HbA1C ≥7%	RCT	40
Orsama2013 [188]	Finland	Primary	Patients with T2D , age 30-70 years HbA1C>6.5%	RCT	48
Thoolen2009 [180]	Netherlands	Primary	Patients with T2D	RCT	180
Moriyama2009 [201]	Japan	tertiary	Patients with T2D	RCT	42
Mohamed2013 [203]	Qatar	tertiary	Patients with T2D	RCT	290
Mash2014 [211]	South Africa	Primary	Patients with T2D	RCT	866
Lujan2007 [155]	US	Primary	Patients with T2D	RCT	141

Study (Year)	Country	HealthCare Setting	Study population	Study Design	Sample Size (n)
Deakin2006 [19]	UK	Primary	Patients with T2D	RCT	301
Crowley2013 [156]	US	Primary	Patients with T2D	RCT	359
Shahrani2012 [204]	KSA	Primary	Patients with T2D, age >30	PPOG	438
Goodarzi2012 [208]	Iran	Primary	Patients with T2D	RCT	81
Baradaran2006 [176]	UK	Primary	Patients with T2D, age >30	RCT	118
Melkus2010 [157]	US	tertiary	Patients with T2D, age 21-65	RCT	109
Graziano2009 [294]	US	Primary	Patients with T2D, age ≥50 years HbA1C ≥7 %	PPOG	119
Khunti2012 [177]	UK	Primary	Patients with T2D	RCT	604
Ko2004 [194]	China	tertiary	Patients with T2D, age 35-70 years HbA1C ≥8 %	RCT	178
Lorig2009 [159]	US	Primary	Patients with T2D, age ≥ 18 years	RCT	294
Osborn2010 [295]	US	tertiary	Patients with T2D, age ≥ 18 years	RCT	91
ridgeway1999 [160]	US	Primary	Patients with T2D	RCT	38
Sixta2008 [161]	US	Primary	Patients with T2D, age ≥ 18 years	RCT	131
Sturt2008 [178]	UK	Primary	Patients with T2D HbA1C>8%	RCT	202
Prezio2013 [162]	US	Primary	Patients with T2D, age 18-75 years	RCT	156
Song2009 [198]	Korea	tertiary	Patients with T2D	PPOG	15
Scain2009 [213]	Brazil	tertiary	Patients with T2D, age 25-75 years	RCT	104
Aghamolaei2004 [209]	Iran	tertiary	Patients with T2D	RCT	71
Anderson2005 [163]	US	Primary	Patients with T2D	RCT	192
Glasgow2010 [117]	US	Primary	Patients with T2D, age 25-75 years	RCT	375
Lorig2010 [164]	US	Primary	Patients with T2D, age ≥ 18 years	RCT	447
Frosch2011 [165]	US	Primary	Patients with T2D, HbA1C ≥8 %	RCT	201
Spencer2011 [166]	US	Primary	Patients with T2D, age ≥ 18 years	RCT	117
Sigurdardottir2009 [190]	Iceland	Primary	Patients with T2D, HbA1C ≥7.5 %	RCT	53
Vincent2007 [167]	US	Primary	Patients with T2D, age 18-75 years	RCT	17
Wattana2007 [202]	Thailand	tertiary	Patients with T2D, age ≥ 35 years	RCT	147

Study (Year)	Country	HealthCare Setting	Study population	Study Design	Sample Size (n)
Sun2008 [195]	China	tertiary	Patients with T2D, age 18-70 years	RCT	150
Shao2017 [74]	China	tertiary	Patients with T2D, age ≥ 18 years	RCT	199
McEwen2017 [78]	US	Primary	Patients with T2D, age 18-70 years, HbA1C≥ 8%	RCT	154
Mehuys2010 [187]	Belgium	Primary	Patients with T2D, age 45-75 years	RCT	288
Korcegez2017 [93]	Cyprus	tertiary	Patients with T2D, HbA1C>7	RCT	152
Jarab2012 [205]	Jordan	tertiary	Patients with T2D, HbA1C>7.5 %	RCT	156
Adolfsson2007 [185]	Sweden	Primary	Patients with T2D, HbA1C ≥6.5 %, age ≤75	RCT	88
Oh 2003 [199]	Korea	tertiary	Patients with T2D	RCT	38
Guner2020 [89]	Turkey	Primary	Patients with T2D, age ≥ 18	PPOG	101
Mollaoglu2007 [186]	Turkey	tertiary	Patients with T2D, age 18-65 years	RCT	50
Pon2019 [70]	Netherlands	Primary	Patients with T2D, age ≥ 18	RCT	193
Kusnanto2019 [69]	Indonesia	Primary	Patients with T2D, HbA1C>7%	RCT	30
Debussche2018 [92]	Mali	tertiary	Patients with T2D, HbA1C ≥8%, age 30-80 years	RCT	140
Coria2020 [88]	Spain	Primary	Patients with T2D, age 18-80 years	RCT	236
Ku2014 [101]	Philippines	Primary	Patients with T2D, age ≥ 20	PPOG	328
Gallegos2006 [173]	Mexico	Primary	Patients with T2D	PPNEC	45
Moreno2018 [181]	Spain	Primary	Patients with T2D, age >30	RCT	518
Grillo2016 [79]	Brazil	Primary	Patients with T2D, age 18-80 years, HbA1C>7 %	RCT	127
Naccashian2014 [82]	US	Primary	Patients with T2D, HbA1C>8 %	PPOG	150
Habibzadeh2017 [77]	Iran	tertiary	Patients with T2D, age 30-70 years	RCT	90
Rygg2012 [183]	Norway	tertiary	Patients with T2D, age 40-75 years	RCT	36

Table 9.4 Characteristics of studies included in this synthesis: Interventions.

Study name	Intervention	Control	Type of Outcome	Skill's related attributes	Information's related attributes	Quality Score
				Attributes		
Adolfsson2007 [185]	Structured group education program	routine care	Immediate	PDA	Rel	30
Aghamolaei2004 [209]	Structured group education program	routine care	Immediate	PDA	X	24
Anderson2005 [296]	Culturally tailored education	wait-listed	Immediate	PDA	Res-Rel	24
Aponte2017 [64]	Group diabetes education using the National Diabetes Educational Program (NDEP)	routine care	Immediate	PDA	Res-Rel	32
Azar2018 [59]	Group diabetes education program based on PRECEDE PROCEED model combined with self-management theory.	Educations based on PRECEDE PROCEED model.	Immediate	DA	X	25
Braun2009 [189]	Strukturierte Geriatrische Schulung, structured geriatric (SGS) structured treatment and teaching programme (DTTP)	routine care	Immediate	DA	X	28
Cani2015 [97]	individualized pharmacotherapeutic care plan (PCP)	routine care	Immediate	DA	Rel	30
Chao2015 [98]	integrated health management model	routine care	Immediate	PDA	Res-Rel	27

| Study name | Intervention | Control | Type of Outcome | Attributes | | Quality Score |
				Skill's related attributes	Information's related attributes	
Deakin2006 [19]	patient-centered, group-based self-management programme (X-PERT) Programme	routine care	Immediate	PDA	Res-Rel	29
Debussche2018 [92]	Structured group education program	routine care	Immediate	PDA	Rel	26
Dizaji2014 [210]	Group diabetes education program	no control	Immediate	PA	Res	15
Azar2017 [76]	Group diabetes education program based on PRECEDE PROCEED model.	routine care	Immediate	A	X	27
Frosch2011 [165]	Structured group education program	received brochure	Immediate	PDA	Rel	29
Goodarzi2012 [208]	Tailored SMS	routine care	Immediate	PDA	Rel	24
gregg2007 [138]	Structured group education program using ACT	Education alone	Immediate	PDA	X	25
Grillo2016 [79]	Structured group education program	routine care	Immediate	PDA	Rel	30
khan 2011 [169]	computer based diabetes self-management program.	provide with an educational brochure	Immediate	DA	X	24
Kim2015 [65]	Structured group education program	no control	Immediate	PDA	Res-Rel	28
Ko2011 [196]	Individually tailored educational programs	no control	Immediate	PDA	X	27
Ku2014 [101]	Community-based diabetes self-management support (DSMS)	no control	Immediate	PDA	Res-Rel	27

| Study name | Intervention | Control | Type of Outcome | Attributes | | Quality Score |
				Skill's related attributes	Information's related attributes	
Ledford2013 [147]	Structured group education program using software	no control	Immediate	DA	Res-Rel	27
Lujan2007 [155]	Structured group education program	one-on-one education	Immediate	PDA	Rel	26
Lynch2019 [53]	Structured group education program	group discussion	Immediate	PDA	Res-Rel	30
Mehuys2010 [187]	Structured group education program	routine care	Immediate	PDA	X	28
miller2002 [141]	Structured group education program	no control	Immediate	PDA	Res-Rel	26
Mohamed2013 [203]	Structured group education program	educational tool kit	Immediate	PDA	X	25
Naik2011 [170]	one-on-one consultation and group education	Traditional diabetes education	Immediate	PDA	Rel	27
Rygg2012 [183]	Structured group education program	waiting list	Immediate	PDA	X	31
Samuel-hodge2009 [142]	Individual counseling, and group education sessions.	minimal intervention (MI),	Immediate	PA	Res-Rel	28
Scain2009 [213]	Structured group education program	routine care	Immediate	PDA	X	26
shakibazadeh2016 [95]	Persian Diabetes Self-Management Education (PDSME) program	routine care	Immediate	PDA	Res-Rel	28
Sigurdardottir2009 [190]	Structured group education program	routine care	Immediate	PDA	Res-Rel	28
Sixta2008 [161]	Structured group education program	routine care	Immediate	PDA	Res-Rel	27

| Study name | Intervention | Control | Type of Outcome | Attributes | | Quality Score |
				Skill's related attributes	Information's related attributes	
Song2009 [198]	Structured group education program -Web-based course	Web-based education	Immediate	PDA	X	20
Spencer2011 [166]	Structured group education program	routine care	Immediate	PDA	Res-Rel	26
sperl-hillen2011 [146]	Peer support education	routine care	Immediate	PDA	Rel	29
steinhardt2015 [143]	resilience-based diabetes self-management education (RB-DSME)	routine care	Immediate	PDA	Res-Rel	25
Sun2008 [195]	Structured group education program	diabetes education	Immediate	PDA	Res-Rel	27
Vincent2007 [167]	Structured group education program	routine care	Immediate	PDA	Res	24
Abdulla2018 [204]	Structured group education program	routine care	Intermediate	DA	X	25
amoako2008 [145]	Structured group education program	routine care	Intermediate	PDA	Res-Rel	26
Ayala2015 [52]	Group diabetes education program	routine care	Intermediate	PDA	Res-Rel	25
Azar2018 [59]	Group diabetes education program based on PRECEDE PROCEED model combined with self-management theory.	Educations based on PRECEDE PROCEED model.	Intermediate	DA	X	25
Chao2015 [98]	integrated health management model	routine care	Intermediate	PDA	Res-Rel	27
Chapman2018 [72]	Structured group education program	routine care	Intermediate	DA	Rel	26
Cheng2018 [54]	Structured group education program	routine care	Intermediate	PDA	Res-Rel	33

Study name	Intervention	Control	Type of Outcome	Attributes		Quality Score
				Skill's related attributes	Information's related attributes	
Deakin2006 [19]	patient-centered, group-based self-management programme (X-PERT) Programme	routine care	Intermediate	PDA	Res-Rel	29
Frosch2011 [165]	Structured group education program	received brochure	Intermediate	PDA	Rel	29
glasgow2006 [140]	computer-assisted, tailored self-management (TSM)	routine care	Intermediate	PDA	Res-Rel	25
Glasgow2010 [117]	self-administered, computer- assisted self-management (CASM),	routine care	Intermediate	PDA	Res-Rel	26
Graziano2009 [294]	automated, prerecorded voice message	routine care	Intermediate	PDA	X	26
Jarab2012 [205]	Structured group education program	routine care	Intermediate	PDA	Res-Rel	27
Jennings2014 [87]	Structured group education program	access to website	Intermediate	PDA	Res-Rel	31
khan 2011 [169]	computer based diabetes self-management program.	provide with an educational brochure	Intermediate	DA	X	24
Ko2011 [196]	Individually tailored educational programs	no control	Intermediate	PDA	X	27
Korcegez2017 [93]	Structured group education program	routine care	Intermediate	PDA	Rel	26
Ledford2013 [147]	Structured group education program using software	no control	Intermediate	DA	Res-Rel	27
Liu2012 [148]	Structured group education program	routine care	Intermediate	PDA	Res-Rel	31

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Study name	Intervention	Control	Type of Outcome	Attributes		Quality Score
				Skill's related attributes	Information's related attributes	
Lorig2009 [159]	diabetes self-management program (DSMP)	routine care	Intermediate	PDA	Res-Rel	28
Mash2014 [211]	Structured group education program	routine care	Intermediate	PDA	X	28
McEwen2017 [78]	Structured group education program	waiting list	Intermediate	PDA	Rel	26
Mehuys2010 [187]	Structured group education program	routine care	Intermediate	PDA	X	28
Moreno2018 [181]	Structured group education program	routine care	Intermediate	PDA	Res-Rel	28
Pon2019 [70]	Proactive interdisciplinary self-management (PRISMA)	routine care	Intermediate	PDA	Rel	31
Reid2018 [71]	Structured group education program	routine care	Intermediate	PA	X	33
Ruggiero2014a [66]	Structured group education program	basic education, educational booklet	Intermediate	PDA	Rel	26
Ruggiero2014b [293]	website access to Diabetes Island	no control	Intermediate	PA	Res-Rel	23
Sadeghian2016 [56]	Structured group education program	unstructured education	Intermediate	PDA	Rel	25
Samuel-hodge2009 [142]	Individual counseling, and group education sessions.	minimal intervention (MI),	Intermediate	PA	Res-Rel	28
sarayani2018 [57]	phone calls consultation	routine care	Intermediate	D	X	29
shakibazadeh2016 [95]	Persian Diabetes Self-Management Education (PDSME) program	routine care	Intermediate	PDA	Res-Rel	28

| Study name | Intervention | Control | Type of Outcome | Attributes | | Quality Score |
				Skill's related attributes	Information's related attributes	
sperl-hillen2011 [146]	Peer support education	routine care	Intermediate	PDA	Rel	29
steinhardt2015 [143]	resilience-based diabetes self-management education (RB-DSME)	routine care	Intermediate	PDA	Res-Rel	25
Thoolen2009 [180]	Structured group education program	routine care	Intermediate	PDA	Rel	28
Torre2013 [125]	SMBG as an individual educational tool	routine care	Intermediate	DA	Rel	29
vanderwulp2012 [175]	Structured group education program	routine care	Intermediate	A	Rel	30
Varney2014 [191]	Telephone coaching	routine care	Intermediate	DA	Res-Rel	30
Vincent2007 [167]	Structured group education program	routine care	Intermediate	PDA	Res	24
Abdulla2018 [204]	Structured group education program	routine care	Post Intermediate	DA	X	25
Adolfsson2007 [185]	Structured group education program	routine care	Post Intermediate	PDA	Rel	30
Aghamolaei2004 [209]	Structured group education program	routine care	Post Intermediate	PDA	X	24
aliha2013 [206]	Structured group education program	routine care	Post Intermediate	DA	Rel	26
anderson1995 [139]	Structured group education program	routine care	Post Intermediate	PDA	Res-Rel	22
Anderson-Loftin2015 [103]	Group diabetes education program	routine care	Post Intermediate	DA	Res-Rel	25

