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Developing a culturally sensitive structured diabetes education programme for people living with type 2 diabetes in Saudi Arabia

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Submitted in fulfilment of the requirements for the Degree of Doctor of Philosophy

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Abstract

Background - Effective self-management plays a role in improving the health and well-being of people living with type 2 diabetes and structured education is vital as a means of preparing people for a lifetime with the disease. However, in recognition of the fact that there is wide diversity in world populations, there is a need for cultural adaptation to ensure relevance in different populations.

Aims - The aim of this research was to determine the requirements for developing a culturally sensitive structured diabetes education programme for people living with type 2 diabetes in Saudi Arabia

Methodology - A total of four individual studies were carried out to address the aims of the research. First, a systematic review of existing literature to summarise the current status and impact of theory-based, culturally adapted self-management education programmes on type 2 diabetes mellitus. This was followed up by two qualitative research studies involving semi-structured interviews with health care professionals involved in the provision of diabetes care and people living with type 2 diabetes respectively in Saudi Arabia. Finally, a secondary analysis of existing datasets from a hospital in Saudi Arabia highlights the diagnosis and care for people living with type 2 diabetes.

Results - Type 2 diabetes self-management education programmes result in significant improvements in people well-being demonstrated by objective measures such as blood glucose and glycated haemoglobin levels. Education served to prepare individuals to embark on the life-long task of lifestyle improvement as a means of improving their glycaemic control and therefore reducing their risk of short-, medium- and long-term complications. Targeted programmes therefore facilitate the achievement of these goals. Culturally relevant self-management education programmes are best provided with dedicated professionals that are familiar with the target culture and who adopt a person-centred approach to the process. The interviews with health professionals and people living with type 2 diabetes in Saudi Arabia demonstrated that while these participants recognised the benefits of self-management for people with type 2 diabetes, they emphasized the importance of

tailoring the approach to the needs of people living with type 2 diabetes. Information should be delivered in the native language of the participants and also recognize and respect elements of culture such as religious beliefs, value systems and customs. Tailoring information and support in such a manner can produce positive effects on dietary and physical activity patterns as well as illness and health-related beliefs. This was of particular importance since many people living with type 2 diabetes felt that it was difficult to identify self-management measures that were suited to the Saudi Arabian context.

Conclusion - Successful behaviour change in people living with type 2 diabetes is greatly facilitated by well-designed, self-management education programmes. The research demonstrated that there is a need for well-developed, structured self-management education programmes to improve the management of type 2 diabetes in Saudi Arabia. Many of the existing programmes do not demonstrate sensitivity to and recognition of cultural and religious nuances that could have an impact on adherence in the target population. The unique characteristics of Saudi society highlight the need for targeted culturally sensitive education programmes for people living with type 2 diabetes. This highlights the increased tendency to adhere to guidelines and measures that are in line with the social, cultural and religious beliefs of the targeted populations. This is of particular significance in view of the fact that culturally adapted type 2 diabetes self-management education programmes have been shown to be effective in improving short-, medium- and long-term outcomes in minority populations.

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List of abbreviations

Acronyms	**Name in full**
WHO	World Health Organization
NICE	National Institute for Health and Care Excellence
MRC	Medical Research Council
MOH	Ministry of Health
DESMOND	Diabetes Education and Self-Management for Ongoing and Newly Diagnosed
KFHM	Diabetes Centre in King Fahad Hospital Madinah
T2DM	Type 2 Diabetes Mellitus
DSME	Diabetes Self- Management Education
EVF	Ecological Validity Framework
HCP	Health Care Professional
CHW	Community Health Workers
HbA1c	Glycated Haemoglobin
BMI	Body Mass Index

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Author’s Declaration

I hereby declare that explicit reference is made to the contribution of other, that this thesis is the result of my own work and has not been submitted for any other degree at the University of Glasgow or any other institutions.

Printed name: Bandar Alhumaidi

Signature:

Chapter 1: Introduction

1.1 Background

Diabetes is a global public health concern because of its high prevalence and associated mortality and morbidity (World Health Organization, 2016). Over 1.5 million people die of diabetes each year, and diabetes ranks 6th as the cause of death worldwide (World Health Organization, 2018). The prevalence of diabetes has been reportedly rising rapidly among middle-income and low-income countries (Islam *et al.,* 2014). According to Kaiser, Zhang and Van der Pluijm (Kaiser*et al.,* 2018), 500 million people had type 2 diabetes worldwide in 2018, with the number projected to increase to 693 million by 2045. Furthermore, they showed that low-income countries have more people with diabetes than high-income countries. Approximately 39.9 (27.9–53.3) million people or 9.2% (6.4–12.3%) of adults aged 18–99 years had diabetes in the Middle East and North Africa (MENA) region in 2017. An estimated 49.1% of people with diabetes are undiagnosed. If the trend continues, the numbers of people in the MENA region with diabetes will more than double to 85.9 (59.5–114.2) million by 2045. When COVID-19 began, governments' responses to new infectious illnesses radically changed, increasing the demand on healthcare personnel. It's still being discussed by health officials what governments can do to stop the spread of COVID-19 which is proved to increase the prevalence of type 2 diabetes.

Diabetes poses a significant economic burden directly on individuals and their families (via treatment costs) and indirectly on the national economies due in part to a loss of workforce productivity as well as the financial impact on the health system (Abdulaziz Al Dawish *et al.*, 2016). Diabetes is one of the leading global causes of rising healthcare expenditure, mortality, morbidity, and loss of economic growth (Silink, 2009). Most developed economies are already spending 10–12% of their healthcare budgets on diabetes treatment. The global healthcare expenditure on people with diabetes was estimated to be USD $850 billion in 2017 (Cho *et al.*, 2018). Self management skills play a major role in patterns of long-term health and well-being in these individuals. Structured education programmes are proposed to improve self-management among people living with type 2 diabetes, especially when coupled with collaborative care planning, screening, and medications (Deakin *et al*., 2006a, UK, 2005). Early measures to prevent complications limit the impact of diabetes on the people resulting in lower spending by the National Health Service (Deakin *et al.*, 2006a). As reported by the WHO (2016), despite our current inability to prevent type 1 diabetes, type 2 diabetes and its associated complications can be effectively prevented, and the mortality associated with all types of diabetes can be reduced. Type 2 diabetes mellitus is a major public health concern in terms of patient morbidity, mortality, and healthcare expenditure. People with diabetes have reduced quality of life, increased healthcare costs, and higher risks of long-term complications, such as cardiovascular disease, stroke, heart failure, renal failure, amputation, and blindness (Leal *et al.*, 2017).

The global increase in diabetes prevalence can be attributed to rapid urbanisation and the unfortunate adoption of a sedentary lifestyle (Cho *et al.*, 2018, Ogurtsova *et al.*, 2017, Shaw *et al.*, 2010). According to a report by the International Diabetes Federation (Cho *et al.*, 2018), the prevalence of diabetes varies based on age group, gender, and income (Figure 1). In 2017, the prevalence of diabetes in middle-income countries among individuals aged 18–64 years was higher than that in high- and low-income countries; however, the prevalence among individuals aged 64–99 years was higher in high-income countries than in middle- and low-income countries. The highest prevalence (22%) was observed in high-income countries among individuals aged 75–79 years, followed by the prevalence in middle-income countries (19%) among individuals aged 60–74 years. In low-income countries, the prevalence of diabetes was highest (8%) among individuals aged 55–64 years.

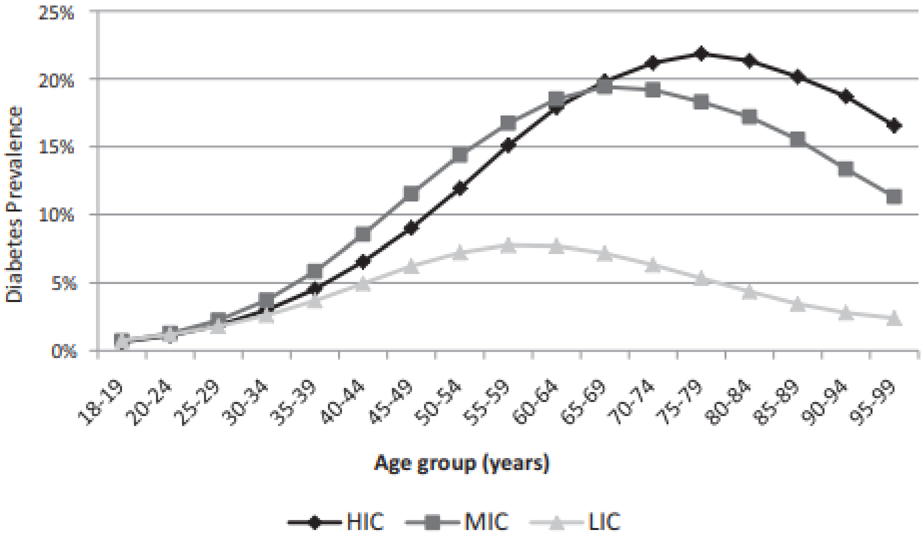


Figure 1: The 2017 prevalence rate of diabetes in high- (HIC), middle- (MIC), and low-income countries (LIC) among individuals in various age groups; from (Cho *et al*., 2018)

The same report revealed that more men aged 18–99 years developed diabetes than women in the same age group in 2017 (Figure 2). The estimated prevalence among men (8.9%) was higher than that among women (8.4%). Moreover, the prevalence of diabetes was highest in the 65–69-year age group among men and the 70–79-year group among women.

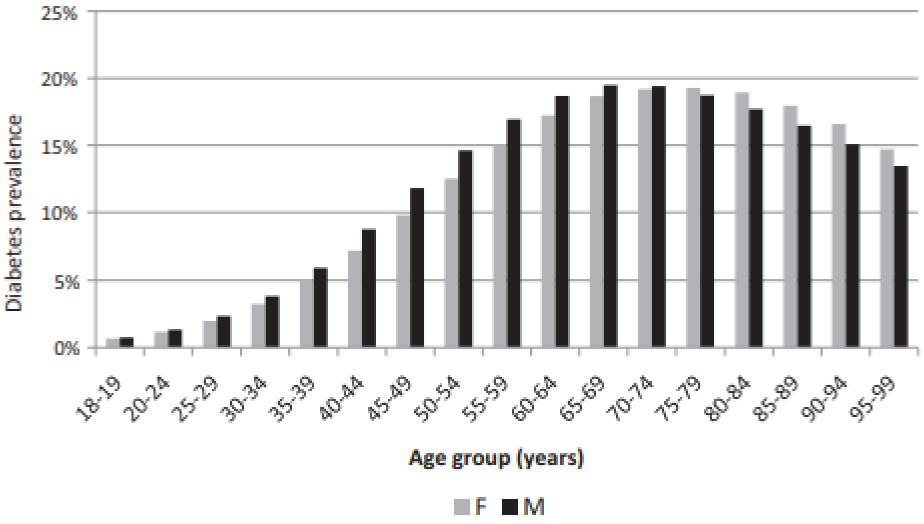


Figure 2: The 2017 prevalence rate of diabetes in males and females in various age groups; from (Cho *et al*., 2018)

1.2 Diabetes in Saudi Arabia

The WHO (2016) reported that Saudi Arabia is ranked seventh in the world for cases of diabetes and second in the Middle East (Abdulaziz Al Dawish et al., 2016). The report also indicates that approximately 7 million people are living with diabetes, while another 3 million are pre-diabetes. Murad, Abdulmageed, Iftikhar & Sagga (2014) investigated the incidence of uncontrolled type 2 diabetes in Jeddah, Saudi Arabia, by surveying various primary healthcare centres in the city and obtaining data regarding glycaemic levels, as well as demographic and clinical variables possibly associated with poor glycaemic control from 400 people with diabetes. They found that over 60% of type 2 diabetes cases were of the uncontrolled type. This refers to poorly controlled diabetes with an increased risk of associated morbidity and mortality. They also recommended that tailored care, including education programmes, should be planned for people with diabetes. The development of a well-structured education programme for the management of type 2 diabetes should consider the education levels of the majority of people with diabetes. Al Baghli *et al.* (2010) reported that low education levels contributed to poor disease management and poor glycaemic control among people with diabetes in their study conducted in Eastern Saudi Arabia. In the absence of disease knowledge, individuals are unable to recognise or acknowledge the seriousness of diabetes and in turn, this can negatively affect desires, intentions and actions to comply with treatment recommendations (Shrivastava *et al*., 2013). However, such cognitions tend to impact self-care behaviours in diabetes, such as physical exercise and healthy eating, more than prescribed drug therapy, as individuals often find it markedly challenging to exert efforts to induce lifestyle change but find the taking of medicines simple and much easier (Webber *et al.*, 2015).

Alshehri (2014) identified deficiencies in diabetes care and potential areas for improvement of medical service provision in the city of Abha through semi-structured interviews with key stakeholders comprising people with diabetes, healthcare professionals, managers, and pharmacists. They also evaluated available resources using a standard checklist, analysed routine healthcare data, administered questionnaires to medical directors and healthcare leaders, and examined the case notes of people with diabetes. They found that limited attention is paid to the health education of people with diabetes in Saudi Arabia.

It is important to improve metabolic control and prevent or delay the complications of diabetes to improve quality of life for people with diabetes, for whom engagement with effective diabetes education-driven self-care is necessary. Mohamed *et al.* (2013) assessed the effectiveness of a culturally sensitive, structured education programme on biomedical knowledge, attitude, and practice measures among 430 people living with type 2 diabetes in Doha, Qatar. The intervention was based on the theory of empowerment, which consisted of four educational sessions for each group of individuals (10–20 people with diabetes per session), lasting for 3–4 hours. The results of the study indicated that there is a lack of well-structured education programmes for the management of diabetes in the Gulf region. For a sound education programme, the structure of the programme must align with the culture and belief system of the people as this influences engagement, which is fundamental to the efficacy of interventions that rely on a self-care component (Brooks *et al.*, 2019). A lack of follow-up in clinics, where doctors are in high demand, reduces the success of educational endeavours. Mohamed *et al.* (2013) recommended the need for structured group-based education for people with diabetes in the Gulf region as it offers them the opportunity to interact, share experience and knowledge, and support each other, freeing them from stigma and instilling hope.

The National Institute for Health and Care Excellence (NICE (2003) in the UK published, in 2003, a guideline on the use of people education models for diabetes (NICE, 2003). This has been recently incorporated into the primary treatment guidelines for type 2 diabetes, which were published in 2015 and updated in 2022 (NICE, 2015). It defines structured education as a planned and graded programme that is comprehensive, flexible, and responsive to people’s needs, as well as their educational and cultural background (NICE, 2003). Such programmes aim to increase people knowledge about their conditions while providing them with information about health related behaviours that help them to control the disease and reduce their risk of adverse conditions. The guideline also recommends that structured people education should be available to all people with diabetes at the time of initial diagnosis and then as required on an ongoing basis. The WHO (2014) recommends the global adoption of culturally sensitive and collaborative programmes of health education for people with diabetes to enhance the participation of individuals and free them from stigma in their self-management. Bearing these recommendations in mind, within this thesis, the research presented focusses on considerations for developing a structured education programme for people living with type 2 diabetes in Saudi Arabia. In the following section, the context of healthcare delivery and diabetes management in Saudi Arabia is discussed.

1.3 Health Care System in Saudi Arabia

The majority of healthcare in Saudi Arabia, a nation comprising a population of 34.8 million persons and thus one of the highest in the Middle East, is provided free of charge to residents through the Ministry of Health, although the health system is augmented by private sector services, which some citizens also have access to as an alternative to public healthcare (Walston *et al.*, 2008). Healthcare is delivered to the population across 13 regions that comprise 20 health directorates but the system is rapidly evolving; having to adapt to changes in population growth and ageing thanks to the uptake and advances in medical treatments over the past few decades (Walston *et al.,* 2008). In addition, the health systems have and continue to support sudden surges in demand, such as during the religious festivals of Hajj and Ramadan that attracts millions in visitors each year, and the COVID-19 pandemic, where there have been in excess of 730,000 cases and almost 9,000 deaths (Walston *et al.*, 2008, Worldometer, 2021).

However, the education and training of health professionals in Saudi Arabia has incurred a challenge in meeting evolving health needs of the population as funding and resources have not been available to ensure the proficiency of care.Also, workers face time pressures and issues with short staffing while addressing the complexities of service users (Walston *et al*., 2008 (Walston *et al.*, 2008). This has questioned the suitability of the health system in being able to provide high quality care and protect the safety of all service users. In response to this issue, the Saudi health system has begun to transition to one similar to that delivered in Western countries, such as the UK and United States, due to observations that such medical models are associated with improvements in clinically important outcomes and population health (Alswat *et* *al.,* 2017). Thus, there has been some movement of healthcare delivery away from more traditional service delivery where health professionals maintain strict control of the process to approaches that respect people autonomy, promote greater integration of care, and advocate novel principles like person-centred care and collaborative decision making. These novel changes are likely to see outcomes from type 2 diabetes improve in line with those observed in the Western world (Khalil *et al.,* 2018).

Cultural sensitivity is defined as a ‘the extent to which ethnic/cultural characteristics, experiences, norms, values, behavioural patterns and beliefs of a target population as well as relevant historical, environmental, and social forces are incorporated in the design, delivery, delivery and evaluation of targeted health promotion materials and programmes’ (Resnicow *et* al, 1999). Specific personal, cultural, religious and socioeconomic characteristics have an effect on patterns of physical exercise and other health-related behaviours which influence the occurrence of type 2 diabetes (Al Slamah *et al,* 2020). Therefore, the importance of cultural sensitivity cannot be overemphasized since applicability to the target environment is central to the effectiveness of self-education programmes for this disease.

In response to the growing health problem, the government and the Saudi Ministry of Health have devised a digital health plan that aims to enhance the overall functioning of digital health in the Country for effective care delivery. This includes endorsement for the national health system's use of telemedicine as part of the vision 2030 (Alghamdi, Alqahtani and Aldhahir, 2020). However, the Saudi Arabia faces challenges in providing free and accessible diabetic treatment to all the citizens. As an example, the economic burden of diabetes on the country has led to reduced quality of care in the health institutions. Increased demand for hospital beds and staff to match international standards has resulted to rise in costs of healthcare and diabetic treatment in the last two decades. The Country's physician-to-nurse population ratio is lower than the worldwide average, posing a significant barrier to the provision of healthcare (Alghamdi, Alqahtani and Aldhahir, 2020). It is therefore imperative that the Saudi government and health authorities engage in efforts to promote healthy diets and exercise regimes for the general population. For those who already have type 2 diabetes, these efforts must include improvements to health education and enhanced people self-management strategies.

1.4 Overview of the Research Problem

The globally high prevalence of type 2 diabetes mellitus has become a major healthcare challenge (Whiting *et al.,* 2011). Furthermore, the economic burden on patients and healthcare systems is huge (Zhang & Gregg, 2017). The International Diabetes Federation has predicted that the prevalence will increase by 8.3% in 2035 (Seuring, Archangelidi and Suhrcke, 2015). Saudi Arabia, which is located in the Middle Eastern region, is currently ranked seventh for the highest prevalence of type 2 diabetes worldwide and is expected to rank sixth by 2035 (Robert *et al*., 2017). Saudi Arabia has a large population of people with diabetes, and the prevalence continues to rise due to obesity and unhealthy dietary habits (Naeem, 2015). Although the present level of diabetes in Saudi Arabia is already concerning, the rising prevalence represents an even greater concern (Al Dawish *et al.,* 2016). One of the reasons diabetes represents a public health crisis is because of the complications it produces and the subsequent expenditure required to treat and minimise these complications, which include cardiovascular diseases, blindness and general disabilities caused by amputation, all of which greatly reduce quality of life of individuals (Al Dawish *et al.,* 2016; Robert *et al.,* 2017). Diabetes-related economic and social problems in Saudi Arabia severely impact the lives of individuals, families, businesses, and the entire society. A recent study from Saudi Arabia indicated that diabetes care accounted for about 13.9% of the total national healthcare budget (Robert *et al*., 2017). Despite such a high budgetary allocation (AlHargan *et al.* 2019), 85% of the people in Riyadh, Saudi Arabia, have been estimated to lack awareness of the type of diabetes they had (type 1 or 2). This underscores the need for education programmes.

High-quality structured education that prepares people for a lifetime with the condition is a key enabler of self-management (Dinneen, 2008). Although various structured education programmes have been initiated in the UK and other Western countries to manage type 2 diabetes, differences in culture, income, and diet make it difficult to establish the effectiveness and implementation potential of such programmes directly in other countries. The high global prevalence of diabetes is attributed to lifestyle, dietary, and other cultural factors. Programmes, therefore, need to be modified according to societal needs. There have been a few attempts to directly adopt structured education programmes in Saudi Arabia to improve glycaemic control, but because these efforts did not consider the values, psychology, and culture of individuals, desired outcomes were not achieved (Al Johani *et al.,* 2015, Alhussein *et al.,* 2021). This thesis is focused on this gap, exploring the need for the development of interventions that are designed in such a manner that they are culturally appropriate for the management of people living with type 2 diabetesin Saudi Arabia.

1.5 Medical Research Council Framework for Complex Interventions

The UK's MRC published a framework for complex interventions in 2006 (with an updated framework published in 2021) to advise and guide the design and development of complex interventions (Skivington *et al*., 2021). This framework was used as a foundation to examine the content and effectiveness of structured education programmes as well as the relevance of cultural adaptation for effective programme development. This should help to generate an intervention that is optimally positioned to improve outcomes for people with T2DM locally and potentially, across other Saudi Arabian settings should other centres adopt a similar approach.

The MRC framework recommends four main stages for developing and evaluating complex health interventions (Craig *et al.*, 2013): (1) development, (2) feasibility and piloting, (3) evaluation, and (4) implementation. The research undertaken and presented in this thesis focuses on the development phase. According to the MRC framework, the first step is the identification of existing evidence for interventions similar to the one under consideration; the researcher must first identify any current or relevant evidence and become familiar with what is already known in the field. This may be achieved by conducting a systematic review if one is not already available. Another early key task is identifying and developing an appropriate theoretical framework based on existing evidence, which if required, can be supplemented with further research, such as interviews or focus groups, ideally with groups targeted by the intervention or with groups potentially involved in its delivery (Skivington *et al*., 2021).

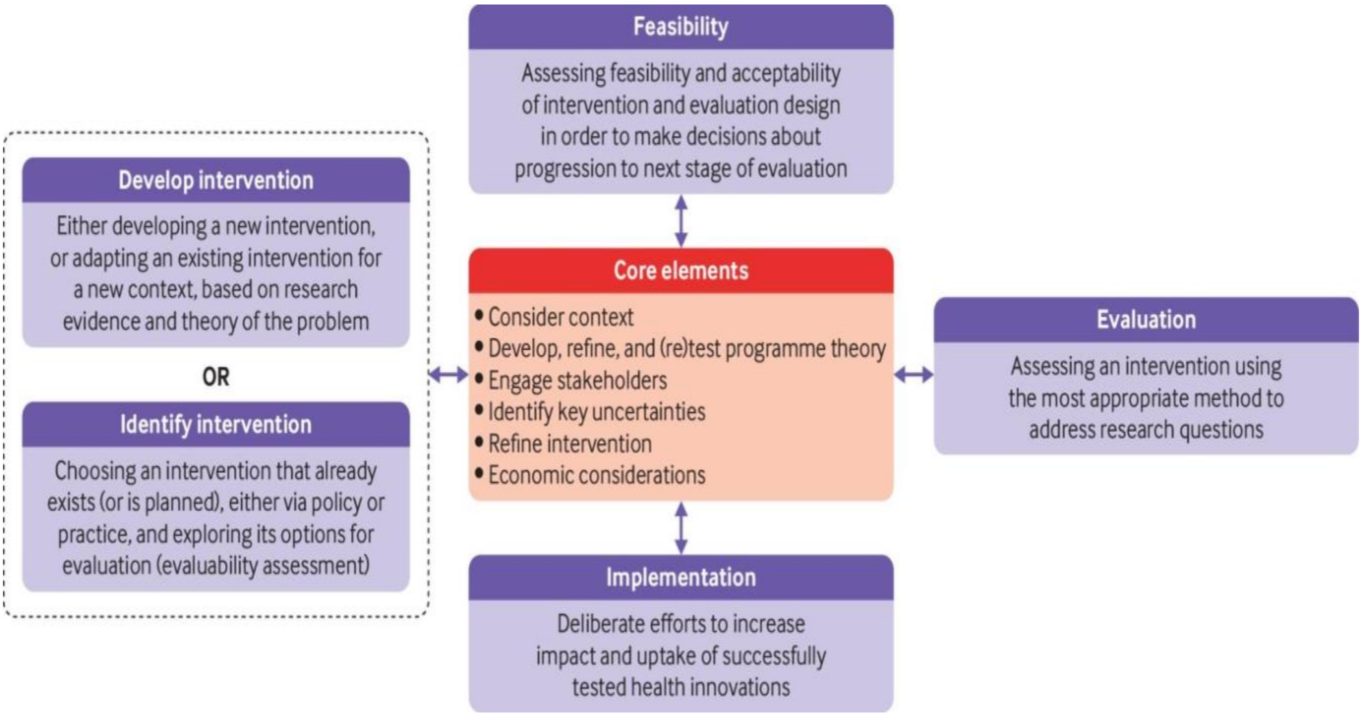


Figure 3: The MRC Framework for Complex Interventions (Skivington *et al*., 2021)

1.6 Research Aims

The aim of the research presented within this thesis was to determine the requirements for developing a culturally sensitive structured diabetes education programme for people living with type 2 diabetes in Saudi Arabia. The research included four distinct studies that each had a specific aim, which aligned with the development phase of the MRC framework and contributed to the overall aim (as stated above).

- **Study 1:** The aim of Study 1 was to determine the effectiveness of theory-based structured self-management education programmes that have been culturally adapted for people living with type 2 diabetes.

- **Study 2:** The aim of Study 2 was to explore the views, experiences and perspectives of healthcare professionals involved in the care of people living with type 2 diabetes regarding self-management education in Saudi Arabia.

- **Study 3:** The aim of Study 3 was to explore the views, perceptions and preferences of people living with type 2 diabetesin regard to the value and provision of self-management education in Saudi Arabia.

- **Study 4:** The aim of Study 4 was to examine the extent and quality of routine data collected on people with type 2 diabetes as to assist in designing, implementing and evaluating the efficacy of future structured education programs.

1.7 Research Questions

The research addressed the following questions:

Study 1:1) How effective are theory-based structured self-management education programmes that have been culturally adapted for people living with type 2 diabetes? 2) What are the components of theory-based structured self-management education programmes for people living with type 2 diabetes? 3) What are the strategies used to make theory-based structured self-management education programmes culturally relevant?

Study 2:1) What are healthcare professionals' perceptions of the feasibility, acceptability, and provision of self-management programmes for people living with type 2 diabetes in Saudi Arabia? 2) What are the preferences, needs, and experiences of healthcare professionals in relation to the provision of self-management education programmes for people living with type 2 diabetesin Saudi Arabia?

Study 3:1) What are the preferences, needs and experiences of people living with type 2 diabetes in relation to self-management in Saudi Arabia? 2) What are individuals 'perceptions of the challenges in engaging with diabetes self-management education programmes? 3) What are individuals 'perceptions on the feasibility, acceptability and accessibility of self-management programmes for people living with type 2 diabetes in Saudi Arabia?

Study 4:1) What routine data is currently collected and available for people living with type 2 diabetes? 2) What is the quality of the routine data collected? 3) What, if any, descriptive analyses can be conducted on routine data to describe the target populationto determine if the levels of glyacaemia/complications highlight the potential benefits of structured education?

1.8 Structure of the Thesis

This thesis includes nine chapters. This current chapter (chapter 1) has outlined the background and significance of this study within the context of epidemiological data from Saudi Arabia, highlighting its increasing incidence of type 2 diabetes and the need to better support and educate people to manage their diabetes in the longer-term. Chapter 1 also includes the aims and research questions of the research undertaken and describes the overall structure of the entire thesis. Chapter 2 provides an overview of diabetes and the management of diabetes, highlighting the importance of and current evidence on self-management of type 2 diabetes both globally and within the context of Saudi Arabia. Chapter 3 discusses the methodology used in this research and the philosophical stance underpinning this research is then discussed.

The research design and methodology, and how these were impacted by and mitigated for during the Covid-19 pandemic, are then presented and the methods of data collection and analysis are described and justified for studies 2 and 3. Chapter 4 discusses the systematic review conducted to synthesise the evidence of the effectiveness of theory-based structured self-management education programmes that have been culturally adapted for people living with type 2 diabetes(Study 1). Chapter 5 presents the results of a qualitative study with health professionals (Study 2). In this chapter the characteristics of participants are described and details on the themes that emerged from thematic analysis are provided. Chapter 6 presents the results of a qualitative study with people with type 2 diabetes, and the characteristics of participants are described, along with details about the themes that emerged from thematic analysis (Study 3). Chapter 7 describes and justifies the methods of the secondary analytical study, which analysed pre-existing data drawn from the hospital records at the KFHM (Study 4). The evidence derived across studies 1-4 are also discussed in relation to the wider literature, in order to help validate the findings. Chapter 8 summarises the results from across the four studies and their context in relation to the wider literature and considers the findings and recommendations regarding development of the self-management programme and other appropriate strategies for people living with type 2 diabetes in Saudi Arabia and overall conclusions and additional recommendations for ongoing research around the topic area.

Chapter 2: Literature Review

2.1 Overview

Chapter 2 provides an overview of diabetes mellitus and diabetes patient education, highlighting type 2 diabetes management particularly current evidence on supporting self-management. Subsequently, this chapter discusses national programmes and the role of self-management in diabetes education and description of models of structured diabetes patient education.

2.2 Diabetes Mellitus

Diabetes mellitus is a metabolic disorder characterised by high blood glucose levels with associated disturbances in carbohydrate, fat, and protein metabolism (WHO, 1999). According to Ogurtsova *et al.* (2017), an estimated 415 million individuals had diabetes in 2015, but this number could increase to 642 million by 2040. Diabetes mellitus can be commonly categorised into three types: type 1, type 2, and gestational diabetes. Type 1 diabetes occurs when insulin production is lacking, requiring the people to subcutaneously inject insulin (American Diabetes Association, 2010). Type 2 diabetes (T2DM) occurs when the body is unable to use insulin properly (American Diabetes Association 2010; Iyer, Jeyalatha & Sumbaly, 2015). Almost 90% of diabetes people have type 2 diabetes, in which the body is unable to adequately respond to the presence of glucose in the blood or the insulin produced cannot act efficiently to internalise the circulating glucose molecules (Jarvis *et al.,* 2010). Excess body weight and physical inactivity are major risk factors for this type of diabetes. It occurs most frequently in adults (WHO, 2016); however, its incidence in children has also been increasing in recent times (Austin *et al,* 2011; WHO, 2016). Gestational diabetes occurs during pregnancy and typically resolves after childbirth, but some people with a history of gestational diabetes subsequently develop type 2 diabetes (American Diabetes Association, 2010). The children of mothers with a history of gestational diabetes are also at increased risk of developing type 2 diabetes in the future. Gestational diabetes is diagnosed through prenatal screening rather than through reported symptoms (Plows *et al*., 2018). Therefore, there is sufficient evidence that diabetes can lead to health complications as well as economic problems at individual and national levels. This research study is however focused on type 2 diabetes mellitus.

2.3 Management of Type 2 Diabetes

Positive lifestyle habits and behaviours play a significant role in the management of chronic health conditions by controlling major determinants of positive health and well-being (Silva *et al,* 2010; Morton *et al,* 2017; Sage *et al,* 2017). The management of metabolic control is paramount to the well-being of people living with type 2 diabetes, and glycaemic control is but one aspect of overall care (Hall, 2007). Type 2 diabetes management is complex because the disease progresses over time and it affects physical and mental well-being. To manage type 2 diabetes, individuals need to consult a range of healthcare professionals, including physicians, nurses, diabetes educators, dieticians, pharmacists, and psychologists (Diabetes Australia, 2011). The principles and goals of managing T2DM include reversing the disease to achieve remission where plausible, or in those where remission cannot be attained, optimising glycaemic control as to reduce the risk of micro- and macro-vascular complications, which are the leading causes of disease-related morbidity and mortality (Reusch and Manson, 2017).

Combining regular, sustained exercise with a modest reduction in caloric consumption is the most effective way to induce type 2 diabetes remission via weight loss (Taylor, 2021).Improving glycaemic control usually requires people to engage with intensive lifestyle changes, including adopting a healthier diet and increasing physical activity levels to promote weight loss, whilst also performing frequent monitoring of glycaemia to tailor self-care measures to mitigate hyperglycaemia, and attending regular and lifelong medical reviews and screening tests for complications (Reusch and Manson, 2017).

Due to the life-changing and inconvenient impact of the diagnosis of T2DM and its related management upon people ’lives, issues of adherence to self-care measures and prescribed therapy are common and this compounds individuals ability to achieve desirable glycaemic control (Khunti, 2019). In turn, people with T2DM and poor adherence behaviours observe a much more adverse course of disease with an earlier onset of complications, increased severity of complications and earlier mortality, than those with more stringent glycaemic control (Polonsky and Henry, 2016). Establishing and achieving behavioural change soon after the diagnosis of T2DM as to optimise lifestyle habits that favour improvements in glycaemia is critical as delays in reducing glycaemia have been associated with a more adverse course of disease and lower treatment responsiveness, than those who adopt early habits that benefit glycaemic control (Pratley, 2013).

As the diagnosis and management of type 2 diabetes can be overwhelming and psychologically distressing, independent of the time since diagnosis, optimising the engagement and self-efficacy of people is fundamental to achieving desirable outcomes (Indelicato *et al.*, 2017). This is particularly important for self-care as a large proportion of people living with type 2 diabetes require intensive support to transition and adapt to management expectations as to improve their health status and given that pharmacological therapy is never usually sufficient alone as to mitigate cardiovascular risk (Bailey, 2013). To engage people, a holistic approach, as well as patient-centred care, information provision, education and counselling are essential requirements of diabetes services (Rutten & Alzaid, 2018). People are encouraged to optimise their knowledge and skills so that they can effectively manage their condition and in tailoring management based on real-time variances in glycaemic control and in response to the presence of complications or activities that may influence glycaemia, such as exercise and alcohol intake (Chester *et al.*, 2018). Self-management support, in the context of long term conditions more generally, can be defined as

> *‘inter-disciplinary group education, based on the principles of adult learning, individualised treatment and case management theory’* (Barlow *et al,* 2002).

The National Standards for Diabetes Self-Management Education and Support (Haas *et al.,* 2014, Beck *et al*., 2017), in the United States of America (USA), describe diabetes self-management education as a collaborative and ongoing process intended to facilitate the development of knowledge, skills, and abilities that are required for the successful self-management of diabetes. In addition to providing individuals with understanding of the condition, it facilitates the development of positive habits, learned actions that are initiated to respond to specific cues such as levels of blood glucose or physical signs and symptoms related to the condition (Beck *et al,* 2017). For this purpose, structured education programmes for diabetes self-management must be developed to educate people and facilitate the adoption of the recommended changes in the behaviour, lifestyle, diet, and physical exercise habits. Additionally, the administration of medication, self-monitoring of blood glucose levels, and foot care will facilitate effective diabetes self-management. The overall aim is to ensure regulation of blood glucose at consistently optimal levels (Beck *et al,* 2017; Chester *et al,* 2018).

Self-management of chronic conditions such as type 2 diabetes is complex and success at self-management flows across a continuum from ineffective to very effective (Mann *et al,* 2013). A wide body of evidence conducted outside of Saudi Arabia has identified that the uptake and adherence to self-management recommendations is often less than ideal; uptake and adherence being seldom known locally due to a paucity of research evidence (Adu *et al.,* 2019, Khunti, 2019). Some pertinent studies have shown that adherence to dietary and physical activity recommendations has varied markedly between 10-80% of people living with type 2 diabetes and this level of adherence is much poorer when compared to prescribed medication adherence; most evidence reporting good adherence among >80% of people (Praet & van Loon, 2009, Rozenfeld *et al.,* 2008). This is mirrored in Saudi Arabia where a recent study among a cohort of 385 people living with type 2 diabetes(Alhaiti et al. ,2020) showed that adherence to drug and non-drug therapies was poor and notably, only 37% of people had received sufficient information regarding lifestyle changes needed to improve their glycaemic control. Other key reasons for poor adherence to type 2 diabetes management recommendations reported across the literature have centred around individual issues including a lack of knowledge of diabetes, insufficient support from care providers and relatives, cultural and religious factors compounding desires to comply with Western medical approaches and a lack of self-efficacy among people to engage and sustain engagement with lifestyle changes (Khunti, 2019).

Despite research highlighting the varied barriers to self-management adherence, few efforts have been instigated to tackle the problem, although structured self-management education programs have proven promising and efficacious in varied Western settings for enhancing adherence behaviours and diabetes related outcomes (Captieux *et al.*, 2018, Chatterjee *et al.*, 2018b). However, the impact of such programs has also been compounded by poor uptake and adherence issues, which suggests that there has been insufficient understanding of individuals needs in regard to education program characteristics and thus, some programs have not been tailored to suit and thus, fail to attract the attention of some groups of people living with type 2 diabetes(Carmienke *et al.,* 2021). Furthermore, the suitability of self-management education programs becomes an issue in populations whose cultural and religious views and beliefs differ from the Western Caucasian models and foundations on which most programs have been developed (Chatterjee *et al.,* 2018b). Qualitative research offers an approach that can address these gaps by eliciting the views, preferences and cultural beliefs of individuals, in order to provide a more in-depth and meaningful understanding into the factors that are likely to hinder and facilitate uptake and adherence to education programmes (Watkins, 2012). Qualitative research exploring individual's views and experiences of education programs for type 2 diabetes is lacking in Saudi Arabia and thus, is desperately required, in order to inform programme development.

2.4 Structured Education Programmes

2.4.1 Purpose and scope of structured education programmes

Structured education programmes are educational courses that are developed and delivered by healthcare professionals, often diabetes specialist nurses or dieticians, to provide in-depth information about diet, physical activity, and medication for managing diabetes. The Institute for Health and Clinical Excellence (NICE) Health Technology Appraisal (HTA) 2003 defined structured education as 'a planned and graded programme that is comprehensive in scope, flexible in content, responsive to an individual's clinical and psychological needs, and adaptable to his or her educational and cultural background' (NICE, 2003). This definition recommends that any diabetes educational programme should be able to provide knowledge, improve skills and be tailored to achieve specific needs and cultural requirements to assist people in adopting and maintaining lifestyle modifications. Furthermore, consensus guidelines recommended that structured and annually accredited education programmes should be offered to people with diabetes and their families and/or caregivers (Powers *et al.,* 2016). There are four essential components of a good-quality self-management education programme: a structured written curriculum; trained educators; quality assurance process; and audit (Table 1; Chatterjee *et al*., 2018). These components ultimately promote the standardisation of self-management education, whilst ensuring education is delivered by appropriately trained persons and in a way that can be evaluated to measure education quality (Carey, Khunti & Davies, 2012). The benefits of using a structured education programme can include improved awareness and understanding of diabetes, psychological adjustment to live with diabetes, improved undertaking of diabetes self-management behaviours, and improved clinical outcomes (Conway, 2009). The common theoretical underpinnings of structured programmes and some examples of existing structured programmes are considered further in sections 2.4.2 and 2.4.3.

Table 1: The fundamental criteria of structured education programmes (Carey, Khunti& Davies 2012).

Philosophy	**Each programme is underpinned by an explicit patient-centred philosophy, which will guide the utilisation of learning theories and hence the delivery of programmes.**
Curriculum	The written document based on a needs assessment establishes the components covered in each session so that all professionals know what is covered in the programme. It explicitly delineates the aims and objectives of the programme through detailed lesson plans, including a description of learner and educator activities.
Trained educators	The educator needs to be an effective information processor, be familiar with learning theories, and have facilitation skills to assist the participants to solve problems and set personal goals. The educator will need to have defined diabetes expertise such as an academic diabetes qualification or equivalent.
Quality assurance	Review is necessary to ensure the programme is delivered as outlined in the curriculum and within the stated philosophy. Initially, this may be internal (self, peer reflection); however, this should ultimately be done by external reviewers and include participant feedback.
Audit	Evaluation of the programme is based on the stated outcomes of the programme and should include data on biomedical parameters, quality of life people with diabetes experience, and the degree of self-management achieved after attending the programme.

2.4.2 Theoretical Underpinnings of Structured Programmes

The development and implementation of structured education programmes is greatly enhanced when they are based on a foundation of established theories (Skinner *et al*., 2013). There are four predominant theories that underpin self-management education for people with diabetes, which have been employed to enhance individual motivation, self-responsibility perceptions and enable individuals to achieve a greater sense of control over their diabetes (Skinner *et al*., 2003). These theories are essential in motivating people living with diabetes toward maintaining a healthy lifestyle through healthy eating, blood glucose monitoring, physical activities and medication compliance. The content of structured educational programme is supported by a theoretical framework that links health behaviour's psychological and self - regulatory factors (Yates *et al*., 2012). The behavioural idea is supported by Bandura's social cognitive theory that can be used to assess how well an educational program's content and structure influence people outcomes.

Theory based structured education can have a major impact on health outcomes and people satisfaction. It provides benefits to persons with diabetes in terms of self-management measures that include teaching people how to self-manage their diet, physical fitness and medication (Pipe-Thomas, 2012). As a result of this concept, people living with type 2 diabetes will be able to make better decisions about how to improve their health in the long term.A theory-based educational programme also tries to refute any myths about the condition, as well as any potentially harmful disease beliefs (Yates *et al*, 2012; Neys, 2017; Wheatley *et al.*, 2021.

2.4.2.1 Self-Regulation Theory

TheSelf-Regulation Theoryas described by Carver & Scheier (1982) focuses on the representation of an individual’s illness or personal model of diabetes as a key determinant of their behavioural and emotional responses to illness (Sauer *et al.,* 2010; Mann *et al.,* 2013; Hampson *et al.,* 2016). This theory identifies five core elements that form illness representations across cultures, including: (1) Identity (What is diabetes? What symptoms are experienced? What is wrong?), (2) Cause (What caused my diabetes?), (3) Timeline (How long will this last?), (4) Consequences (How will diabetes affect me now and in the future?), (5) Treatment effectiveness (How good is my treatment at controlling or curing my diabetes?).It is thought that individuals hold a set of beliefs about their conditions, that are often deeply seated or engrained, but through the above elements, disparities between individual beliefs and those of the medical model can be overcome as to promote collaborative working (Leventhal *et al.*, 1984).

The value of Self-Regulation Theory in T2DM self-management is clear; helping to enhance self-control through promoting and strengthening autonomy. These described benefits also echo those arising from the self-determination theory (section 2.5.3) but ultimately, its use can improve an individual's planning and problem solving abilities as to overcome or cope with the challenges of self-care, whilst also enabling them to project the likely impacts of self-care decisions, in order to inform healthier decision making and in turn, control over glycaemia (Scollan-Koliopoulos *et al.*, 2011). Outside of diabetes, the Self-Regulation theory has been used effectively to facilitate self-management of osteoarthritis (Kao & Tsai, 2020); asthma (Sage *et al*., 2017) and obesity (Tougas *et al.,* 2015). However, it is important to highlight that self-regulation theory suffers from some limitations, including assumptions that changes in individual's knowledge and perceptions are likely to guide behaviours and thus, fails to account for the non-emotional factors that influence self-care adherence (Scollan-Koliopoulos *et al.*, 2011). In addition, self-regulation theory assumes that individuals' perceptions and judgements of self-care are objective and reliable but in truth, self-evaluation is inherently prone to subjectivity and cognitive biases (Cameron *et al.*, 2017). It has been found that the strength and capacity to self-regulate can be improved by practice and repetition, suggesting that this might be of benefit in the adoption of practices and behaviours that could lead to improved glycaemic control and overall health in people with T2DM (Cameron *et al.*, 2017; Sauer *et al.,* 2010).

2.4.2.2 Dual-Process Theory

The Dual-Process Theory is used to guide the process of education and address individuals' current understanding of diabetes. The Dual-Process theory originated from work in cognitive psychology by Epstein (1994) and Hammond (1994). It emphasises the importance of both self-discovered and informed means to understanding how self-care can be integrated into and become a part of individuals lives (Neys, 2017). people education relies predominantly on mental processing, with people playing rather passive roles, mostly listening to healthcare professionals informing them about their illness. In such instances, healthcare professionals are seen as experts who should be listened to and whose advice should be followed. However, the information provided is usually generic and easily rationalised as irrelevant to the individual. Where attitudes do change, they tend to be surface changes and are susceptible to further change under the influence of others. Such people might also accept contradictory information from other “experts”, who may be healthcare professionals, relatives, friends with diabetes, or the media.

The Dual-Process Theory overcomes these issues by emphasising the need to actively involve individuals in the learning process. This means providing individuals with the least possible information from which to learn. It has been used to encourage active self-management in conditions such as hypertension, rheumatoid arthritis, chronic obstructive pulmonary disease and chronic back pain (Morton *et al.,* 2017; MacIver *et al.,* 2021). However, limitations to the dual-process theory include its focus upon dichotomous features that co-occur rather than being influenced by multiple or more than two combinations of its features; type 1 theory comprising efficient, unintentional, uncontrollable and unconscious and type 2 theory comprising inefficiency, intentional, controllable and conscious (Neys, 2017; Langford, 2020).Thus, some features are likely to co-align depending upon the context of application of the dual-process theory, which is likely to hinder its role in self-management education but not when combined with the other dominant theories described herein (Langford, 2020).

2.4.2.3. Self-Determination Theory

The Self-Determination Theory is an approach that identifies three basic needs that determine the impact of social activities and contexts on personal development throughout an individual’s life; the need for autonomy, the need for competence, and the need for relatedness (Ryan & Deci, 2000, 2000b). Autonomy describes being able to act personally. Competence is a reflection of a sense of personal effectiveness when acting within one’s environment, and relatedness reflects connections to society in general (Ryan & Deci, 2000). The Self-Determination Theory focuses on the difference between controlled and autonomous motivation. Controlled motivation means doing things for extrinsic reasons, such as to make others happy or to receive a contingent reward. Autonomous motivation, in contrast, means doing things for intrinsic reasons or oneself.

The greater the individual's sense of competence, the greater intrinsic autonomous motivation and therefore the likelihood of successful self-care, weight loss, and glycaemic control. This is one of the most useful and observed theories in action within self-management programs; and it has been used to facilitate active self-management in encouraging physical activity (Silva *et al.,* 2010; Ng *et al.*, 2012), weight loss (Ng *et al.,* 2012); type 1 diabetes (Austin *et al.,* 2011) and cancer (Howell *et al.,* 2019) programmes. Studies by Williams *et al* (1998) has shown that autonomous motivation can be enhanced through incorporated self-reported assessments into self-care education, in order to enable individuals to postulate their own outcomes and treatment needs to become healthier (Williams et al, 1998; Austin *et al.*, 2011 ; Koponen *et al.*, 2018). In turn, individual awareness and reflection on self-reported assessments can permit persons to become greater advocates for their future health and wellbeing; information promoting increases in self-determination and self-care efforts to optimise glycaemic control (Skinner *et al.*, 2003).

Self-Determination Theory is considered to have limitations in self-management and treatment of diabetes. The theory focuses on intrinsic motivation that means that the effective of the theory depends on the people's decision. The health supervisors and caretakers therefore have little control over the success of the theory. There is a lot of ambiguity around the idea of self-determination. In the event that an individual does not accept the existence of free will, the notion of self-determination becomes very unlikely (Ryan & Deci, 2000; Ng *et al*, 2012; Howell *et al,* 2019).

2.4.2.4 Social Learning Theory

The Social Learning Theory focuses on individuals' perceptions of their ability to enact behaviours and follow through on action plans (Skinner *et al.*, 2003). In psychological terms, this is referred to as self-efficacy, but it is very similar to the concept of self-confidence. Self-efficacy is one of the most consistent predictors of successful self-care behaviour and has been incorporated into most health psychology models (Mohebi *et al*., 2013). The value of social learning theory in education programs likely arises from the availability and use of validated measures of self-efficacy, whilst other theories posited in this section are less amenable to objective measurement (Chen *et al*., 2015, Nugent & Wallston, 2016). Thus, the value of non-social learning theories in diabetes education programmes may not have been completely clear because of issues with measurement.

The theory of Social Learning is predicated on a number of assumptions, one of which is that people pick up knowledge via observation, despite the reality that this is not always the case. In addition to this, it is presumed that cognitive processes have an effect on behaviour, and that change is not always brought about through learning. In conclusion, it implies that behavioural reinforcement and punishment may also impact learning (Skinner *et al*., 2003). This means that Social Learning Theory is limited in neglecting the impact of the accountability of an individual’s actions by placing greater focus upon external factors constrained within society. In addition, the theory does not account for the influence of role models upon learning and behaviour; role models being important in self-management education where care workers are expected to inspire and engage individuals in achieving behavioural change (Horsburgh & Ippolito, 2018).

One of the most frequently employed theories in the treatment of chronic diseases like diabetes mellitus is the Social Learning Theory (Skinner et al, 2003; Mohebi *et al*, 2013; Nugent & Wallston, 2016). Many researchers have previously proposed a Social Cognitive Theory model in predicting self-care among people living with type 2 diabetes (Ghoreishi *et al,* 2019). In addition, managing good self-care is extremely essential to decrease the morbidity and mortality of people with diabetes. Self-care practices such as raising awareness, feeling competent, and exercising self-restraint might impact an individual's behaviour. People' compliance with self-care tasks may be influenced, motivated, and aided by using the theory (Ghoreishi *et al*., 2019).

2.4.3 Examples of Structured Education Programmes

It is important to identify factors that contribute to the effectiveness of structured education programmes since such detail is vital to the development of such programmes in different locations and cultures. Structured education programmes are critical in assisting individuals to learn about diabetes control and self- management (Loveman *et al*, 2003; Deakin *et al,* 2005). Such programs enable people living with diabetes to learn how to maintain proper blood glucose and minimize risks associated with type 2 diabetes. Chapter 4 presents the findings from a systematic review of theory-based, culturally adapted structured education programmes in type 2 diabetes. By way of a preface to this and to introduce the common components of structured education programmes, the following section highlights some selected education programmes which have been commonly used to assist people living with type 2 diabetes in the management of their condition.

There are several structured education programmes targeting a range of health conditions in present day populations. For diabetes related education, researchers in Europe and North America have developed several structured educational programmes, including the DESMOND, and X-PERT, which have been adopted across varied settings to optimise the self-care behaviours of persons with diabetes (Giles *et al.,*2010). These two models are particularly considered since they are some of the most commonly used worldwide. In addition, they are based on a combination of several theories of learning and structured in such a manner to facilitate the adoption of positive self-management amongst affected populations (Khunti *et al.,*2012). Evidence describing the characteristics and impact of these programs is provided within sections 2.4.3.1 -2.4.3.2.

2.4.3.1 DESMOND Structured Education Programme

DESMOND (the acronym for Diabetes Education and Self-Management for Ongoing and Newly Diagnosed)is a structured education programme developed in the United Kingdom (UK) based on the quality criteria of National Institute for Health and Clinical Excellence (NICE) as previously discussed in section 2.4.1 (Carey, Khunti & Davies, 2012; Khunti *et al.*, 2012a). The DESMOND programme has been implemented in 103 health organisations across the UK, Republic of Ireland, Gibraltar, and Australia. This programme is based on the self-management theories including the dual process and the social learning (Khunti *et al.,* 2012) as previously described in sections 2.4.2.2-2.4.2.4. The intervention is administered as a group programme based on a written curriculum deemed to fit the largest number of participants, delivered in a community setting and integrated into routine care. The facilitators are registered healthcare professionals who have received formal training to facilitate the programme. A quality assurance programme is also conducted to ensure that trainers/facilitators deliver the education with consistent quality to support people with diabetes. The DESMOND program is available for any people living with type 2 diabetes within the UK who are receiving care under the National Health Service; physicians can refer people to one of three types: DESMOND for newly diagnosed people, DESMOND for those with established type 2 diabetes and DESMOND for Black and Minority Ethnic persons who lack fluency in the English language (Diabetes UK, 2019).

The Dual-Process theory is one of the theories that is relevant (Stone *et al,* 2008 in the DESMOND program as it involves sharing people living with diabetes experiences and information with the health supervisors in order to device the most suitable treatment method. The curriculum includes time for people to “tell their story”, information about diabetes and how it is optimally managed, the potential risks of diabetes, self-monitoring, diet changes, exercise, and dealing with stress and emotional issues. At the end of the course, people are encouraged to develop a personal action plan. DESMOND supports people in identifying their own health risks and responding to them by setting their own specific behavioural goals. The curriculum content is largely focused on encouraging participants to adopt good lifestyle behaviours characterised by physical activity, cardiovascular risk factors, and good food choices. The programme is delivered in groups of up to 10 people with diabetes and supportive family members or carers. The programme was designed to be delivered within a total of 6 hours over 1 day or 2 half days. Two trained educators deliver it in two three-hour sessions or one six-hour session (Conway, 2009).

Studies in the UK and the US have shown that the DESMOND program is markedly effective in improving various outcomes that are important in type 2 diabetes, such as weight, smoking cessation, illness beliefs, depression, glycaemic control and cardiovascular risk, when compared with standard care (Skinner *et al.*, 2006, Khunti *et al.*, 2008; Khunti *et al.,* 2012 Khunti *et al,* 2012b; Minet *et al.,* 2010; Chatterjee *et al.,* 2018; Wheatley *et al*, 2021). In one of the seminal trials exploring the impact of DESMOND, Davies *et al.* (2008)found that glycated haemoglobin levels decreased by a meaningful 1.5% at 12 months of follow-up, versus usual care controls; however, the difference was not found to be statistically significant (1.5% v. 1.2%, p>0.05). The extent of glycaemic improvement was much more favourable than non-structured education programs; a meta-analysis of 47 randomised controlled trials showing a mean reduction in glycated haemoglobin of 0.4% (Minet *et al.*, 2010). Yet the longer-term efficacy of DESMOND has not been desirable with Khunti *et al.* (2012b) showing non-significant differences in glycaemic control at three years follow-up versus usual care controls. This may simply suggest that education programs for T2DM may need to be provided on a regular or protracted basis however, rather than being isolated interventions delivered at a single point in time.

A recent real-world evaluation of DESMOND revealed that the mean reduction in glycated haemoglobin at 6 and 12 months were 0.7% and 1.0%, respectively, versus usual care controls and thus, highlighting its value in improving self-care efficacy and behaviours (Chatterjee *et al.*, 2018a). Furthermore, the program has been shown to be cost-effective, another factor that is of significance in the search for suitable self-management programme for settings like Saudi Arabia where funding and resources are limited (Gillett *et al.*, 2010). However, while there appears to have been relatively good success with the use of this programme in many countries of the world, there isn’t much research pointing to the benefit in social, economic and cultural settings such as those found in Saudi Arabia. This therefore leads to the question of how suitable the programme might be within settings that differ from the settings in which the programme was introduced and assessed.

2.4.3.2 X-PERT Structured Education Programme

The X-PERT structured education programme was introduced in the UK for people with T2DM (Deakin *et al.*, 2006a). It provides people with the confidence, knowledge, and skills necessary to self-manage their diabetes. This programme is fundamentally based on the theories congruent with and related to those described in section 2.4.2 In discovery learning, the learner is a problem solver who uses tools and information to gain knowledge through discovery (Deakin *et al.*, 2006a). Empowerment helps people discover and use their innate ability to control their diabetes (Anderson, 2005). This programme empowers the people to develop the skills and confidence required to improve diabetes self-management and achieves sustained improvements in clinical, lifestyle, and psychosocial outcomes for people living with type 2 diabetes. It also encourages people with diabetes to be experts at living with their condition and to actively participate in the learning process. Additionally, they are encouraged to develop autonomy by working in partnership with healthcare professionals to implement effective self-management. Empowered participants with diabetes are valued and accepted as being experts at living with their condition. They are encouraged to participate actively in the learning process and discuss their feelings towards living with their condition and the effect it has on their day-to-day lives (Skinner & Cradock, 2000).

This focus on increasing people knowledge and understanding of their conditions, the risks and the actions that can improve their health increases their competence and therefore their autonomy in line with the principles of the Self-Determination Theory. The programme curriculum is therefore designed in a manner that aims to build participants' confidence and skills and is focused on achieving people empowerment and people activation. However, it relies on social learning and dual process as a means of increasing people knowledge and therefore achieving such people empowerment (Mandalia *et al.,* 2014). X-PERT aims at generating a shared experience for the person with diabetes, for which family and friends are invited along with the people. The programme is usually conducted for a group of 16 participants and runs for 2 hours over 6 consecutive weeks. The final 20 minutes of each session are set aside for goal setting, as the aim of the X-PERT programme is to empower people to self-manage their type 2 diabetes.

A people manual is provided at the beginning of the course. It covers background information, and additional material is added each week. Thus, this programme enables them to make decisions regarding their diabetes self-care. According to UK audit statistics, this programme significantly improves body weight, waist circumference, self-empowerment, cholesterol, physical activity levels, vegetable and fruit intake, blood pressure, diabetes knowledge, treatment satisfaction, and body mass index (Deakin & Whitham, 2009). The efficacy of the X-PERT program has been reflected in the findings of Deakin *et al.* (2006b) where significant improvements in glycated haemoglobin of 0.6% were achieved at 14 months, then compared to 0.1% among controls, which was a statistically significant difference ($p<0.05$). The extent of improvement in glycaemic control was similar, albeit slightly inferior to that of DESMOND. Moreover, the effect size reflected a number of people needed to prevent additional diabetes medication use of four, meaning that exposure to X-PERT would prevent the need for diabetes medication use for one in every four persons.

In addition, the number needed to decrease diabetes medication was seven and thus, reflecting the beneficial effect of structured education upon individuals' self-care behaviours and the impact of such behaviours upon glycaemic control. A more recent evaluation of X-PERT; a study based on a large cohort of 3,342 people with T2DM, found that meaningful reductions in glycated haemoglobin were achieved as compared to usual care (-8.6 mmol/mol, $p<0.001$(Wheatley *et al.*, 2021)). There were also significant improvements in body weight, body mass index, fasting blood glucose, lipid profiles and blood pressure in the intervention group versus controls (all $p<0.05$) and thus, showing that the program helped to not only improve diabetes control but also cardiovascular risk. Notably, patient empowerment was found to have improved by 20% on average and thereby, supporting the usefulness of theoretically driven education programs for T2DM (Wheatley *et al.*, 2021).This therefore highlights the fact that the introduction of structured education in self-management for people with type 2 diabetes can lead to significant improvements in objective measurable measurements of patient function and well-being. This section has highlighted the nature of existing structured education programmes for people living with T2DM. This includes the theories serving as the foundation for the programmes as well as patterns of demonstrated effectiveness among target populations. They have been shown to have an impact in improving glycaemic control as well as short-, medium- and long-term outcomes in people with type 2 diabetes. It however serves to further emphasise the fact that the programmes are of particular benefit primarily within populations in majorly westernized countries (Wheatley *et al.*, 2021). However, the effectiveness of the self-management programmes is determined by the patient's cultural beliefs and adaptations as discussed in the next section and subsequently explored further in chapter 4.

2.5 Cultural Adaptation of Structured Education Programmes

Whereas there is wealth of literature highlighting the effectiveness of various type 2 diabetes mellitus self-management education intervention programmes, it is important to evaluate the cultural acceptability of any of these programmes before deciding on which one to implement. There is a wide range of attitudes and behaviours among people living with type 2 diabetes. Personal and cultural perceptions are viewed as important aspects to a favourable response in self-management and treatment. This section evaluates the importance of cultural background and adaptation on self-management programmes for people living with type 2 diabetes.

2.5.1 Importance of cultural adaptation

Largely, current structured education programs have been evaluated in white Caucasian populations and thus, the content and delivery lacks sensitivity to cultural and religious nuances, which can directly influence. The need to adapt educational programs to be congruent with the cultures of specific population groups with type 2 diabetes, such as diets, levels of physical activity and beliefs, has been reflected in a range of literature reporting upon diabetes outcomes and disparities in access to diabetes services (Hadjiconstantinou *et al.*, 2021). In any regard, the cultural adaptation of self-management programs for diabetes is inarguable given that culture-orientated care is almost synonymous with person-centred care, which has become the accepted standard of high quality care for persons with chronic disease in varied western settings (Goff *et al.,* 2020). Tailoring self-management education to culture is important as culture often dictates the rules by which members of said culture must comply, in order to remain a part of said culture and to achieve the benefits of belonging to such culture whether these are religious or non-religious outcomes (Hadjiconstantinou *et al.*, 2021). Indeed, spiritual wellbeing is a pertinent wider factor that can influence individual wellbeing and desires to engage in self-care efforts in persons with chronic disease and thus, tailoring self-management programs to cultural orientation is plausibly key to improving diabetes control and cardiovascular risk (Onyishi *et al.,* 2021).

One of the key problems of utilising established self-management programs for persons of minority ethnic groups and thus, differing cultural orientations, is that the provision of education is often compounded by language barriers and the acceptability of exercise and dietary recommendations is lacking due to poor congruence with cultural views, beliefs, ways of life and conveniences (Goff *et al.,* 2020). Qualitative research exploring the lived experiences of persons of minority ethnic groups in regard to exposure to non-culturally tailored education programs for diabetes has supported the former statement with individuals finding it difficult to understand and adopt the recommended self-care measures due to conflicts with culture (Ricci-Cabello *et al.,* 2014, Jager *et al.,* 2019). Difficulties in tailoring education for groups with different cultures is also observed from a care provider standpoint as language barriers often remain a hindering issue (Adu *et al.,* 2019). Such incongruence is likely to fuel ethnic disparities in outcomes from type 2 diabetes, which is an already extensive problem, with research showing that such groups observe more limited access to vital diabetes services, as well as poorer glycaemic control, higher insulin resistance and greater risk of micro- and macro-vascular complications, as compared to non-minority ethnic groups (Rodríguez & Campbell, 2017, Mathur *et al.*, 2020).