Study name	Intervention	Control	Type of Outcome	Attributes		Quality Score
				Skill's related attributes	Information's related attributes	
Aponte2017 [64]	Group diabetes education using the National Diabetes Educational Program (NDEP)	routine care	Post Intermediate	PDA	Res-Rel	32
Ayala2015 [52]	Group diabetes education program	routine care	Post Intermediate	PDA	Res-Rel	25
Boehm1993 [129]	Group diabetes education program	routine care	Post Intermediate	PDA	X	25
Braun2009 [189]	Strukturierte Geriatrische Schulung, structured geriatric (SGS) structured treatment and teaching programme (DTTP)	routine care	Post Intermediate	DA	X	28
Brown2007 [168]	Group diabetes education compressed program	extended intervention education program	Post Intermediate	PDA	Res-Rel	26
Cani2015 [97]	individualized pharmacotherapeutic care plan (PCP)	routine care	Post Intermediate	DA	Rel	30
Chapman2018 [72]	Structured group education program	routine care	Post Intermediate	DA	Rel	26
Cheng2018 [54]	Structured group education program	routine care	Post Intermediate	PDA	Res-Rel	33
Coria2020 [88]	Structured group education program	routine care	Post Intermediate	PDA	Res-Rel	26

| Study name | Intervention | Control | Type of Outcome | Attributes | | Quality Score |
				Skill's related attributes	Information's related attributes	
Crowley2013 [156]	Structured group education program	routine care	Post Intermediate	PDA	Rel	29
davis2010 [135]	Diabetes Telecare DSME intervention	routine care	Post Intermediate	PDA	Res-Rel	28
Deakin2006 [19]	patient-centered, group-based self-management programme (X-PERT) Programme	routine care	Post Intermediate	PDA	Res-Rel	29
Debussche2018 [92]	Structured group education program	routine care	Post Intermediate	PDA	Rel	26
defeudis2018 [104]	Conversation Map program	routine care	Post Intermediate	PDA	X	26
depue2013 [134]	Group diabetes education program based on PRECEDE PROCEED model.	routine care	Post Intermediate	PDA	X	30
Escamilla2015 [171]	Structured group education program	routine care	Post Intermediate	PDA	Res-Rel	32
estey1990 [172]	Individual telephone calls consultation	standard 3-day education program.	Post Intermediate	PDA	Res-Rel	25
Frosch2011 [165]	Structured group education program	received brochure	Post Intermediate	PDA	Rel	29
Gallegos2006 [173]	Structured group education program	routine care	Post Intermediate	PDA	Res-Rel	28

Study name	Intervention	Control	Type of Outcome	Attributes		Quality Score
				Skill's related attributes	Information's related attributes	
gathu2018 [91]	Empowerment based diabetes education programme	routine care	Post Intermediate	PDA	Res-Rel	29
glasgow2006 [140]	computer-assisted, tailored self-management (TSM)	routine care	Post Intermediate	PDA	Rel	25
Glasgow2010 [117]	self-administered, computer- assisted self-management (CASM),	routine care	Post Intermediate	PDA	Res-Rel	26
Goodarzi2012 [208]	Tailored SMS	routine care	Post Intermediate	PDA	Rel	24
goudswaard2004 [179]	Structured group education program	routine care	Post Intermediate	PDA	X	29
Graziano2009 [294]	automated, prerecorded voice message	routine care	Post Intermediate	PDA	X	26
gregg2007 [138]	Structured group education program using ACT	Education alone	Post Intermediate	PDA	X	25
Grillo2016 [79]	Structured group education program	routine care	Post Intermediate	PDA	Rel	30
Guner2020 [89]	Structured group education program	routine care	Post Intermediate	PDA	Rel	29
Hailu2018 [68]	Structured group education program	routine care	Post Intermediate	PDA	Rel	28
Jaipakdee2015 [99]	computer-assisted instruction (CAI)	routine care	Post Intermediate	PDA	Rel	28

Study name	Intervention	Control	Type of Outcome	Attributes Skill's related attributes	Attributes Information's related attributes	Quality Score
Jarab2012 [205]	Structured group education program	routine care	Post Intermediate	PDA	Res-Rel	27
khan 2011 [169]	computer based diabetes self-management program.	provide with an educational brochure	Post Intermediate	DA	X	24
Khunti2012 [177]	diabetes education and self-management programme (DESMOND)	routine care	Post Intermediate	PDA	Rel	30
Kim2015 [65]	Structured group education program	no control	Post Intermediate	PDA	Res-Rel	28
Ko2004 [194]	Structured group education program	routine care	Post Intermediate	PDA	Rel	26
Korcegez2017 [93]	Structured group education program	routine care	Post Intermediate	PDA	Rel	26
Ku2014 [101]	Community-based diabetes self-management support (DSMS)	no control	Post Intermediate	PDA	Res-Rel	27
Kusnanto2019 [69]	Structured group education program	group education and a leaflet	Post Intermediate	PDA	Res-Rel	26
Ledford2013 [147]	Structured group education program using software	no control	Post Intermediate	DA	Res-Rel	27
Lee2011 [200]	Structured group education program	routine care	Post Intermediate	PDA	Res-Rel	28

Study name	Intervention	Control	Type of Outcome	Skill's related attributes	Information's related attributes	Quality Score
				Attributes		
Lorig2009 [159]	diabetes self-management program (DSMP)	routine care	Post Intermediate	PDA	Res-Rel	28
Lorig2010 [164]	Internet-based diabetes self-management program (IDSMP)	routine care	Post Intermediate	PDA	Rel	29
Lujan2008 [155]	Structured group education program	one-on-one t education	Post Intermediate	PDA	Rel	26
Lynch2019[53]	Structured group education program	group discussion	Post Intermediate	PDA	Res-Rel	30
Mash2014 [211]	Structured group education program	routine care	Post Intermediate	PDA	X	28
McElfish2019 [90]	Structured group education program	routine care	Post Intermediate	PDA	Rel	31
McEwen2017 [78]	Structured group education program	waiting list	Post Intermediate	PDA	Rel	26
Mehuys2010 [187]	Structured group education program	routine care	Post Intermediate	PDA	X	28
Melkus2010 [157]	diabetes self-management training (DSMT)	conventional group diabetes education	Post Intermediate	PDA	Res-Rel	29
Merakou2015 [105]	Structured group education program	routine care	Post Intermediate	PDA	X	26
Mohamed2013 [203]	Structured group education program	educational tool kit	Post Intermediate	PDA	X	25

Study name	Intervention	Control	Type of Outcome	Attributes Skill's related attributes	Attributes Information's related attributes	Quality Score
Mollaoglu2007 [186]	Structured group education program	routine care	Post Intermediate	PDA	Rel	25
Moreno2018 [181]	Structured group education program	routine care	Post Intermediate	PDA	Res-Rel	28
Murray2017 [86]	Structured group education program	routine care	Post Intermediate	PDA	Rel	32
Naccashian2014 [82]	Structured group education program	no control	Post Intermediate	PDA	X	27
nishita2012 [149]	The Hawai'i Demonstration to Maintain Independence and Employment (Hawai'i DMIE) life coaching model	No treatment concurrent	Post Intermediate	PDA	Res-Rel	29
Noh2010 [197]	Structured group education program using eMOD (electronic Management of Diabetes)	Diabetes educational books	Post Intermediate	PDA	Rel	27
Oh 2003 [199]	telephone intervention	routine care	Post Intermediate	PDA	Rel	24
Orsama2013 [188]	Structured group education program using technology	routine care	Post Intermediate	PDA	Rel	26
Osborn2010 [295]	Structured group education program	routine care	Post Intermediate	PDA	Res-Rel	20
Paz-Pacheco2017 [94]	Structured group education program	routine care	Post Intermediate	DA	Res-Rel	27

| Study name | Intervention | Control | Type of Outcome | Attributes | | Quality Score |
				Skill's related attributes	Information's related attributes	
Peimani2017 [207]	Structured group education program	routine care	Post Intermediate	PA	Res-Rel	28
Philis-Tsimikas2011 [150]	Structured group education program	routine care	Post Intermediate	PDA	Res-Rel	29
Pon2019 [70]	Proactive interdisciplinary self-management (PRISMA)	routine care	Post Intermediate	PDA	Rel	31
Prezio2013 [162]	Structured group education program	routine care	Post Intermediate	PDA	Res-Rel	28
Quinn2011 [151]	patient-coaching system and clinical decision support	routine care	Post Intermediate	PDA	Res-Rel	30
Rosal2011 [152]	Structured group education program	routine care	Post Intermediate	PDA	Res-Rel	30
Ruggiero2014a [66]	Structured group education program	basic education, educational booklet	Post Intermediate	PDA	Rel	26
Ruggiero2014b [293]	website access to Diabetes Island	no control	Post Intermediate	PA	Res-Rel	23
Rusdiana2018 [83]	Structured group education program	no control	Post Intermediate	DA	X	22
Rygg2012 [183]	Structured group education program	waiting list	Post Intermediate	PDA	X	31
Sadeghian2016 [56]	Structured group education program	unstructured education	Post Intermediate	PDA	Rel	25

| Study name | Intervention | Control | Type of Outcome | Attributes | | Quality Score |
				Skill's related attributes	Information's related attributes	
Samuel-hodge2009 [142]	Individual counseling, and group education sessions.	minimal intervention (MI),	Post Intermediate	PA	Res-Rel	28
Scain2009 [213]	Structured group education program	routine care	Post Intermediate	PDA	X	26
schillinger2009 [144]	automated telephone self-management support with nurse follow-up (ATSM)	routine care	Post Intermediate	DA	X	25
Shahrani2012 [204]	Structured group education program	no control	Post Intermediate	PDA	X	23
shakibazadeh2016 [95]	Persian Diabetes Self-Management Education (PDSME) program	routine care	Post Intermediate	PDA	Res-Rel	28
Shao2017 [74]	Structured group education program	routine care	Post Intermediate	DA	Rel	29
Shayeghian2016 [84]	Structured group education program based on acceptance and commitment therapy (ACT)	routine care	Post Intermediate	DA	X	22
Sigurdardottir2009 [190]	Structured group education program	routine care	Post Intermediate	PDA	Res-Rel	28
Song2009 [198]	Structured group education program -Web-based course	Web-based education	Post Intermediate	PDA	X	20

| Study name | Intervention | Control | Type of Outcome | Attributes | | Quality Score |
				Skill's related attributes	Information's related attributes	
Speer2008 [123]	Structured group education program	no control	Post Intermediate	DA	Res	30
Spencer2011 [166]	Structured group education program	routine care	Post Intermediate	PDA	Res-Rel	26
steinhardt2015 [143]	resilience-based diabetes self-management education (RB-DSME)	routine care	Post Intermediate	PDA	Res-Rel	25
Sturt 2006 [174]	Self- Efficacy Goal Achievement (SEGA)	no control	Post Intermediate	PDA	Rel	25
Sturt2008 [178]	Structured group education program	routine care	Post Intermediate	PDA	Res-Rel	30
Sun2008 [195]	Structured group education program	diabetes education	Post Intermediate	PDA	Res-Rel	27
Torbjornsen2014 [182]	Structured group education program using smartphone	routine care	Post Intermediate	PDA	Res-Rel	29
Torre2013 [125]	SMBG as an individual educational tool	routine care	Post Intermediate	DA	Rel	29
Varney2014 [191]	Telephone coaching	routine care	Post Intermediate	DA	Res-Rel	30
Wattana2007 [202]	Structured group education program	routine care	Post Intermediate	PDA	Rel	25
Welch2011 [153]	Structured group education program	routine care	Post Intermediate	PDA	Rel	26

Study name	Intervention	Control	Type of Outcome	Attributes		Quality Score
				Skill's related attributes	Information's related attributes	
Yuan2014 [192]	Structured group education program	routine care	Post Intermediate	PA	Res-Rel	30
Aghamolaei2004 [209]	Structured group education program	routine care	Long-term	PDA	X	24
albikawi2016 [102]	Diabetes Self-Efficacy Enhancing Intervention Package (DSEEIP)	routine care	Long-term	PDA	Rel	25
amoako2008 [145]	Structured group education program	routine care	Long-term	PDA	Res-Rel	26
Cani2015 [97]	individualized pharmacotherapeutic care plan (PCP)	routine care	Long-term	DA	Rel	30
Chao2015 [98]	integrated health management model	routine care	Long-term	PDA	Res-Rel	27
Chapman2018 [72]	Structured group education program	routine care	Long-term	DA	Rel	26
Deakin2006 [19]	patient-centered, group-based self-management programme (X-PERT) Programme	routine care	Long-term	PDA	Res-Rel	29
Azar2017 [76]	Group diabetes education program based on PRECEDE PROCEED model.	routine care	Long-term	A	X	27
Jaipakdee2015 [99]	computer-assisted instruction (CAI)	routine care	Long-term	PDA	Rel	28
Kim2015 [65]	Structured group education program	no control	Long-term	PDA	Res-Rel	28
Landim2011 [212]	Structured group education program	no control	Long-term	PDA	Res	24
Liu2012 [148]	Structured group education program	routine care	Long-term	PDA	Res-Rel	31

Study name	Intervention	Control	Type of Outcome	Attributes		Quality Score
				Skill's related attributes	Information's related attributes	
Lynch2019 [53]	Structured group education program	group discussion	Long-term	PDA	Res-Rel	30
Mash2014 [211]	Structured group education program	routine care	Long-term	PDA	X	28
Moreno2018 [181]	Structured group education program	routine care	Long-term	PDA	Res-Rel	28
nishita2012 [149]	The Hawai'i Demonstration to Maintain Independence and Employment (Hawai'i DMIE) life coaching model	No treatment concurrent	Long-term	PDA	Res-Rel	29
Peimani2017 [207]	Structured group education program	routine care	Long-term	PA	Res-Rel	28
Rygg2012 [183]	Structured group education program	waiting list	Long-term	PDA	X	31
Samuel-hodge2009 [142]	Individual counseling, and group education sessions.	minimal intervention (MI),	Long-term	PA	Res-Rel	28
schillinger2009 [144]	automated telephone self-management support with nurse follow-up (ATSM)	routine care	Long-term	DA	X	25
steinhardt2015 [143]	resilience-based diabetes self-management education (RB-DSME)	routine care	Long-term	PDA	Res-Rel	25
Sun2008 [195]	Structured group education program	diabetes education	Long-term	PDA	Res-Rel	27
Wattana2007 [202]	Structured group education program	routine care	Long-term	PDA	Rel	25
Wu2011 [121]	Structured group education program	routine care	Long-term	PDA	Rel	27

*Taking Action (A), Decision Making (D), Problem Solving (P); Patient Provider Relationship (Rel), Resource Utilization (Res), None (X)

Section C : Quality of studies

The quality of the studies was assessed using the MethodologicAl STandard for Epidemiological Research (MASTER) scale. All studies were assessed against the 36 safeguards and seven broad standards for each of the four main outcomes: immediate (Figures 10.1-10.2), intermediate (Figures 10.3-10.4), post intermediate (Figures 10.5 to 10.9), and long-term outcomes (Figures 10.10-10.11). The least deficient standards across studies were equal recruitment, and equal implementation. The most deficient standards found across studies were equal ascertainment, and equal prognosis. Counts of implemented safeguards were used to rank studies relative to each other and the ranking was used for bias-adjustment in this analysis.

Quality assessment by study outcomes:

Immediate outcome:

There were 39 studies that assessed the immediate outcome (knowledge scores), and due to the large number of studies we presented the data across two figures (Figures 10.1-10.2). The median (IQR) quality safeguard count was 27 [25-28]. The most deficient standard across studies were equal ascertainment, and equal prognosis. Regarding equal ascertainment, only 13% of the studies had the outcome assessors blinded. In 7.7% of the studies, caregivers were blinded and in 5.1% of the studies the analyst(s) were blinded. In only half of the included studies, were key confounders addressed (51 %) and most of the latter had key baseline characteristics adjusted or had participants that were randomly allocated. In only around 7.7% of the 39 studies, was there evidence that the allocation procedure was adequate and concealed. The least deficient standards were equal recruitment (>=95% of studies), and equal implementation (>=97% of studies) (Figure 10.1-10.2).

Intermediate outcome:

There were 39 studies that assessed the intermediate outcome (physical activity) and data is presented in two figures (Figure 10.3-10.4). The median (IQR) of the implemented safeguard counts was 27 [26,29]. Among these studies, the most deficient standards were equal ascertainment, and equal prognosis. Regarding equal ascertainment, only 18 % of the studies had the outcome assessors blinded. In 10% of the studies, analysts were blinded and in 5.1% of the studies the caregivers were blinded. Only half of the included studies had confounders adjusted or had participants that were randomly allocated. In around 13% of the 39 studies the allocation procedure was adequate and concealed. The least deficient standards were equal recruitment(>=95% of studies), equal implementation(all studies), and temporal precedence (82%) (Figure 10.1-10.2).

Post intermediate outcome:

There were 99 studies that assessed the post intermediate outcome (HbA1c%), and due to the large number of the studies data is shown across five figures (Figure 10.5 to 10.9). The median (IQR) of the implemented safeguard counts was 27 (25,29) among these studies. The most deficient standard was equal ascertainment, and equal prognosis. Regarding equal ascertainment, only 15 % of the studies had the outcome assessors blinded. In 5.1% of the studies, caregivers were blinded and in 4 % of the studies the analysts were blinded. Again, confounders were adjusted or participants were randomly allocated in 48% of the 99 studies. In around 12% of the 99 studies the allocation procedure was adequate and concealed. The least deficient standards were equal recruitment(>=93%), equal implementation(>=99%), and temporal precedence(>=81%)(Figure 10.5 to 10.9).

Long term outcome:

There were 24 studies that assessed the post intermediate outcome (QoL), due to the large number of the studies these were reported across two figures (Figures 10.10 & 10.11). The median (IQR) of the implemented safeguard counts was 27.5 (25.5,28.5) among these studies. The most deficient standard was equal ascertainment, and equal prognosis. Regarding equal ascertainment, in only 12.5 % of the studies were the outcome assessors blinded. In 4.2 % of the studies, analysts were blinded and none of the studies had the caregivers or participants blinded. Key confounders or participants that were randomly allocated was observed in 41.7% of the studies, and in none of the studies was their evidence of an allocation procedure that was adequate and concealed. The least deficient standards were equal recruitment(>=95.8%),equal implementation(100%), and temporal precedence(>=79.2%; Figures 10.10-10.11).

Figure legends:
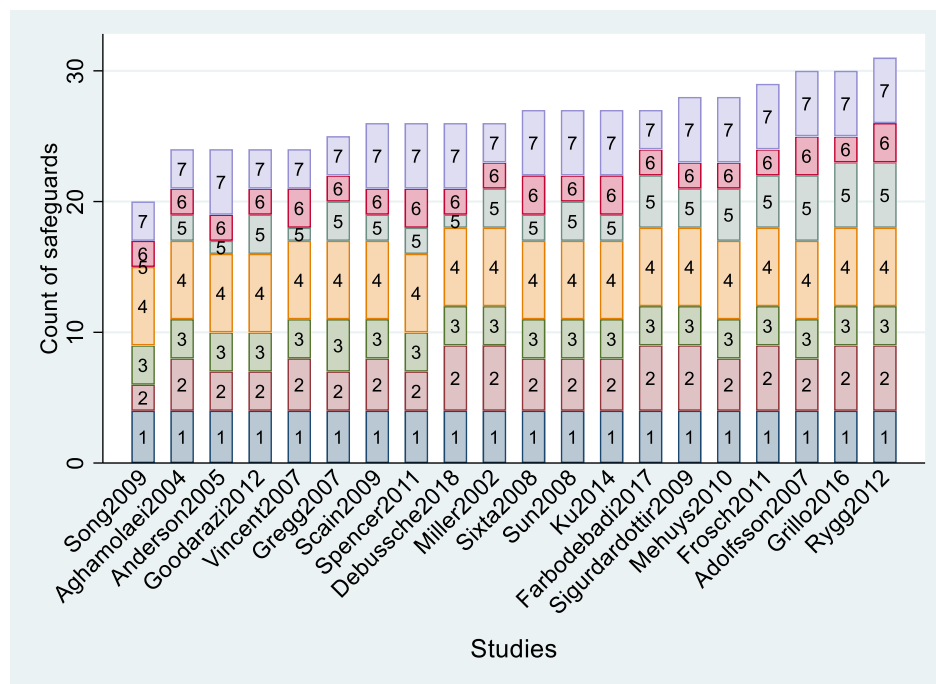
Figure 9.1 Immediate outcome (Knowledge)-Group A

*Standards (1= equal recruitment, 2= equal retention, 3= equal ascertainment, 4= equal implementation, 5= equal prognosis, 6= Sufficient analysis, 7= Temporal precedence)
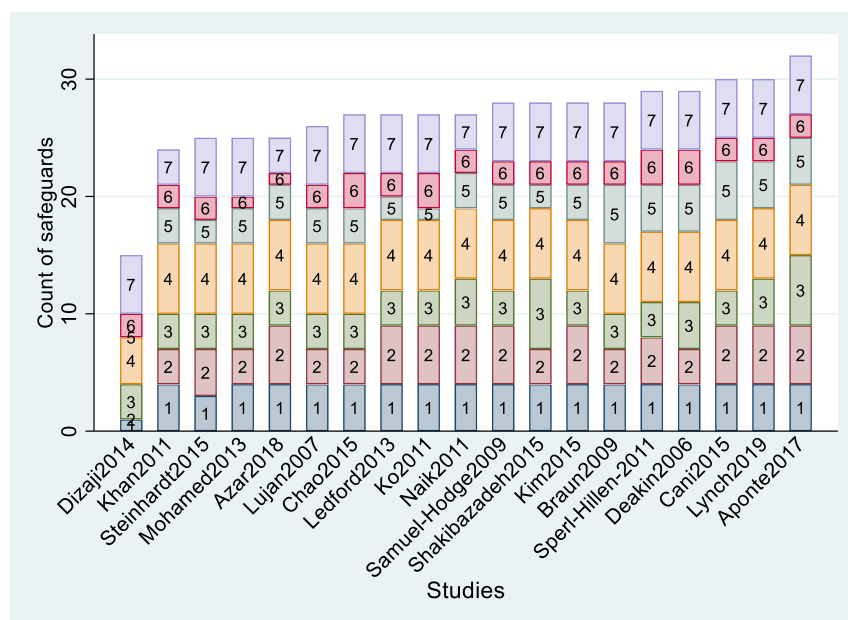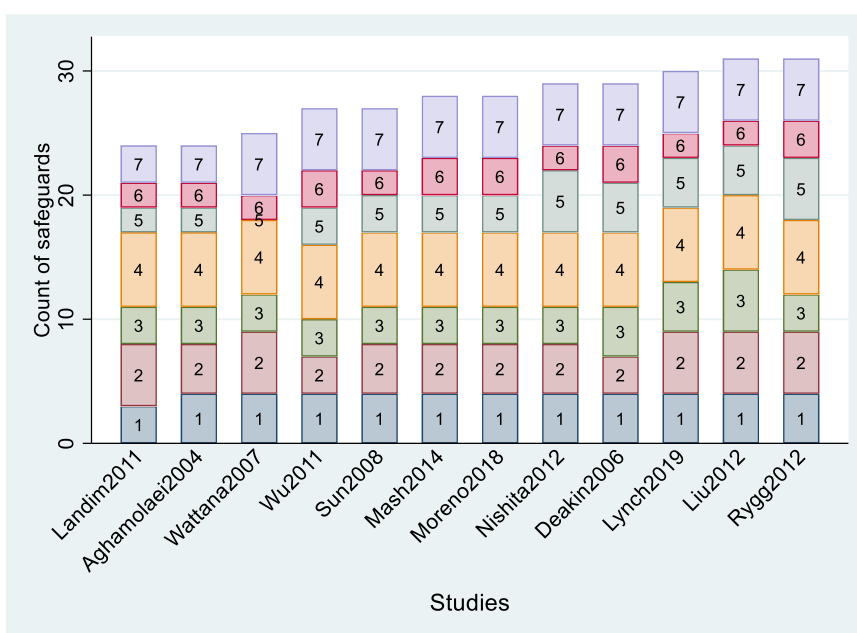

Figure 9.2 Immediate outcome (Knowledge)- Group B

*Standards (1= equal recruitment, 2= equal retention, 3= equal ascertainment, 4= equal implementation, 5= equal prognosis, 6= Sufficient analysis, 7= Temporal precedence)

2. Intermediate outcome (Physical Activity):
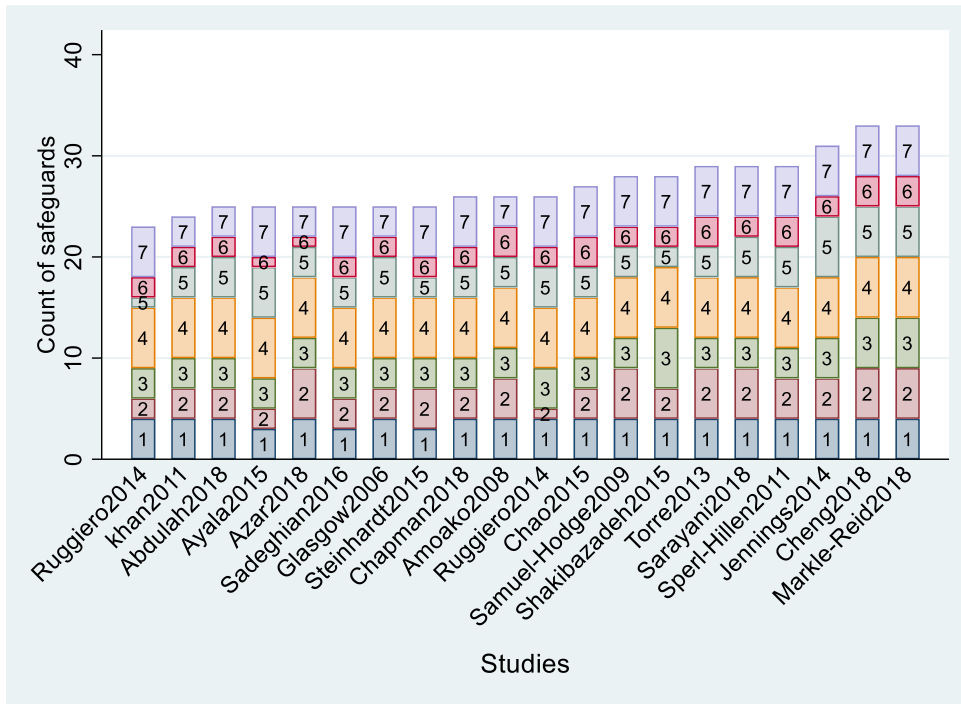
Figure 9.3 Intermediate outcome (Physical Activity)-Group A