The value of culturally tailored self-management education programs has been evidenced in a recent meta-analysis of 37 studies where significant reductions in glycated haemoglobin levels by a mean of 0.3% were observed, as compared to baseline (Ricci-Cabello *et al.*, 2014). The efficacy of culturally tailored education programs for type 2 diabetes is likely under-estimated however, given that most evaluations of such programs, in the initial introduction period, have identified a number of difficulties and lessons learned to revise programs in the future (Yeary *et al.,* 2017, Alaofè *et al.*, 2021, Andersen *et al.,* 2021). Furthermore, research examining the issue of tailoring programmes to people of different cultural backgrounds have typically occurred within the context of the host country such as the UK (Hadjiconstantinou *et al.*, 2021). Research exploring the role and impact of culturally-adapted self-management education programs within the Gulf States has been scarce due to a lack of such programs having been designed or modified based on currently used programs in the western world *(Al Slamah et al*., 2020, Saha *et al.*, 2013). It was for these reasons that the work presented within this thesis began with a systematic review which aimed to understand the effectiveness and components of theory based structured education programmes for people living with type 2 diabetes which had also undergone some cultural adaptation to the populations they aimed to target (Chapter 4). The relevance of the findings of that review to Saudi Arabia are addressed later in the thesis.

2.5.2 Frameworks for cultural adaptation

Besides, evaluating the cultural acceptability of each programme by reviewing existing literature, it is important to determine how previous researchers have culturally adapted the interventions to fit the specific population group they are targeting. This is accomplished by a review of the literature on various frameworks used for cultural adaptation of the intervention and the outcome of each culturally adapted intervention. Many culturally adapted self-management education programs for type 2 diabetes have been founded upon the Cultural Adaptation Process Model (Domenech-Rodríguez & Wieling, 2004; Domenech-Rodríguez & Bernal, 2012).

The Cultural Adaptation Process Model (Domenech-Rodríguez & Wieling, 2004) aims to identify and account for three key components of culture; 1) the ethno-cultural beliefs among person groups, 2) tailoring evidence-based interventions to conform to such beliefs and 3) adapting the interventions to suit patient preferences and experiences among those belonging to a specific cultural group (Domenech-Rodríguez & Bernal, 2012). The model also encourages interventions to be delivered in the native persons language as this not only assists understanding of information communicated but it also promotes and demonstrates sensitivity and respect of culture to individuals, which can optimise acceptability, uptake and adherence; factors known to be vital in the context of type 2 diabetes (Domenech Rodríguez & Bernal, 2012, Khunti, 2019). Furthermore, the Cultural Adaptation Process Model aims to tailor interventions based on service user reported barriers and facilitators of adherence to specific recommendations, which is in regard to both prescribed therapy and self-care and thus, being relevant to self-management education for type 2 diabetes (Domenech-Rodríguez & Bernal, 2012). However, some limitations to this model include a point-in-time cultural tailoring of interventions, which may fail to recognise and respond to nuances over time that service users may become more accepted to and observe greater efficacy should such modifications be employed to maximise adaptation (Sit *et al*., 2020).

Other models used to culturally adapt clinical interventions, albeit not currently observed for self-management education programs for diabetes (Perera *et al*., 2020), are the Heuristic Framework for Cultural Adaptation (Barrera & Castro, 2006) and the Ecological Validity Model (Bernal *et al*., 1995).The Heuristic Framework for Cultural Adaptation (Barrera & Castro, 2006; Perera et al., 2020) seeks to gather information from population groups regarding how interventions can be tailored to suit their cultural and individual needs, followed by pilot design and testing of the adapted intervention and further tailoring as to optimise the interventions overall acceptability and impact upon important outcomes (Barrera *et al*., 2013). In contrast, the Ecological Validity Model (Bernal *et al*, 1995) has a more specific focus upon the intervention content as perceived by care providers (Barrera Jr & Castro, 2006). This is of particular importance in the case of T2DM, the intervention content plays a major role in ensuring that people receive information and education content that is of relevance to their condition as well as the specific cultural context (Bernal *et al*, 1995). This focus of the Ecological Validity Model on content and ensuring that it is congruent with sociocultural and religious patterns within the target location is of vital importance within the Saudi Arabian context which differs significantly from westernized cultures. Furthermore, the Ecological Validity Model is also one of the foremost in facilitating the identification of critical elements that could benefit from cultural adaptation as a means of increasing the uptake and adherence to recommended treatment plans for disease conditions (Barrera & Castro, 2006; Barrera *et al*., 2013; Bernal *et al*., 1995). The Ecological Validity Framework (EVF) model was therefore adopted in the current study (Chapter 4) to recognize the cultural congruence or acceptance in self-management education programs.

2.6 Summary

This chapter reviewed the literature relating to self-management of type 2 diabetes, diabetes care and national programmes. The chapter has shown that there is a major role for self-management in diabetes education and emphasised the importance of structured patient education in type 2 diabetes as a means of fostering active patient involvement in their care. The chapter has also demonstrated that while there is a place for self-management programmes, it is important that these programmes are designed in a manner that is sensitive to the differences in language, culture and beliefs of the people with type 2 diabetes. It therefore emphasised the importance of cultural adaptation to increase the effectiveness of such programmes among ethnic minorities in countries such as the UK and the US. Cultural adaptation is also of relevance in the development of structured self-management programmes in other countries such as Saudi Arabia. The next chapter, Chapter 3, will discuss the methodology and methods used in this study.

Chapter 3: Methodology and Methods

3.1 Overview

Chapter 3 provides an insight into the research design, theoretical underpinnings and the aims of each study in the research project. The overall justification for the approach to the study is described in the following chapter. The research methodology and methods for the qualitative studies undertaken in this thesis (Studies 2 and 3) are also more broadly explained and justified in the following chapter. The methods undertaken in the systematic review (Study1) and secondary data analysis (Study 4) are described separately within their respective chapters (Chapter 4 and Chapter 7).

3.2 Research Aims

This research was undertaken to determine the prerequisites for developing or adapting a culturally sensitive structured diabetes education programme for people living with type 2 diabetes in Saudi Arabia. The research project comprised four distinct studies that had specific aims:

- **Study 1:** This study aimed to synthesise studies on the effectiveness of theory-based structured self-management education programmes that have been culturally adapted for people living with type 2 diabetes. This was necessary to understand the status of the current primary research evidence and to ultimately inform the other three studies noted below.

- **Study 2:** This study aimed to explore the perspectives of healthcare professionals regarding the self-management education programmes for people living with type 2 diabetes including the perceived challenges and any issues experienced by service users in relation to gaining access to these programmes in Saudi Arabia. This was important in identifying the factors hindering or facilitating the use and uptake of self-management education locally, in order to guide ongoing practice and program delivery.

- **Study 3**: This study aimed to identify the perspectives of people living with type 2 diabetes regarding diabetes self-management and challenges and to explore the preferences and needs of these individuals with regard to diabetes self-management programmes. This study was also important as it sought to identify the varied patient-valued factors influencing the uptake of and adherence to self-management education. In turn, this could affect diabetes control and cardiovascular risk and thus, eliciting the information was important for recognising how current programs could be tailored to optimize adherence and support people in their longer-term management of type 2 diabetes.

- **Study 4**: This study aimed to analyse the scope, content and quality of routine data at KFHM (e.g., patients' demographic data, glycaemic control, type of treatment, type 2 diabetes complications and last follow-up clinic visit) collected as part of clinical care. This was necessary to identify whether existing data collected was sufficient and feasible for monitoring patient outcomes from type 2 diabetes and outcomes in response to self-management education exposure, which would permit future evaluation of program efficacy, at least to some extent.

3.3 Research Overview

The research undertaken in this thesis was informed and guided by the MRC Framework for developing and evaluating complex interventions (Craig *et al.,* 2008; Skivington *et al.,* 2021). Specifically, the work undertaken comprises mixed methods research across multiple phases involving a combination of quantitative and qualitative methods to achieve the research objectives. This represents a focus on the core elements and thereafter the development of the intervention phases of this framework. Accordingly in identifying the core elements and informing the development stage of a future intervention, a systematic review methodology was used to collect and analyse data from the extant literature on type 2 diabetes self-management programmes (Study 1, discussed further in Chapter 4). Next, a qualitative approach based on semi-structured interviews was used to compile the perspectives of people living with type 2 diabetes and their healthcare teams in Saudi Arabia (Studies 2 and 3, the findings of which are discussed in Chapters 5 and 6). Finally, routinely gathered data from KFHM were examined for scope, quality and content and then included in the analysis (Study 4, discussed further in Chapter 7). In accordance with the development stage of the MRC framework, these elements were considered to be important in: (i)identifying existing programmes that could potentially be adapted to a Saudi context; (ii) engaging stakeholders to identify their perceptions towards structured education programmes, aspects related to the context in which a potential programme would be situated and potential barriers and facilitators to engagement in such a programme and (iii) identifying and making recommendations for the future outcome and evaluation of a potential structured education programme.

3.4 Research Design and Theoretical Position

3.4.1 Philosophical Position

As summarised in Subsection 3.3, the overall research design comprised a mixed-methods approach that facilitated the achievement of the various research objectives. The mixed-methods research methodology is frequently used to merge specific findings from different data sources and perspectives (quantitative and qualitative research) for triangulating the research objective (Carter *et al.,* 2014), though this was not the objective of the design employed herein. The adoption of this approach in this research study was aimed at ensuring a complete investigation that provides the best opportunity to answer the research questions (Doyle *et al.,* 2009).

The mixed-methods design in the current research is based on the philosophical perspective of pragmatism and provides a framework that ensures a focus on deriving knowledge that could be used to change/induce actions in current and ongoing practice; to recognise and acknowledge the relationship between individual experiences and behaviours (herein, the behaviour is self-care/management); and to inquire into topics by using an experiential approach and to identify the factors that influence self-management uptake and adherence (Kelly & Cordeiro, 2020). Thus, the pragmatic approach sustains focus to elicit the likely research outcomes and answer specific sub-questions on diabetes self-management, which are essential to inform the key implications and recommendations for clinical practice (Kaushik & Walsh, 2019).

Alternative perspectives to pragmatism, including a purist lens of interpretivism and positivism alone, were considered to be less suitable for this research. First, interpretivism assumes that social reality is not a single entity or objective but rather an outcome that is influenced by social experiences, contexts and constructions, including language and consciousness, and seeks to understand the reasons why individuals think or act in a specific way (Goldkuhl, 2012). This was important in addressing the aim of this study, but this perspective alone wouldn't have allowed for an evaluation of the quality and scope of existing quantitative data that may be useful to use in the future design, development and evaluation of a structured education programme (addressed in Study 4). Given that the research aligned with the developmental phase of the MRC framework, it was considered appropriate to explore different data sources and types that could be used to support the future development and evaluation fo such a programme.

Similarly, however, a purist positivist approach was not appropriate since positivism adheres to factual knowledge by measuring variables via direct observation and thus, positivist researchers tend to adopt distant positions to that of participants in order to generate highly objective evidence (Park, Konge & Artino, 2020). Such research is often typified by objective, measurable results from studies that can be readily replicated (Everest, 2014). However, this does not provide information relating to contextual features and characteristics that might influence patterns of illness and health-related behaviours (Berkovich, 2018; Collins & Stockton, 2018) which was of relevance to the purpose of the current study. Hence, a combination of approaches underpinned by both interpretivism and positivism was important for addressing the range of different questions posed in the current study.

Research questions were answered using different approaches depending on the susceptibility of the information needed to generate evidence on applicability (Chowdhury, 2014). The approaches include qualitative and quantitative research methods to investigate philosophical pragmatism. In view of the wide range of intervening factors, variables and stakeholders a multiplicity of approaches and methods would facilitate a complete understanding that could guide future efforts in this endeavour. The study therefore necessitated application of mixed method approach to develop complete insights and understanding of the phenomenon under examination. Health services implementation and assessment are always evolving, and a pragmatic approach allows for more adaptability to these changes (Cresswell *et al*, 2011; Halcomb & Hickman, 2015; Cresswell & Cressell, 2018).

3.4.2 Mixed Methods Designs

Research in the field of health is often characterised by the need to explore complex interventions that often require collaboration, cooperation and interactions between a range of different stakeholders in multidisciplinary health care teams (Shifferdecker & Reed, 2009). Mixed methods research, while a continuously evolving approach to research, has become relatively common in health and health related research studies. This is due in part to the fact that health care service delivery is a complex phenomenon and often requires different elements of data collection and subsequent analysis to appropriately capture this complexity (O'Cathain *et al*, 2008; Tariq & Woodman, 2010). One of the main elements of the definition of mixed methods research is the fact that such research involves the 'mixing' of widely different quantitative and qualitative research methods in a single study (Cresswell *et al.,* 2011; Halcomb & Hickman, 2015; Saunders *et al.*, 2016) therefore producing both objective numerical as well as subjective, non-numerical data to provide what has been argued to be a well-rounded view of the phenomenon being examined (O'Cathain *et al*, 2008; Saunders *et al.,* 2016).

Alternative methodologies that are frequently used in qualitative research include ethnography and grounded theory. Ethnography refers to the exploration of social interactions and behaviours that predominantly arise within groups or teams with an aim to gain insight into the views, actions and reasoning for a specific social phenomenon (Reeves, Ayelet & Hodges, 2008). As the ethnographic theory is not designed to capture individual nuances and differences of opinion (Jones & Smith, 2017), the ethnographic approach was considered to be unsuitable for eliciting important person-orientated issues in research that explores individuals' and health professionals' views of T2DM self-management. Similarly, grounded theory, which seeks to derive novel information when information about a specific topic and enable researchers to posit new theories about reported data from individual accounts (Chun Tie, Birks & Francis, 2019), was an unsuitable approach for evaluating the topic of interest in the present research.

It is acknowledged that attention to the research questions play a major role in determining the choice of methods for any single proposed study. However, it is important to note that mixed methods research are of particular benefit in studies where a range of different perspectives provides better insights and understanding of the phenomenon under examination (Halcomb & Hickman, 2015). This was relevant to the focus of the current study.

A factor that is often worth considering is the fact that mixed methods research has the potential to produce significantly large volumes of data (O'Cathain *et al.,* 2008; Cresswell *et al.,* 2011; Saunders *et al.,* 2016) and as such cannot be adopted without preparation and thought. However, there have been the development of several guidelines that have facilitated the conduct of mixed methods research in health and health related research that include qualitative and quantitative approaches. In addition to a careful consideration of the research questions to determine the relevance of mixed methods, researchers need to determine the relative predominance of the different data types in the overall study and develop sampling strategies in line with these decisions. (Schifferdecker & Reed, 2009; Cresswell *et al.,* 2011; Halcomb & Hickman, 2015). It is anticipated that with clear adherence to available guidelines, there is a place for carrying out mixed methods research in a manner that provides answers to a complex question that has implications for managing people with type 2 diabetes in the future. Accordingly, in the context of the current study, the adoption of a pragmatic paradigm and use of inductive mixed method approach enabled the maintenance of a relatively broad and open approach to data collection to permit an in-depth, focused analysis of the data of interest with regard to different aims (Creswell & Creswell, 2018) and was crucial for gaining insight into the essential components of an effective T2DM self-management education programme. Subsections 3.5 and 3.6 present the rationale for the methodological approaches adopted in the current study.

3.5 Rationale for the Systematic Review Approach in Study 1

The MRC framework for complex interventions (Craig *et al.,*2008; Medical Research Council, 2012) recommends that the best available evidence should be used for the systematic development of complex interventions. A systematic review allows the gathering of all of the evidence on the research topic, refined by the use of specific inclusion criteria, to answer the research question (Cochrane Collaboration, 2011). Systematic reviews constitute a good information-gathering approach (Mulrow, 1994) as a wide pool of data can be systematically searched and screened for quality (Maltby *et al.,* 2013), which makes the data more reliable for use in decision making and allows evaluation of the consistency and generalisability of the findings from participant subgroups (Maltby *et al.*, 2013). Another benefit of systematic reviews is that they facilitate a precise and powerful estimation of treatment effectiveness or the potential risks associated with an intervention (Gough, Oliver & Thomas, 2012) whereas limiting bias and strengthening the accuracy and reliability of the conclusions (Pollock & Berge, 2018). Therefore, the systematic review method was adopted for Study 1 to identify and evaluate the relevant literature in this field and to gather high-quality data that could be used as a basis for the planned intervention.

A literature review was necessary to, first, summarise the current status and impact of theory-based, culturally adapted self-management education programmes for people living with type 2 diabetes and, second, to identify current methodological issues and persistent knowledge gaps across the primary research base in order to guide the methodology of the proposed mixed-methods study. Moreover, it was important to decipher, prior to the designing and conducting of the mixed-methods study, whether the primary evidence base comprised programs and populations that could be generalised to the local Saudi context (Steckler, 2008). Indeed, due to health-care system disparities in the health operations, population characteristics and the characteristics and acceptability of self-management programs between Western and non-Western countries, such as Saudi Arabia, it was necessary to design a mixed-methods study following the completion of the systematic review.

In Saudi Arabia, type 2 diabetes is one of the most prevalent and burdensome health problems and, based on epidemiological projections of a continued increase in prevalence in the foreseeable future, imminent action is needed to address the current and ongoing disparities in service user demand and limited service capacity (Naeem, 2015). Both locally and internationally, increased self-care through the wider implementation of self-management programs to encourage people’s autonomy and accountability for their health and wellbeing (Masupe *et al.,* 2018) remains one of the advocated means for improving type 2 diabetes outcomes. However, it is prudent to determine whether self-management of type 2 diabetes would be acceptable to the local Saudi population and whether program implementation is feasible in the context of the current diabetes service operations, funding and resource availability, particularly in congruence with cultural beliefs that are vested in the Western medical model of care and treatment. Chapter 4 elucidates the methods and findings of the systematic review.

3.6 Rationale for the Use of Qualitative Methodology in Studies 2 and 3

In health care research, qualitative methods facilitate access to individual views, perspectives and expectations from a situation or phenomenon, or enable the studying of a topic that is difficult to investigate with quantitative methods (Morse & Field 1995). Understanding experiences, beliefs, attitudes, and behaviours is crucial to clinical care because these aspects have a profound effect on perception of health, health-seeking behaviour and adherence to treatment. Furthermore, qualitative research can play a role in generating hypotheses for quantitative research, providing insights that can be used to help interpret the findings of quantitative research and enabling individuals and clinicians to say, in their own words, what matters to them and why (Patton, 1990; Morse & Field, 1995).

The MRC framework for developing complex interventions suggests that authors should identify the evidence base (the reason why the systematic review was conducted first) followed by the recognition and application of theory, in order to understand interventional needs (Craig *et al.,* 2008). These data are best gathered through a qualitative research method, such as interviews, as this can help derive individually valued, important information that cannot be feasibly or reliably captured through quantitative research methods (Jamshed, 2014). Yardley *et al.* (2015) emphasised the importance of qualitative research when developing clinical interventions. The participants of an intervention often use the intervention autonomously; therefore, understanding how the participants will use the intervention(s) is vital to designing an effective intervention. Therefore, this research used methodsto gather in-depth evidence for developing self-management interventions. The evidence generated, in turn, was used to identify people's perceptions towards the need for, the potential design of, and their engagement with a structured education programme.

Much of the qualitative literature on patients 'views and experiences of self-management has identified that various barriers to the uptake and adherence of programme and self-care activity exist across all patients, care provider, service and system levels (Jain *et al.,* 2020). Even qualitative research that was recently conducted in Saudi Arabia has revealed the existence of similar barriers to patient's acceptance of self-management as a diabetes management approach; however, the additional problem of insufficient tailoring of programmes to conform to the Saudi culture hinder the initiative further (Al Slamah *et al.,* 2020). Given the paucity of qualitative evidence on the perceptions and perspectives of people living with type 2 diabetesin Saudi Arabia, there was a need for an in-depth exploration of this gap. This knowledge gap was further compounded by the lack of Saudi-specific evidence on research to develop complex interventions, such as self-management education programmes, which research can be used in other settings to inform programme development where the programmes have been observed to result in meaningful improvements in T2DM outcomes (Davies *et al.,* 2020; Jafari *et al.,* 2021; Berger *et al.,* 2017; Captieux *et al.,* 2018). Most of the existing evidence base comprises evidence from research that has focused upon the efficacy of diverse self-management education programmes; thus, programme design and development/revision have suffered due to the lack of qualitative research to explore program acceptability and impact from the patient and clinician perspective (Captieux *et al.,* 2018). In this research, the qualitative methodology was a key aspect for addressing the knowledge gap and for guiding the development of a self-management education programme that possesses sufficient potential to confer clinical effectiveness when evaluated at a later time point.

3.6.1 Semi-Structured Interviews

With regard to the rationale for the qualitative methods chosen in Studies 2 and 3, semi-structured interviews were chosen for several reasons. First, interviews are commonly used to explore the participants' perceptions and understanding of the research topic (Braun & Clarke, 2006). Interviews provide in-depth, rich data about personal experiences in specific socioeconomic and geographical circumstances (Braun & Clarke, 2014), and this characteristic was considered an important requirement in the present study, wherein interviews were used to gather the views of type 2 diabetes participants and their health care team on diabetes self-management as well as to identify common themes among their experiences. A semi-structured interview approach facilitates questions that elicit both closed and open-ended responses from participants and ensures that responses remain not only focused upon a specific topic of interest but also, by enabling elaboration, avoid truncating participants' views/responses and thereby facilitate the capturing of more meaningful and in-depth answers to specific issues (Jamshed, 2014).

In contrast, an alternative to data collection in qualitative research involves focus groups, which are interviews conducted among small groups of participants (Jamshed, 2014). Though this approach can often be useful in enhancing the efficiency and convenience of interviewing, the responses attained can sometimes result in bias when dominant members of a group provide most of the responses and the views of others go unrecognised (Nyumba *et al.,* 2018). Therefore, the trustworthiness of focus group data depends upon the interviewer's approach to and supervision of the interview process, whereby balanced participation across group members is encouraged (Jamshed, 2014). However, ongoing restrictions arising from the COVID pandemic meant that it wasn't possible to organise large groups of individuals for the purpose of conducting focus groups. Therefore, the one-to-one semi-structured approach to interviewing was employed among both people living with type 2 diabetesand clinicians involved in their care.

Both clinicians and people living with type 2 diabetes were chosen because the views of both parties can facilitate the development of the self-management intervention by ensuring that the programme is culturally sensitive and accounts for patient preferences and clinician views about crucial program content that is essential to improve type 2 diabetes control and outcomes. Furthermore, the reported barriers to self-management uptake, which were considered important factors for evaluation in the present study, could be used to refine the programme by eliminating or minimising such barriers to optimise programme uptake and long-term adherence. Chapters 5 and 6 present the findings of the qualitative Study 2 and Study 3, respectively.

3.7 Rationale for the Use of Secondary Data Analysis in Study 4

The secondary data analysis applied a quantitative perspective to data collected from an existing database of people with type 2 diabetes registered at the KFHM. The analysis of the extent and quality of data collected was necessary to obtain not only an understanding of the service user's needs (e.g., patient demographics, glycaemic control, type of treatment, type 2 diabetes complications and follow-up) but also for informing the potential evaluation of a future structured education programme. This study design was congruent with a retrospective type of observational research because historical data were collected from an electronic database (Wickham, 2019). The secondary methodological approach was necessary in view of the ease and convenience of analysing pre-existing data collected by the diabetes centre and facilitated an analysis with regard to the time and funding constraints that precluded the design and conduct of a primary observational study (Aveyard, 2018). Despite the benefits of analytical research involving a retrospective design, including an ability to rapidly derive information from pre-existing data, such research can suffer from various limitations due to the temporality of the data (Sedgwick, 2014). Due to the lack of control over the exposure and outcome variables collected, such research can be subject to issues of selection, confounding and information biases, as well as issues of generalisability (external validity) because the populations included may be restricted to comprise specific characteristics (Pannucci & Wilkins, 2010). These observations of the data were necessary to inform judgements about the extent and quality of data that are currently collected by the local diabetes service and, thus, to devise strategies to improve data collection to benefit an ongoing evaluation. Previous type 2 diabetes research has revealed that secondary analytical methods can derive useful evidence to help guide ongoing data collection and the development of interventions or tailoring as a means to optimise the quality of care and, consequently, the patient outcomes (Al Slamah *et al.,* 2020; Schmidt *et al.,* 2019; Harvey, Craney & Kelly, 2002). This is exemplified by Al *Slamah et al.* (2020) whose focus groups helped highlight the importance of cultural beliefs and lifestyles on patterns of patient adherence and commitment to the self-management programmes. Chapter 7 describes the research methods and findings obtained from Study 4.

3.8 Research Setting

The research was conducted at a Diabetes Centre in King Fahad Hospital Madinah (KFHM) which was established in 1979 and is managed by the Ministry of Health (MoH) in the Kingdom of Saudi Arabia. KFHM is one of the largest referral hospitals in Madinah and consists of five floors with a total capacity of 500 beds. The four clinical centres affiliated with KFHM include the Specialized Dental Center, the King Abdulaziz Center for Kidney Patients, the Endocrine and Diabetes Center and the Center for Oncology and Hematology. KFHM is one of the most important hospitals in Madinah as it provides a range of specialist services for most of the prevalent and burdensome health issues that affect the population. In the first half of 2020, KFHM provided integrated medical services to 170,221 registered patients across a number of medical specialties and departments as well as the affiliated centres, and the statistics presented by the Director of KFHM, indicated that 20,580 registered patients visited the Endocrine and Diabetes Center. People with diabetes who are referred to KFHM by their general practitioners or other hospitals are offered ongoing individual counselling by dieticians, nurses or physicians as well as group education delivered by a multidisciplinary health care team. The services provided focus on various themes, such as diabetes treatment, prevention of diabetes-related complications, self-monitoring of blood glucose and maintaining a good diet and physical activity levels. People living with type 2 diabetes registered with the hospital and HCPs working in the Diabetes Centre of KFHM were invited to participate in the current study.

3.9 Qualitative Research Procedures in Studies 2 and 3

This section provides a detailed description of the participants, data collection, data analysis and ethical considerations in the qualitative studies.

3.9.1 Sampling Strategy

The population for Study 2 included multidisciplinary HCPs at the diabetes centre who were involved in the care of people with type 2 diabetes at the time of the study. Three types of HCPs were involved in this research: doctors specialising in medical management, with knowledge and experience of the condition and of self-management support; nurses involved in the treatment and management of people with type 2 diabetes and dieticians focusing on dietary changes which are crucial to diabetes self-management. These health professional groups were selected for inclusion in the interviews as they comprise the majority of professionals involved in the multidisciplinary care of people with type 2 diabetes both in Saudi Arabia and worldwide (McGill *et al.,* 2017). As a result, such health professionals are considered to have important insights that would help inform the development or adaptation of a future diabetes education and self-management programme. HCPs involved in this study were required to have at least 1 year of experience in providing care to people living with type 2 diabetes at the local diabetes centre. This requirement was included to ensure that the HCPs involved in the study fully understood the challenges regarding diabetes and were able to provide accurate information on self-management among people living with type 2 diabetes. HCPs who were not directly involved in diabetes care were excluded. Practitioners with less than 1 year of diabetes management experience were excluded as it was considered that they might not be able to offer insightful views of diabetes self-management due to their relatively new qualification/training status.

Study 3 included people living with type 2 diabetes who visited and were registered at the diabetes centre at KFHM for routine care and follow-up. These people included adult men and women (age ≥18 years) who were able to communicate in Arabic and provided written informed consent for study participation. The recruitment strategy was based on the person’s age, sex, time from initial diagnosis, treatment regimen (diet controlled, oral medication, insulin or both), level of education, presence or absence of diabetes-related complications and previous experience with self-management programmes. This approach was devised to enable the observer researcher to recognise or understand a broad range of different perspectives and experiences of self-management and to explore different needs from a future self-management programme. Exclusion criteria were refusal to participate in the study, people diagnosed with type 1 diabetes, people younger than 18 years and/or mentally challenged individuals or individuals with impaired ability to communicate in or understand Arabic. Participants were assured of the confidentiality of the data collected during the study. Sufficient time was given to each participant to read and understand the information sheet and to decide on voluntary participation.

3.9.2 Sample Size

For the qualitative studies, the target sample sizes were based on best practice recommendations for qualitative research and those similar to previously research after having also explored the views of HCPs and patients with regard to diabetes self-management education (Frost *et al.,* 2014; Gomersall, Madill & Summers, 2011). Thus, the qualitative sample size was expected to include 15–20 participants per group (30–40 participants in total covering both HCPs and people living with type 2 diabetes), but the actual sample size was simultaneously determined with the data collection as the research design incorporated data saturation (Saunders *et al.,* 2017). This involved recognising the point at which no additional information was gathered from participants, in order to ensure that interviewing was not prematurely terminated (Saunders *et al.,* 2017).

3.9.3 Recruitment

Health professionals were recruited using a purposive sampling technique because this was necessary to identify a range of professional groups and invite those who met the inclusion criteria and would be willing to participate in the research study. Purposive sampling is important when recruiting health professionals who were most likely to provide rich accounts of information pertaining to the views, perceptions and beliefs regarding the role of self-management for people living with type 2 diabetes in Saudi Arabia (Palinkas *et al.,* 2015). Though purposive sampling forms a type of selective recruitment that potentially contains an inherent risk of selection bias, the approach was necessary for the former reasons, particularly as no other appropriate methods were amenable to recruiting the defined professional group (Martinez-Mesa *et al.,* 2016).

After obtaining permission from the Director of the Diabetes Centre of KFHM, HCP recruitment was initiated via an email with an invitation for study participation (Appendix 1) and the participant information sheets (Appendix 2). HCPs who expressed an interest in study participation (either by responding directly to the researcher via email or telephonically) in the two weeks after the initial email contact, were contacted before the interview to discuss the research study. All participants read, understood and signed formal informed consent forms. The consent forms comprised all relevant information about the research study to enable the provision of informed and valid consent by the participants including: the purpose of the research study; participant requirements; and data management to protect subject confidentiality. Furthermore, participants were informed of their principal research and human rights, including the right to withdraw their consent at any time point, following which all the data collected from them would be permanently deleted. Consent forms were distributed by email to all health professionals recruited, which were signed for the principal researcher.

Recruitment of people living with type 2 diabetes participants commenced with a visit by the researcher to the diabetes centre at KFHM to explain the purpose of the study and the exclusion and inclusion criteria to the nursing staff who subsequently identified potential participants from outpatients attending routine follow-up clinic visits. A total of 30 potential participants were sent invitation letters with patient information sheets for participation in this study (Appendices1and 3). Due to cultural and religious restrictions, a female member of staff (SA) at the KFHM facilitated the initial approach to the recruitment of female participants and the subsequent data collection from this participant group. The researcher contacted potential male participants to confirm their willingness to participate, answer any questions and arrange the time and venue for the interviews. Similarly, a female member of staff (SA) contacted female participants to discuss the study further and address their questions and arrange the time and venue for the interviews.