*Standards (1= equal recruitment, 2= equal retention, 3= equal ascertainment, 4= equal implementation, 5= equal prognosis, 6= Sufficient analysis, 7= Temporal precedence)
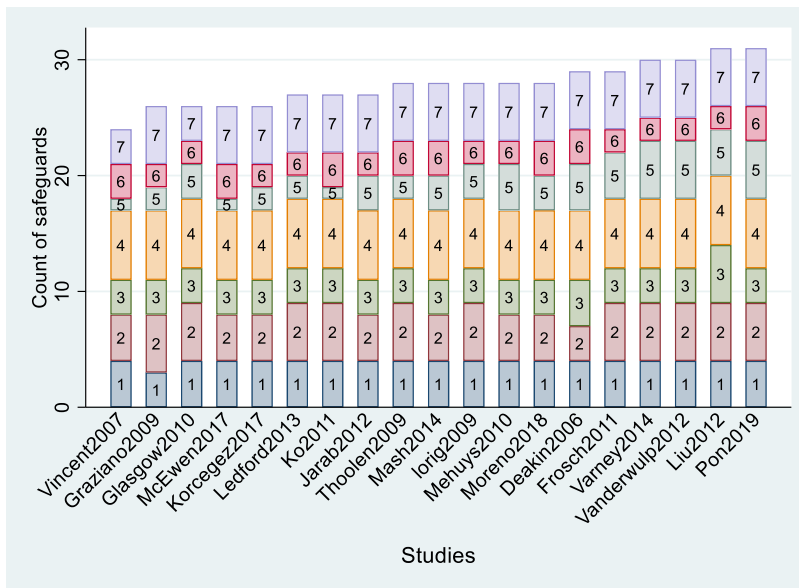
Figure 9.4 Intermediate outcome (Physical Activity)-Group B

*Standards (1= equal recruitment, 2= equal retention, 3= equal ascertainment, 4= equal implementation, 5= equal prognosis, 6= Sufficient analysis, 7= Temporal precedence)

3. Post intermediate outcome (HbA1C)
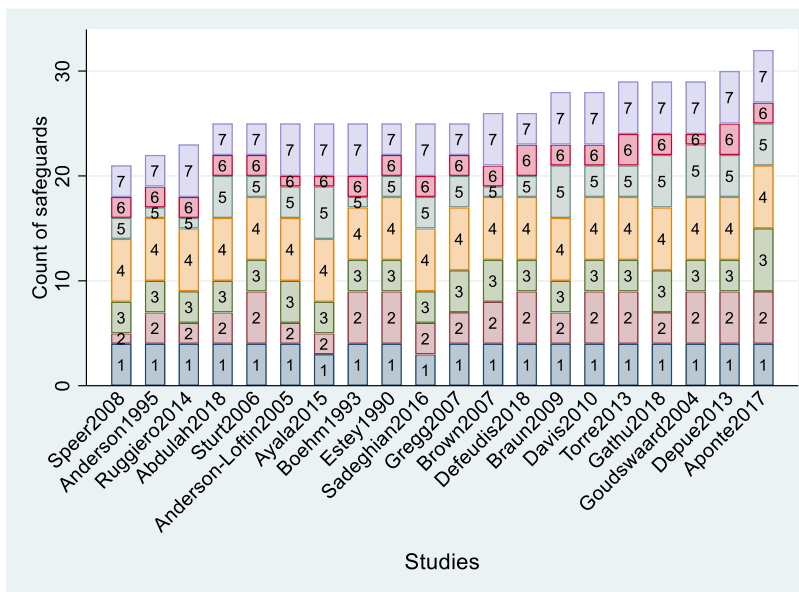
Figure 9.5 Post intermediate outcome (HbA1C)-Group A

*Standards (1= equal recruitment, 2= equal retention, 3= equal ascertainment, 4= equal implementation, 5= equal prognosis, 6= Sufficient analysis, 7= Temporal precedence)
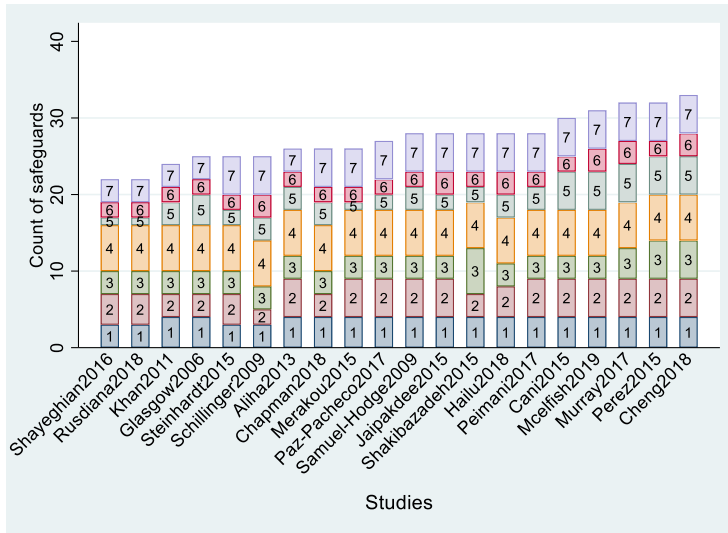
Figure 9.6 Figure 5 Post intermediate outcome (HbA1C)-Group B

*Standards (1= equal recruitment, 2= equal retention, 3= equal ascertainment, 4= equal implementation, 5= equal prognosis, 6= Sufficient analysis, 7= Temporal precedence)
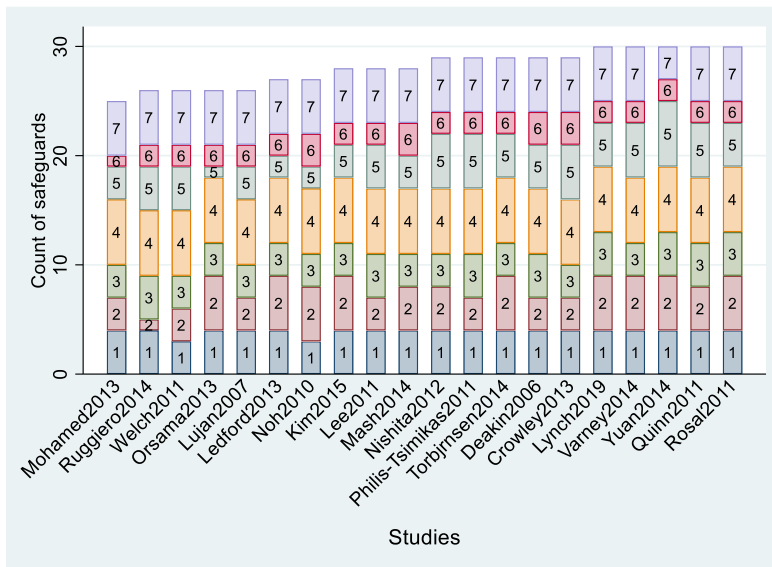
Figure 9.7 Post intermediate outcome (HbA1C)-Group C

*Standards (1= equal recruitment, 2= equal retention, 3= equal ascertainment, 4= equal implementation, 5= equal prognosis, 6= Sufficient analysis, 7= Temporal precedence)
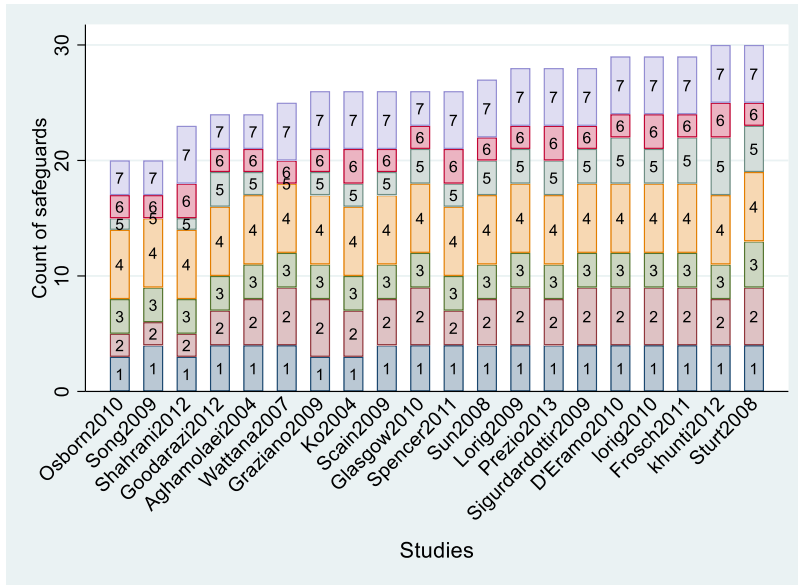
Figure 9.8 Post intermediate outcome (HbA1C)-Group D

*Standards (1= equal recruitment, 2= equal retention, 3= equal ascertainment, 4= equal implementation, 5= equal prognosis, 6= Sufficient analysis, 7= Temporal precedence)
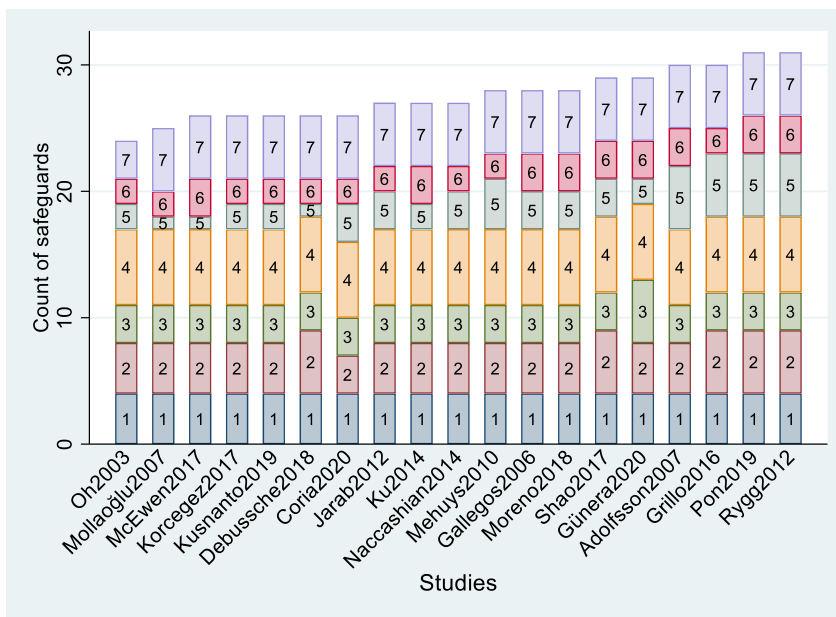
Figure 9.9 Post intermediate outcome (HbA1C)-Group E

*Standards (1= equal recruitment, 2= equal retention, 3= equal ascertainment, 4= equal implementation, 5= equal prognosis, 6= Sufficient analysis, 7= Temporal precedence)

4. Long term outcome (Quality of Life):
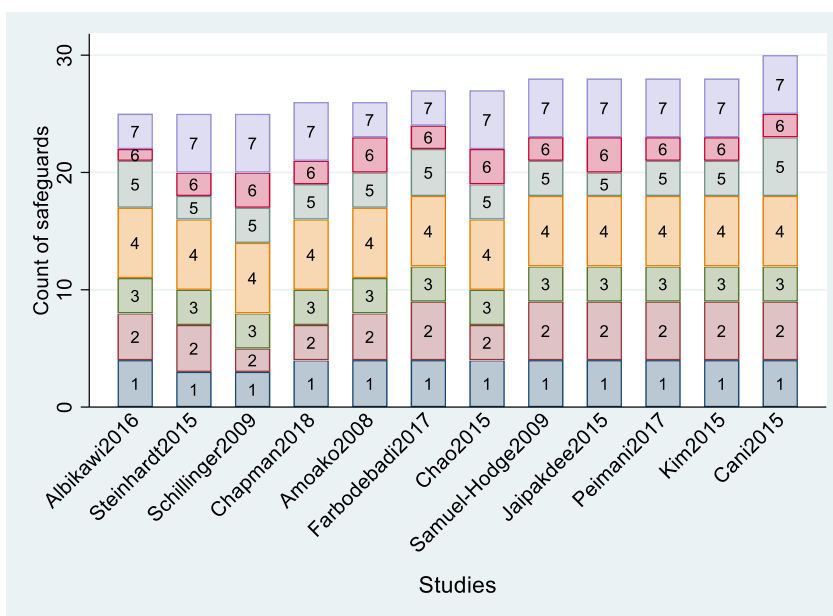
Figure 9.10 Long term outcome (Quality of Life)- Group A

*Standards (1= equal recruitment, 2= equal retention, 3= equal ascertainment, 4= equal implementation, 5= equal prognosis, 6= Sufficient analysis, 7= Temporal precedence)

Figure 9.11 Long term outcome (Quality of Life)- Group B

*Standards (1= equal recruitment, 2= equal retention, 3= equal ascertainment, 4= equal implementation, 5= equal prognosis, 6= Sufficient analysis, 7= Temporal precedence)

Section D: Doi plots

*Immediate (outcome==1) Knowledge

- Complete PDA

LFK index = 1.12 (minor asymmetry)
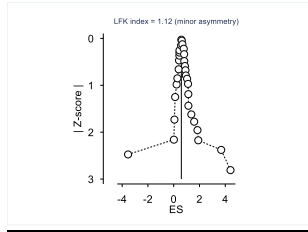
**Interm (outcome==2) Physical Acitivity

- Complete PDA

LFK index = 1.28 (minor asymmetry)
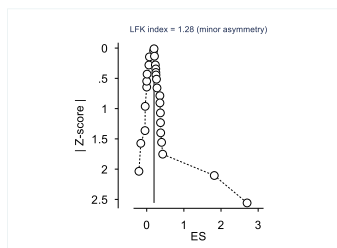
**Postinterm (outcome==3) HbA1C

- Complete PDA

LFK index = -1.40 (minor asymmetry)
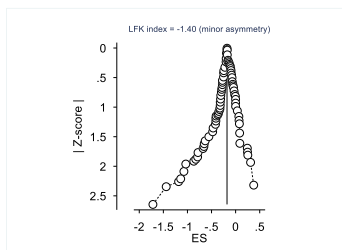
*Longterm (outcome==4) Quality of life

- Complete PDA

LFK index = .88 (no asymmetry)
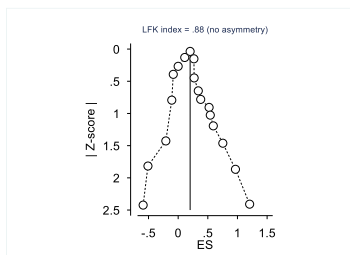
Chapter 6 Supplementary file

Table 9.5 Item and reliability analysis- A: Section I (Intentions)

Item	Obs	item-test correlation	item-rest correlation	average interitem correlation	alpha
s1q1	300	0.641	0.5653	0.4965	0.9156
s1q2	300	0.6446	0.5695	0.496	0.9154
s1q3	300	0.6395	0.5637	0.4968	0.9157
s1q4	300	0.7041	0.6385	0.4865	0.9125
s1q5	300	0.7603	0.7048	0.4777	0.9096
s1q6	300	0.7715	0.7181	0.4759	0.909
s1q7	300	0.7058	0.6406	0.4863	0.9124
s1q8	300	0.7937	0.7447	0.4724	0.9078
s1q9	300	0.8287	0.787	0.4668	0.9059
s1q10	300	0.7418	0.6829	0.4806	0.9105
s1q11	300	0.7468	0.6888	0.4798	0.9103
s1q12	300	0.7274	0.666	0.4829	0.9113
Test scale				0.4832	0.9182