3.9.4 Data Collection Procedure

Data for studies 2 and 3 were collected from September to December 2020 via semi-structured interviews with HCPs and people living with type 2 diabetes participants, respectively.

3.9.4.1 Interview Guide Development

Two different interview topic guides were developed (i.e., one for the patient interviews and one for those with the HCPs –Appendices4 and 5). The interview topic guides were developed and refined based on the findings of the systematic review of self-management that was undertaken by the researcher. Specifically, the questions in the semi-structured interview covered topics pertaining to participant preferences, needs and experiences on current T2DM self-management and inquired into the cultural appropriateness of self-management education. Moreover, the interviews explored various facilitators and barriers of self-management within routine diabetes care. These topics were identified from the systematic review and, thus, were sufficiently positioned to elicit all important information needed to address the central research question. Probing questions were used to elicit in-depth descriptions from the participants. Two interviewers were employed to conduct data collection: one who was fluent in both English and Arabic (BA) and another who was fluent in Arabic (SA; for female participants only).

3.9.4.2 Pilot Interviews

Before conducting interviews in qualitative research, it is advisable to pilot the interviews (Gill *et al.,* 2008). Accordingly, a pilot interview were conducted using the translated interview guide with one HCP and one patient in order to check the wording of the interview questions and to determine whether the questions were phrased in a simple manner to enable clear and accurate understanding by the participants. In addition, the pilot interviews allowed the researcher to establish the clarity of the topic guide and to determine effectiveness of the questions in eliciting responses and the feasibility of participants in answering the questions within the time allocated. Furthermore, it was important to identify contextual details including location of the interview and level of privacy that could ease the participants and ensure that they were comfortable during the interview process. The final series of questions was amended and discussed with the supervisors to ensure that substantial, focused and meaningful responses could be elicited from the participants.

There was however no subsequent debriefing carried out for the main interviews. This decision was made because of the fact that the interviews were conducted within the context of bustling diabetes clinics. The time limitation made it difficult to ask participants to wait longer for a full debriefing at the end of the working day. Furthermore, it was anticipated that the pilot interviews had helped to provide the researcher with valuable insight into the contextual features and characteristics that could have an impact on the resulting evidence.

3.9.4.3 Interviews with HCPs

Prior to commencing the interview, the researcher briefly explained the nature of the study, gave participants a chance to ask any questions, and assured them of the voluntary nature of participation and their right to withdraw without giving any explanation at any time during the study. The interviews were conducted face-to-face by the researcher (BA) in the consultation rooms of the relevant HCPs at the diabetes centre. In accordance with the participants’ preferences, all interviews were conducted in Arabic and were estimated to last for 30–60 minutes. HCPs were asked to complete a brief questionnaire on demographics, including: age, sex, specialty, educational level, years of experience, and length of engagement with self-management educational programmes (Appendix 6). The researcher made field notes after each interview to highlight responses that were common, deviated from the expected responses or contained information that was verbally and/or non-verbally emphasised. Interviews continued until no new data were apparent, thereby promoting the attainment of data saturation as a means of limiting the risk of bias in data collection. Thus, data collection and analysis occurred simultaneously to help attain data saturation, which is an important means for enhancing the dependability of the data obtained. Saturation provides a theoretical basis for terminating data collection and, thus, avoids bias related to truncation of data collection (Saunders *et al.,* 2017). While it is acknowledged that there has been some debate over the role of saturation in different data collection methods (Gill *et al.,* 2008; Saunders *et al.,* 2017), data collection was continued until no new themes or data were revealed. Therefore, the overall sample size for the qualitative research was determined by the point when saturation was attained.

3.9.4.4 Interviews with people living with T2DM

All interviews were conducted by the researcher (BA) and the female nurse (SA) in a diabetes education room within the Diabetes Centre of KFHM. Before commencing each interview, the researcher reviewed the participant information sheet again and answered any questions that the participant had with regard to the study. Moreover, prior to the interviews with each participant, the researcher clarified the aim of the study, which was to investigate the participant’s views and experiences with regard to diabetes self-management and emphasised that the main focus of the research was to explore the issues that participant’s experience with their health care team and the health care system in general. Furthermore, participants were reassured that their participation would not affect the care services that they received as all responses would be anonymised before analysis and would not be communicated to the health care team.

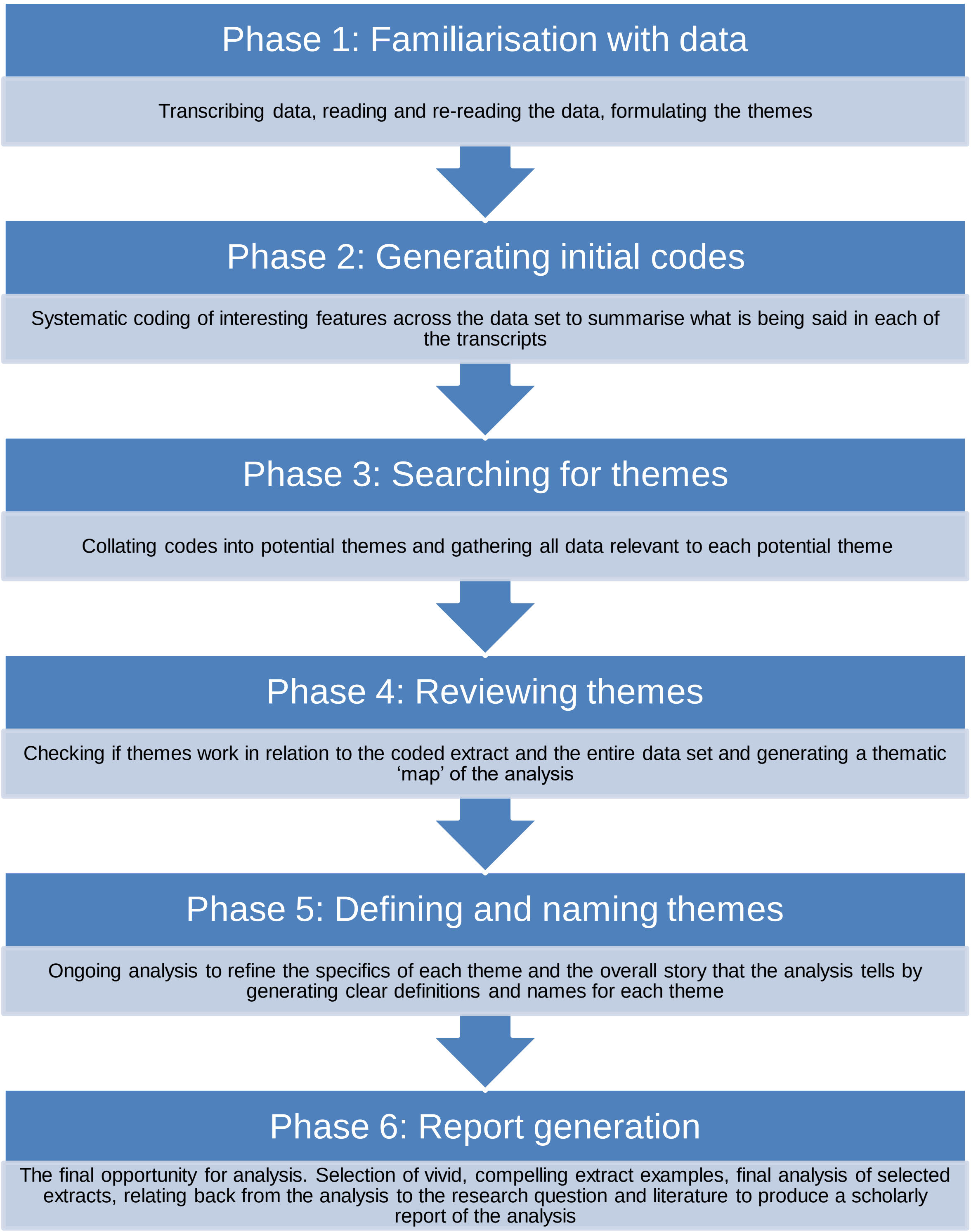
Each interview lasted for 30–60 minutes. At the beginning of each interview, the interviewer introduced himself or herself and explained the objective of the semi-structured discussion. Participants were reminded that the content of their interview was confidential and would only be discussed with supervisors. Moreover, participants were reminded of their right to refuse to answer any question and to stop the interview at any time. However, no participant refused to answer any question or asked to stop the interview. All interviews were audio-recorded; participants were asked to use only their first names during the interview and were assured that their names would not be used in the transcript. During the interview, participants were asked to complete a brief questionnaire on demographics, including: age, sex, duration of diabetes, current treatment, educational attainment, presence of diabetes-related complications and previous experience with self-management programmes (Appendix 7). Since more than a single interviewer was conducting the interviews with the participants, debriefings at the end of each day of interviews helped develop summaries of overall impressions, experiences and findings. The debriefing was carried out by the researcher by at the end of each day by sitting with the individual responsible for collecting the research data. The daily discussions related to the patterns of flow and the tenor of the day’s interviews. The notes taken during this debriefing were also viewed as a component of the data. This was aimed at increasing the self-reflection of the interviewers' influence on, and potential bias during, the data collection process. It has been suggested that peer debriefs have the benefit of providing valuable insights for interpreting thematic content in qualitative research (Reñosa*et al*, 2019; Simoni *et al,* 2019).

3.9.4.5 Transcription

Data transcription is an important stage in qualitative research, particularly when conducted using the interview method. Data transcription is frequently considered a technical task that does not involve the extensive application of cognitive functions (Kumar, Little, & Britten, 2003); however, Bailey (2008) argued that the process of transcription requires reduction, interpretation and representation to ensure that the text produced is readable and meaningful. Therefore, data transcription cannot be construed as an easy task and requires complete attention and concentration to understand the conversation and to reflect on situational and non-verbal responses. To achieve a high level of accuracy, to avoid possible errors in the translation process and to improve veracity, three main factors that affect the quality of translation must be considered carefully by researchers conducting qualitative research in the field of nursing: the translator, the back-translation and the culture and language (Chen & Boore, 2010). In the qualitative studies included in the present research, the researcher repeatedly listened to the recordings several times to gain familiarity with the data and to ensure that all relevant aspects were captured accurately during transcription. The transcripts were read and compared with the recording to verify the accuracy and mistakes, if any, were corrected. The bilingual researcher, whose native language was Arabic, translated the final version of the transcripts from Arabic to English. To ensure that the translation was as accurate as possible, transcripts of early interviews were discussed with the researcher's supervisory team, which comprises native English speakers. The anonymity and confidentiality of participants were maintained at this supervisor-review stage by anonymising the transcripts to exclude all participant-identifying information and all transcripts were given unique codes and numbers.

3.9.5 Data Analysis

The key aim of qualitative data analysis is to elicit the vividness of the descriptions of phenomena by participants (Dey, 1993). The analysis and interpretation of qualitative data collected in this study followed well-established procedures for the rigorous analysis of data collected through semi-structured interviews. The interview data were analysed using inductive thematic analysis, as broadly proposed by Braun & Clarke (2006), which involves the identification and reporting of themes from a data set. Thematic analysis is centred on a formalised process involving analytical steps, and ensured that the thematic analysis in this study was transparent and facilitated a reflective process. Thematic analysis was chosen as an analytical method in this study because it is independent of theory and epistemology, and facilitates a rich, detailed account of data: ‘thematising meanings is one of the few shared skills across qualitative analysis’ (Holloway & Todres, 2003, p. 347). In addition, thematic analysis is a useful and flexible method for qualitative research that is useful across different methods (Braun & Clarke, 2006). The data analysis in this study adhered to the principles of thematic analysis described by Braun & Clarke (2006) that include data familiarisation, initial coding and theming of the data and review and confirmation of the codes and themes, as described further below and depicted in Figure 3.



Phase 1: Familiarisation with data

Transcribing data, reading and re-reading the data, formulating the themes

Phase 2: Generating initial codes

Systematic coding of interesting features across the data set to summarise what is being said in each of the transcripts

Phase 3: Searching for themes

Collating codes into potential themes and gathering all data relevant to each potential theme

Phase 4: Reviewing themes

Checking if themes work in relation to the coded extract and the entire data set and generating a thematic 'map' of the analysis

Phase 5: Defining and naming themes

Ongoing analysis to refine the specifics of each theme and the overall story that the analysis tells by generating clear definitions and names for each theme

Phase 6: Report generation

The final opportunity for analysis. Selection of vivid, compelling extract examples, final analysis of selected extracts, relating back from the analysis to the research question and literature to produce a scholarly report of the analysis

Figure 4 : Overview of thematic analysis approach described by Braun and Clarke (2006) that was applied in the qualitative studies.

During Phase 1 of familiarization with the data, the researcher read and listened to all transcripts several times and at different stages to gain familiarity with the data. The researcher formulated a few general ideas about key codes and potential themes and interesting insights that the data generated. The generation of initial codes are considered an important element for data analysis and involves the creation of precise, descriptive labels for important features of the data that are relevant to the research question. In phase 2, after re-reading the first few transcripts and reviewing the range and depth of the data, a list of initial codes to categorise or index the data were generated with the assistance of the research supervisors. In the third phrase, after all the raw data were initially coded and collated, possible combinations of different codes were considered in order to derive potential themes that were then refined in relation to the extracted codes and the data set. Accordingly, in the fourth phase all the codes for each theme were re-read to explore the interrelationship of the themes with each other and with regard to the sociocultural context wherein they emerged (Crowe *et al.,* 2015). Then the fifth phase had the credibility of the reviewed themes considered by relating them back to the data set and discussing them with the supervisors in relation to the research question. Finally, in the final phase, by relating back to the research questions, the meanings gleaned from the participants' experiences were described in a meaningful text that was thematically organised and illustrated with quotes that were representative of the perceptions and experiences that were recorded.

3.9.6 Data Rigour

Besides data saturation, several techniques were employed to enhance the trustworthiness of the qualitative data because qualitative research is inherently prone to researcher subjectivity bias: a factor that contributes to impairments in credibility, dependability and confirmability (Noble & Smith, 2015). Moreover, it is important to note the various controversies pertaining to the recognition of the point of data saturation as well as the achievement of a general consensus around its importance by reflecting or promoting the credibility of the data that has been captured (Saunders *et al.,* 2017). The majority of qualitative studies that employ saturation utilise subjective means to determine the point of saturation, though a few qualitative studies have used more objective and reliable statistical approaches (Braun & Clarke, 2021). However, to ensure simplicity in data collection and analysis, the researcher utilised a subjective approach to identify the point of saturation, particularly as such an identification of the attainment of saturation has not been found to invalidate the findings of qualitative research as compared to research wherein saturation has been statistically assessed (Hennink & Kaiser, 2022).

First, member checking (respondent validation) was undertaken by establishing the participants 'views on whether the data reported in the analysis accurately reflected their original responses and the meaning of such responses. This technique optimises the dependability and confirmability of qualitative data (Birt *et al.,* 2016). One of the measures taken was to confirm the accuracy of the reported findings with two randomly selected subjects. Secondly, additional confirmability of the data was achieved through investigator triangulation, which involved agreement between the researcher and one of the supervisors, experienced in qualitative research, on the codes and themes that emerged from the data (Adams, Bateman & Becker, 2015).

It was important to acknowledge that when one is undergoing a research project, one does so influenced by their previous experiences. This means that there is the potential that it is not always possible for the researcher to see the whole picture at all times (Creswell *et al,* 2011; Everest, 2014). At every stage of the research process it is therefore important to remain conscious of how one's personal experiences could have an impact on narrative research (Doyle *et al,* 2009). The philosophical outlook of the researcher in this thesis has had an impact on several elements of the research including but not limited to the choice of method, questions for the participants, the interpretation of their responses as well as how these findings are presented (Creswell *et al,* 2011). Reflexivity is of benefit in such situations since it involves active reflection on personal characteristics, experiences, values and beliefs that could influence the research process (Halcomb & Hickman, 2015). In addition there was also a lot of thought about the researcher's roles as the researcher leading the study as well as a Saudi national with insight into the surrounding social, cultural and religious environment (Everest, 2014). It was therefore vital that an effort was constantly made to remain aware of this during the project. To achieve this, the principal researcher retained a meticulous log and journal of all research processes that were undertaken, as a reflective form of practice permits the recognition of researcher subjectivity and stimulates actions that minimise the emergence of bias in the reported data (Noble & Smith, 2015). The benefits provided by these actions served to emphasise the importance of such measures to provide valuable in-depth insights and understanding of areas under investigation. The conclusion was therefore that such methods would be considered for future research if this was deemed necessary.

Furthermore, the researcher considered the feasibility of deviant case analysis, but as the interviews with people living with T2DM and HCPs did not generate any concerns pertaining to deviant data (data not congruent with or representing an extreme difference from that reported by other participants), this process was not considered necessary (Seawright, 2016).

3.9.7 Ethical Considerations

Ethical considerations are viewed as the moral principles that are followed throughout the research process (Saunders *et al.,* 2009). A number of ethical considerations are likely to arise throughout all phases of research, including those related to obtaining informed consent, maintaining anonymity and confidentiality and deciding a course of action when poor practices are identified. Any potential ethical issues should therefore be taken considered to reduce harm to both participants and researchers (Creswell, 2003; Gomm, 2004; Saunders *et al.,* 2009). In this research, the following ethical issues were considered. Ethical approval for this study was obtained from the Ethics Committee of the College of Veterinary, Medicine and Life Sciences Research at the University of Glasgow (reference number: 200190149; Appendix 8) and from the Institutional Review Board (number: H-03-M-084), General Directorate of Health Affairs, Madinah (Appendix 9).

The ongoing COVID-19 pandemic also presented an ethical dilemma since the need for social distancing and safety raised questions about the feasibility of conducting a research study without providing any additional risks to the people involved and the researchers (Hsu *et al,* 2021). It was also important to consider the possibility of replacing face-to-face interactions with other alternatives that involved the adoption of remote technologies (Bierer *et al*, 2020; Hsu *et al,* 2021). However, it has been noted that there is need for caution when making the decision to reduce or completely cancel in-person visits for clinical research (McDermott & Newman, 2021). Following a review of the protective measures and practices at the study organizations during the time of data collection, a decision was taken that there would be no additional risks to all participants and interviewers in conducting face to face data collection. It was therefore decided to proceed with the study using face-to-face interviews as planned.

Written informed consent was obtained from all participants before participation in the study and all participants agreed to be audio-recorded (Appendix 10). Moreover, all participants were provided complete information in Arabic with regard to the study to enable an informed decision about their participation in the study. The consent forms contained information on the purpose of the research, the participant requirements, data collection methods, data management and analysis as well as reminders about the participants' fundamental rights with regard to the research. Importantly, the participant recruitment process eschewed any coercion with regard to participation by avoiding the use of incentives and by ensuring that the investigator maintained a disconnected position from the consent process. All participants were informed that their participation in the study was voluntary and that they were free to withdraw from the study, without being obligated to give notice or provide any explanation. The policies designed to protect participant privacy and data confidentiality were stated clearly on the informed consent form. No participant will be individually identifiable in any publications that may arise from the work, and all personal information was kept confidential. The information obtained from the studies was exclusively used for the research purpose for which it was obtained. Furthermore, to maintain sensitivity to the cultural and religious values and beliefs of participants, a female researcher undertook data collection from female participants. This strategy helped mitigate any potential distress caused during the study and allowed accurate translation of information to ensure understanding by the participants.

Anonymity and confidentiality are important ethical considerations (Creswell, 2013), and the research complied with the General Data Protection Regulation (GDPR) for data storage and management throughout the study period to ensure that data integrity and confidentiality were maintained. All audio-recordings, transcripts and documents related to the participants were digitally organised, encrypted and stored (Data Protection Act, 2018) in a password-protected laptop that was accessed only by the researcher. All interviews were recorded using a password-protected digital recorder, which was secured in a locked cabinet that was accessible only to the researcher, and all recordings were downloaded directly onto the laptop. Audio-recordings were transcribed and anonymised to ensure that all participant-identifying information was converted into numerical codes. All participants were assigned an identification number as recommended by Braun and Clarke (2013), and the personal details pertaining to each participant were securely maintained by the researcher in a locked filing cabinet in accordance with the codes of practice stipulated in the Data Protection Act (2018). All information that was obtained was anonymised such that individuals reading the research reports would be unable to identify the contributors of the information. Secure data storage for 10 years has been ensured in accordance with university regulations.

3.10 Summary

This chapter outlines the rationale for the pragmatist, mixed method research design and the aim of each study included in the research project. The chapter then described the methodology used in each study. The overall aim of the four studies described in this chapter was to determine the requirements for developing a culturally sensitive structured diabetes education programme for people living with T2DM in Saudi Arabia. A systematic review, two qualitative studies and a quantitative study were conducted to achieve this aim. The main ethical considerations related to confidentiality and anonymity, informed consent and fair participant selection and measures to address the abovementioned concerns included clear consent procedures and secure data storage.

Chapter 4: Systematic review of theory-based, culturally adapted structured education programmes for people living with type 2 diabetes (Study 1)

4.1 Overview

This chapter presents Study 1 which was systematic review to describe and assess the effectiveness of culturally adapted theory-based structured self-management education programmes for people living with type 2 diabetes. This helps highlight the potential benefits and opportunities for the adaptation of self-management programmes within the target population of Saudi Arabia. The methods by which the systematic review was undertaken and its findings are described in the sections below.

4.2 Aims and Research Questions

Study 1 aimed to synthesise studies on the effectiveness of theory-based structured self-management education programmes that have been culturally adapted for people living with type 2 diabetes. In this study, three research questions were posited :1)How effective are theory-based structured self-management education programmes that have been culturally adapted for people living with type 2 diabetes? 2) What are the components of theory-based structured self-management education programmes for people living with type 2 diabetes? 3) What are the strategies used to make theory-based structured self-management education programmes culturally relevant?

4.3 Methods

4.3.1 Search strategy

The literature search was conducted in the following databases: MEDLINE, EMBASE, CINAHL, and the Cochrane Central Register of Controlled Trials (CENTRAL). The search was carried out using the PICOS framework (P: Participants; I: Intervention being considered; C: Comparison intervention; O: Outcome measurements; S: Study Design) (Davies, 2011), (see Table 2). The searches were conducted from 1996 to October 2019. The included studies were limited to those published in the English language, and the search terms included key terms and synonyms of the following terms: ‘type 2 diabetes mellitus ’or ‘non-insulin dependent diabetes mellitus ’or ‘diabetes mellitus ’and ‘health education ’or ‘diabetes education ’or ‘self-management ’and ‘cultural adaptation’. These search terms were combined with appropriate Boolean operators and adapted for each specific database (where required), using card operators conforming to the functionality of each individual database. The electronic searches were supplemented with a search of key authors who were identified from papers in the search results. No journals were hand searched as all the major related journals were indexed in the aforementioned databases. Finally, reference lists within the studies found by the above methods were also reviwed for any additional sources.

Table 2: PICOS search strategy and criteria for considering studies for this review.

Population	Only adults living with T2D, with or without complications of diabetes, male and female, aged ≥ 18 years. Studies focussing on type 1 diabetes mellitus (T1DM), gestational diabetes and a mixture of T2DM with T1DM or other chronic conditions, were excluded.
Intervention	Only structured self-management education programmes that were underpinned by a specific theory and had been culturally adapted in some way for people with T2D. 'Culturally appropriate' structured education programmes were defined here as education programmes tailored to the cultural or religious beliefs and linguistic skills of the community being approached, likely taking into account literacy skills (Overland 1993). Interventions that did not align with this definition were not included. Examples of these could include adapting established structured education programmes with innovative delivery methods, such as using community-based health advocates, delivering the information to same-gender groups or adapting dietary advice to fit the likely diet of a particular community.
Comparator	Either a control group not receiving the intervention or a control group that received a non-culturally tailored intervention.
Outcomes	Primary outcome: glycosylated haemoglobin A1c (HbA1c) level. Secondary outcome: Clinical outcomes of blood pressure, body mass index (BMI) and waist circumference. Behavioural outcomes of diabetes self-management, diabetes knowledge, medication adherence, physical activity levels, and other measures of general and psychological health and adverse events.
Study Design	This review only considered primary studies of randomised controlled trials (RCTs).

4.3.2 Study selection

The studies retrieved from the electronic database searches were exported to Covidence systematic review software (www.covidence.org) to manage the screening and selection processes. To determine which studies should be assessed further, two reviewers (Bandar Alhumaidi, BA) and a second reviewer, (Zainab Awal, ZA) independently scanned the abstract, title or both sections of every record retrieved by the searches to determine eligibility as per the inclusion criteria. Discrepancies arising over the eligibility of the studies were resolved through the involvement of a third reviewer (supervisor, Lisa Kidd, LK).

4.3.3 Data extraction and management

Two bespoke forms were used to extract the relevant data: (1) a study characteristic form and (2) an extraction table devised from the Ecological Validity Framework (EVF) model to permit recognition of the cultural congruence or acceptance of self-management education programs across data components noted below (Bernal *et al.,* 1995). The first form aimed to obtain certain characteristics of the included studies: study characteristics, participant characteristics and intervention characteristics. The study characteristics included: title, authors, reference, country, language of publication, design (duration, method) and setting (primary or secondary care). The intervention characteristics considered included: type and content of the intervention, duration of the intervention, intervention delivery method and the educator. The participant characteristics included: total number and numbers in comparison groups, sex, age, biomedical and diabetes parameters, existence of diabetic complications, sociodemographic and ethnic characteristics and educational level. Data on the following diabetes-related clinical outcomes were also extracted: glycaemic control as measured by HbA1c levels, blood lipids, blood pressure and BMI. Behavioural outcomes included dietary behaviour, physical activity behaviour and medication adherence (see Table 2 for details of the characteristics of all the studies included in this review).

As noted, the second form was adapted from the EVF model (Bernal *et al.,* 1995) and examined the extent of cultural congruence in self-management programs across studies investigated within the review. The EVF was adopted because it was one of the first and most widely cited frameworks used to identify the critical elements in which cultural adaptation can influence uptake and adherence to treatment regimens or programs on both a superficial and culturally deep level. The framework comprises eight core domains: language, persons, metaphors, content, concepts, goals, methods and context, and thus, cultural congruence across these domains was assessed based on a yes/no premise (Bernal *et al.,* 1995).

4.3.4Assessment of the risk of bias in included studies

The Cochrane Collaboration's Risk of Bias tool (CCRBT) for RCTs was used to assess the methodological quality of the included studies (Higgins & Green, 2011). The tool comprises seven domains: random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective outcome reporting and other sources of bias. The CCRBT assesses studies as having a 'low', 'unclear' or 'high' risk of bias to give an overall risk of bias rating for each study. Two reviewers (BA and ZA) assessed each trial independently. There were no disagreements between the reviewers. A study was rated as having a "low risk of bias" if it attained "Yes" for all domains with no other serious concern noted, as "unclear risk of bias" if it attained "probably no or probably yes" for one or more key domains (1-4), and "high risk of bias" if it attained "No" for one or more key domains. The results of the assessments of bias are displayed in Table 4.4 and these are expanded on under each bias domain thereafter.

4.3.5 Data synthesis strategy

A narrative synthesis was used for this review, which allowed the reviewer to systematically highlight and summarise the different types of evidence included in the selected studies (Snilstvelt, Oliver & Vojtkova, 2012). This involved critical and comparative discussion and reporting of the self-management interventions, along with recording the characteristics of the population targeted, the types of outcomes measured and the study's overall quality. The narrative synthesis also considered a textual description of the method of culturally adapting the self-management interventions. Although a meta-analysis offers the advantage of pooling of study findings, the heterogeneity in the designs of the included made meta-analysis less feasible and so a narrative synthesis was chosen. Using the same data extraction sheet and the same critical appraisal tool for the entire process improved transparency and standardised the procedure.

4.4 Results

The initial search returned 6,421 articles. Of those, 1,508 were duplicates and removed. No additional relevant papers were identified from other sources. The titles and abstracts of the remaining 4,913 potentially relevant records from the electronic database searches were screened for eligibility. From the title and abstract screening, 84 studies were deemed eligible and full text-versions of those were retrieved for further screening. Of the 84 articles, 13 were selected for the next stage and were assessed independently by BA and ZA. The other 71 were excluded for various reasons (Fig. 4). The PRISMA (Liberati *et al.,* 2009) flow diagram that summarises the study selection processes is provided in Fig. 4. .Table 2 in the Supplementary Information summarises the characteristics of the included studies

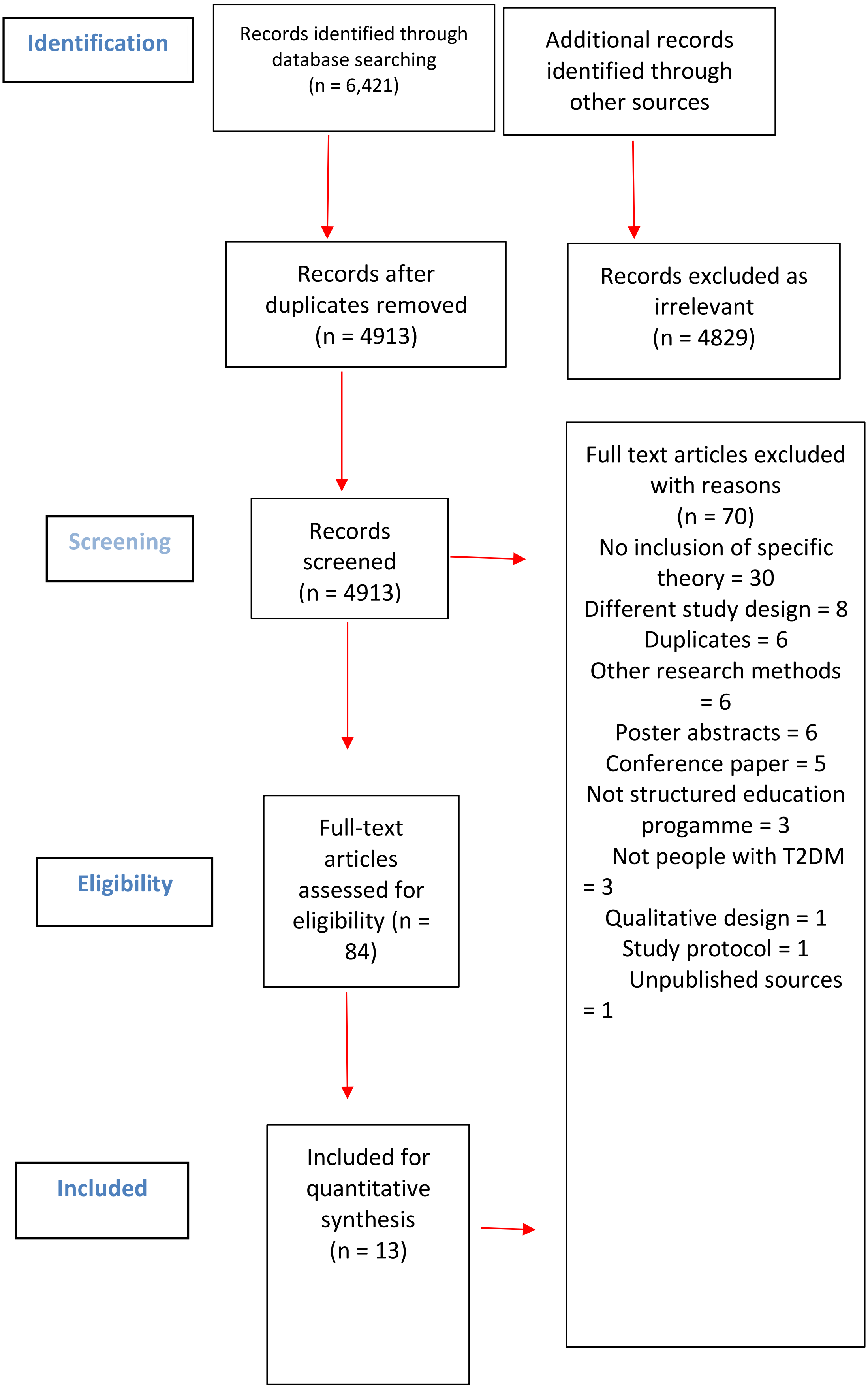


Figure 5: PRISMA flow diagram of study selection.

4.4.1Summary of included studies and participants

Of the 13 included studies, 12 studies were conducted in the United States of America, whereas the last was conducted in Canada (n=1). Overall, the cumulative sample size of participants across the studies included in this review was 2,215. The sample size ranged from 17 (Vincent *et al.,* 2008) to 318 (Babamoto *et al.,* 2009) and the samples were evenly randomised into either intervention or control groups. However, the study by Sinclair *et al.* (2013) had an uneven randomisation for the intervention and control groups (60/40, respectively). This was because of a concern over diabetes-related complications in the community involved in the study; the community partners expressed a desire to offer the Partners in Care intervention to individuals as soon as possible. The studies included people from a diverse range of ethnic groups including African-American, Mexican-American, Puerto Rican, Portuguese, Native Hawaiian and Hispanic-Latino. Spanish was the most dominant spoken language across the studies. The study by D'Eramo *et al.* (2010) conducted in southern New England in the US included only women, whereas the remaining 12 studies included both sexes with ages ranging from 18 to 75 years. Socioeconomic and literacy characteristics, where reported, are summarized in Table 2 in the Supplementary Information.

Table 3: Characteristics of the studies included in the review

Authors and Country	**Design**	**Participants (sample size)**	**Experimental conditions**	**Data collection**	**Main findings**
Babamoto *et al.* (2009) **USA**	RCT	Patients of Hispanic/Latin American ethnicity with T2DM within the first six months of diagnosis (n = 318) Age: >18 years Sex 64% females 36% males	**I:** Culturally tailored self-management strategy with focus on disease education provided by bilingual Hispanic Community Health Workers (CHWs) with diabetes or who had experienced the disease through a family member or friend delivered the study intervention. Duration: 10 weeks Follow-up: 6 months **C:** No intervention (usual care)	Behavioural Risk Factor Surveillance System, from the Centres for Disease Control and Prevention. Medication Behaviour Scale to assess medication-taking behaviour and adherence. The Diabetes Knowledge Questionnaire, a measure of diabetes knowledge in both English and Spanish was used to facilitate the CHW education sessions. Clinical Measures: Fasting Blood Glucose (FBG) and Body Mass Index (BMI)	Participants in the intervention group observed improvements across all outcome measures, as compared to controls. Baseline clinical indicators as well as self-reported health indicated that all treatment groups were characterized by poor dietary and exercise habits and poor medication adherence.. However, there were significant differences between the control and test groups at the 6 month follow up including differences in health states, medication adherence, diets, physical activity and knowledge about their conditions. No mention of glycaeimc control here
De Pue *et al.* (2013) **USA**	RCT	Samoan Hawaii patients with a clinical diagnosis of T2DM, mentally competent, able to consent, and unlikely to leave American Samoa for 4 months (n = 268) Age: >=18 years (mean 55 years) Sex: 62% females, 38% males	**I:** Self-management intervention comprising support and person-centredness delivered by community health workers and nurses. The intervention content was guided by both diabetes risk and self-selected goals. Duration: not reported Follow-up: 12 months **C:** participants were told they would begin their programme in 1 year. In the meantime, they received usual care.	Glycaemic control was measured as HbA1c to reflect BG over a 3-month period. Dietary intake was assessed with a validated Samoan food frequency questionnaire. Adapted Hill-Bone High Blood Pressure Therapy Scale to assess medication adherence Physical activity was measured using the World Health Organisation STEPS interview items	The culturally adapted nurse-CHW team intervention was able to significantly improve diabetes control among participants in the intervention group There were significant improvements in HbA1c at the end of treatment and at follow up in participants in the intervention group when compared with participants in the normal care (control) group. Clinically significant changes were also greater in individuals at higher risk in both control and test groups.

D'Eramo *et al.* (2010) **UK**	RCT	African-American women with T2DM (n = 109) Sex: 100% females Age: 21-65 years	**I:** The experimental intervention consisted of a series of 11 weekly group sessions. The first six sessions (each 2 hr in duration) provided culturally relevant cognitive behavioural diabetes self-management training. Duration: 11 weeks Follow-up: 24 months **C**: 10-week usual diabetes health education	Glycaemic control (HbA1c (primary outcome) and fasting blood glucose (FBG)). blood pressure, lipid levels and weight were obtained at baseline and at 3, 6, 9, 12, and 24 months Diabetes knowledge was assessed using a 25-item self-administered questionnaire Anxiety measured by Crown-Crisp Index, a 48-item self-rated scale. 25-item Problem Areas in Diabetes Survey PAID (diabetes-related emotional distress)	The findings suggest that both methods of diabetes education combined with care can improve metabolic control, QOL, and perceptions of provider care. Baseline analysis demonstrated that the female participants were all obese (BMI ≥ 28); had poor glycaemic control Marked improvements in glycaemic control (up to 1%) and FBG in control and experimental groups between baseline and 3 months. These were maintained by 12 months in both groups. However, only the experimental group maintained these improvements at 24 months.
Gucciardi *et al.* (2007) **Canada**	RCT	Sample (n = 61). Persons with diagnosis of T2D, speaking Portuguese, and willing to participate in the Portuguese education programme Age: mean = 60 years Sex: 42 females, 19 males	**I:** Portuguese-speaking educators provided initial assessments and ongoing individual follow-up visits for each Portuguese patient. A multidisciplinary health care team facilitated group education and counselling. Duration: 15 hours over 3 consecutive weekdays Follow-up: 3 months. **C:** diabetes counselling and usual care	Summary of Diabetes Self-care Activities Questionnaire (SDCA) to assess knowledge, attitudes and intentions towards self-monitoring, physical activity and dietary adherence. Glycaemic control: Baseline and post-intervention (3 months) HbA1C	The findings provide preliminary evidence that culturally competent group education in conjunction with individual counselling may be more efficacious in shaping eating behaviours than individual counselling alone for Canadian Portuguese adults with T2D. The findings also suggest that both counselling and counselling with group education improve attitudes, subjective norms, PBC, intentions and adherence to nutrition management.
Lujan *et al.* (2007) **USA**	RCT	Mexican-Americans with T2DM and able to speak English or Spanish (n = 150) Age: 40 years or older Sex: not specified	**I:** Intervention was delivered by a team of bilingual clinic employees called “promotoras”, who had received 60 hours of training on diabetes self-management. A 2-hour, participative group class and telephone follow-up of the intervention participants. A team of 2promotoras delivered the class weekly for 8 weeks Duration: 2 hrs, 8 weeks Follow-up: 6 months. **C:** usual care	Assessed diabetes knowledge using a 24-item bilingual (English & Spanish) diabetes knowledge questionnaire (DKQ). A 25-item bilingual diabetes health belief model (DHBM) assessed participants' beliefs about their ability to manage diabetes. Glycaemic control using HbA1c levels	No significant changes in glycaemic control or diabetes knowledge at 3 months follow-up but these changed to significant improvements in test participants in contrast to than controls at 6 months.

Osborn *et al.* (2010) **USA**	RCT	Puerto Ricans with a formal diagnosis of T2DM and within first year of diagnosis (n = 118). Age: 18 years or over Sex: not reported	I: The intervention was delivered by a bilingual medical assistant of Puerto Rican heritage who had received approximately 40 hours of training in diabetes self-management, motivational interviewing, safety and ethics. There were also intervention activities delivered by a Registered Dietician/Certified Diabetes Educator (also of Puerto Rican heritage) and a health psychologist. Duration: 90 -minute session Follow-up- 3 months C: Usual care	HbA1c was measured with a National Glycohemoglobin Standardized Programme (NGSP) certified, point-of-care immunoassay device Summary of Diabetes Self-care Activities Questionnaire (SDCA) was used to assess self-monitoring, physical activity and dietary adherence.	Diabetes Self-Care: There were significant differences in behaviours such as food label reading and diet adherence among test participants at follow up. Glycaemic Control: There was a reduction in HbA1c from baseline in both groups of participants but it was only significant in the intervention group. The findings support the use of the Information Motivational Behaviour (IMB) model to culturally tailor diabetes interventions and to enhance patients' knowledge, motivation, and behaviour skills needed for self-care.
Prezio *et al.* (2013) **USA**	RCT	Mexican Americans with physician's diabetes diagnosis receiving oral drug treatment (n = 180). Age: 18 years and over Sex: 60% females and 40% males	**I:** Bilingual CoDE health worker, an adult female lifelong member of the local Mexican American community, with a high school equivalency delivered the intervention **C:** Received usual medical care at the discretion of the clinic physicians for the first 12 months. Duration: 8 weeks Follow-up: 12 months.	Measured HbA1c using a Bayer DCA 2000 + Analyzer1, rigorously maintained for quality control. Blood pressure was determined as an average of three readings obtained 10 min apart using a digital sphygmomanometer by trained clinic staff. Measured weight on a digital scale, and BMI was calculated using the standard formula (kg/ m^2).	The average reductionin HbA1c levels from baseline to 12 months was 0.7% greater for the CoDE internvention than the usual care group. No significant differences in blood pressure thought to be due to the fact that all participants were normotensive at the baseline. This study supports the effectiveness of CHWs as diabetes educators/case managers, functioning as integral members of the health care team in community clinic settings serving uninsured Mexican Americans.

Rosal *et al.* (2011) **USA**	RCT	Puerto Ricans (Latin) withT2DM diagnosis within 6 years (n = 201). Age: 18 year or over Gender: 76.6% females and 23.4% males	**I:** The intervention consisted of an intensive phase (12 weekly sessions) followed by a maintenance phase (8 monthly sessions). The intervention targeted knowledge gaps and misinformation, promoted positive attitudes towards diabetes self-management (i.e., self-efficacy) and facilitated learning of skills for change in several health behaviours (i.e., diet, PA, SMBG, medication intake). Duration: 12 months. **C:** Participants in the control group received no intervention.	Audit of Diabetes-related Quality of Life General quality of life. Perceived stress (measured by the 4-item Perceived Stress Scale) Assessed comorbidities and healthcare utilisation with medical record audits. Clinical outcomes: HbA1c, dietary quality and self-monitoring of blood glucose levels.	This study showed that intensive interventions tailored to the needs of low-income Latinos can result in clinically important short-term improvements in glucose control and glucose variability. Baseline characteristics for all these variables were measured at the beginning of the research and followed up at 4 and 12 month intervals. Significant intervention effects were found in HbA1c for both test and control groups (greater in test group) at 4 and 12 months. There were significant associations between intervention attendance and improvements in HbA1C levels; improvement in dietary quality, exercise as well as self-monitoring of blood glucose levels in the short term (12 months)
Ruggerio *et al*. (2014) **USA**	RCT	English and Spanish speaking adults with T2DM for at least 6 months (n = 270). Age: 18 years or over Sex: 68.6% female, 22.4% male.	**I;** The MAC Intervention used two delivery approaches: face-to-face coaching during diabetes-related routine clinic visits and brief monthly telephone follow-up. MAC clinic based (face-to-face) coaching sessions were designed to be brief (< 30 minutes) and be delivered quarterly during routine diabetes care visits. **I -2:** TAU (Treatment as usual) Duration: 30-minute face-to-face and 15-minute telephone interviews Follow-up: 12 months.	Summary of Diabetes Self-care Activities Questionnaire (SDCA) to assess self-monitoring, physical activity and dietary adherence. Glycaemic Control: HbA1c measured at each of the follow-up end points. Other information: socio-demographic characteristics; diabetes duration; the use of insulin; BMI, depressive symptoms and self-care confidence.	The overall findings of this study demonstrate that all groups reported improvements in self-care across time, especially from baseline to six months, but no intervention effect was found and no differences were found for A1C.

Samuel-Hodge *et al.* (2009) **USA**	RCT	Members of African-American Churches and living within 50 miles of church (n=201). Age: 20 years or over Sex: 54% females and 46% males	**I**: Special Intervention (SI) included four components for participants with diabetes and 2 components for the church members. The intervention was given, in part, by a church diabetes advisor (CDA). Duration: 90-120 minutes, 12 weeks Follow-up: 12 months. **C:** Control group received minimal intervention of informational pamphlets and 3 bimonthly newsletters with general health information.	Physiological measures included A1C, weight and blood pressure. A1C was determined from a finger-stick sample collected at the participant's church (Bio-Rad, Hercules, CA). Actigraph (Shalimar, FL) monitor, formerly known as the CSA WAM 7164 activity monitor; a small uniaxial accelerometer worn on the waist. Dietary intake measured by the Fred Hutchinson 12-page Food Frequency Questionnaire at baseline and at 8 months follow-up Diabetes knowledge using the Diabetes Knowledge Scale	Special intervention significantly improved short-term metabolic control, diabetes knowledge, and diabetes-related quality of life when compared with the minimal intervention. The improvement of HbA1c levels were statistically significant for participants with a baseline level of ≥ 7% at the 8-month follow up but there was no significant difference between groups at 12 month follow up There were no differences between the groups for most of the dietary outcomes The improvements in physical activity for the participants in both groups were minimal for SI groups. In contrast there was reduced physical activity at both follow ups for the MI group of participants.
Sinclair *et al*. (2013) **USA**	RCT	Native Hawaiian Filipino, or other Pacific Islander with T2DM, English speaking, (n = 82) Age: 18 years and over Sex: 63% female, 37% male	**I:** Curriculum materials emphasised ADA clinical guideline goals for blood glucose, A1c, blood pressure, and lipids (31). Social Cognitive Theory provided the conceptual foundation for Partners in Care with an emphasis on behavioural capability, self-control procedures, emotional coping response, and self-efficacy. Duration: 1 hr, 12 weeks Follow-up: 3 months. **C:** Wait List Team	The primary outcome of this study was A1c, which is measured as a percentage of haemoglobin that is glycated (expressed as A1c %). Other clinical indicators: lipid panels; blood pressure; weight and height Summary of Diabetes Self-care Activities Questionnaire (SDCA) was used to assess self-monitoring, physical activity, dietary and medication adherence. Diabetes-related distress (anxiety, depressed mood, fear etc) was measured by the Problem Areas in Diabetes scale	There were significant baseline adjusted differences in blood glucose level; adherence to diets and blood pressure between the two treatment groups. This study demonstrated that an appropriately designed, community-based programme requiring little technology and few healthcare resources can have positive effects by improving understanding, self-care behaviours, and glycaemic control among Native Hawaiians and Pacific People with T2D. However, it was also recognized that it was important to identify means of ensuring participant engagement and retention in such treatment programmes to maximize the benefit.

Spencer *et al.* (2011) **USA**	RCT	Adults with physician-diagnosed T2DM, self-identified as African-American or Latino-Hispanic, and living in targeted zip codes (n = 183) Age: 18 years and over	Intervention : Trained CHWs, known in this study as family health advocates, promoted healthy lifestyle and diabetes self-management activities. Duration: 2 hr 11 weeks Follow-up: 6 months.	CDC's Behavioural Risk Factor Surveillance System for assessment of physical activity. Physiological measures of HbA1c, LDL cholesterol and blood pressure from medical records. Measured self-management knowledge by participants' response to the validated question ''How well do you understand how to manage your diabetes?" Physical activity and dietary practices were assessed through questions from the CDC's Behavioural Risk Factor Surveillance System.	Intervention group observed a significant improvement in glycaemic control from 8.6% at baseline to 7.8% at six months follow-up ($p<0.01$). Controls did not observe the same effect. Significant improvements in cholesterol levels from baseline to six month follow up was also observed in the intervention group, insignificant change in the control group. There was also significant improvements in patient adherence to routine blood glucose testing and daily diabetes medications in the intervention group in contrast to the control group (from the baseline to the six month follow up) However both intervention and control groups showed significant improvements in physical activity.
Vincent *et al.* (2008) **USA**	RCT	Mexican-American, Spanish speaking and T2DM diagnosis (n = 17). Age: 18–75 years Sex: 71% female, 29% male	**I:** The culturally tailored intervention used in this study integrated strategies for enhancing self-efficacy, such as using demonstration and a return demonstration of self-glucose monitoring to enhance skill mastery. **C:** The control group received the usual care and education given at the clinic, which generally consisted of a 10– 15 min encounter with a physician or NP two to four times per year. Duration: 8 weeks. Follow up: unclear	Demographic information (age, gender, formal education, marital status, income). Glycaemic control: HbA1c, blood glucose, weight and BMI Physical activity levels using a pedometer An 8-item Spanish version of the Self-efficacy for Diabetes Scale was used to measure self-efficacy levels. This scale addresses an individual's level of confidence in performing various diabetes self-management behaviours; and has been found to be reliable. Spanish version of the Diabetes Knowledge Questionnaire for the level of diabetic knowledge of participants	Results showed that the intervention group observed positive improvements in self-care activities and a sense of control over their diabetes health. There was a significant reduction in weight and BMI from baseline to follow-up in the intervention group. This is in contrast to the control group that had a slight increase in weight and BMI at follow up In addition there was improved diabetes knowledge, self-efficacy, blood glucose and HbA1c in the intervention group although this was not of statistical significance

4.4.2 Risk of bias in included studies

Details of the risk of bias in the included studies have been summarised in (Table 4).

Table 4: Summary of risk of bias assessment.

S/N	**Bias domains / Authors**	**Random sequence generation**	**Allocation concealment**	**Participant and personnel blinding**	**Blinding of outcome assessors**	**Incomplete outcome data**	**Selective outcome reporting**	**Other sources of bias**	**Risk of bias rating**
1	Babamoto *et al.* (2009)	Yes	no information	Yes	no information	Yes	Yes	Yes	**Some concerns**
2	DePue *et al.* (2013)	Yes	No	Yes	Yes	Yes	Yes	Yes	**High**
3	D’Eramo *et al.* (2010)	Yes	no information	probably yes	no information	probably yes	Yes	Yes	**Some concerns**
4	Gucciardi *et al.* (2007)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	**Low**
5	Lujan *et al.* (2007)	No information	probably yes	Yes	no information	No	No	Yes	**Some concerns**
6	Osborn *et al.* (2010)	Yes	Yes	Yes	No information	Yes	Yes	Yes	**Low**
7	Prezio *et al.* (2013)	Yes	No	No	No	No information	Yes	No information	**High**
8	Rosal *et al.* (2011)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	**Low**
9	Ruggerio *et al.* (2014)	Yes	No information	No	No	Yes	No information	No information	**High**

10	Samuel-Hodge *et al.* (2009)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	**Low**
11	Sinclair *et al.* (2013)	Yes	Yes	Probably Yes	No information	No	No	Yes	**Some concerns**
12	Spencer *et al.* (2011)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	**Low**
13	Vincent *et al.* (2007)	Yes	Yes	Yes	No information	Yes	Yes	Yes	**Low**

Key: Yes = low risk of bias for domain. No = high risk of bias for domain. Some Concerns = unclear risk of bias for domain.

4.4.3 Overall quality of the evidence

On the basis of the assessment of quality of the included studies presented here, six studies received an overall low risk of bias, three studies received a high risk of bias rating, and the remaining four studies raised some concerns with an unclear risk of bias rating. Consequently, of the 13 studies included in this review, six studies were of high methodological standard, whereas seven studies were of lower methodological quality, as assessed using the CCRBT (Higgins & Green, 2011). The main sources of bias leading to suboptimal quality judgements (high or unclear risk of bias) were a lack of or unclear blinding and allocation concealment and biases related to incomplete data and selective reporting. No significant concerns regarding attrition bias across all studies were observed.

4.4.4 Theoretical Underpinning of Study Interventions

According to the data extracted from the studies, the authors explicitly described the interventions and the control groups where appropriate. Interventions were based on a range of different theories, including the Health Behaviour Change Theory (Babamoto et al., 2009; DePue *et al*., 2013; Gucciardi *et al.,* 2007), Social Learning Theory and Trans-theoretical Model of Behaviour Change (D'Eramo *et al.,* 2010), the Theory of Community Empowerment (Lujan *et al.,* 2007), the Information Motivational Behavioural Model Skills model of health behaviour change (Osborn *et al.,* 2010), Social Cognitive Theory (Prezio *et al.*, 2013; Rosal *et al.,* 2009; Sinclair *et al.,* 2020; Vincent, 2009), Empowerment and Trans-theoretical theories of Behaviour Change (Ruggiero *et al.,* 2014), Social Cognitive and Adult Learning theories (Samuel-Hodge *et al*., 2009) and Empowerment, Self-Determination and Autonomy Motivation theories (Spencer *et al.,* 2011). Lujan *et al.* (2007) employed the Social Cognitive Theory while delivering the interventions on self-efficacy; they considered that the higher people's sense of self-efficacy, the more likely they were to make the necessary lifestyle changes and actively manage their conditions. This is important because there is evidence to suggest that self-management improves diabetes control (Hernandez, Hume, & Rodger, 2003; Holman & Lorig, 2004; Lorig, Ritter, & Gonzales, 2003; Whittemore, 2000; 2.4.2.1, 2.4.2.2, 2.4.2.3, & 2.4.2.4).

4.4.5 Characteristics of Self-Management Programs

The specific self-management programs were described as follows:

- culturally acceptable diabetes education and monitoring initiative delivered by trained lay persons including frequent assessment of progress, recognising and addressing barriers and facilitating problem solving using culturally adapted materials (Babamoto *et al.,* 2009),
- self-management education based on the US National Diabetes Education Program guidelines with cultural adaptations of content and support (DePue *et al.,* 2013),
- a tailored diabetes education program with focus upon optimising coping skills and psychological and psychosocial wellbeing (D'Eramo *et al.,* 2010),
- a national self-management program comprising either one-to-one counselling or group education classes with focus upon addressing cultural influences of health status (Gucciardi *et al.,* 2007),
- a culturally adapted diabetes education program based on American Diabetes Association (ADA) guidelines (Lujan et al., 2007; Vincent, 2009),
- a culturally adapted diabetes education program with focus upon inducing behavioural change (Osborn *et al.,* 2010),
- self-management program based on ADA guidelines with a focus upon intensive education (Prezio *et al.,* 2013),
- a culturally tailored self-management program with emphasis upon motivational interviewing and person-centred counselling (Rosal *et al.,* 2009),
- a culturally adapted education program with a focus upon patient coaching (Ruggiero *et al.,* 2014),
- self-management education centred around one-to-one counselling and group-based education sessions (Samuel-Hodge *et al.,* 2009),
- diabetes education program with focus upon optimising adherence and self-care activities through acknowledging and addressing cultural barriers (Sinclair *et al.,* 2020) and,
- A culturally tailored diabetes program with focus upon education and disease monitoring and reactivity to variances in glycaemic control to induce behavioural change (Spencer *et al.,* 2011).

Intervention duration ranged from 5 weeks (Osborne *et al.,* 2010) to 12 weeks (Samuel-Hodge *et al.,* 2009) and follow-up periods ranged from 3 to 24 months post-intervention. All studies were conducted in Westernised countries and the specific interventions delivered have been summarised previously in (Table 2).

4.4.6 Outcome measurement

Primary outcomes across studies were mostly glycaemic control as ascertained through glycated haemoglobin (HbA1C) measurements, whereas secondary outcomes included diabetes self-management activities or extent of behavioural change including physical activity, diet blood-glucose testing, foot care, medication adherence and smoking (Toobert *et al.,* 2000). Overall diabetes knowledge was assessed using the Summary of Diabetes Self-care Activities Questionnaire (SDCA) (Toobert *et al.,* 2000). These outcomes were generally assessed at 3-, 6- and 12-months 'time points across studies. The use of internationally accepted measures for monitoring the control of diabetes as well as questionnaires to assess levels of knowledge facilitated comparison between the different research studies (Saunders et al, 2016).The instruments used to assess improvements in self-management included: the Behavioural Risk Factor Surveillance System (Nelson *et al.,* 2001), Morisky Self-Reporting Medication Behaviour Scale (Culig and Leppee, 2014) and the Diabetes Knowledge Questionnaire (Eigenman, Skinner & Colagiuri, 2011), among various other tools that have been summarised in Table 2 Such tools were reported to have observed sufficient validity in prior psychometric analyses and thus, there was minimal risk of outcome measurement bias. Variance in the types of tools used for secondary outcome measurements between studies could account for differences in outcomes reported in the results section. Of note, some studies adapted outcome measurement tools to the population of participants included by translating tools into the local language. This could introduce another source of bias given that studies included in this review did not re-test the psychometric validity of the instruments.

4.4.6.1Effects of interventions on glycaemic control HbA1c

All 13 studies included in this review assessed the outcome of HbA1c levels and most of the studies reported a decrease in the HbA1c measures of participants engaging with the diabetes self-management intervention. These findings were, however, not significant in four studies: Vincent *et al.* (2008), Babamoto *et al.* (2009), D'Eramo *et al.* (2010) and Ruggerio *et al.* (2014). The remaining studies reported similar baseline HbAc1 levels in both groups participating in the study and they reported a significant reduction among the participants, favouring the intervention group in each study (DePue *et al.,* 2013; Gucciardi *et al.,* 2007; Lujan *et al.,* 2007; Osborn *et al.,* 2010; Prezio *et al.,* 2013; Rosal *et al.,* 2011; Samuel-Hodge *et al.,* 2009; Spencer *et al,* 2011; Sinclair *et al.,* 2013). Among these trials, DePue *et al*. (2013) attributed the significant improvements in HbA1c (8.2% at baseline to 7.2% at six months and 7.7% at 24 months) to an 11-week culturally tailored self-management intervention with a focus upon enhancing coping skills of American Samoan participants, whilst Gucciardi *et al.* (2007) showed that similar improvements could be attained with a much briefer intervention program (three days comprising 4-5 hours per day). The mean improvement in HbA1c was 0.5% at three months follow-up. Similar extent of HbA1c reduction was also observed by Lujan *et al.* (2007); 8.2% at baseline to 7.7% at six months following a six-month program, Osborn *et al.* (2010); 7.8% to 7.2% at three months follow-up but of an unclear program duration, and Rosal *et al.* (2011) and Samuel-Hodge *et al.* (2009); mean change 0.5% at 8-12 months follow-up. More marked reductions in HbA1c were reported by Prezio *et al.* (2013); mean change 1.6% from baseline to 12 months, Sinclair *et al.* (2013); mean reduction 1.1% at 3 months follow-up, and Spencer *et al.* (2011); mean change 0.8% at six months follow-up. Such findings were based on a more intensive self-management programmes delivered over a longer duration of time and/or comprising the principles of person-centredness.

In studies reporting a decrease in HbA1c levels, the change was observed in both the intervention and control groups (DePue *et al.,* 2013; Gucciardi *et al.,* 2007; Lujan *et al.,* 2007; Osborn *et al.,* 2010; Prezio *et al.,* 2013; Rosal *et al.,* 2011; Samuel-Hodge *et al.,* 2009; Spencer *et al.,* 2011; Sinclair *et al.,* 2013). Vincent *et al.* (2008) differed in that were no significant differences in the changes in glycaemic control occurring in test and control groups of participants in thia study. Furthermore Ruggerio *et al.* (2014) demonstrated no differences in the changes in glycaemic control between their test and control groups. For some studies with demonstrable improvements in control, these changes were more likely to be sustained in test groups in the long term (D'Eramo *et al.,* 2010; Prezio *et al.,* 2013; Rosal *et al.,* 2011; Samuel-Hodge *et* *al.,*2009). This greater effect at 12 months after intervention was attributed to the participants' improved diabetes knowledge, dietary behaviour and self-efficacy at this time point of the outcome assessment (D'Eramo *et al.,* 2010; Prezio *et al.,* 2013; Rosal *et al.,* 2011; Samuel-Hodge *et al.,* 2009).

4.4.6.2 Effects of interventions on blood pressure, BMI and waist circumference.

Six of the included studies (Vincent *et al.,* 2008; Babamoto *et al.,* 2009; Samuel-Hodge *et al.,* 2009; D'Eramo *et al.,* 2010; Rosal *et al.,* 2011; DePue *et al.,* 2013; Prezio *et al.,* 2013) assessed blood pressure, BMI and waist circumference outcomes. However, only Samuel-Hodge *et al.* (2009) found a statistically significant change in any of these measurements. It is important to note that not all of the studies under this domain assessed the same variable. Samuel-Hodge *et al.* (2009) found that blood pressure had slightly reduced in the intervention group and was lower in the control group, with a statistically significant difference in diastolic blood pressure at 8-month follow-up (−3.3 mm Hg, $p<0.001$); however, this effect disappeared at 12-month follow-up (−1.7 mm Hg, $p=0.22$). This observation suggests that the intermittent improvement in blood pressure in the intervention group could have been because of the educative components of self-management that led to improved adoption of healthy lifestyle changes. However, the limited program duration and failure to reinforce such improvements may have promoted a reversal of healthy lifestyle behaviours, thereby ameliorating the improvement in diastolic blood pressure. Similarly, Rosal *et al.* (2011) showed no significant improvements in long-term blood pressure control with systolic and diastolic averages failing to differ meaningfully from baseline levels (systolic: 127 vs. 128 mm Hg; diastolic: 80 vs. 80 mm Hg; both $p>0.05$). Other studies did not report the specific values measured for blood pressure, BMI and waist circumference at follow-up owing to a lack of statistical significance, a factor that could amount to reporting bias. Of note, some of the study cohorts comprised or could be categorised into predominant socioeconomic groups, which could have accounted for a proportion of the variance in the outcome effects reported. For example, 53% of population in the study of Babamoto *et al*. (2009) had a low socioeconomic status at baseline assessment but the authors did not account for this in the statistical analyses to observe whether the outcomes differed between participants with low or higher socioeconomic statuses. Similar observations were also evident in the study of D'Eramo *et al*. (2010), Gucciardi *et al.* (2007), Rosal *et al.* (2011) and Samuel-Hodge *et al.* (2009). Thus, although the socioeconomic statuses were similar between the intervention and control groups, this factor is likely to, and to an extent more than other demographic variables, have affected the outcome effects reported in this narrative. It is recognised that socioeconomic status is one of the factors that exerts an influence on health and health related behaviours in many populations and is often the focus of action on socioeconomic determinants of health in different target populations (Bambra *et al.*, 2009). It is therefore an element that benefits from further investigation in the future.