Table 9.6 Item and reliability analysis- B: Section II (Actions and social factors)

Item	Obs	item-test correlation	item-rest correlation	average interitem correlation	alpha
s2q1	300	0.6301	0.5407	0.1957	0.773
s2q2	300	0.5137	0.4074	0.2054	0.7835
s2q3	300	0.565	0.4655	0.2011	0.779
s2q4	300	0.2377	0.1091	0.2286	0.8057
s2q5	300	0.2758	0.1489	0.2254	0.8029
s2q6	300	0.235	0.1063	0.2288	0.8059
s2q7	300	0.6154	0.5236	0.1969	0.7744
s2q8	300	0.6332	0.5442	0.1954	0.7727
s2q9	300	0.6884	0.6093	0.1908	0.7675
s2q10	300	0.6351	0.5465	0.1952	0.7725
s2q11	300	0.7072	0.6318	0.1892	0.7656
s2q12	300	0.6183	0.5269	0.1966	0.7741
s2q13	300	0.6478	0.5613	0.1942	0.7714
s2q14	300	0.1169	-0.0142	0.2387	0.8144
s2q15	300	0.511	0.4042	0.2056	0.7838
Test scale				0.2058	0.7954

Table 9.7 Item and reliability analysis- C: Section III (Impacts and consequences)

Item	Obs	Sign	item-test correlation	item-rest correlation	average interitem correlation	alpha
s3q1	300	+	0.6584	0.5387	0.3107	0.7829
s3q2	300	+	0.7035	0.5951	0.3016	0.7755
s3q3	300	+	0.6976	0.5876	0.3028	0.7765
s3q4	300	+	0.6586	0.5389	0.3106	0.7828
s3q5	300	+	0.4325	0.2724	0.3562	0.8157
s3q6	300	+	0.5452	0.4019	0.3335	0.8001
s3q7	300	+	0.6031	0.471	0.3218	0.7915
s3q8	300	+	0.7101	0.6035	0.3003	0.7744
s3q9	300	+	0.6325	0.5067	0.3159	0.787
Test scale					0.3171	0.8069

Table 9.8 Item and reliability analysis- D: Section IV (Affect)

Item	Obs	Sign	item-test correlation	item-rest correlation	average interitem correlation	alpha
s4q1	300	+	0.5667	0.3179	0.1975	0.5517
s4q2	300	+	0.5715	0.324	0.1958	0.5491
s4q3	300	+	0.4877	0.2203	0.2247	0.5917
s4q4	300	+	0.5864	0.3431	0.1907	0.5409
s4q5	300	+	0.6297	0.4001	0.1758	0.5161
s4q6	300	+	0.6007	0.3617	0.1858	0.5329
Test scale					0.1951	0.5925

Table 9.9 Detailed case scenarios related to the attributes

1. Problem Solving

Scenario Overview
A 48 years old lady, who is married and lives with her family of four kids is working as a teacher in middle school near her home. She developed T2D 10 yrs ago post GDM. At diagnosis she was started on Metformin (Glucophage 500 mg) only, then over time another medication was added to her daily regimen. Today she attended the diabetes clinic, and her physician decided to add a third medication, so she was now on Metformin (Glucophage) 1000 mg twice a day, Gliclazide (Diamicron) 90 mg once daily & Dapagliflozin 10 mg once daily. She was referred to diabetes educator to discuss how she will use the new medication. She has poor glycemic control with HbA1c 9.5%, and class II obesity with BMI 37 kg/m^2. She also complains of numbness, tingling and muscle weakness in both feet.
At the educator visit it was discovered that she used to get distracted and missed taking her medication(s) or takes diabetes medication(s) at the wrong times, due to poor organization. This was missed by the busy physician who then added more medication. She also complained of lack of time to eat breakfast: She has to be at work by 7:30 am and has to get the kids ready and off to school. She complained "I don't have time to eat breakfast". She also had persistent pain in her right hand due to inflammation in her joint. "It's hard to open the container that the test strips come in" she said. "And they're so tiny, I usually drop the strip once I get one out". She avoids checking her blood sugar at work because her colleagues are looking at her or at home in front of her husband because her readings are high and usually gets criticism from him. Her numbers are bad all the time so she felt it was useless to check blood sugar, and this brings her mood down. She doesn't want to be reminded of having diabetes. She always says "Those sticks hurt! I just can't stand to punch myself". She is afraid to go too low & she doesn't want to embarrass herself by having a hypoglycemic reaction in front of other people. So, she keeps herself "a little on the sweet side". She complained that "Healthy food is too expensive & I can't make two types of meals for me & my family". She also said she was taught to eat all the food on her plate and feels guilty when she doesn't finish her meal. She gets too hungry whenever she goes on a diet. She said that feeling starved just made her want to binge later. Finally, she also reported that she can't do a proper foot exam because she has trouble reaching/seeing/feeling her feet, due to obesity.
Interaction & Possible Answers:
  1. How can we help her to follow her medication regimen?
  ✓ Organize all your diabetes supplies in one central place so you have everything you need when it comes to medication time.

1. Problem Solving

- ✓ keep a small kit with supplies at your workplace.
- ✓ Set an alarm (on your watch, clock, or cell phone) to remind you when your medication dose is due.
- ✓ Until you get a firm habit in place, post little reminder notes to help you remember when your medication is due.
- ✓ Seek help of your peer to support you in solving the problem.

2. How can we help her to manage taking her Breakfast?

- ✓ Fix simple breakfast items before going to bed. Choose breakfast foods or meal replacements that can be eaten on the go.
- ✓ Get up 15 minutes earlier. Eat while the kids are eating breakfast.

3. How can we help her to manage diabetes monitoring?

- ✓ Find a private place to monitor. Learn to monitor discreetly.
- ✓ Tackle one thing at a time: work on monitoring at a certain time of the day (for example, morning). Once monitoring at that time becomes more routine, add monitoring at other times of the day. If your self-care efforts do not result in improved blood glucose results, consider discussing your efforts with your healthcare provider for possible dosage, or medication change.
- ✓ Acknowledge your husband's interest in your diabetes. Thank him for his concern. Ask him to help you come up with a plan to prevent above-target results. Ask for his support in carrying out the plan.
- ✓ Lance the side of the finger, where there are fewer nerve endings.
- ✓ Learn how to "milk" blood down to your fingertips.
- ✓ Adjust the depth control on your lancing device. Use a lancet with a thinner gauge.

4. How can we help her to prevent hypoglycemia during work and leisure time ?

- ✓ Pay attention to your early symptoms of hypoglycemia (what are they?). At the first symptom, check your glucose level.
- ✓ Regular glucose monitoring can let you know if you are trending downward.
- ✓ Be prepared to treat low glucose by keeping glucose tablets, hard candy, or other fast-acting carbohydrate options with you at all times.
- ✓ Monitor your glucose level frequently to know where you stand. If you see your glucose level decreasing, you can be prepared to treat it before it gets too low. If the level is low on a regular basis, notify your provider.

5. How can we help her to manage her maintain her dietary needs?

- ✓ It's not necessary to buy healthy food, Everyday foods can be worked into a meal plan. The main things to watch are total calories, total carbohydrates, and portion control.
- ✓ Go with smaller portions.
- ✓ Use a smaller plate so portions feel bigger.

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1. Problem Solving
✓ At restaurants, ask that half be placed in a to-go container before the plate is brought out to you.
6. How can we help her to manage her foot issues?
✓ Use a mirror to help visualize your feet. Try a mirror with an attachment that allows you to prop it up on a hard surface (the floor or a chair) and angle it upward so you can see your foot. A mirror with a telescoping handle is also very helpful if you can't bend your legs or back to examine your feet.
Ask someone else in your home to take a look at your feet every day.

2. Decision Making
Scenario Overview A 50 years old man has had T2D for 20 yrs, HbA1c was 9.5%, BMI 35 kg/m^2 . He also had hypertension and dyslipidemia. He was on degludec (Tresiba) 30 unit SC at night and Novorapid 10-unit SC at lunch time, metformin 1000 mg BID and empagliflozin 10 mg PO. He is taking dulaglutide 1.5-unit SC weekly, valsartan 80 mg daily and atorvastatin 10 mg. His fasting glucose remains between 8 - 9 mmol/L and post prandial glucose record on three days was 12, 14 and 17 mmol/L. His BP was 160/110 (stage 2 hypertension). He had visited his relatives on a celebration and there were plenty of sweets and candies that were distributed in addition to the dinner meal itself which he was obliged to eat, and he later developed increased thirst, a dry mouth and blurred vision. He used to skip his medications when he was going out for visit. He was unclear what he could do, and which medications were important in this situation. He was not able to differentiate between high and low blood sugar signs and symptoms and did not take medication when he was outside. Sometimes at home he feels ill "shaky, fogy, sweaty and hungry after some injections and was not sure if this was due to low or high blood sugar. He usually lies down on the bed when he feels ill. He was not aware of his medication actions or the important of taking the medication on time as prescribed. Also, he doesn't know why his weight is increasing after started on insulin. He was also unsure what actions to take regarding healthy choices when he was part of a social gathering. Interaction & Possible Answers 1. How can we help him to manage the high blood sugar? Also, how he can avoid developing high blood sugar? ✓ How do I know I am hyperglycemic – symptoms and through glucometer checks – when to check, ✓ Target of blood sugar, target for fasting, target for random, target post-meals ✓ What is your action – medication action (including insulin) and other action (e.g. fluid intake, physical activity etc), note that physical activity will help to lower blood sugar if BG <13.5 mmol/L.

2. Decision Making

- ✓ When do you need help? , consult your health care provider when in doubt (Contact the hotline).
- ✓ Anticipate changes related to what you eat and avoid such foods. Anticipate what will happen when you miss medications
2. How can we help him to recognize low blood sugar? How to prevent low blood sugar? How to treat low blood sugar?
- ✓ Low blood sugar BG < 3.8 mmol/L.
- ✓ Symptoms of low blood sugar are: headache, hungry ,shaky, fogy, sweaty, cold, pale & fast heart beats.
- ✓ Taking your medication as ordered is very important to avoid hypoglycemia.
- ✓ Know mechanism of action of diabetes medication (talk about increasing insulin vs insulin sensitizing mechanisms)
- ✓ Follow meals and snacks as prescribed, Do not skip meals.
- ✓ Treat low blood sugar, use 15 g of simple carbohydrate such as 150 ml of juice, 4-5 GlucoTabs or water with three teaspoons of sugar.
- ✓ After 15 minutes you should check again your blood sugar level if it is ≤ 3.8 mmol/L you have to take a snack or a meal (such as banana or small sandwich) to avoid blood sugar from dropping again. if it is still low after this meal, repeat the process.
- ✓ Know the best ideal times for checking your blood sugar. The following times could be suggested by your HCP:
    - ➢ Before each meal
    - ➢ 2 hours after a meal
    - ➢ In the middle of the night
    - ➢ Before physical activity, to see if you need a snack.
    - ➢ During and after physical activity
    - ➢ If you think your blood sugar might be too high, too low or falling.
    - ➢ When you are sick or under stress
- ✓ The following are the recommended targets for normal blood sugar levels:
    - ➢ fasting blood sugar: 4.4–7.2 mmol/L
    - ➢ Two hours after meal: <10.0 mmol/L,
    - ➢ However, the target blood glucose differs from one person to other, discuss your target with your HCP.
3. How can we help her to understand the medication action and its relationship to her medication regimen?
- ✓ Attend the diabetes education classes on medication management.
- ✓ Consult your HCP about any medication you use before you start.
- ✓ Make sure to take medication on the right time as prescribed.

2. Decision Making

- ✓ Link the action of the medication to the timing (pre-post meals),e.g. Insulin secretion drugs should be taken before meal and insulin sensitivity drugs should be taken during or post meal. Insulin could cause low blood glucose level if taken without food.
- ✓ One of the side effects of some medication that can cause weight gain if they did not follow diet regimen.
4. How can we help her to manage her diet during any events?
    - ✓ Think before you fill your plate.
    - ✓ Start with salad.
    - ✓ Follow the healthy plate regimen.
    - ✓ Avoid soft drinks and juices.
    - ✓ Take fresh fruits instead of cakes and sweats.
    - ✓ Choose a small portion.
    - ✓ Pay attention to your carbohydrate intake and don't eat fast and eat slowly.

3. Taking Action

Scenario Overview

A 42 years old woman, divorced was living alone, working as secretary. She was diagnosed with T2D 5 yrs ago and is on dual oral therapy (Metformin 1000 mg BID and glimepiride 4 mg od). Her weight was 85 kg , and she gained 5 kg since she started the medication. She is usually having two main meals throughout the day (Lunch and dinner), with frequent snacks at night. She is facing difficulty in reducing weight inspite of trying many diet regimens in the past and lacks motivation to undertake physical activity. She decided to stop taking glimepiride due to weight gain, however without taking the medicine her blood glucose level reaches 14 to 17 mmol/L after meals. Her last HbA1c was 9%, and last eye exam was 6 months ago, and she cannot recall her last foot exam. She was not clear on the impact of diet and physical activity on control of her blood sugar. Her lunch sometimes was from fast food restaurants, with frequent unhealthy snacks at night.

Interaction & Possible Answers
- ✓ How can we help her to maintain a healthy weight and normal blood sugar level?
- ✓ Make healthy changes in lifestyle such as eating healthy and doing exercise.
- ✓ Try to know about the physical activity impact on weight and controlling blood sugar levels.
- ✓ Do not stop taking your medication by yourself without consulting your health care provider.

3. Taking Action
✓ How can we help her to follow a healthy diet? ✓ The healthy diet should involve three main meals (breakfast, lunch, dinner) and two healthy snacks (piece of fruits, or nuts). ✓ Having diabetes does not mean you cannot eat food you enjoy. You can keep eating the foods you like. Just make sure to include lots of nutritious. ✓ Healthy choices. Healthy, nutritious choices include whole grains, legumes (dried beans, peas, and lentils), fruits, vegetables, non-fat or low-fat dairy, and lean meats, such as fish and poultry. These foods are high in vitamins, minerals, fibers, and lean protein, and low in saturated fat, cholesterol, and refined sugar. ✓ Learning about serving sizes is also key to meal planning. ✓ Understand the elements of food labels. These labels tell you how many calories, carbohydrates, protein, and fat are in each serving. ✓ How can we help her to start physical activity? How many minutes of exercise, and what type of exercise you think is best for her? ✓ Start to increase the daily activity gradually such as moving in your office during your work, walk to your colleague's office instead of calling, use stairs, etc. ✓ Find a company while working out like family member, or friend. ✓ Start walking for at least 30 minutes for 5 days in a week. ✓ Check glucose level before exercise and during exercise. ✓ Take healthy snack before exercise to prevent the low blood sugar. ✓ Continue the regular exercise to reduce insulin resistance and weight gain. ✓ Exercise can help people with T2D to prevent long-term complications, especially heart problems. ✓ How can Ms. Farah follow a screening regimen to avoid complications? ✓ Foot and eye test should be done on regular basis to avoid future complications. ✓ Diabetes can damage your nerves, particularly those in your feet. Sometimes this will lead to numbness or burning or tingling in the feet. ✓ Check your feet regularly for cuts, ulcers, and blisters. These can become infected if left untreated. ✓ Diabetes can also cause the blood vessels at the back of the eyes to leak (its known as diabetic retinopathy). But the more you can control your blood sugar levels over the years, the less chance you have of developing serious problems. ✓ Make sure you have an annual eye and feet test with a specialist so that any potential serious problems can be detected early on and treated.

3. Taking Action

- ✓ How can we help her to understand food portions and what are healthy ingredients?
- ✓ The size of the plate usually determines the size of the portions, so you want to start with a reasonably sized plate.
- ✓ The half of the plate should have filled with no starchy vegetables. No starchy vegetables are lower in carbohydrate, so they do not raise blood sugar very much. They are also high in vitamins, minerals, and fiber, making them an important part of a healthy diet.
- ✓ Fill one quarter of your plate with lean protein foods.
- ✓ Foods high in protein such as fish, chicken, lean beef, soy.
- ✓ Fill one quarter of your plate with carbohydrate foods.
- ✓ Foods that are higher in carbohydrate include grains, starchy vegetables, beans and legumes, fruit, yogurt, and milk. These foods have the greatest effect on blood sugar.
- ✓ Choose water or a low-calorie drink. Water is the best choice because it contains no calories or carbohydrates and has no effect on blood sugar. Other zero- or low-calorie item include.
- ✓ Space out your meals and make sure you have enough overall calories. Include snacks so you don't go more than 3 hours without eating. Move to taking action
- ✓ Eat slowly. Put your fork down between bites. It takes at least 15 minutes for the brain to get the message that you have just eaten.

Include more vegetables so that you feel fuller. Choose raw vegetables or fruits that require more chewing.

4. Resource Utilization

Scenario Overview

A 55 yrs old man who is married but living alone and working as a civil engineer with T2D for the past 7 years. Initially HbA1c was 6.8 % and he was started on metformin 1 g twice daily, he was in compliance to a healthy lifestyle and monitored his blood sugar regularly. His blood sugar values were within the target. He was regularly following in a private clinic and the whole treatment cost was fully covered by the company where he worked. Suddenly he lost his job and the financial support, and he stopped all medication and monitoring of blood sugar. furthermore, he adopted unhealthy habit (smoking) due to stress from his current situation. The HbA1c level increased to 11.5%, and his doctor started him on an insulin (Lantus) 15 units once at night and empagliflozin 10 mg once daily . With his friend's support, he got a new job, but with less income. Gradually his blood glucose reading was back to within the target. The

4. Resource Utilization

current challenges he faces are how to afford the cost of diabetes care with his new work condition and utilize available resources. He was unaware of several resources available and what can be accessed online

Interaction & Possible Answers

1. How can we help him to know about other alternative facilities which are accessible if medical care is required, and what are the required documents to receive medical care in each facility ?
   - ✓ Other health care facilities are private clinics where he was treated initially.
   - ✓ Access the public clinics in primary health care by either walk in or appointments if the situation is non urgent. PHCC, can be accessed by all the population either citizens or residents, there are variety of specialty are in PHCC, the cost is very minimum if compared to private.
   - ✓ In case of urgent need, walk into emergency department.
   - ✓ In case of serious complication, you can access the hospital for advanced care and treatment.
   - ✓ Most of the services are free of charge with minimum cost.
   - ✓ Industrial hospital and Red Crescent hospital are available for bachelor workers.
   - ✓ With the valid health card, you still have an access all public clinics and hospital (access to doctor, diabetes educator, medication, lab test, podiatry, dietician, , and smoking clinic).

2. How can we help him to access other supportive community resources?(Which provides other than medical care such as QDA, and charity institutions)
   - ✓ Access to charity institutions is available and can be an option if the treatment cost is beyond his economic ability.

Examples Charity in Qatar :
   - ✓ Qatar Charity working hours : 07:30 am to 03:30 pm
   - ✓ Sheikh Eid Charity working hours: 8 am to 9 pm
   - ✓ Qatar Diabetes Association (QDA) The working hours :8-11 am &4 pm – 8 pm call 44547334.
   - ✓ QDA can provide glucometer and blood sugar testing strips with less price or for free, also they have dietician who can assist in healthy diet planning and provide food exchange list and the area which might have affordable prices. Furthermore, they have gym.

3. How can we help to access the available technological resources and be able to obtain latest health information from valid reliable web pages?
   - ✓ Needs adequate information on how to utilize technology in order to obtain the necessary information for better diabetes care.
   - ✓ Access to trusted web pages to gather more information about diabetes self-management if he has the basic technology literacy.

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4. Resource Utilization

Example of public web page:
- ✓ https://www.hamad.qa/EN/your health/Diabetes/Patient-And-Public-Information/Pages/default.aspx
- ✓ https://diabetesed.net/resources-for-patients/
- ✓ https://diabetesed.net/page/_files/4-Steps-to Control-Your-Diabetes--English_829.PDF
- ✓ furthermore, there are mobile application which provide the link between the health care provider and patient, most of the time.

Lists of smartphone application for diabetes self-management
1-OneTouch Reveal:

OneTouch Reveal
Diabetes
LifeScan Europe GmbH   Medical
E Everyone

☐ Add to Wishlist

This diabetes management app pairs with the OneTouch Verio Flex and the OneTouch Verio Reflect blood glucose meter to track your readings over time. The app will notify you about any recurring patterns (e.g., times when your blood glucose is too high or too low) so you know to take action, and it pulls your data into 14-, 30-, and 90-day summaries that you can share with your doctor or diabetes educator. OneTouch Reveal also can track your blood glucose, steps, weight, heart rate, and more all in one place.

2-Health2Sync:

Health2Sync 4+
Diabetes Management
H2 Inc.
★★★★★ 4.7 • 289 Ratings
Free · Offers In-App Purchases
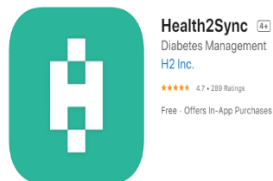
4. Resource Utilization

Its free app where You can manually enter your blood glucose values or buy a special cable to upload your glucometer readings to the app. For every glucose entry, add notes about medications, mood, exercise, and meals (you can even add a photo of your meal for a quick record), and then track your trends over the course of the day and long term. This app also has features for tracking blood pressure, weight, and HbA$_{1c}$.

3- Glucose Buddy:

Glucose Buddy Diabetes Tracker
Blood Sugar, Carb, A1C Manager
Azumio Inc.
#154 in Medical
★★★★★ 4.8 • 19.9K Ratings
Free · Offers In-App Purchases

This app free for both applicable to iPhone and android. Like other glucose trackers, Glucose Buddy lets you input blood glucose, medication, and meals, and track trends over time. But it also includes an extensive food database, and it lets you scan bar codes to grab nutrition information from food products. It syncs to the Dexcom Continuous Blood Glucose Monitoring system, as well as the Apple Health app to track your steps and other physical activity. All that data can be exported to printable reports you can bring to your medical visits. It also includes a 12-week diabetes education plan that features five-minute lessons to help you better manage your diabetes. You'll need to subscribe to the premium version to access the HbA$_{1c}$ calculator and get rid of the ads.

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4. Resource Utilization

4-Diabetes M:

Diabetes:M 17+
Sirma Medical Systems JSC
Designed for iPad
★★★★★ 4.6 • 766 Ratings
Free · Offers In-App Purchases

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is a diabetes log app with all the features you'd hope for: test time reminders, a nutritional log and tracking system, integrations with fitness apps, and blood sugar trend mapping. The app also offers an insulin bolus calculator based on the nutritional information you add. Use the app's powerful tools to look at trend graphs and charts in adjustable timeframes, so glucose control is back in your hand, or, with the Apple Watch app, on your wrist. If you upgrade to the subscription service, the app allows you to have multiple profiles.

5. Patient Provider Relationship

Scenario Overview

A 45 yrs old lady who is married was diagnosed with T2D since 12 yrs, and is on empagliflozin 25 mg, and Sitagliptin/Metformin 50/1000 mg (BID), and recently started Insulin Glargine 15 units (bedtime).

She is not adherent to insulin use, as her friend told her that her grandmother has passed away when she started using insulin, therefore, she stopped using the insulin as she thinks that insulin is not beneficial and afraid that it will harm her body. Consequently, her blood glucose levels are not within the normal range, fasting is above 9 mmol/L and 2-hours-post meal is above 13 mmol/L. She usually consumes unhealthy main meals and irregular snacks and rarely practices physical activity due to her busy schedule. Lately she started feeling numbness and heat in her foot especially at nighttime, she neither remembers when was her last foot examination nor her retinal examination. Her next medical appointment was after one year. She was not clear on who, when and how she could access a specialist to assist her, and what were the services that the health care provider can provide to her?

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5. Patient Provider Relationship
Interaction & Possible Answers

1. How can we help her understand *whom* to contact among her health care providers?
2. How can we help her understand *how* to contact her health care providers?
3. How can we help her understand *when* to contact her health care providers?

   A) Diabetes educator:

she can attend the Diabetes Educator walk-in clinic to understand

a) Insulin use and its mechanism of action in the body, to discuss with diabetes educator the benefits and side effects of insulin use. In addition to have an educational session including demonstration of insulin pen use and sites of injections in order to be ready to inject insulin independently and correctly.

b) Help her with understanding what is the importance of regular home glucose monitoring and how it can help her to reach her glycemic target.

c) Check the accuracy of the glucometer to make sure it is working properly.

How

1. Visit the outpatient clinic, diabetes education walk-in clinic.
2. Visit the glucometer clinic for glucometer check-up.

When:

1. When there is a concern about the use and side effects of insulin or oral hypoglycemic agents.
2. In case of noticing that the glucometer is not working properly.

   B) Dietician:

She can consult the dietician regarding

a) Developing a healthy meal plan, the dietician can help her know about healthy food plate, food exchange list and carb counting.

b) Provide her an individualized nutrition counselling for lifestyle improvements.

c) Empower her to develop her physical activity plan that works for her schedule. For example, walk for 30 minutes 5 days/week.

How:

1. Visit the dietician walk-in clinic.
2. Get a referral form the primary physician and book an appointment with the dietician through calling 16060.

When:

1. When the patient has concerns about the amount and type of food that he/she can consume as well as the duration and intensity of exercises that is suitable for his health condition.

2. For regular follow-up appointments.

C) Physician:

She can schedule an appointment to meet the physician to:

a) Discuss with the physician the type of regimen and the importance of insulin injection initiation when indicated according to her current HbA_{1c} and blood glucose readings in order to reach a better glycemic control.

b) The physician will refer her to the ophthalmologist and podiatrist to have annual retina and foot examinations.

How:

1. Book an appointment with the physician through calling 16060.
2. Visit the emergency department.

When:

1. Visit the physician regularly for follow-up and to discuss the need to modify treatment regimen.
2. Visit the emergency in case of urgent and life-threatening situations such as diabetes ketoacidosis.

D) Ophthalmologist:

The ophthalmologist (in the retina clinic)

a) Do a comprehensive retina screening for her including dilated eye exam. For this exam, drops placed the eyes that dilates the pupils to allow a better view inside the eyes to inspect for abnormal blood vessels, growth on new blood vessels, bleeding or retinal detachment.

b) Emphasize on the importance of retina screening and encourage her to attend the clinic for regular annual follow-ups.

How:

1. Get a referral from their primary physician and book an appointment through calling 16060.
2. Attend the retina clinic as a walk-in.

When:

1. Regular follow-up to have annual screening
2. In case of noticing changes such as sudden vision changes.

E) Podiatrist:

The podiatrist can help with:

a) Comprehensive foot examination to inspect foot problems including infections, injury, bone abnormalities and inspection of nerve damage using. Foot inspection assessment includes assessment of foot pulses, and 10-g monofilament sensations tests, which is a soft nylon fiber, called a monofilament that will be placed over the foot and toes to test the foot's sensitivity to touch.

5. Patient Provider Relationship

b) Educate her about proper foot care practices, including wearing comfortable and right fitting shoes, importance of washing and thoroughly drying the foot, how to properly inspect the foot daily, emphasize on the importance of not walking barefooted, and educate on how to trim the toenails regularly and straight across the nail.

c) Encourage her to attend the clinic for regular annual follow-ups.

How:
1. Get a referral from their primary physician and book an appointment through calling 16060.
2. Attend the podiatry clinic as a walk-in.

When:
1. Regular follow-up to have annual screening.
2. In case of noticing sudden changes such as, swelling in the foot.

F) Pharmacist:

She can go to the pharmacy and consult the pharmacist regarding

When to use insulin or oral hypoglycemic agents.

How:

Visit the pharmacy.

When:

When there is a concern regarding the time of using insulin or oral hypoglycemic agents.

How can we help her to contact after regular working hours?

1) Diabetes educator:

Diabetes education hotline service, available from 7 am-7 pm.

2) Dietician:

Qatar diabetes association, available from: 8 am–2 pm , 5–8 pm.

3) Private pharmacist:

Private pharmacists are available 24/7.

4) ED physician:

ED physicians are available 24/7.