4.4.6.3 Effects of interventions on diabetes self-management.

The results for diabetes self-management were measured with various measures of diabetes knowledge, dietary behaviour physical activity, adherence and self-monitoring across studies, which likely accounted for inter-study variances. Four of the 13 studies included synthesis (Lujan *et al.,* 2007; Samuel-Hodge *et al.,* 2009; Sinclair *et al.,* 2013; Vincent *et al.,* 2008;) and they assessed diabetes knowledge, with the significance level set at 0.05 in all four studies. Physical activity was assessed by seven studies (Babamoto *et al.,*2009, Osborn*et al.,* 2010, Rosal *et al.,* 2011, Ruggerio *et al.,* 2014; Samuel-Hodge *et al.,* 2009, Spencer *et al.,* 2011, Vincent *et al.,* 2008,). Five studies identified an improvement in the level of physical activity of the participants in both the intervention and control groups (Gucciardi *et al.,* 2007; Ruggiero *et al.,* 2014; Samuel-Hodge *et al.,* 2009; Sinclair *et al.,* 2020; Spencer *et al.,* 2011). However, two studies (Ruggerio *et al.,* 2014, Vincent *et al.,* 2008), whichexplored the impact of culturally adapted self-management programs upon African American and Hispanic persons and Mexican Americans, respectively, found evidence to suggest a significant change between groups, favouring the intervention in each study. For example, in the study by Vincent *et al.* (2008), the intervention group participants recorded their mean number of steps, which increased from 4175 to 7238 per day, and this was a statistically significant increase from baseline to the end of the intervention.

Among the eight studies that assessed dietary behaviour, only two found evidence to suggest an improvement in dietary behaviour (Osborn *et al.,* 2010; Spencer *et al.,* 2011). There was clearly no evidence for the effectiveness of the intervention on dietary behaviour among the participants in either group in the majority of studies that assessed this outcome. The only aspect of effectiveness observed was the reading of food labels, which was reported by Osborn *et al.* (2010) and which was statistically significant, favouring the intervention group. However, this did not translate into better dietary behaviour. Indeed, this finding highlights one limitation ofspecific educative approaches; optimising awareness of food content in terms of calories and macronutrients is important but is only likely to useful if the information can be used to coach individuals in selecting healthier foods and adhering to healthy diets such to optimise weight loss and in turn, improve glycaemia. Studies by Babamoto *et al*. (2009), Rosal *et al*. (2011) and Ruggrio *et al*. (2014) found statistically significant evidence to suggest an effect of the intervention on the dietary behaviour of the participants in the intervention groups, but this was not directly correlated with weight loss or glycaemic control.

Diabetes self-management in terms of adherence was assessed by three studies (Gucciardi *etal.,* 2007; Osborn *et al.,* 2009; Spencer *et al.,* 2011). However, the variables assessed in each study to measure ‘adherence’ were different. Spencer *et al.* (2011) assessed adherence to blood glucose testing, medications and foot care. The intervention group significantly improved their adherence to testing blood glucose, as recommended, but there was no significant difference between groups (Spencer *et al*., 2011). The control group significantly improved adherence to daily diabetes medications between baseline (88%) and 6-month follow-up. Participants within the intervention group significantly improved adherence to inspecting the inside of their shoes every day at the 6-month follow-up and this improved significantly compared with the control group. Gucciardi *et al*. (2007) found that intentions to adhere to nutrition recommendations were improved compared to self-reported nutrition adherence and this was statistically significant. Osborn *et al.* (2010) also found a similar effect on adherence to set a diet regime at the 3 months post-intervention.

Finally, four studies assessed self-efficacy/self-monitoring as an outcome and three studies found a significant improvement in self-efficacy/self-monitoring among the participants (D'Eramo *et al.,* 2010; Lujan *et al.,* 2007; Sinclair *et al.,* 2020; Vincent, 2009). Self-efficacy improvement was mainly seen in medication-taking, foot care and blood glucose monitoring and these improvements were seen at both the six- and 12-month time points of the assessment. D'Eramo *et al.* (2010) found diabetes self-efficacy to improve three months post-intervention, but this was not sustained by 24 months post-intervention. These findings, again, suggest that self-management programmes provide clinical efficacy in the immediate term, but positive effects attenuate over time following program completion. This may be due to individuals' perceptions concerning active monitoring of anthropometric and clinical data by others during program engagement but when programs are completed and direct monitoring is absent, desires and motivations to sustaining behavioural change are likely to ameliorate.

4.4.6.4 Effects of interventions on general/psychological health and adverse events.

Babamoto *et al*.'s (2009) study focused on the effects of community health workers (CHWs) delivering individual educational sessions to Hispanics. Outcomes of interest included levels of diabetes related knowledge, medication adherence as well as HbA1c and BMI levels, The study identified that whereas no between-group differences were observed at the baseline, at the 6-month follow-up significant between-group differences were observed in health status, emergency department (ED) admissions, and medication-taking behaviour. At follow-up, the proportion of people in the CHW group who reported "very good" or "excellent" health increased from 5% to 57% ($p < .05$). In contrast, no significant changes in health status were observed in the case management or standard provider care group. Self-reported ED admissions in the previous 6 months did not change significantly in the CHW and case management groups. By contrast, ED admissions from diabetes and related complications increased significantly from 13% to 28% ($p < .05$) in the standard provider care group.

D'Eramo *et al.* (2010) also found that with regard to psychosocial factors, a significant group-by-time interaction was observed with the experimental intervention group participants sustaining lower levels of diabetes-related emotional distress at 24 months compared to the control-group participants. Somatic anxiety initially declined in both groups ($p < .0001$) but by 24 months, it had started to increase in the two groups. Diabetes knowledge increased initially and remained high in both groups ($p < .0001$). Perceived family support increased over time in both groups ($p < .05$), with the experimental-group participants having significantly higher levels of support at 24 months (group time $p < .02$). Samuel-Hodge *et al.* (2009) reported that the general health status did not differ between groups, but that diabetes-related mental well-being improved in the special intervention group and worsened in the minimal intervention group, with the difference significant at 8-month and 12-month follow-up.They also reported that during follow-up, one SI participant died from stroke and one MI participant died from advanced chronic obstructive pulmonary disease. Spencer *et al.* (2011) reported that no adverse effects were noted among the participants as a result of the intervention.

4.4.7 Cultural sensitivity in the interventions

Populations to which these review studies had been tailored to include African American (D’Eramo *et al.,* 2010; Samuel-Hodge *et al.,* 2010; Spencer *et al.,* 2011); Hispanic/Latin American (Babamoto *et al.,* 2009; Osborne *et al.,* 2010; Rosal *et al.,* 2011; Ruggerio *et al.,* 2014; Spencer *et al.,* 2011); Mexican American (Lujan *et al.,* 2007; Prezio *et al.,* 2013; Vincent *et al,* 2008); Samoan Hawai/Pacific Islanders (DePue *et al.,* 2012; Sinclair *et al.,* 2013) andPortuguese Canadian (Gucciardi *et al.,* 2007).There are therefore no studies focused specifically on individuals in Saudi Arabia or of Saudi Arabian descent.For this review, the assessment of the extent of the cultural adaptation of studies employed the Ecological Validity Framework (EVF) (Bernal *et al.,* 1995). The EVF was conceptualised for the purposes of increasing the cultural sensitivity of interventions and subsequently augmenting both the ecological and external relevance for the target populations (Bernal *et al.,* 1995). Grounded in Bronfenbrenner’s Ecological Systems Theory, the EVF posits that social validity and positive treatment outcomes result from an alignment between the client’s experiences as it relates to their experienced cultural context and the cultural components present within a treatment (Bernal & Rodriguez, 2012). As part of this framework, the individual’s culture, language and worldview can be adapted to each of the following eight treatment domains, which describe where cultural adaptation can occur:

language, persons, metaphors, content, concepts, goals, methods and context (see Table 4.5).

From the results presented, ‘metaphors ’and ‘persons ’were the least explored domains of the EVF (Samuel-Hodge *et al.*, 2009, DePue *et al.*, 2013) and ‘language ’ was the most explored domain (Babamoto *et al*., 2009, D'Eramo Melkus *et al.*, 2010, Gucciardi *et al.*, 2007, Lujan *et al.*, 2007, Osborn, 2010, Prezio *et al.*, 2013, Rosal *et al.*, 2011, Ruggiero *et al.*, 2014, Sinclair *et al.,* 2013, Spencer *et al.*, 2011, Vincent, 2009). According to Resnicow *et al.* (1999), the cultural sensitivity model identifies two distinct content areas: deep culture, which includes the aspects of culture such as beliefs, value systems and norms, and surface culture, which refers to elements such as language, food and customs. In this review, the informing evidence tended to comprise interventions that incorporated both surface and deep cultural adaptations, as accounting for and being sensitive to individuals' beliefs and values, whilst addressing culturally specific aspects of diabetes self-care were important in improving outcomes. Specifically, three studies utilised deep cultural adaptations (DePue *et al*., 2013, Prezio *et al.,* 2013, Samuel-Hodge *et al.,* 2009), two studies comprised surface cultural adaptations (D'Eramo *et al.*, 2010, Gucciardi *et al.*, 2007) and seven studies used both surface and deep adaptations (Lujan *et al.,* 2007, Osborn, 2010, Rosal *et al*., 2011, Ruggiero *et al.*, 2014, Sinclair e*t al*., 2013, Spencer *et al.*, 2011, Vincent, 2009).

Several steps and measures were taken to ensure a clear and understandable intervention that was culturally appropriate and syntonic to the specific culture of participants in the verbal and written language used to screen the process. This was evident across all included studies. The first step in adapting an intervention to one that is increasingly cultural appropriate or sensitive is translation. Translation was reported by each study providing relevant details of the approach, such as the number of translators involved and their qualifications, and this ultimately ensure that the educational or supportive content of the interventions were sufficient to permit accurate comprehension by individuals. In addition, accurate translation of such content was also key to preventing any misinterpretations or information, which have been previously found to fuel misconceptions of diabetes self-management across ethnicity minority groups (Abubakari *et al.*, 2013; Goff *et al.*, 2020). Deep-level adaptation was noted in most of the studies across the domains of concepts, contents, methods and context to redress some of the cultural and comprehensive issues (Lujan *et al.,* 2007, Osborn, 2010, Rosal *et al.*, 2011, Ruggiero *et al.*, 2014, Sinclair *et al.*, 2013, Spencer *et al.*, 2011, Vincent, 2009, DePue *et al.,* 2013, Prezio *et al.,* 2013, Samuel-Hodge *et al.*, 2009).

Among these domains, the most commonly adapted domain was concepts. In this domain, the authors reported the use of items in the instruments that demonstrated more culturally sensitive concepts to screening, excluding confusing or difficult items, or presenting participants with clarifying examples framed within the investigated cultural values and traditions (Lujan *et al.*, 2007, Rosal *et al.*, 2011, Ruggiero *et al.,* 2014, Spencer *et al.*, 2011, Vincent, 2009, Prezio *et al.*, 2013, Samuel-Hodge *et al.,* 2009). Following the concept domain was the method domain incorporated into the interventions among three included studies (DePue *et al.*, 2013; Osborn, 2010, Sinclair *et al.*, 2013,). The methods domain is a vital component of the EVF as it represents the capacity of populations within a culture to accommodate or accept delivery of an intervention to improve health or wellbeing (Resnicow *et al.,* 1999).

Researchers in some studies included in this review incorporated family members into the intervention process (Babamoto *et al.*, 2009, Spencer *et al.,* 2011), as recommended by Bernal *et al.*(1995), as the inclusion of family members is a means of ensuring cultural compatibility. Moreover, family-centred care has become an increasingly population and efficacious approach to improving outcomes in persons with chronic diseases, such as diabetes, and thus, providing dyadic potential (family and culture) to improving the outcomes from type 2 diabetes among ethnic minorities (Cheraghi *et al.,* 2015). Moreover, family-centred diabetes care/support may offer ethnic minority groups additional potential in improving disease control due to harbouring cultures that are family-orientated *(Shepherd et al.*, 2018). However, among some of the included studies in this review, the specific cultural adaptations among the interventions evaluated were not always clearly defined and most tended not to comprise a family-orientated approach. Due to incompleteness of the intervention conditions (how the interventions were culturally tailored), this is likely to preclude inferences of causation between the interventions and diabetes-related outcomes. Despite this, the evidence presented suggests that, at least some tailoring of interventions to the culture of ethnic minority groups, are generally effective in improving clinically important diabetes outcomes.

Table 5: Cultural Adaptation

The Ecological Validity Framework (EVF)								
1. Language: Does the study report use a culturally appropriate language, idioms, regionalism words, and slang in both written and verbal forms is responsive to the cultural group? **2. Persons:** Does the study highlight ethnic and interactional match considerations between patient and provider? **3. Metaphors:** Does the study used of metaphors and/or symbols shared by the target group? **4. Contents:** Does the study address cultural knowledge of values, customs and traditions shared by the target group? **5. Concepts: Does** the study present any a theoretical framework to the development of the intervention to the targeted culture? **6. Goals:** Are the screening goals between people and deliverer of the intervention constructed within the context of cultural values, customs, and traditions? **7. Methods:** Do the study methods and strategies to achieve the outcomes of the intervention and the methods used to generate culturally relevant strategies? **8. Context:** Does the study consider the social, economic, historical, and political contexts?								
Authors	**Language**	**Person**	**Metaphor**	**Content**	**Concept**	**Goals**	**Methods**	**Context**
Babamoto *et al*. (2009)	Yes	Yes	Yes	Yes	Yes	Yes	No	No
DePue *et al.* (2013)	Yes	No	No	No	Yes	Yes	Yes	No
D'Eramo *et al*. (2010)	Yes	No	No	No	Yes	No	No	No

Gucciardi *et al.* (2007)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	yes
Lujan *et al.* (2007)	Yes	Yes	No	No	Yes	No	No	No
Osborn *et al.* (2010)	Yes	Yes	Yes	Yes	Yes	Yes	No	No
Prezio *et al*. (2013)	Yes	Yes	No	Yes	Yes	No	No	No
Rosal *et al.* (2011)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No
Ruggerio *et al.* (2014)	Yes	Yes	Yes	No	Yes	No	No	No
Samuel-Hodge *et al.* (2009)	Yes	Yes	Yes	No	Yes	Yes	No	Yes
Sinclair *et al.* (2013)	Yes	Yes	Yes	Yes	Yes	No	No	Yes
Spencer *et al*. (2011)	Yes	Yes	No	No	Yes	Yes	No	No
Vincent *et al.* (2008)	Yes	Yes	No	Yes	Yes	No	Yes	Yes

4.5 Summary of results and chapter

Thirteen RCTs of culturally sensitive diabetes self-management interventions with 2,215 participants were included in the review. Although the interventions in all of the studies included in this review were underpinned by different theories considered appropriate for the outcomes assessed, there was sufficient evidence to suggest that the theories employed improved the uptake of the intervention, leading to better outcomes. For example, Community Empowerment Theory was the basis for the intervention in the study by Spencer *et al.* (2011), and this allowed the transfer of diabetes knowledge and expertise, and the sharing of knowledge about how to control diabetes. The authors suggest that this enhanced participant’s confidence and the feeling of being empowered to improve their health, as evidenced by the optimal HbA1c levels and their increased diabetes knowledge. Overall, the results analysed from all the studies included in this review suggest that theory-based culturally sensitive diabetes self-management interventions can improve HbA1c, knowledge about diabetes and its management among individuals suffering from type 2 diabetes, and likely those with lower socioeconomic status. This statement was based on low socioeconomic status being a common feature observed across studies, whilst other sociodemographic variables that could have influenced the outcome effects, such as race/ethnicity, geographic location, age, marital status and educational attainment were more balanced across both the intervention and control groups. Due to the subsequent financial difficulties that participants in these studies would have likely encountered, such stress could have impaired their ability to adhere to self-management approaches to self-care due to poor affordability of healthy foods and/or access to exercise facilities or the purchase of sports equipment. However, as the relevant studies included in this review did not account for socioeconomic status within the statistical analyses, it was not clear if and how much of the variance such variables would have accounted for in terms of improvement in glycaemic control, weight and other cardiovascular risk factors requires further exploration.

In response to the review questions posed for this Phase of research, several important pieces of knowledge have been recognised as have key recommendations for ongoing research into the field of self-management education for diabetes.

Research Question 1: How effective are theory-based structured self-management education programmes that have been culturally adapted for people living with type 2 diabetes?

This review showed that the intervention programs were associated with meaningful (0.5-1.0%) improvements in glycated haemoglobin levels, which is clinically important in view that similar reductions are only attainable with known effective pharmacotherapies (Chaudhury *et al.* 2017). However, the use of education programs should be considered in view of the low to modest quality of underpinning evidence, although evidence-based practice principles would stipulate that this is the best-available evidence and thereby, can be used to guide ongoing practice (Sackett, 2000).

Research Question 2: What are the components of theory-based structured self-management education programmes for people living with type 2 diabetes?

Theories used to inform the design of the self-management interventions included Health Behaviour Change Theory, Social Learning Theory, the Trans-theoretical Model of Behaviour Change and the Theory of Community Empowerment, reflecting a broader range of theories that identified in Chapter 2. However, it was also apparent that the most clinically effective self-management interventions (those that attained the largest reductions in HbA1c) comprised a person-centred treatment model which has been previously recognised as being key to optimising behavioural change among people living with type 2 diabetes (Rutten, Van Vugt and de Koning, 2020).

Research Question 3: What are the strategies used to make theory-based structured self-management education programmes culturally relevant?

Based on the intervention characteristics noted in subsection 4.4.5, it was difficult to ascertain the specific factors defining the cultural aspects of the self-management programs due to limited and/or unclear reporting among the informing studies. However, it appeared that culturally-tailored programs involved dedicated and trained professionals who were familiar with the service users' cultures and used a person-centred approach to adapt their communication and supportive interactions to account for individuals most valued needs, to overcome or resolve any aberrant beliefs arising from culture and in eliminating issues of comprehension due to language barriers. Notably, there were no culturally tailored self-management interventions that had been trialed in Saudi Arabia and this was a major finding of this review. In the following chapter, Chapter 5, the findings from the qualitative interviews conducted with healthcare professionals in Saudi Arabia are presented.

Chapter 5: Qualitative findings from interviews with health professionals (Study 2)

5.1 Overview

This chapter presents the findings of Study 2 which qualitatively explored the views of healthcare professionals (HCPs) towards self-management education programmes for people living with type 2 diabetes, the perceived challenges in their use and any issues experienced by service users in relation to gaining access to these programmes in Saudi Arabia. First, the characteristics of the participants are detailed. Following this, three main themes arising from the thematic analysis, are presented and discussed. The findings from this study contributed to the understanding of the requirements for developing a culturally sensitive structured diabetes education programme for people living with type 2 diabetes in Saudi Arabia.

5.2 Participant Characteristics

In total, 16 participants (9 male, 7 females; age range, 25-54 years) Saudi HCPs were included in this study. The participating HCPs included six doctors, seven nurses and three dieticians. All HCPs had at least one year of experience providing care for people living with type 2 diabetes and at least one year of that work experience was in Saudi Arabia. With regards to experience in self-management education programmes, only five of the participants had prior experience in delivering and/or attending courses in self-management education. Table 5.1 summarises the details of the participants' characteristics.

The professionals' quotations have been anonymised to protect confidentiality but a coding system has been used to denote the gender and profession of participants; M: male, F: female, PD: practice doctor, PN: practice nurse and PDT: practice dietician. This was to enable reflection on the varying contexts from which the quotations were derived.

Table 6: Demographic characteristics of the health professional participants

HCPs	N=16
Physicians	6
diabetic nurses	7
Dieticians	3
Gender	
Male	9
Female	7
Age (in years)	
25–34	2
35–44	10
45–54	4
Qualification	
Diploma	4
Bachelor	5
Higher Degree	7
Years of experience	
1 - 4 years	5
5 -9 years	9
Over 10 years	2
Experience in undertaking and/or delivering diabetes education session	5

5.3 Thematic Analysis

Using the principles of thematic analysis described by Braun and Clarke (2013), that comprised data familiarisation, initial coding and theming of the data and review and confirmation of the codes and themes, a total of three main themes and seven subthemes were identified (Table 7).

Table 7: Summary of themes and subthemes.

Themes	**Sub-Themes**
1. Perceived views regarding the value of self-management programs	1.1 Care provider views and perceptions of people’s needs
2. Role of information provision and people education in addressing knowledge and awareness of type 2 diabetes self-management	2.1 Medium and purpose of information and education delivery 2.2 Importance of timing in optimising uptake and sustained engagement with type 2 diabetes self-management
3. Factors influencing the adoption, availability and uptake of self-management programs	3.1 Integration of diabetes care services and inter-agency working as a factor influencing the need for formal diabetes education 3.2 Cultural acceptability of self-management 3.3 Barriers to self-management programs for people living with type 2 diabetes 3.4 Standards and guidelines regarding self-management approaches to type 2 diabetes care

The themes and subthemes are discussed in the following bodies of text with supportive quotations of the health professionals. A summary highlighting the coding descriptors and the evidence informing the codes and themes that emerged from professionals' views and thus, informed the subthemes and main themes are provided in Appendix 11.

The following thematic subheadings detail the results of the thematic analysis in accordance with the standard reporting approach for qualitative research studies (Braun & Clarke, 2013).

5.3.1Theme 1: Perceived views regarding the value of self-management programs

This first theme explores the views of health professionals regarding the purpose of self-management programs both from the perspectives of themselves and those expressed by people living with type 2 diabetes in their care.

5.3.1.1Subtheme 1.1: Care provider views and perceptions of peoples' needs

Doctors reported that self-management programs were key to empowering people in becoming increasingly responsible for their own health through taking a more proactive approach to health-related decision making and adjusting behaviour to those that facilitated improvements in glycaemic control and/or diabetes complication risk. Indeed, one physician noted that the evidence, based on their clinic experiences of managing people living with type 2 diabetes, was that self-management type programs with an educational focus were markedly effective in improving diabetes outcomes with meaningful improvements in glycaemic control being attainable within three months of completion.

> "the evidence is my attempts to implement the program inside the clinic in the educational aspect, with repeated visits, there are remarkable results with a clear progression of peoples 'cases within a period of three months." [FPD-2]

This professional noted that the program's success was, at least in part, due to the initiative being founded upon key theoretical principles of self-management education and utilising the approaches employed within the United Kingdom and United States.

> "self-management has clear theoretical and empirical grounding in research.. outcomes have improved in countries, the UK and USA, we should follow in their steps." [PMD-6]

The value of self-management was even reflected in professionals’ views about the reversibility or curability of type 2 diabetes in those with insulin resistance secondary to obesity or overweight status, which through information about healthy lifestyle habits and inducing behavioural change, could lead to meaningful weight loss and in turn, remission of diabetes. In contrast to the former reports, one professional found that self-management programs had not been optimally effective in achieving meaningful improvements in glycaemic control for the majority of people, suggesting that the programs had not been useful in empowering people, although the professional did not elaborate on the perceived reasons for limited success.

> “I am not sure...... Self-management programs do not seem suitable for Saudi persons with diabetes, I think they need more directive care.” [FPN-9]

Other professionals reported that the integration of self-management programs would not only incur positive effects upon diabetes end-points but would lead to improvements in service efficiency. This included reductions in demand and pressure upon specialist clinics, decreases in the number of people presenting with acute glycaemic emergencies, lowering of micro- and macro-vascular complication risk and in turn, the incidence of co-existing chronic diseases, and reductions in direct healthcare costs. In addition, physicians perceived that the introduction of self-management programs would reduce the number of unnecessary visits to specialist clinics, which simply wasted time, resources and costs.

> “it relieves pressure on clinics, emergencies and drainage on chronic diseases, such as heart failure.” [MPD-3]

> “the number of useless visits will decrease, saving time, money and resources.” [MPN-12]

Moreover, the healthcare professionals noted that formal self-management programs could also lead to meaningful improvements in people ’psychological wellbeing, quality of life and in turn, mental health, which could impart positive effects upon mental health services and related outcomes, although such statements were speculative and not based on actual observations or locally-derived evidence. Furthermore, participants reported that self-management initiatives were useful in enhancing individuals coping abilities and resilience in dealing with the stressful and demanding nature of diabetes treatment regimens and in overcoming the sequalae of complications, which were seldom impactful upon physical function and independence.

> “role of enhancing the people educational aspect is not to measure the people cumulative diabetes level and dispense appropriate treatment… rather, the people must be taught how to deal with the disease and its complications and in becoming resilient to stress of diabetes.” [MPD-1]

> “self-management will achieve several positive aspects, including relieving pressure on diabetes services and increasing awareness of diabetes control and the mental health of people so they can then take actions to sustain a quality of health and living, as well as improving physical function and independence.” [MPD-1]

Overall professionals believed that self-management education programs were critical to improving people knowledge of diabetes with regard to the impact of the disease upon their health, how to manage diabetes to enhance glycaemic control, the risk of complications due to poor glycaemic control and how to avoid complication onset, how to deal with complications and how to care for self to benefit psychological, emotional and social wellbeing.

> “their level of knowledge about the disease is very poor… their educational background is wrong.” [FPN-6]

In addition to these outcomes, physicians stated that education was key to enhancing people ’knowledge to a desirable and even specialist level such to optimise glycaemic control as much as possible, in order to improve and even normalise prognosis. This was particularly important as physicians recognised that people ’level of knowledge was generally poor across their clinics and this represented the initial factor that needed addressing if clinical outcomes were to improve. One physician held a vision that one day in Saudi Arabia, the majority of people would have sufficient knowledge and information to self-medicate with diabetes treatments, in order to improve the timeliness of drug commencement and in turn, the control and prognosis of diabetes. In addition, one professional had found that the provision of intensive diabetes education had improved people ’adherence to diabetes medications, which not only benefitted glycaemic control and the risk of diabetes complications, but it also improved the control of co-existing diseases and illnesses. Overall, this was found to benefit the people ’ overall health status, in terms of physical and mental wellbeing, both from the perspectives of people and the perspectives of clinicians themselves.

> “People is the one who controls and participates in the decision-making about his health condition, the medications he needs, and the diet with the doctor.. this can be promoted as self-management can increase respect for autonomy and enhance self-efficacy in tailoring diabetes care to their glycaemic control and daily variances in blood glucose readings.” [MPD-14]

5.3.2Theme 2: Role of information provision and people education in addressing knowledge and awareness of type 2 diabetes self-management

This theme explores the role and importance of information provision and education in type 2 diabetes and in guiding people to engage with self-management recommendations. The first subtheme focuses upon the intended purpose of information and education in type 2 diabetes, as well as indicating the optimal mediums for information and education delivery, particularly given the context of the COVID-19 pandemic. The second subtheme highlights the importance of timing in people education with provision between the early and later stages of diagnosis influencing uptake and adherence to self-management.

5.3.2.1 Subtheme 2.1: Medium and purpose of information and education delivery

This subtheme identifies and discusses the professionals 'accounts concerning the optimal approaches to delivering self-management education. Participants tended to report that due to time constraints of delivering education on a one-to-one basis, those group-based education sessions were most effective in providing as many people as possible with timely access to self-management programs. Moreover, professionals recognised that value of group-based education as many people would teach one another about diabetes and their experiences, as model people, which often proved more useful than educator-provided content alone.

> "People use technology to support what we provide [education], they have group forums and discuss diabetes within local networks" … this saves us time in clinic." [FPD-2]

In this regard, participants noted that word-of-mouth sharing of information could help people familiarise with others about diabetes experiences and help to improve problem solving and emotional wellbeing. Some respondents also found that people who attended group-based education also used social media, such as WhatsApp, to connect with one another and share information about how to tackle the various problems that type 2 diabetes conferred upon them.

> "From what I have noticed, people desire self-management education as they recommended it to other people and so… then more desire for education and a cycle ensues." [FPN-13]

> "YouTube and other social media has been praised by people in clinic.. I think they use this to widen their knowledge and interact with other people with diabetes." [FPD-1]

This was viewed as a marked positive as it saved clinicians valuable time from addressing people non-urgent issues and in turn, this helped them to focus upon reviewing and managing diabetes status to help attain key clinical targets in the future.

However, HCPs recognised that it was important for people -based education programs/sessions to be supervised or monitored by trained professionals, in order to help identify incorrect knowledge shared between people and to provide the correct information to ultimately, protect people wellbeing.

> "Group education is useful for the diabetes service… it saves us time, particularly when we have little staff." [FPN-4]

> "I teach him the correct information.. the errors will be corrected… education must be delivered by trained professionals in diabetes." [FPN-9]

Physicians also noted that people benefitted from education as it prepared them emotionally and psychologically for commencing intensive and relatively invasive diabetes treatment, such as insulin injections, which were often perceived as being painful and inconvenient.

> "We prepare the person psychologically, because it is a new thing in his life, he will take needles every day, meaning this is a new thing in his life." [MPN-7]

Thus, through supporting individuals by using a counselling approach, people tended to be in a better state of mental wellbeing and preparedness to embark on a lifelong course of diabetes treatment providing the problem was not remissible through reductions in insulin resistance via weight loss and lifestyle change. In addition to enhancing psychological wellbeing, professionals reported that education was key to improving people 'general happiness and contentedness within their lives and in enabling them to live positively and symbiotically with diabetes rather than experiencing persistent and lifelong distress.

> "The one who has the ability will have more satisfaction and happiness, and you notice that he separates between visits because he has more confidence and comes with more specific questions. Others, his thoughts become more confused, it depends on the type of the people, but the majority have more satisfaction." [FPD-3]

Moreover, education was reported to improve people understanding of type 2 diabetes and the specific ways in which glycaemic control varied throughout the day and in response to specific exposures, and in turn, how to manage such variances in glycaemia to benefit physical and mental health. In effect, physicians believed that people had to feel positive about the treatment and decision-making processes, in order to engage with programs to a desirable effect.

> "The most important step is for the people to feel that he is a participant in making the decision and not the doctor gives orders." [MPD-14]

> "This almost did not take us time to understand the disease and how he can control his disease without resorting to a doctor except in emergency cases." [MPN-7]

In terms of formats for delivering education, some professionals reported that video-conferencing applications and remote consultations were markedly useful in delivering convenient and timely consultations with people. These enabled access to general diabetes care but could also be used as platforms to support remote self-management education programs, which was necessary in view of the ongoing COVID-19 pandemic.