Table 9.10 Patient expected learning outcomes

Attributes	Patient expected learning outcomes
Problem solving	1. Able to maintain medication adherence across different social situations 2. Knows how to adapt and maintain a healthy meal plan across life events 3. Able to maintain blood sugar monitoring in different environments like work and leisure 4. Able to predict and avoid external factors that may lead to hypoglycemia 5. Able to maintain healthy eating in the face of life stresses (e.g. culture, finances, no time, parties etc) 6. Able to deal with monitoring of complications by overcoming barriers
Decision making	1. Able to deal effectively with hyperglycemia events 2. Able to deal effectively with hyperglycemia events 3. Can link medication use with their mechanism of actions 4. Can decide on best practice on meals outside the home e.g. at events
Taking Action	1. Capable to maintain a healthy weight and normal blood sugar level 2. Adept maintaining a healthy diet 3. Qualified to start and maintain effective physical activity 4. Complain with screening regimen to avoid complication. 5. Understand food portions concept and ingredients
Resource Utilization	1. Aware of all accessible facilities for medical care and requirement. 2. Recognize all supportive community resources 3. Ability to access the valid available online resources and information
Patient Provider Relationship	1. understand the role of each health care providers 2. Ability to know the pathway of contacting the health care providers 3. Know and understand when to contact her health care providers

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Appendix A

Focus Group Question Set

Intention

·   What motivates you to manage your diabetes?

·   What prevents you from managing your diabetes?

Perceived Consequences

·   If you stop actively making decisions about your diabetes, what are the

likely outcomes?

Social Factors

·   What life factors will help you to engage with your DSM?

·   What life factors will prevent you from engaging with your DSM?

Affect

·   How do you feel when you are thinking about DSM?

·   Can you describe your feelings when you think about having diabetes?

Additional questions emerged from participants' responses to the main

questions. Different additional questions emerged in the different groups.

Dear participant,

This survey was developed to learn about the intention of people with diabetes to self-management. Your participation is voluntary, and you can withdraw at any time from the study. All information will be used for research purposes only and will be kept anonymous and strictly confidential.

Completing the questionnaire takes around 10 minutes. If you have questions or concerns, please contact to the research team at:

Ms. Manal Othman (LPI of the study), Mobile No: 55593317, Email address: mothman@hamad.qa

Thank you for participating in this survey.

IMPORTANT

Please feel completely secure when you answer this questionnaire because it is completely nameless and there is no way you can be identified as the person who filled it since there is no personal info or even handwriting – you just have to tick or circle your answer. The only person who will see this form is Ms. Manal and this form will be destroyed after computer coding and analysis.

Demographics

SR number _____

Age ^{0}□ <25 ^{1}□ 25-34 ^{2}□ 35-44 ^{3}□ 45-54 ^{4}□ ≥55

Sex ^{1}□ M ^{2}□ F

Nationality ^{1}□ Qatari ^{2}□ non-Qatari Asian ^{3}□ non-Qatari Arab ^{4}□ non-Qatari other

Social Status ^{1}□ Single ^{2}□ Married ^{3}□ Divorce ^{4}□ Widow

Educational Level ^{0}□Primary (or less) ^{1}□Elementary/Secondary ^{2}□Bachelor ^{3}□ Master/MD/PhD or equivalent.

Living Status ^{1}□ with Family ^{2}□ Alone ^{3}□ Shared Accommodation

Work Status ^{1}□ Government ^{2}□ Private ^{3}□ None/retired ^{4}□ others please specify

………………………

Years of being diagnosed with diabetes ^{0}□ <5 ^{1}□ 5-9 ^{2}□ ≥10

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Please circle one option in each question below:

Section I (Intentions)	Highly unlikely	Unlikely	Neither likely nor unlikely	Likely	Highly likely
1.1. How likely is it that you will self-manage your diabetes by reducing food intake when it is necessary (e.g. when you have high blood sugar or symptoms).	1☐	2☐	3☐	4☐	5☐
1.2. How likely is it that you will self-manage your diabetes by exercising when it is necessary (e.g. high blood sugar or symptoms).	1☐	2☐	3☐	4☐	5☐
1.3. How likely is it that you will always monitor your blood glucose as per instructions of your health care provider.	1☐	2☐	3☐	4☐	5☐
1.4. How likely is it that you will continue to self-manage your diabetes if you do not have any complications.	1☐	2☐	3☐	4☐	5☐
1.5. How likely is it that you will continue to cope with your self management if you have to do it yourself alone.	1☐	2☐	3☐	4☐	5☐
1.6. How likely is it that you will maintain the discipline required to self-manage your diabetes	1☐	2☐	3☐	4☐	5☐
1.7. How likely is it that you will self manage your diabetes even when you are away from home (i.e. carry your medications and keep doing your diabetes management).	1☐	2☐	3☐	4☐	5☐
1.8. How likely is it that you will remain in control of your diabetes and will be able to self-manage it for your whole life.	1☐	2☐	3☐	4☐	5☐

1.9. How likely is it that you will be committed to self-manage your diabetes inspite of the changes required to your lifestyle	1☐	2☐	3☐	4☐	5☐
1.10. How likely is it that you will develop a strict daily routine/plan to self-manage your diabetes	1☐	2☐	3☐	4☐	5☐
1.11. How likely is it that you will self manage your diabetes even when you have life stresses, and your diabetes is not under control	1☐	2☐	3☐	4☐	5☐
1.12. How likely is it that you will self-manage your diabetes if it is inconvenient, and requires effort.	1☐	2☐	3☐	4☐	5☐
2. Section II (Actions and social factors)	**Strongly disagree**	**Disagree**	**Neutral**	**Agree**	**Strongly Agree**
2.1. The work pressure/stress prevents me from self managing my diabetes	5☐	4☐	3☐	2☐	1☐
2.2. The hot weather in Qatar does not motivate me to exercise on a regular basis	5☐	4☐	3☐	2☐	1☐
2.3. The family gatherings that include different sweet food and drinks prevent my diabetes self-management	5☐	4☐	3☐	2☐	1☐
2.4. Thinking of my family and beloved ones encourages me to self-manage my diabetes	1☐	2☐	3☐	4☐	5☐
2.5. Family support helps me to self-manage my diabetes	1☐	2☐	3☐	4☐	5☐
2.6. Peer support or group therapy helps me to self-manage my diabetes.	1☐	2☐	3☐	4☐	5☐

2.7. There is often limited access to healthy food or home cooked food due to busy work or lack of affordability.	5☐	4☐	3☐	2☐	1☐
2.8. Cooking a healthy food after the long working day is a self-management challenge for people with diabetes	5☐	4☐	3☐	2☐	1☐
2.9. It is not easy for me to communicate with the health care system, or health care provider in order to understand diabetes self-management.	5☐	4☐	3☐	2☐	1☐
2.10. I cannot self-manage properly because I do not like to check my blood sugar levels in front of others and at my work	5☐	4☐	3☐	2☐	1☐
2.11. I find it difficult to self-manage my diabetes because it limits my activities and I cannot enjoy the food	5☐	4☐	3☐	2☐	1☐
2.12. lack of glucose monitoring tools prevents me from self-managing my diabetes.	5☐	4☐	3☐	2☐	1☐
2.13. Costs of self-management (e.g. Blood sugar strips) are quite high and I cannot always afford to self manage my diabetes.	5☐	4☐	3☐	2☐	1☐
2.14. My regular follow-up by the medical team encourages me to self-manage my diabetes	1☐	2☐	3☐	4☐	5☐
2.15. long length of time between appointments affects my ability to self-manage my diabetes	5☐	4☐	3☐	2☐	1☐

3. Section III (Impacts and consequences)	Strongly disagree	Disagree	Neutral	Agree	Strongly Agree
3.1. Self management through following a healthy diet helps me control my diabetes	1☐	2☐	3☐	4☐	5☐
3.2. Self management through following regular physical activity helps me control my diabetes.	1☐	2☐	3☐	4☐	5☐
3.3. Self management through self monitoring of my blood sugar helps me control my diabetes.	1☐	2☐	3☐	4☐	5☐
3.4. Self management through better knowledge about my medications and making required changes helps me control my diabetes.	1☐	2☐	3☐	4☐	5☐
3.5. When I stop self-managing my diabetes, I find it difficult to maintain good diabetes control by just taking the doctors prescription.	1☐	2☐	3☐	4☐	5☐
3.6. Fear of needing to take more treatment or start insulin injections in the future motivates me to self manage my diabetes.	1☐	2☐	3☐	4☐	5☐
3.7. Fear of developing defects in my organs motivates me to self manage my diabetes	1☐	2☐	3☐	4☐	5☐
3.8. Seeing the impact of diabetes on my family and grandparents motivates me to self manage my diabetes	1☐	2☐	3☐	4☐	5☐
3.9. My fear of the progress of my diabetes motivates me to self manage it.	1☐	2☐	3☐	4☐	5☐

4. Section IV (Affect)

The thought of me NOT self-managing my diabetes makes me feel:

4.1	Extremely guilty 5☐	Very guilty 4☐	Neutral 3☐	Somewhat guilty 2☐	Not at all guilty 1☐
4.2	Extremely worried 5☐	Very worried 4☐	Neutral 3☐	Somewhat worried 2☐	Not at all worried 1☐
4.3	Extremely insecure 5☐	Very insecure 4☐	Neutral 3☐	Somewhat insecure 2☐	Not at all insecure 1☐

When I think of self-managing my diabetes, I feel

4.4	Extremely depressed 1☐	Very depressed 2☐	Neutral 3☐	Somewhat depressed 4☐	Not at all depressed 5☐
4.5	Extremely sad 1☐	Very Sad 2☐	Neutral 3☐	Somewhat sad 4☐	Not at all sad 5☐
4.6	Extremely fearful 1☐	Very fearful 2☐	Neutral 3☐	Somewhat fearful 4☐	Not at all fearful 5☐

Appendix C

<table>
<tr><td colspan="2" align="center">مؤسسة حمد الطبية
Hamad Medical Corporation
HEALTH - EDUCATION - RESEARCH   صحة - تعليم - بحوث</td></tr>
<tr><td>1. Title of research</td><td align="right">1. عنوان البحث</td></tr>
<tr><td>Development and evaluation of a structured Diabetes Self-Management Intervention Program for Type 2 Diabetes in Qatar. Phase 1</td><td align="right">تطوير و تقييم برنامج تدريبي للرعاية الذاتية لمرضى السكري في قطر وفق لمنهاج علمي - المرحلة الأولى</td></tr>
<tr><td>2. Principal Investigator</td><td align="right">2. الباحث الرئيسي</td></tr>
<tr><td>Dr. Manal Othman – Hamad Medical Corporation</td><td align="right">د. منال مسلم — مؤسسة حمد الطبية</td></tr>
<tr><td>3. Why are we inviting you to join this research?</td><td align="right">3. لماذا ندعوك للإنضمام إلى هذا البحث؟</td></tr>
<tr><td>The investigator and colleagues at Hamad Medical Corporation (HMC), Primary Health Care Corporation (PHCC) and Qatar Diabetes association (QDA) are conducting this research.

You are invited to participate because you suffer from type 2 diabetes and reside in the State of Qatar, because we believe that your participation will definitely help us in answering the research question.</td><td align="right">الباحث وزملائه في مؤسسة حمد الطبية, مؤسسة الرعاية الصحية و الجمعية القطرية للسكري ينوون اجراء هذا البحث.

أنت مدعو/ه للمشاركة لأنك تعاني من السكري النوع الثاني و مقيم في دولة قطر، إيمانًا منا بأن مشاركتك ستساعدنا حتمًا في الإجابة على سؤال البحث.</td></tr>
<tr><td>4. What should you know about this research?</td><td align="right">4. ما الذي يجب أن تعرفه عن هذا البحث؟</td></tr>
<tr><td>• We will explain the research to you
• Whether or not you join is your decision (you can accept or refuse no matter who is inviting you to participate)
• Please feel free to ask questions or mention concerns before deciding, or during or after the research
• You can say yes but change your mind later
• We will not hold your decision against you</td><td align="right">• سنقوم بشرح البحث لك بشكل وافٍ
• قرار انضمامك للمشاركة بهذا البحث أو عدمه يعود لك (يمكنك قبول أو رفض المشاركة بغض النظر عن من يدعوك للمشاركة)
• لك مطلق الحرية بأن تسأل أي سؤال قبل اتخاذ قرارك, أو خلال أو بعد المشاركة بالبحث.
• إذا وافقت على المشاركة, بإمكانك أن تغير رأيك لاحقاً
• لن يستخدم قرارك ضدك بأي حال من الأحوال</td></tr>
</table>

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5. Who can you talk to?	‏5. مع من يمكنك التحدث؟
If you have questions or concerns, or if you think the research has hurt you, talk to the research team at: Dr. Manal Othman, Mobile No: 55593317, Email address: mothman@hamad.qa If you have questions about your rights as a volunteer, or you want to talk to someone outside the research team, please contact • HMC-IRB Office at irb@hamad.qa • PHCC Research Department (PHCC-IRB) at researchsection@phcc.gov.qa ,	لطرح أية أسئلة أو مناقشة أي مخاوف, أو إذا كنت تعتقد أن البحث قد أضر/يضر بك, قم بالتحدث مع فريق البحث على: د. منال مسلم على رقم الجوال: 55593317 و البريد الإلكتروني: mothman@hamad.qa إذا كان لديك أسئلة حول حقوقك كمشارك بالبحث، أو كنت ترغب في التحدث مع شخص من خارج فريق البحث، يرجى الإتصال ب: • مركز الأبحاث, مؤسسة حمد الطبية, إيميل: irb@hamad.qa • إدارة الأبحاث الإكلينيكية , مؤسسة الرعاية الصحية الأولية, إيميل: researchsection@phcc.gov.qa
6. Why are we doing the research?	‏6. لماذا نقوم بهذا البحث؟
Currently type 2 diabetes is affecting around 1 out of every 7 adults in our community and it is expected to affect even more in the future. Fortunately, it is a disease that can be managed by lifestyle changes and adherence to the medical management plan based on the instructions of the treating physician. This research aims to know the extent of your knowledge of the concept of self-care for diabetes patients and your personal experience with training programs for self-care for diabetes that you may have received previously on a visit to diabetes clinics. We also want to know from you the weaknesses that exist in the current training programs for diabetes self-care programs. This information will guide us to develop a structured diabetes self-management training program for type 2 diabetes, according to a scientific curriculum based on theories of behavior change, commensurate with the Qatari environment and culture.	في الوقت الحالي، يصل عدد المصابين بداء السكري من النوع الثاني في دولة قطر إلى ما يقارب واحد من كل سبعة بالغين، ويُتوقع زيادة العدد خلال السنوات القادمة. لحسن الحظ يعد داء السكري من الأمراض الممكن السيطرة عليها، وذلك من خلال تغيير نمط الحياة والالتزام بالخطة العلاجية بناءا على إرشادات الطبيب المعالج. يهدف هذا البحث إلى التعرف على مدى معرفتك لمفهوم الرعاية الذاتية لمرضى السكري و تجربتك الشخصية مع برامج التدريب للرعاية الذاتية لمرض السكري التي قد تكون تلقيتها سابقًا في إحدى الزيارات لعيادات السكري.كما تريد أيضًا أن تتعرف منك على نقاط الضعف الموجودة في برامج التدريب الحالية للرعاية الذاتية لمرض السكري. سوف تر شدنا هذه المعلومات لتطوير برنامج تدريبي متخصص للرعاية الذاتية لمرض السكري من النوع الثاني وفقا لمنهاج علمي مبني على نظريات تغير السلوك يتناسب مع البيئة و الثقافة القطرية.