> "The people benefitted from the experience [remote consultations] and is still benefitting from it during the coronavirus pandemic, and the method is present in the form of lectures through the Zoom program that include both theoretical and practical side in addition to dialogue to ask people problems." [FPD-2]

In most cases, the HCP recognised that access to specialist diabetes care and diabetes outcomes had deteriorated as a result of the cancellation of routine in-hospital services due to the pandemic. However, the use of Zoom and other video applications was critical to ensuring the continuity of care whilst maintaining public safety by preventing avoidable in-person contact and potential transmission of the virus.

> “they need more time, but due to work pressure and the Corona pandemic, we reduce the time [spent with people] as much as possible… we do need change… telehealth is a growing area and one that could help us.” [FPN-13]

Alternative approaches to delivering self-management education prior to and during the COVID-19 pandemic included traditional lecture-based content delivered online, which was perceived to be useful in distributing important and appropriate diabetes content to enhance learning about diabetes. Delivery of educational content via the former mediums was considered a clinical imperative as most diabetes clinics had no established self-management initiatives as are commonplace in the majority of western countries; an observation reported to be an issue prior to the COVID-19 pandemic but one that worsened during the pandemic. However, one specialist reported that there was a lack of technology and applications specifically developed or designed for providing self-management education and that the field had to improve accessibility, in order to have potential in providing the intervention for all people living with type 2 diabetes.

> “there are currently no programs… but those delivered via technology could reduce pressure upon our services and that of others during the pandemic.” [FPD-2]

> “we have a dedicated online education service with content for diabetes that has been useful for people.. this should be used everywhere.” [FPD-7]

Finally, participants reported that it was important to confirm or reshape people’ knowledge of diabetes, in order to inform them of how the problem could be managed lifelong and in enhancing their confidence and skills to become experts in self-managing diabetes.

> “Many people have poor or incorrect knowledge… this is important to correct so they can understand and desire to manage diabetes in the long term.” [MPD-2]

From some HCP’s perspectives, correcting misconceptions that dietary factors were a direct cause of diabetes was key to establishing new and healthier dietary habits, in order to benefit glycaemic control in the short- and long-term. Moreover, most professionals had encountered people in marked psychological distress due to acquiring misinformed knowledge about the adverse effects of diabetes, which tended to be related to those with poorly controlled disease with advanced systemic complications, which did not apply to those with a new diagnosis. Thus, correcting knowledge early in the course of diagnosis via self-management education, was also crucial to resolving people distress.

> “some people come to clinic and have stress… stress that arises from knowledge about the worst cases of diabetes when the problem is poorly controlled.” [MPN-7]

> “we [the diabetes team] need people to have no stress and be confident in improving their health… stress was due to misunderstandings and fear of complications.” [MPN-1]

5.3.2.2 Subtheme 2.2: Importance of timing in optimising uptake and sustained engagement with type 2 diabetes self-management

This subtheme reports upon the specific accounts of professionals that suggested that it was critical to instigate self-management education at specific time points during the course of disease within time windows or opportunities that were perceived to enhance the efficacy of diabetes education. Participants interviewed tended to believe that self-management would yield optimal clinical efficacy and instigate positive behavioural change if the intervention was delivered at the time of or soon after diagnosis of type 2 diabetes. This was perceived to be due to people being more influential at the time of diagnosis and emotional vulnerable due to such states acting as potent cognitive motivators to induce a clinically meaningful change in their behaviours.

> “It is better to activate the concept of self-management in the first visits to the people and before the symptoms of the disease appear, which allows the doctor

> to provide them with information about the disease and how to avoid complications and deal with them.” [MPD-1]
>
> “education at the time of diagnosis or not late after, is important, the information is needed to allow people to make choices about their lifestyles that affect diabetes… good habits in the beginning may be maintained going forwards and this can benefit outcomes. [MPD-4]

This was considered to be of the upmost importance as professionals had previously encountered people with poor glycaemic control and advanced diabetes with debilitating complications, which correlated with people reports that they were never provided with enough information or education early in the course of diabetes. Therefore, clinicians found that a large proportion of people were poorly motivated at the time of diagnosis as to exert efforts to optimise their glycaemic control, particularly as treatment recommendations were inconvenient and viewed as unrealistic and unachievable. As a consequence, such people tended to observe protracted distress of having diabetes and observing their health deteriorate over time, as opposed to promoting improvements in glycaemic control and complication risk.

> “the first thing is to correct the people’s information… people are emotional and overwhelmed in most cases and this is a key time to shape and influential their future lives through simple information giving.” [FPN-9]
>
> “people do not have motivation at the time of diagnosis, in most cases, as they find diabetes difficult to accept and the treatment can be overwhelming and often does not fit into their everyday lives.” [FPN-6]

Such accounts were also supported by nutritionists who stated that education at the time of or soon after diagnosis was key to supporting people in tackling the varied impacts diabetes imparted upon people ’everyday lives. This included diet, exercise and other lifestyle habits and routines, which were key to enabling individuals to co-exist with their disease, rather than adopting a rejective or resistant position that would have been detrimental to prognosis.

> “We need to educate people about the diet of diabetes to help improve glycaemic control early following diagnosis.” [FPN-2]

Diabetes specialists even suggested that it was important to offer self-management education to people with pre-diabetes, in order to improve self-efficacy prior to the potential onset of overt type 2 diabetes such to reduce the acute and chronic risks of persistent hyperglycaemia without delay.

> “self-control is also an excellent step… we are looking to teach them before they have diabetes.” [MPD-1]

Participants also reported that suboptimal knowledge of diabetes and the relationship between glycaemia and complications was prevalent across most people with newly diagnosed disease and thus, perceived that self-management was essential in the initial stages of diagnosis to help improve knowledge, address any misconceptions and to in turn, optimise adherence to management recommendations before the adoption of unhealthy habits prevailed. Indeed, professionals found that people with diabetes had acquired knowledge of the disease and misconceptions about the course of illness from persons without the appropriate education and credentials, such as neighbours and friends.

> “people with inadequate knowledge of diabetes find it difficult to understand the connection between glucose levels and complications like cardiac disease.” [FPD-4]

In contrast to views that people benefitted from information provision at the time of diagnosis, other professionals reported that it was not wise to educate people soon after diagnosis given that diagnosis itself was emotionally overwhelming and any information communicated would not be absorbed or consolidated with people’s mindsets.

> “First visit; no, possibly second or third visit, the people can benefit fully after the third visit… time is needed to comprehend and come to terms with the large amount of information about diabetes.” [MPN-7]

Thus, one nurse suggested that people with newly diagnosed diabetes benefitted most from education provided at a delayed time period, often weeks to months following the initial diagnosis, in order to ensure people had psychologically adjusted to and accepted the diagnosis and as a result, were cognitively prepared to absorb the excess amount of information needed to tackle the problem.

> “Some people benefit from a period of time to adjust to the diagnosis of diabetes… thereafter, education can be provided during a time of concentration.” [MPN-1]

5.3.3 Theme 3: Factors influencing the adoption, availability and uptake of self-management programs

This theme comprised three subthemes that were constructed based on various key external factors influencing the uptake and use of self-management education with type 2 diabetes practice. The subthemes related to the integration of diabetes care services, the cultural acceptability of self-management and the value of standards and guidelines for self-management education.

3.5.3.1 Subtheme 3.1: Integration of diabetes care services and inter-agency working as a factor influencing the need for formal diabetes education

This subtheme recognises the value of multi-disciplinary care within the context of type 2 diabetes and how impairments to one aspect of care can lead to negative downstream implications upon glycaemic control and other diabetes related outcomes. Doctors recognised that providing integrated care ranging from psychologist to nutritionist input with education across all components was important for people living with type 2 diabetes as outcomes could be affected by one or more needs going unmet.

> “there must be an integrated educational staff, which includes a psychologist, a nutritionist, an educator, and a doctor…these deal with the problem quickly and urgently.” [FPN-9]

Most HCPs recognised that multi-disciplinary diabetes care had improved over the past decade with access to specialists for advice and treatment recommendations for people being readily accessible and within a rapid time frame such that limited any negative effects upon people ’glycaemic control and/or everyday lives.

> “multi-disciplinary diabetes care has grown in popularity… research has shown that it can improve outcomes to a meaningful degree.. we must use the same approach.” [FPD-6]

HCPs also suggested that education needed to be tailored or weighted towards areas of diabetes care that demanded the most attention. In this regard, clinicians suggested that some areas of diabetes care, such as nutrition and exercise, were more effective than others in promoting favourable glycaemic control and in reducing cardiometabolic risk, whilst others were less effective and needed greater resources and/or funding to improve diabetes care quality.

> “[the] people’s needs the participation of more than one party to achieve a high level of education that serves this group to support them, such as the nutrition aspect, for example.” [FPD-2]

In one example, one HCP noted that education by nutritionists was highly important as the consumption of foods and drink products was the most frequent and influential factor of both acute and chronic glycaemic control and was thereby, critical to achieving favourable outcomes in the long term and particularly in lowering the risk of micro- and macro-vascular complications.

> “there is a prevalent problem of diet here in Saudi Arabia and diabetes… nutrition can be considered the most important factor influencing individuals lives and health.” [FPD-2]

However, there was marked variance in the access to and availability of multi-disciplinary team members across professional's clinics and this had meant that education had been weighted towards one or few factors influencing diabetes control. Thus, the lack of person-centred education, as perceived by healthcare professionals, appeared to impede the ability of people to achieve improvements in glycaemic control or in others, this failed to prevent deteriorations in chronic glycaemia.

> "We must have a full team that includes a consultant endocrinologist, a specialist in diabetes, education and nutrition, so that the people knows all the necessary information…there is no complete team here, as the presence of the team is very important for people." [FPN-6]

Limited access to diabetes clinics was also reported for people who were living within remote villages of Saudi Arabia and care providers simply had no means to meeting the care needs of these individuals as care was overseen by general practitioners who had infrequent contact with specialist centres and hospitals. However, in a few cases, specialist diabetes educators had been distributed to remote villages to assist in improving the quality of diabetes care and related outcomes, which was perceived to have been integral to developing the initial foundations for improved integration of care in the future.

> "in villages outside of the main cities, there are very limited diabetes services and clinicians with diabetes experience.. this has been a problem but recently, there is diabetes educators who have helped to address knowledge problems across remote areas of the Kingdom." [MPD-8]

3.5.3.2 Subtheme 3.2: Cultural acceptability of self-management

The content within this subtheme identified that the Saudi culture influenced people acceptance of self-care principles and the uptake and adherence to self-management programs for type 2 diabetes. One physician suggested that the Saudi culture was a factor compounding people 'uptake and adherence to self-management programs as they found that individuals often searched for care providers to listen to and address their concerns and most-valued needs regarding diabetes, implying that their social networks were poorly supportive of self-care principles.

> “The people searches for someone who understands and listens to him during his visit to the clinic.” [FPD-2]

Through engaging with group-based education initiatives, physicians reported that people often created their own culture of diabetes care within a close circle of those in similar circumstances, which not only generated strong mutual support among the group, but it also contributed to positive wellbeing and greater efforts in adhering to healthy self-care activities.

> “people networks have been useful I believe as those with a longer diagnosis and more experience of diabetes can share important knowledge with others, those with a more recent diagnosis, which has been supportive for some people, improved wellbeing and promoted proactivity in self-treatment.” [MPD-5]

However, other participants reported that group-based discussions were not effective in inducing sustainable behavioural change in people or in attaining improvements in diabetes control as this was deemed to be a result of local cultures that did not advocate inter-person mingling. Such views among local Saudi’s were judged to be a result of fears and anxiety concerning stigma and discrimination of persons with diseases like type 2 diabetes, which had deep-seated and engrained origins among society due to erroneous beliefs about the causes of ill health.

> “but regarding group discussion, many people don’t respond to it…obstacles are related to culture in Saudi Arabia, and it is not administrative, but the problem is in the people themselves, such that the females must be alone.” [MPN-8]

> “stigma and discrimination of individuals with diabetes is a problem that fuels fear; fear arising from extreme and erroneous perceptions of the causes of diabetes.” [FPN-1]

Much of the aversiveness to group-based discussions was evident for female people who were found to be confined by the Saudi culture as individuals and restricted in integrating or mixing with others, and particularly with persons of the opposite sex. This ultimately, compounded people 'uptake and adherence to self-care initiatives and conflicts with professionals' views regarding the favourability of group-based education due to the ability to educate large groups of people at one-point in time.

> "female people tend to struggle with diabetes education, mostly in groups, as the culture does not encourage mixing of males and females." [FPD-2]

Culture in Saudi Arabia was also perceived to impair people receptiveness of information provided by healthcare professionals as they found that some people held preferences for listening and responding to information provided by their families and support networks. Thus, there appeared to be a level of distrust in the medical profession for reasons of persistent misconceptions held by members of society.

> "a good culture, succeeds in educating people …."I do not think now the Saudi society is an educated society, and we accept change… there is some lack of trust in the medical profession." [FPD-3]

This contrasts with other professionals' views in this study, where they perceived that people held overwhelming trust in the profession but is likely due to the marked variances in diabetes care quality that exist across the region. One participant, an endocrine specialist, reported that the Saudi culture was not intrinsically accepting of self-management principles as the population was minimally educated in health and disease and were resistant to change. The professionals 'potential solution to overcoming such cultural issues was to develop dedicated self-management programs for groups of persons with a shared problem; type 2 diabetes, but these had to comprise trained professionals as prior education had been delivered by volunteers, which had created variance in program feasibility, acceptability and effectiveness.

> "culture is sometimes a problem but it can be address.. we need programs that are both culturally sensitive and focus upon specific aspects of diabetes, we also

> need trained educators with experience in managing people with diabetes.” [FPN-4]

> “people are willing and trust their doctors to improve their health.. we just need to make sure the education is correct and delivered by trained persons.” [FPD-1]

Feasibility and acceptability of the diabetes educational programs was also found to be affected by language differences of people with most information content only available in Arabic and thus, compounding access to important information for those speaking other languages.

> “it is possible to make publications about the disease in several languages to educate people more broadly.” [MPD-1]

Despite language issues among non-Arabic speaking individuals, persons speaking Arabic and able to access diabetes education materials were reported to benefit from contemporary information sources, such as magazines, the internet and social media, which implied that the Saudi culture had and continued to change in line with western cultures that promote self-learning through advances in information technology and the media.

> “young people can change the way they eat and their lifestyle and learning about health and disease, such as with media and magazines, but the elderly do not have the same ability to change.” [MPN-8]

Indeed, other professionals reported that the culture among their people had changed over time to one that was more acceptive and reactive to disease, which was in stark contrast, to religious and non-religious views that disease was simply a punishment from God or was a result of magic and curses placed upon them.

> “people have become more acknowledging of the causes of diabetes and other problems… these views are more scientific rather than traditional and erroneous

> beliefs about magic and curses… these views have previously led to poor outcomes.” [FPD-1]

However, clinicians reported that older people tended to be much more resistant to change and with the concept of self-management and thus, generational views and beliefs appeared to persist throughout the life-course of those with diabetes and this negatively impaired the ability of people to optimise their glycaemic control. Saudi culture also compounded the ability of people to accept the dietary restrictions recommended by diabetes treatment regimens as the choice of foods and the timing of meals would be markedly different to their traditions and routines.

> “in our culture, people have strong beliefs about diet, it is important and as diabetes changes diet, this is not always possible for them to change… some say that diet is all they enjoy in life, so how do we change it?.” [MPDT-10]

3.5.3.3 Subtheme 3.3: Barriers to self-management programs for people living with type 2 diabetes

Participants recognised that problems with organisational culture were a hindrance to ensuring the standardisation of type 2 diabetes care across the local hospital as it failed to prioritise intensive and person-centred care, which appeared to generate inequities in access to effective diabetes therapies including self-management education.

> “research has found patient-centred diabetes care to be important… diabetes care does need to be personalised so a change in our approach and culture is needed.” [FPN-1]

Indeed, one professional noted that a people had only received education 20 years following their initial diagnosis, which was viewed as a failure of care as knowledge about how diabetes control could be improved was attained too late in the course of illness.

> “one people admitted to having received education at the time of diagnosis.. 20 years ago.” [FPD-2]

Some professionals held positive beliefs about the role and efficacy of self-management but simply had insufficient time to deliver the intensive education needed for most people with diabetes, which was often in the order of hour-long sessions.

> “The information about type 2 diabetes was not spread enough to avoid the disease or reduce complications, due to the lack of time and the high pressure on the clinics.” [FPD-2]

However, some professionals reported that people were sufficiently educated and informed and that education could be provided in only 10-15 minutes, suggesting that prior experiences and people researching capabilities influenced the workload of physicians and thus, the intensity of self-management content needed. Despite this, physicians reported that there was an excess amount of information for people to learn about diabetes and in most cases, lessons could only be learned through experience of living with diabetes, which could take three, four or even six months to acquire. Information that was difficult to educate tended to be reflected around managing the individual variances in glycaemia and adjusting medication doses to attain better long-term control over glycated haemoglobin levels.

> “needs a long period of up to three months, or four, or even six months to learn what the meaning of diabetes is, what are medications, what do complications mean, and how do I protect myself from them.” [FPN-9]

> “if a new case needs 20 minutes but at least half an hour, and this is difficult in the outpatient clinics with the pressure, but as much as possible I try to allocate enough time for them.” [FPD-3]

Other professionals reported that they had no access to dedicated or standardised self-management programs within their diabetes clinics and this compounded the ability to educate people as they lacked key resources, such as information leaflets, diagrams and other resources, which were required to optimise the education of older people.

Moreover, one professional reported that improving the marketing of self-management across the Saudi population was key to promoting improvements to diabetes care and outcomes on a large scale through optimising access to people in need of self-management and in encouraging them to attend and complete said programs.

> “we must focus on the marketing side, linking departments with each other at the level of health centres, schools, malls, after the return of normal life, as in the past, with all of that, with linking departments, the program will succeed greatly.” [FPD-2]

Another participant reported that should population-level support for self-care programs would be highly valuable as this would reduce the obstructionsto implementing formal self-management education programs for diabetes. The participant also noted that Saudi 2030 vision policy would provide this support, as well as funding, although confidence in whether this would be geared towards tackling diabetes was lacking. Professionals also highlighted that support at the policy level was essential to improving the conditions for implementing successful self-management programs as this was necessary to instigate training programs for educators at the pre- and post-graduate levels but that improving partnerships between services would be key to overcoming these issues. Moreover, respondents recognised that key points in the annual calendar, such as World Diabetes Day and times when deployment of national diabetes campaigns occurred in other countries, were important events that attracted support to re-enforce and re-invigorate programs with even more funding and drivers but the reach of such initiatives were lacking in Saudi Arabia.

> “building a partnership between the Ministry of Health and the universities so that there are training and educational and awareness programs.” [MPDT-5]

> “improving the integration of diabetes care and diabetes care quality requires more support and funding and resources from the government.” [FPN-4]

One professional recognised that diabetes education for older persons often had to be delivered in the presence of their relatives or spouses, in order to act as a memorable source of information for repetition at a later time point; thus suggesting that forgetfulness was a barrier to self-management. However, the caveat was that not all older persons had family or spouses to assist in consolidating their learning of new information about diabetes.

> “so someone must be educated with them, I cannot teach a people over the age of 65, I teach him alone, there must be his son with him or his family.” [FPN-9]

In contrast, younger persons with diabetes were perceived to be more receptive and self-efficacious in understanding and utilising taught information about diabetes and much of the positive effects of information provision upon persons lives originated and spread throughout dedicated social media platforms for people living with type 2 diabetes. This was postulated to be a result of generational effects with younger persons having much greater access to quality information thanks to advances in technology, than compared to older persons who had no such opportunities.

> “the young group has good knowledge compared to the elderly, and this is a modern impression that may have contributed to informing young people of social networking sites and ease of access to information.” [MPD-3]

> “if the people are young, they have greater motivation for self and in improving their health as they can see the negative impact of ill health upon their future lives…. I have found these people to be more proactive in using information and engaging with education to achieve better health.” [MPD-1]

Professionals even reported that younger people simply had greater potential in improving their prognosis from diabetes by seeking support from care providers regarding the correctness of trial and error approaches to managing variances in blood glucose levels. Relaying of messages among older persons was not perceived to be possible due to differences in cognitive ability and information technology awareness and competence of older persons.

> “send me WhatsApp messages, and they tell me: I had such a sugar level and used such insulin, is this method correct? I tell him: Correct. Then he treated himself until his cumulative sugar level was high, but with his control, God willing, and he became a doctor himself.” [MPN-7]

Professionals ’reports of people views concerning the value of self-management programs with a dominant lifestyle modification component comprising exercise were perceived to be of little use to older persons as such individuals were not always able to partake in sufficient activity due to age-related declines in musculoskeletal function and/or co-existing musculoskeletal conditions, such as arthritis. Moreover, other individuals admitted being embarrassed by sports attire and thus, failed to purchase or possess such items to facilitate engagement in rigorous physical activity. Furthermore, older persons tended to report that they did not feel mentally able to partake in exercise due to persistent feelings of tiredness and fatigue, which was mostly attributed to old age as opposed to co-existing mental illnesses.

> “exercise recommendations need to be personalised… older people can’t do the same activity as younger people due to problems with the musculoskeletal system, as well as feeling tired and mentally depressed.” [FPD-2]

However, in contrast to the issues faced by older people living with type 2 diabetes, other professionals reported that people benefitted from self-management components other than exercise as these were simply to understand, engage with and were convenient to the routines and daily lives of individuals, which was an important factor influencing compliance and program completion.

> “some people are not capable of completing some diabetes treatments, such as exercise in older persons or those with physical disabilities.”[MPN-8]

In addition to the former barriers, other factors compounding the adoption of formal self-management programs included poor staffing levels, that meant clinicians were restricted to prioritising the most important clinical needs of people attending clinics and thus tending to neglect education, as well as insufficient facilities to deliver individualised or group-based education.

> “we do not have a lecture hall in the centre, and we must have a team for teaching and content preparers.” [FPN-6]

Short staffing placed considerable pressure upon physicians in managing the demands of people attending clinics, particularly, as the needs of older persons and those with advanced diabetes complications required intensive individual input. In one example, a physicians reported that people with diabetic retinopathy were unable to utilise information technology to understand educational content and thus, these individuals required on-to-one education within clinics, which consumed much time and meant that there were prolonged waiting times and delays in care that impacted other service users.

> “diabetes service is short staffed… we need more resources to help improve care.” [FPN-1]

> “when we educate people, this is intensive and time consuming.. this worsens problems with waiting time for other people.” [FPD-8]

One doctor even reported communicating with people personally over the telephone in a bold effort to sustain the quality of care whilst facing unprecedented time pressure within the inpatient setting.

> “We are trying to make people reach the level that they only visit the clinic for cumulative analysis every six months, so that they can establish the level of sugar using treatments and how to deal with symptoms of high blood glucose and how to avoid them.. I do this by telephone to ensure engagement and understanding.” [FPN-6]

Whilst there was recognition that advances in information technology and the internet had improved health outcomes, and that this was helping to overcome the outdated paternalistic cultures driving authoritative care, some professionals reported conflicting anecdotes. Such professionals found that some people declined education and simply wanted to follow physician-derived treatment plans as these contained the ultimate treatment goals and individuals already knew how to meet such goals through lifestyle modification and/or pharmacotherapy for diabetes.

> “Some people do not search for the educational aspect and are satisfied with obtaining the treatment plan, while others are keen on the education process and visiting educational clinics.” [MPDT-5]

3.5.3.4 Subtheme 3.4: Standards and guidelines regarding self-management approaches to type 2 diabetes care

Professionals reported that the Saudi Arabia Ministry of Health were developing better guidelines for the integration of formal self-management programs for people living with type 2 diabetes as were already in existence for persons with type 1 diabetes. Indeed, participants recognised that high quality diabetes care had to be guided by specialist and set evidence-based criteria, in order to improve the standardisation of care, the equity of access to care and to overall, optimise diabetes outcomes for all people living with type 2 diabetes.

> “there are no universal guidelines to help guide diabetes care… these need to be developed specifically to the Saudi context.” [MPN-6]

However, physicians also recognised that the best possible diabetes care had to focus upon individualising education with person-centred principles, in order to help optimise information delivery and reception and to identify and attempt to resolve any individual barriers to complying with diabetes treatment recommendations. Indeed, it was acknowledged that current diabetes guidelines were lacking in emphasis regarding the personalisation of diabetes education and care, which was perceived to be impeding efforts to encourage people in becoming more self-efficacious.

> “personalised diabetes education and care is critical… diabetes is complex and individualising care is needed to overcome complexities and meet people valued needs.” [FPD-1]

A lack of specificity among national guidelines for managing type 2 diabetes in Saudi Arabia and/or the limited use of such guidelines to inform diabetes care among participants was found to have resulted in practice variances across the local regions. Variances were mostly in relation to the extent of multi-disciplinary team input into the care of people living with type 2 diabetes and in turn, the self-care activities advocated by various professionals. For example, some regions utilised all members of the team, such as nutritionists and podiatrists, whilst others relied upon general practice physicians alone.

> “I have witnessed different diabetes practices, some intensive input from different health professionals in diabetes, others being solely managed by a general practice doctor, guidelines need to promote multi-disciplinary diabetes care and within each specialty, self-management.” [MPD-1]

Moreover, professionals noted that treatment for diabetes had differed considerably across local diabetes clinics and this often existed with poor practices that exposed people to a risk of harm related to adverse drug effects; poor self-management leading to insufficient help seeking and protracted tolerance of adverse effects and thereby, promoting poorer outcomes. In addition to improving the adherence to national guidelines in informing diabetes care, the professional informing the previous statement also suggested that consolidating multiple clinics into one large central clinic could help to address problems with treatment and outcome disparities, particularly if self-management programs were to be delivered to large cohorts of people at any one time.

> “the Ministry of Health needs to consolidate diabetes services and introduce large-scale self-management programs to help improve outcomes on a meaningful level.” [MPDT-5]

5.4. Summary of findings and chapter

The purpose of this study was to explore the views, experiences and perspectives of healthcare professionals involved in the care of people living with type 2 diabetes regarding self-management education. Health professionals involved in the study included diabetes specialist doctors, diabetes nurses and general physicians. Thematic analysis revealed three main themes that explored views regarding the perceived value of self-management education (theme 1), the role of information provision and education (theme 2), the factors influencing the use of self-management programs (theme 3).

Theme one revealed that most participants recognised the value of self-management with people complaint with such regimes achieving meaningful improvements in glycaemic control and cardio-metabolic risk. The second theme comprised two subthemes. The first subtheme (medium and purpose of information and education delivery) revealed that healthcare professionals opted to utilise group-based approaches to education as this was convenient and feasible in view of time limitations and other practice stressors that impeded intensive one-to-one education. However, some professionals recognised the growing value of telehealth in education delivery, particularly in light of the ongoing COVID-19 pandemic. Participants reported that the purpose of education was to prepare people both in terms of emotional readiness and knowledge, in order to embark on a protracted journey of improving their lifestyles as to optimise glycaemic control and the risk of diabetes-related complications. In addition, most healthcare professionals found that education played a key role in correcting erroneous knowledge or misconceptions that people had acquired from unclear or invalid information sources. The second subtheme (importance of timing in optimising uptake and sustained engagement with type 2 diabetes self-management) ultimately revealed that providing education soon after the diagnosis of diabetes was key to enabling people access to information as to instigate behavioural change and generate healthy habits early in the course of disease as to maximise the benefits upon glycaemic control and cardio-metabolic risk. However, early education provision was viewed to require some diligence in view that people are often overwhelmed with information and stress in the early stages of diabetes. Thus, some people may require delayed or ongoing education to ensure knowledge is tailored to promote improvements in physical health.

Theme three explored the factors influencing the advocating and use of self-management programs; subtheme one (integration of diabetes care services and inter-agency working as a factor influencing the need for formal diabetes education) providing insight into the current deficiencies in diabetes service operations and inter-disciplinary working as key barriers to effective program uptake. In addition, participants reported that education had to include all aspects of multi-disciplinary diabetes care, in order to provide people with the optimal means to improving their health status. However, some participants noted that access to multi-disciplinary diabetes care was not available in some regions of Saudi Arabia and in some instances, care was directed by non-specialists, which was perceived to be inadequate and a failure of care. In keeping with the people component of this research, healthcare professionals also recognised the issue of Saudi Arabian culture as it impeded the acceptability of self-management among people. Importantly, there were also scant perceptions among participants that some people held distrust in the medical profession and uncertainty in utilising information sought from credible sources. Other perceived barriers to self-management program uptake included organisational cultures that neglected personalised care, incomplete awareness and belief in self-management education among some professionals, issues of delivering education to all people with diabetes and a lack of specific guidelines. The following chapter details the findings of qualitative interviews of people living with type 2 diabetes.

Chapter 6: Qualitative findings from interviews with people living with type 2 diabetes (Study 3)

6.1 Overview

This chapter presents the findings of Study 3 which explored the views, perceptions and preferences of people living with type 2 diabetes in regard to the value of self-management education and the challenges they faced. First, the characteristics of the participants are detailed. Following this, four main themes, the product of the thematic analysis, are presented and discussed. The findings of this study contributed to the understanding of the requirements for developing a culturally sensitive structured diabetes education programme for people living with type 2 diabetes in Saudi Arabia.

6.2 Participant Characteristics

In total, 14 participants (8 men, 6 women; age range, 35-65 years) with T2DM were interviewed. Twelve participants were married, and two reported being divorced. With regard to the educational status, six participants attained a college degree, five attained a secondary school degree, and three had completed primary school. The time from T2DM diagnosis ranged from 7 months to 25 years. Treatment modalities included diet control, oral medication, a combination of diet and oral medication as well as insulin Ten participants had diabetes-related complications. Regarding diabetes education, three participants reported receiving diabetes education through formal healthcare services, and the others reported receiving none. The demographics of the 14 participants are summarised in Table 6.1. The participants' quotations have been anonymised to protect confidentiality but a coding system has been used to denote the gender of participants; M: male, F: female, P: participant. This was to enable reflection on the varying contexts from which the quotations were derived.

Table 8:Demographic characteristics of people with T2DM participants

Gender	
Male	8
Female	6
Age Group (years)	
30-39	1
40-49	7
50-59	5
60+	1
Marital Status	
Married	12
Divorced	2
Level of education	
Primary	3
Secondary	4
University and above	7
Duration of diabetes (years)	
1-5 years	4
6-10 years	5
>10 years	5
Diabetes management	
Oral medication	4
Diet + oral medication	8
Insulin	2
Complications of diabetes	
No	4
Yes	10
Attended diabetes education session	
No	11
Yes	3

6.3 Thematic Analysis

Using the thematic analysis principles coined by Braun & Clarke (2013) that described data familiarisation, initial coding and theming of the data and reviewing and confirming the codes and themes, a total of four main themes and nine subthemes were constructed during the data analysis. Table 9 summarises the main themes and subthemes that arose from the interviews.

Table 9: Summary of themes and subthemes.