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7. How long will the research take?	٧. كم من الوقت سيستغرق هذا البحث؟
The research takes place over a period of 12 months in total. However, we require your presence only once in the QDA or HMC to attend the group discussion which will take about 30 minutes. We may contact you later via telephone/email if required.	سيستغرق إكمال البحث سنة واحدة. خلال هذه المدة، سيتطلب منك الحضور مرة واحدة فقط في الجمعية القطرية للسكري أو مؤسسة حمد الطبية لحضور حلقة نقاشية و الذي قد يستغرق ثلاثون دقيقة. قد يتم التواصل معك عن طريق الهاتف/البريد الإلكتروني من قبل فريق البحث لاحقًا إذا تطلب الأمر.

8. How many people will take part?	٨. كم عدد الأشخاص الذين سيشاركون بهذا البحث؟
We plan to study around 30 participants, and it will be recruited from HMC.	نحن نخطط لدراسة آراء ما يقارب 30 مشارك من مؤسسة حمد الطبية.

9. What happens if you take part?	٩. ما الذي سيحدث اذا قررت الاشتراك بهذا البحث؟
If you agree to join, we will ask you to do the following: • You will be contacted by the research team to take part of the project. • The research team will explain the purpose of the project and provide you with all information related to your participation. • Once you agree to participate you will be asked to sign the consent form. • You will be asked to attend group discussion either face to face or online for 30 minutes. • The group discussion will consist of 10 people with type 2 diabetes who attended any diabetes self-management program or received self-management education and it will be run by research team. • You will be asked to attend the group discussion in HMC, or QDA physically or virtually through online web once.	اذا وافقت على المشاركة, سنطلب منك القيام بما يلي: • سيتم الاتصال بك من قبل فريق البحث للمشاركة في المشروع. • سيشرح فريق البحث الغرض من المشروع ويزودك بجميع المعلومات المتعلقة بمشاركتك. • بمجرد موافقتك على المشاركة ، سيُطلب منك التوقيع على نموذج الموافقة على المشاركة في البحث. • سيُطلب منك حضور حلقة جماعية/ فردية نقاشيه إما وجهًا لوجه أو عبر الإنترنت لمدة 30 دقيقة. • سيحضر الحلقة الجماعية ما يقارب 10 أشخاص مصابين بداء السكري من النوع الثاني ممن تلقوا خدمة التثقيف الصحي للرعاية الذاتيه لمرض السكري أو تلقوا تعليمًا حول الإدارة الذاتية وسيدير النقاش فريق البحث. • سيُطلب منك حضور الحلقة النقاشية في مؤسسة حمد الطبية أو الجمعية القطرية للسكري إما وجهًا لوجه أو عبر الإنترنت مرة واحدة. • سيُطلب منك التعريف بنفسك وسيقوم فريق البحث بالتعريف عن أنفسهم. • سيُطلب منك مشاركة تجربتك حول خدمة التثقيف و التعليم للرعاية الذاتية لمرض السكري من خلال أسئلة مفتوحة يطرحها فريق البحث. • سيتم تسجيل البيانات لعرض التحليل. سيتم التعامل مع جميع المعلومات المسجلة بسرية تامة عن طريق التشفير قبل تطبيق الدراسات التحليلية.

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• You will be asked to introduce yourself and the research team will also introduce them self to you. • You will be asked to share your experience about diabetes self-management program through open ended questions raised by the research team. • The data will be recorded for the purpose of the analysis. The information recorded is confidential and will be anonymized before analysis.	
10. Could the research be bad for you?	**١٠. هل يمكن لهذا البحث ان يضرك؟**
Participating in the research is not anticipated to cause you any disadvantages or risks. The potential physical and/or psychological harm or distress will be the same as any experienced in everyday medical care.	لا يُتوقع أن تؤدي المشاركة في البحث إلى أية مخاطر. كما إن الأذى الجسدي و / أو النفسي المحتمل سيكون بنفس الدرجة المتوقعة من الخدمات الروتينية في الرعاية الطبية اليومية.
11. Could the research be good for you?	**١١. هل يمكن لهذا البحث أن يفيدك؟**
There will be no direct benefit to you, but your participation is likely to help us find out more about the importance of self-management, education and awareness of diabetes. The results of this research will help to develop a diabetes self-management program in Qatar.	يجدر بالإشارة أن مشاركتك في هذا البحث لن تعود بالنفع المباشر عليك، إلا أنها قد تساهم في معرفة المزيد عن أهمية الرعاية الذاتية والتثقيف والتوعية بمرض السكري. كما ستساعد نتائج هذا البحث في تطوير برنامج الرعاية الذاتية لمرض السكري في قطر.
12. What happens to information about you?	**١٢. ما الذي سيحدث للمعلومات عنك؟**
All your information will be securely stored at LPI password protected laptop and will not be accessed by anyone outside of the research team. We will not be sharing information about you to anyone outside of the research team. Any information about you will be coded to completely protect your identity. This is my PhD project. All information taken for the thesis defense committee will be presented in a written report and an oral presentation. In the event	يضمن فريق البحث السرية التامة في نقل المعلومات لكل المشاركين، حيث سيتم تشفيرها وحفظها في نظام (سيرفر) آمن في الجهاز الشخصي للباحث الرئيسي ولن يتم مشاركتها مع أي شخص خارج نطاق فريق البحث. هذا مشروع تخرج جامعي. سيتم عرض جميع المعلومات المأخوذة للجنة مناقشة الأطروحة في تقرير مكتوب وعرض شفهي. في حال وافق المشروع المعايير الأكاديمية العالمية، سيتم عرض ملصق للبحث في المؤتمرات العالمية ونشره في صحف علمية.

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نموذج الموافقة على الاشتراك ببحث علمي
RESEARCH CONSENT FORM

English	العربية
that the project meets international academic standards, a poster for research will be displayed at international conferences and published in scientific journal.	
13. What if you don't want to join?	**13. ماذا لو كنت لا تريد المشاركة؟**
Your participation in this research is entirely voluntary, as you may choose to participate or not. If you choose not to participate it will not affect the quality of the services, you receive at this health care organizations. Although we value your input, you may choose to drop out of this study at any time point.	يجب التنويه بأن مشاركتك في هذا البحث هو أمرٌ اختياريٌ تماماً (حيث يحق لك المشاركة من عدمها). كما أن قرار مشاركتك من عدمها لن يؤثر بأي شكل من الأشكال على جودة الخدمات التي تتلقاها في مراكز الرعاية الصحية. وعلى الرغم من تقديرنا الشديد لأهمية مشاركتك، فإن هذا لا يعني عدم قدرتك على الانسحاب في أي مرحلة من مراحل هذه المشاركة، حيث يمكنك اتخاذ قرار الانسحاب عند الرغبة.
14. What if you join but change your mind?	**14. ماذا لو انضممت الآن ولكن غيرت رأيك لاحقاً؟**
If you decide to withdraw from the study, you can do so at any time. You do not have to give a reason and you will not have any penalty.	اذا قررت الانسحاب من الدراسة، يمكنك القيام بذلك في أي وقت. لست مضطراً لإعطاء سبب لذلك ولن يترتب عليك أية تبعات أو عقوبة.
15. What else should you know?	**15. ما الذي الذي يجب أن تعلمه أيضاً؟**
We appreciate your taking part in this study. Please be aware that we are not paying volunteers for taking part.	على الرغم من تقديرنا لمشاركتك في هذا البحث، الرجاء العلم أن فريق البحث لن يقوم بدفع أي مبلغ مالي جراء تطوعك للمشاركة.

نموذج الموافقة على الاشتراك ببحث علمي
RESEARCH CONSENT FORM

Signature Page for Capable Adult	صفحة التوقيع للمشارك البالغ العاقل
Volunteer	**المشارك**
I voluntarily agree to join the research described in this form.	أوافق طوعاً على الانضمام الى البحث المشروح في هذا النموذج
Printed Name of Volunteer	الاسم الكامل للمشارك بالبحث
Signature of Volunteer Date	التوقيع التاريخ
Person Obtaining Consent	**الشخص الحاصل على الموافقة**
I document that: • *I (or another member of the research team) have fully explained this research to the volunteer.* • *I have personally evaluated the volunteer's understanding of the research and obtained their voluntary agreement.*	أشهد أني: • أنا (أو أحد أعضاء فريق البحث) قمنا بشرح البحث بشكل وافي للمشارك بالبحث • قمت شخصياً بتقييم فهم المشارك بالبحث والحصول على موافقته/ها الطوعية.
Printed Name of Person Obtaining Consent	الاسم الكامل الشخص الحاصل على الموافقة
Signature of Person Date Obtaining Consent	التوقيع التاريخ
Witness (if applicable)	**الشاهد (عند الضرورة)**
I document that the information in this form (and any other written information) was accurately explained to the volunteer, who appears to have understood and freely given Consent to join the research.	أشهد أنه تم شرح المعلومات الواردة في هذا النموذج بدقة (وأية معلومات أخرى مكتوبة) للمشارك بالبحث. إنه يبدو أنه قد فهم البحث وأن موافقته على الإنضمام إلى هذا البحث طوعية.
Printed Name of Witness	الاسم الكامل للشاهد
Signature of Witness Date	التوقيع التاريخ

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Appendix D

Conditional Ethics Approval   December 10th, 2020

Dr. Suhail Doi
College of Medicine
Qatar University
Phone: +974 4403 7854
Email: sdoi@qu.edu.qa

Dear Dr. Suhail Doi,

Sub.: Research Ethics Expedited Approval
Ref.: Student, Manal Othman / e-mail: mo1806160@student.qu.edu.qa
Project Title: "Development and evaluation of a structured Diabetes Self-Management Intervention Program for Type 2 Diabetes in Qatar"

We would like to inform you that your application along with the supporting documents provided for the above project, has been reviewed by the QU-IRB, and having met all the requirements, except HMC MRC and PHCC IRB Committees' approval letters, is granted a Conditional Expedited Approval based on the following category(ies) listed in the Policies, Regulations and Guidelines provided by MOPH for Research Involving Human Subjects. Your approval is for one year effective from the date of submission of the missing document(s).

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1) *Present no more than minimal risk to human subject, and*
2) **Involve only procedures listed in the following category(ies).**

Category 2: Collection of blood samples by finger stick, heel stick, ear stick, or vein puncture.
Category 4: Collection of data through noninvasive procedures.
Category 7: Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

Please note that this is a conditional approval notifying you that QU-IRB review of your application is complete and has no further ethical concerns. However, it does not permit you to commence any part of the study until the final letter with the final approval number is issued, which is contingent upon the receipt of the HMC MRC and PHCC ethics approval letters.

Documents Reviewed: QU-IRB Application Human Subject-Mo_14 Oct,2020, First Submission_QU-IRB Checklist_MO_14 Oct,2020, Study Protocol, Data Collection Form, Consent_form_part1, Consent_form_part2, Study Tools, QU-IRB Review Forms, responses to IRB queries and updated documents.

Missing document(s): HMC MRC, and PHCC ethics approval letters.

Also note that expedited approvals are valid for a period of one year and renewal should be sought one month prior to the expiry date to ensure timely processing and continuity. Moreover, any changes/modifications to the original submitted protocol should be reported to the committee to seek approval prior to continuation.

Your Research Ethics Expedited Approval Number is: **QU-IRB 1440-EA/20 Conditional.** Kindly state this number in all your future correspondence to us pertaining to this project. In addition, please submit a closure report to the QU-IRB upon completion of the project.

Best wishes,
Dr. Ahmed Awaisu
Chairperson, QU-IRB

Institutional Review Board
(IRB)
Office Of Academic Research

Appendix E

مؤسسة حمد الطبية
Hamad Medical Corporation
HEALTH · EDUCATION · RESEARCH · البحوث · التعليم · الصحة

APPROVAL LETTER

MEDICAL RESEARCH CENTER

HMC, DOHA-QATAR

Ms. Manal Musallam Othman	Date:21st February 2021
007813	
Director of Patient Education	
Medicine	
Hamad Medical Corporation	
Doha-Qatar	
Protocol No:	MRC-01-20-963
Study Title:	Developing a structured culturally sensitive interventional diabetes self-management program for type 2 diabetes in Qatar.
Team Member List:	Dr. Buthaina Ibrahim A. Alowainati , Dr. Mahmoud Ali Humeidan Zirie , Dr. Samya Ahmad Al-Abdulla , Dr. Suhail A Doi , Mr. Ragae Ahmad Mohammad Dughmosh , Mrs. Hanan Khudadad , Ms. Manal Musallam Othman
Hospitals/ Facilities Approved :	Hamad General Hospital (HGH)
Review Type :	Full Board
Decision :	Approved
IRB Approval Period :	14/02/2021 to 13/02/2022

The Medical Research Center has reviewed and approved the request for the above mentioned research study to be conducted in HMC on condition that continual approval from the HMC Institutional Review Board (IRB) is renewed as per the review board's terms.

This study must be fully compliant with all the relevant sections of the 'Rules and Regulations for Research' at HMC and the Medical Research Center should be notified immediately of any proposed changes to the study protocol. Wherever amendments to the initial protocol are deemed necessary, it is the responsibility of the Principal Investigator to ensure that appropriate reviews and renewed approvals are in place before the study will be allowed to proceed.

Please note that only official, stamped versions of the IRB approved documentation are to be utilized at any stage in the conduct of this study and follow the validity dates as mentioned in the IRB stamped documents. The research team must ensure that progress on the study is appropriately recorded in ABHATH, the online research system of the Medical Research Center.

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We wish you success in this research and await the outcomes in due course.

Yours sincerely,

Prof. Michael Paul Frenneaux
Chief of Scientific, Academic and Faculty Affairs
Hamad Medical Corporation

Date: 21st February 2021