Themes	**Sub-Themes**
1. Understanding of type 2 diabetes and the principles of diabetes management and glycaemic targets	1.1 Understanding of type 2 diabetes as an organic disease entity 1.2 Understanding of diabetes self-management
2. Barriers to diabetes self-management	2.1 Lack of information provision and diabetes education in the early stages after diagnosis 2.2 Status and role of professional and social support 2.3 The Impact of diabetes upon everyday life
3. Cultural mediators of type 2 diabetes self-management	3.1 Cultural beliefs and traditions that promote unhealthy dietary intake 3.2 Cultural beliefs and traditions that promote a sedentary lifestyle
4. Perceived views of desired approaches to self-management education	4.1 Provision of personalised diabetes care 4.2 Desires for and characteristics of formal diabetes programmes and courses

These themes and subthemes have been described in detail in the following sections with quotations taken from the original participants to support the content as suggested by Braun and Clarke (2013). A summary of the coding process and evidence has been provided in Appendix 12.

6.3.1Theme 1: Understanding of type 2 diabetes and the principles of diabetes management and glycaemic targets

This first theme reports upon the variation in the understanding of type 2 diabetes and the role and purpose of diabetes management by people affected by the disease. This encompasses two subthemes: people understanding of type 2 diabetes, that covers views regarding the causes of diabetes and its impact upon the risk of complications, and people understanding of diabetes self-management. Suboptimal understanding of diabetes was prevalent across people, and this may impact their ability to understand how self-management education can help to promote better physical health.

6.3.1.1 Subtheme 1.1: Understanding of type 2 diabetes as an organic disease entity

This subtheme highlights people understanding of type 2 diabetes including the pertinent cause of the problem; chronic hyperglycaemia, and the impact of this issue upon short- and long-term complications. In the absence of understanding the causes of diabetes and the reasons for poorly controlled blood glucose levels, people are unlikely to acknowledge and uptake treatment recommendations and particularly those that demand self-efficacy and therefore, self-management activities.

Across participants, there was varied understanding in the causes of diabetes with some believing that there was a strong genetic component due to heritability and the problem having been diagnosed in multiple family members and passed on, whilst others suggested that diabetes was a punishment from God and that the disease was an inevitable and pre-defined issue within their lives that could not have been avoided.

> “my mother is diabetic, and my brothers most of them have it.. we have an inheritance to diabetes.” [PM-2]

> “Punishment by God, I could not control or prevent it, so far I struggling with it.. my journey has been set.” [PM-9]

Perceptions of aetiology appeared to influence beliefs about the efficacy of diabetes treatments recommended by clinicians. Those reporting an inheritable component tending to be compliers with treatment, whilst the converse appeared true for those who believed diabetes was a Deity-dictated punishment for previous misdoings.

> “I know that diabetes is in my family but I also known that treatment works as I seen in my friends with diabetes.. for this.. I try to follow the medical orders.” [PM-2]

> “I am originally from a family with diabetes, my father and my mother were diabetic, indeed we are a diabetic family...” [PF-3]

> “I have no hope with the treatment.. we are not meant to alter our paths, God has set them so there is no point in trying to take medication, it will not change my life.” [PM-5]

There were even reports of erroneous causes of diabetes with the consumption of excess sugar or sugary foods and drinks being the most commonly reported cause and such participants even advised their children to avoid sugar, in order to prevent diabetes in the future.

> “high sugar in diet caused my diabetes so now I move away from sugary drinks and sweets that contain high sugar.” [PM-2]

This belief may suggest that people had little understanding of the correlates between excess weight and type 2 diabetes; the predominant cause of insulin resistance and in turn, type 2 diabetes. Moreover, there appeared to be little understanding of the fundamental consequences of diabetes and the importance of addressing these problems. People focused upon controlling acute blood glucose and in meeting relatively arbitrary targets, which could have detracted from optimal self-management due to little knowledge regarding the correlation between acute and chronic glycaemia. Some participants also had trouble remembering aspects of diabetes education provided to them in the early stages of diagnosis, suggesting that a lack of ongoing regular education may be responsible for poor people knowledge of diabetes.

> "I control its percentage every day so that it should not exceed 120, 125 at most, I don't let its percentage rise above that." [PM-3]

> "I do not remember anything [about self-management education]." [PM-6]

> "I don't know anything." [PF-5]

There was however, some correct knowledge and concern over the complications of diabetes with most people identifying that common problems for persons with diabetes were eye problems (retinopathy), kidney problems (nephropathy) and heart issues (cardiovascular disease). However, participants did not appear to be aware of the causal association between those complications and glycaemic control.

> "very important for people with diabetic is to examine some organs that are not usual to be examined periodically, such as the eye, kidneys, where the examination is done periodically every six months, or a year… until it is confirmed that there are no complications." [PM-2]

> "Those who have diabetes have a problem with the nerve which is numbness and anaesthesia." [PF-1]

Some individuals reported that it was important to have their organs screened for diabetes complications on a 6-12 monthly basis but this was thought to be simply to confirm the absence of one or complications as opposed to guiding ongoing management on how to prevent the onset and risk of said complications.

> “checking for complications is important.. if absent, I am doing well.” [PM-4]

> “I have discovered complications on the kidneys and the eyes.” [PF-3]

Other participants expressed intense fears about the complications of diabetes given their limb-, sensory- and life-threatening nature and they held strong desires to continue leading their usual lives and retaining their independence and freedom.

> “sometimes one refrain from doing some things for fear of complications.” [PM-2]

This was also reflected in people ’views of the recent COVID-19 pandemic. Having heard about the extent and morbid and mortal impact of the virus, participants reported that type 2 diabetes and its complications were as deadly as COVID-19 due to the serious organ systems the problem affected and the subsequent effects of organ failure upon individual’s lives.

> “diabetes can be more dangerous than the Coronavirus, it can and control your internal organs - the heart, kidneys, nerves, and many other things.” [PM-5]

Such perceptions appeared to be due to the cardiovascular complications of diabetes with individuals recognising that the onset of heart disease or a serious acute heart event would directly threaten their life or their independence should they survive an associated hospital admission.

> “I have seen heart disease and heart failure in my family.. I do fear diabetes as it can affect the heart.. I do not wish to go into hospital at this time [COVID-19]… I may not survive.” [PM-1]

6.3.1.2Subtheme 1.2: Understanding of diabetes self-management

This second subtheme describes people understanding of the principles and purpose of diabetes self-management. Most participants recognised that lifestyle changes were a fundamental part of diabetes management and required a degree of self-motivation and desire to engage with such recommendations.

> “diabetics need to follow lifestyle advise and obtain a balance in exercising and eating, to know their calorie burning rate per day, and to balance it with the calories they eat.” [PM-6]

Specifically, individuals reported that diet was a critical factor influencing diabetes control and this demanded a transition from a relatively unhealthy dietary intake to one that was nutritionally balanced and low in simple and complex carbohydrates to avoid disruption to acute and chronic glycaemia.

> “reduce high sugar and improve diet.. better sugars.” [PM-8]

> “I balanced more on healthy eating and my life has become moe organised regarding food and matters like that.” [PF-2]

In addition, some participants recognised that adopting a healthy diet was to ultimately promote weight loss and whilst this correlation was mentioned during the interviews, the people did not appear to recognise that excess weight was the primary reason for type 2 diabetes in the first instance with adiposity driving insulin resistance.

> “Second thing is the locomotor system, such as exercise and walking… to lose weight and become healthier.” [PM-2]

Furthermore, with regard to complementing lifestyle recommendations, most participants identified that increased physical activity was necessary to attain better diabetes control. However, this understanding did not appear to be correlated with their perception of the importance of weight loss and decrease in insulin resistance. However, few participants recognised and acted upon the principle of energy balance (calorie input versus calorie expenditure) and this is likely to have affected the impact of activity and dietary activities and in turn, weight loss and diabetes control.

> “everyone has told me that exercise is important, important in lowering blood glucose and protecting from heart disease… I already walk and on my feet all day working.” [PM-8]

> “The basis that diabetics [*sic*] need to follow is to balance between walking and wating, to know their burning rate per day and to balance it with the calories they eat’. [PF-4]

Perhaps of more concern, was that people did not highlight the specifics of physical exercise that were necessary to support weight loss. In effect, there was no emphasis regarding the duration, intensity or frequency of physical exercise that participants were expected to adhere to, in order to lose a clinically meaningful level of body weight. One people reported that all persons with diabetes should walk at least 4-5 kilometres each day but there was no consideration of how fast individuals should walk this distance or whether this was based on credible research evidence.

> “a diabetic should walk approximately four to five kilometers per day at least.” [PM-2]

Thus, individuals appeared to use misguided judgements regarding the intensity of engagement with recommended lifestyle recommendations. However, participants did note that engaging in physical exercise would improve their sleep and/or would help to avoid the insomnia associated with diabetes medications, which could have subsequent benefits upon their ongoing capacity to adhere to self-management regimes.

> “I noticed that extra exercise helps me to sleep better and I feel better for more sleep… the medication used to stop me sleeping but that has improved.” [PM-1]

While most people recognised that diabetes medications were key to attaining optimal glycaemic control and reducing their risk of micro- and macro-vascular complications, there were reports that COVID-19 had impacted the availability of drugs and doctors had to be re-distributed to providing frontline care for the critically unwell. Therefore, there were views that self-management was more important than ever to engage with given the risks of not being able to consult with their diabetes specialists and/or in accessing their usual medications.

> “during COVID-19, the media and the Ministry of Health are categorically neglecting diabetes… people are reliant upon self-management but they do not know how to do this or are incapable of guiding themselves.” [PM-5]

6.3.2 Theme 2: Barriers to diabetes self-management

This second theme focuses upon describing the varied barriers to people adhering to self-management for type 2 diabetes, which comprises two subthemes: barriers related to a lack of information provision and education soon after diagnosis, the health and status of professional and social support regarding diabetes, and the impact of diabetes upon people’ quality of life.

6.3.2.1Subtheme 2.1: Lack of information provision and diabetes education in the early stages following diagnosis

This subtheme highlights the important of professionals in providing information and education during the early stages following diagnosing people living with type 2 diabetes as this acted as a key barrier to self-management. People reported that information provision in the initial stages following diagnosis of diabetes was poor.

> “They did not provide me with anything, not information or services.” [PM-1]

> “During pregnancy, they prescribed injections to me, then I returned to the pills without any explanation, unfortunately the doctor used to say ‘the session is over’, dispenses the treatment and ends the session.” [PF-3]

> “No, they didn’t give information in the past. I just went to the health center because of a feeling of distress that comes to me at bedtime, so I conduct the test at the health center, and they told me that the diabetes level was 150.” [PF-4]

Other individuals reported relying upon their previously diagnosed family members to share information about diabetes and diabetes management. Following the acquisition of information from relatives, participants tended to conduct their own research using the internet to establish the underlying problem and how to control glucose levels in the bloodstream.

> “I have brothers who have a lot of experience in the disease because most of them have it, so I sat with them, and gave me some ideas and something like that, and then I do research.” [PM-2]

> “I receive information though my research, I am constantly searching and asking about it, also through campaigns that are held in malls and other places. These things help me frankly.” [PF-3]

However, there was no reference to the source of such information and whether content was credible and evidence based to guide self-management, which could have promoted the adoption of maladaptive lifestyle habits and health behaviours and thereby, detracting from achieving desirable glycaemic control.

In contrast, one people who was a dentist noted that as they were familiar with how to access credible information through journals, they conducted their own research to inform their own management of diabetes. Whilst this option does not seem amenable to other participants in the study, reliance upon self-research presents some risks, such as information overload, mixed findings across research studies, and unclear validity of research due to lack of critical appraisal skills.

> “I try to research diabetes myself but there is so much information, everywhere, different messages and ways of controlling diabetes… I did not know what to trust.” [PM-5]

Other individuals reported that they received no information in the initial period following diagnosis and this conveyed both uncertainty and anxiety upon the individual as the next stage of follow-up was two months after diagnosis. As such, the participants did not know whether to comply with the treatment prescription and feared for their glycaemic control worsening considerable in the interim prior to the receipt of information and education.

> “first time I visited a diabetic doctor, he told me: You are a diabetic patient, and this is your treatment, and goodbye.” [PF-3]

> “I was then worried about my glucose level.” [PM-7]

> “Only then [after the diagnosis] I started looking for how to eat a suitable diet for a diabetic? What should I follow? How to eat? Is there a certain eating pattern that you stick to? What is useful to him [the doctor]? What do I follow to discipline because he is not disciplined?” [PF-3]

Other individuals reported giving up caring for themselves as a result of insufficient education about diabetes, which led such persons to consuming their usual unhealthy diets and leading a sedentary lifestyle. As a result, this led to a considerable worsening of glycaemic control upon first clinical review, which was not to the surprise of participants but was met with anger and frustration due to the little information they had received at the time of diagnosis.

> “I did not care and continued to eat our usual food including fats, meat, and poultry.” [PM-3]

> “later I found in clinic that my blood glucose was too high, the doctor explained why but I did not know how to achieve this.. no one told me about diet and exercise.” [PM-3]

6.3.2.2 Subtheme 2.2: Status and role of professional and social support

This subtheme highlights the importance of both professional and social support for people living with type 2 diabetes and when such support is lacking, how the issue acts to impede self-management. Professional support in the early stages following diabetes diagnosis appeared to be lacking with participants often feeling overwhelmed by the diagnosis itself. In effect, people would have been happy to be provided with information or education and valued the need to understand diabetes but in the absence of ongoing support and tailoring of information to suit individuals' needs, people were uncertain on how to translate the available (often generalised) information into self-care measures or simply became forgetful of important information about glycaemic control.

> “I was only listening to the advice of my doctor, but after a while, the doctors left me the field on some days… I was suffering inside with no one to guide me through the first few months.. it was traumatizing.” [PM-2]

> “I do not remember anything, but what I do remember and want to ask about is why do the tests sometimes come in different rates, go up or down? I mean that, I just attend the tests and take the information from them.” [PF-4]

In turn, this was found to act as a significant barrier to self-management as participants needed a reasonable amount of time to come to terms with the diagnosis, to absorb, expand upon, discuss and consolidate learnt information about diabetes and to gather the intrinsic strength and resources needed to engage with treatment recommendations. As such, the majority of people did not appear to have sufficient self-efficacy or the motivation to tackle diabetes through intensive self-care activities, such as rigorous physical activity, strict compliance with a healthy diet, smoking cessation, abstinence from alcohol, among other lifestyle changes, instead expecting health professionals themselves to furnish them with information and skills needed to take care of their diabetes.

> “without information and education about diabetes, it was impossible to know how to improve my lifestyle.” [PM-7]

One participant even admitted being in psychological shock due to the diagnosis and encountered a prolonged period of denial and as a result, failed to accept and uptake management recommendations until a later time point when their glycaemic control had markedly deteriorated. Only until this people received education in diabetes and diabetes management did their psychological shock resolve and as a result, self-care activities were employed to improve their overall health status.

> “I was psychologically shocked when I found out about it and did not accept it [diabetes diagnosis]”… [following the receipt of diabetes education] “I changed the time of afternoon medicine for the evening and replaced it with the evening medicine and the sugar level became excellent.” [PM-1]

This experience suggests that people diagnosed with diabetes are not signposted to any psychological or other support services to assist persons in overcoming the initial distress of diagnosis or in preventing the development of complicated grief type reactions.

There were also reports from people that diabetes doctors were not supportive of participant-researched diets that were considered healthy, such as low carbohydrate and high fat diets. This was reported by people to be due to doctors' judgements that high fat would increase cholesterol and in turn, cardiovascular risk. Thus, there was some conflict in the advice and support given over how to attain rapid and effective glycaemic control between people and doctors.

> “most doctors are against this diet, as I have faced many doctors who are against this diet.” [PM-2]

There was also evidence from other participants of people having to experiment with the timing of diabetes medication taking, with some correlating morning versus evening administration with blood glucose levels, in order to improve their long-term diabetes control.

> “I follow up with a doctor who wrote me a medicine, but I changed it… I go to a specialist doctor and I noticed a big difference with him.” [PM-1]

However, even when some people ' medications were desirable for controlling blood glucose levels, adverse effects were an issue compounding adherence but despite reporting such issues, clinicians were not supportive of adjusting medications in view of the glycaemic control achieved.

> “I achieved sugar targets with medication but the side effects were not pleasant.. I asked to change but the doctor said it was the best drug and so I tried to tolerate it.” [PM-3]

In contrast, other participants found that diabetes experts at specialist centres were markedly effective in inspiring them to engage with simple life changes to benefit their diabetes control and overall health. Such doctors were reported to be rare but appeared to be sought after given the relatively passive nature of current management approaches.

> “at the specialist diabetes clinic, the staff are really helpful, all my needs are attended to and I usually on target to achieving my personal targets for sugars.” [PM-1]

> “Two years ago, I once asked a nurse who was in the defense medical centre and she was very cooperative.... I have suffered from it for eight years and she is the first nurse to explain to me about these matters. May God bless the Diabetes Center”. [PF-3]

In contrast, the support and advice given by non-specialists was reported to be inadequate and inferior to that found on the television and in videos available online. Similarly, people from families without a history or knowledge of diabetes received little support from their friends and family members as the majority of persons had little to no knowledge of diabetes and how to manage the problem from a lifestyle perspective.

> “No one helps me; I take care of myself because sugar is considered in society as a normal thing... I rely on family as the doctors in family care are not supportive.” [PM-6]

> “my relatives do not understand diabetes so they cannot help me.” [PM-8]

> “Controlling diabetes from my point of view is that it is a subjective factor from the self, the person is the one who controls the eating.” [PF-3]

In response to queries about levels of support at home to ensure adherence to the prescribed dietary and physical activity recommendations, one participant indicated that she felt as if she was doing everything on her own.

> “No, no one’s helping me, I’m myself.’ [PF-3]

6.3.2.3 Subtheme 2.3: The Impact of diabetes upon quality of life

This final subtheme discusses participants ’views regarding the impact of diabetes upon their everyday living and quality of life and how such impacts impeded self-management. Some people desired to avoid diabetes medication to control their glycaemia due to the adverse effects and long-term complications of some drugs, which were often viewed, albeit erroneously, as harmful as diabetes complications. Such perceptions were based on the premise that medications would be taken for a long period of time (further highlighting deficiencies in diabetes knowledge) and that some people attained adequate glycaemic control and even remission when adhering to lifestyle recommendations alone.

> “ [I try] not to use drugs that cause many complications because it is known that diabetes medications last for long periods.” [PM-2]

Individuals also perceived diabetes as a condition inevitably linked to individual suffering, both mentally and physically, suggesting that fear and/or stigma of diabetes were commonly encountered by participants in this study. Although most people reported diabetes to negatively impact their everyday lives and routines with disruption to their occupation and relationships, some reported that one had to co-exist with the disease, in order to cope with and not be mentally affected by the burden of diabetes.

> “I have been suffering for 11 years.. the people must accept his disease and coexist with it.” [PM-1]

> “diabetes affects all aspects of my life… I think about it all the time… there is no escape.” [PM-2]

In regard to the dietary inconveniences of diabetes management, people tended to find this one of the most problematic aspects of self-management as it affected each meal time in terms of planning, sourcing foods and the social aspect of eating and drinking with both their families and friends.

> “the diabetes diet is just difficult.. it is not easy to comply with a healthy diet all the time.” [PM-9]

> “I have a diabetic patient [*sic*] at home that I see, because he is young, and he eats fried foods such as hamburgers, and these things and he drinks Pepsil. Because he sees himself as young and I don’t know if he has complications or something like that”. [PF-1]

One participant reported some extreme measures in going out to source herbal remedies to assist in curing diabetes and in protecting them from diabetes related complications independent of their glycaemic control.

> “I went to them and used natural turmeric, gum arabic, and organic products that are beneficial to the body, specifically the kidneys.” [PM-1]

Some participants also found that their friends were unsupportive of their need to adhere to stringent diabetes management recommendations as these were a disruption to leading a happy and content life. Social supports stated that people should do as they please as life was too short and that the treatment of disease was over-medicalised and based on false and unclear premise of research evidence.

> “My friends and close mates advised me not to care about that [diabetes treatment] and to eat and not to give the matter any concern and to deal normally as I am still young.” [PM-3]

> ‘Sometimes they [family members] decide what food is right for me, but they are all busy with their lives”. [PF-6]

Female and older people frequently perceived that the dietary and physical activity restrictions needed to attain a desirable level of diabetes control were markedly burdensome and were often perceived as unrealistic and unachievable. This appeared to arise from persons being emotionally overwhelmed, as well as limited coping skills and resilience, lack of support and poor self-efficacy to accept and engage with medical recommendations.

> “two important things, first: burning calories, movement and walking, and second healthy food… people do not realize the challenges in sticking to these tasks everyday… some days upset as I cannot stick to the plan.” [PM-7]

> “For example, if I walk and burn calories, I reduce the dose. If I ate normal food and did not walk, I take my full dose. I learned so from my experience”. [PF-4]

As such, one participant reported expending efforts to find easier alternatives to eating a healthy diet and engaging in physical activity, but the reasons for these views were not clear and those pertaining to an unwillingness to partake in exercise could have been due to co-morbid health problems that limited physical function.

> “one must navigate problems to come up with solutions to eating healthier and exercising as doctors expectations are not always a match for person’s abilities.” [PM-3]

6.3.3 Theme 3: Cultural mediators of type 2 diabetes self-management

This third theme focuses upon the impact of the Saudi Arabian culture upon the everyday lives and lifestyle habits of people living with type 2 diabetes and how said culture thereby influenced uptake and adherence to self-management.

6.3.3.1 Subtheme 3.1: Cultural beliefs and traditions that promote unhealthy dietary intake

This first subtheme focuses upon how the Saudi Arabian culture influences people ' dietary preferences and habits. The Saudi Arabian culture appeared to have a considerable impact upon the desires and ability of people to comply with healthier dietary recommendations of diabetes management with participants reporting that overcoming the cultural barriers to diabetes control was necessary to improve health status. Some participants reported that they were frequently invited to dinner parties and felt compelled to attend and eat the food provided out of respect for their friends and relatives. Often, the dietary intake at such events was unhealthy with foods and drinks that were high in sugar and carbohydrates and thus, impairing people ' glycaemic control.

> “I know what the dinner system is there (parties in Saudi households) , it is known to be high in calories, sugars, and carbohydrates.. this is not good for sugar control.” [PM-2]

> “Our food pattern in Saudi Arabia is the problem [referring to difficulty with adhering to a healthy diet]: dates, rice, carbohydrates, pasta as well as the presence of salad on our list is few, but rice is at lunch and dinner”. [PF-3]

Only one participant highlighted that they would make a conscious effort to eat dinner prior to family events, in order to avoid consuming unhealthy foods and drinks, or instead, they attended and would only consume a small amount of unhealthy food. This helped them avoid eating large amounts of foods that could impact their glucose levels negatively while also ensuring that they were able to avoid offending their hosts by refusing meals in their homes as entertaining visitors is an important cultural norm. Whilst it was not clear whether the participant had disclosed their diabetes status to others in society, the reasons for compelled consumption of unhealthy foods and drinks could be due to the lack of disclosure and/or fear of being stigmatised and outed by their supports.

> “I would try to maintain social relations but instead of eating the food provided, I would eat some of my own food, healthy food, before attending, and then only eating a small amount of food at the party.” [PM-4]

Wider society was also found to place a role in encouraging the consumption of unhealthy diets with restaurants and other eateries tending to serve unhealthy foods and drinks and having very few healthy options, which meant that participants did not seem to enjoy going out with their spouses and children.

> “the diabetic gets tired a lot because he is not able to eat all the foods, but the people should not deprive himself but avoiding night-time snacks was important for morning sugars.” [PM-4]

There were also hierarchical and religious aspects that appeared to influence people ' willingness and ability to comply with dietary recommendations. One people was unable to follow the doctor-advised dietary program and only until a religious awakening did they find the capacity to dismiss their unhealthy dietary habits and adopt more wise decision making regarding food and drink choices. In turn, this awakening appeared to empower the people and lead to ongoing improvements in self-management efforts to improve their diabetes control and overall health and wellbeing.

> “I continued in the random food program for years… until thank God, my Lord honoured me ’I realised my case, I began to educate myself, understand about diabetes more. [PM-3]

Another participant believed that their life and the disease of diabetes was in the hands of God and that the deity would shape their remaining life course in accordance with pre-defined expectations, in order to benefit the higher order and society within Saudi Arabia. Whilst this enabled the people to accept the diagnosis and to avoid chronic denial and psychological distress that may have discouraged them from engaging in self-management activities, it also encouraged them to adopt their usual unhealthy dietary intake. As a result, the people reported following most diabetes recommendations stringently with a rigorous routine and minimal to no transgressions but it was not clear whether poor adherence to dietary recommendations impacted their diabetes control and long-term risk of complications.

> “I was convinced that the disease is in the hands of God Almighty, so I lived with this disease… I followed my usual diet but took medication by the doctor.” [PM-5]

6.3.3.2 Subtheme 3.2: Cultural beliefs and traditions that promote a sedentary lifestyle

This subtheme expands upon the cultural factors influencing self-management by discussing how culture promoted sedentary lifestyles and discouraged people from engaging in exercise recommendations. One participant reported that gastric or bariatric surgery was the only means to them losing weight as they were unable to lose weight naturally, via exercise and diet, due to the cultural traditions within Saudi Arabia and traditions in their local community. Thus, there was some underlying beliefs that the health system would take a proactive position in assisting people with diabetes in losing weight through radical means, which is in contradiction to the effort and cognitions needed to engage in self-management activities for a reasonable period of time; time necessary to attain optimal diabetes control and/or to achieve remission.

> “the evidence is that if a diabetic performs gastric sleeve surgery, he will notice the disappearance of the disease.” [PM-1]

Participants who had engaged in exercise reported personal preferences regarding the specific physical activities they undertook and enjoyed but there was recognition that exercise prescriptions needed to be age-specific, in order to optimise adherence. Thus, for most people, a lack of clarity regarding the appropriate of exercise for their age, as well as any comorbid health problems, was a considerable barrier to weight loss and diabetes control.

> “exercise regimes have never been convenient to our traditions and everyday lives… there is no personalisation.. for example, there are different capabilities of older and younger diabetics.” [PM-8]

Participants emphasised simple walking as the primary mode of exercise, highlighting a lack of intensity in physical activity and a culture that is accepting of a rather sedentary lifestyle.

> “the majority of people who suffer from diabetes are retired and have free time... this people can benefit from walking.” [PM-5]

> “Then walking and movement, and for me from my experience I have to move even if at home, move my muscles and hands and I must walk regularly”. [PF-1]

> “Diet should be balanced, which are three meals a day and exercise hould include walking from about half an hour to an hour a day”. [PF-2]

> “The basis that diabetics need to follow is to balance between walking and eating”. [PF-4]

The accounts of participants included in this study also demonstrated evidence of the increasing westernisation of Saudi Arabia and as a result, increasing adoption of western cultures that are known to drive sedentary lifestyles and promote other unhealthy lifestyle habits. In one example, some participants recognised the importance of diabetes education but took excessive measures to watch television programs and online videos regarding diabetes, which distracted them from breaks in sedentary time and reduced the number of opportunities to engage in physical activity.

> “Saudi culture is not that traditional anymore, the west has taken influence, our people are not very active, we eat unhealthy in groups and avoid high exertion.” [PM-7]

> “I educated myself in fact through television programs and YouTube via the Internet. [PM-3]

One participant indicated that she did not feel that educational sessions conducted within the health facilities would be of any benefit to her as a source of health education and information.

> “No, I follow up on television and get that information. I follow doctors on televisions and I benefit a lot from them”. [PF-4]

There were also wider and indirect accounts of participants that suggested the Saudi culture promoted poor knowledge and awareness of prevalent health issues. This was mostly ascertained from reports of unexpected diagnoses of diabetes with people having very little knowledge of the problem, despite Saudi Arabia being one of the most burdened nations to non-communicable diseases.

> “I discovered that I had diabetes while I was sleeping in the hospital and had no knowledge of it before… I later found that that Saudi Arabia has a big problem with diabetes.. one of the worst places in the world for diabetes.” [PM-4]

This may suggest that the Saudi culture does not overly believe in the Western medical model and the associated research evidence and thus, promoting widespread issues of poor health knowledge across the population. Aside from these factors, cultural influences placed upon Saudi citizens in terms of emphasising the hard working role of males, was also seen as a factor compounding the ability of service users to comply with physical activity recommendations. In this regard, some people reported that persons with diabetes and who were retired had considerably more free time to focus upon meeting exercise goals, whilst those in part- or full-time employment were likely to have much fewer opportunities to achieve their activity goals.

> “some people are busy, some are not, retirement or work influences the exercise level, in the morning with work hours it is impossible but for others this is easy.” [PM-7]

Working participants reported having little free time outside of their occupational lives to engage in exercise for two main reasons; fatigue and tiredness following a working day and needing to rest to go back to work the following day without a negative effect upon performance, and desires to spend time with family and friends in the free time they had.

> “outside of work, I expected to do exercise, but this is impossible, I have a family, children and other jobs to do.” [PM-3]

Although the Saudi culture was recognised as a factor hindering diabetes control for most people, culture was not considered to be a modifiable problem and thus, participants recognised that self-management was important but required care providers to develop rapport and connect with people on a meaningful level and in an inspiring way.

> “it is difficult to change, culture influences us as a whole [people with diabetes] , so we need help, personally and with motivation and encouragement, it is easy to fall back into old ways.” [PM-6]

6.3.4 Theme 4: Perceived views of desired approaches to self-management education

This final theme focuses upon people perceived approaches and preferences regarding self-management education in terms of personalised education and the characteristics and conveniences of education programs.

6.3.4.1 Subtheme 4.1: Provision of personalised diabetes care

In this subtheme, participants ’accounts suggested that a higher frequency of professional diabetes care and support was needed to benefit self-management efforts, given that persons tend to digress from healthy lifestyles to old habits. This highlights the complex but influential cognitions of humans when leading lives; to benefit, prosper and enjoy, as opposed to feeling restricted and confined to the recommendations of others. Thus, such individuals suggested that to avoid ongoing transgressions in relation to diabetes, they would need to consult their doctor for support and advice on what they should be doing and how to get back on track with controlling their disease.

> “we are human, sometimes there is some kind of transgression, you know human beings, but it always goes back to the line and pays attention.” [PM-2]

> “The hospital administration gives us direct advice if there is a problem with measuring blood sugar and something like that. I was follow up my case in the diabetes center”. [PF-2]

Whilst a direct reference to personalised diabetes care was not observed, it appeared that greater individualisation of care was needed to avoid future transgressions as people needed to hear the status of their diabetes control (glycated haemoglobin level), in order to revert to their prior transgression efforts in maintaining or increasingly adopting a healthy lifestyle. This also impacted compliance with self-management efforts given that participants felt a need to hear the importance of stringent glycaemic control from their responsible doctors, in order to sustain the desire and self-efficacy to continue to adhere to lifestyle recommendations and to adjust their efforts in line with the self-monitoring of glucose levels.

> “my blood glucose were important, I keep a diary, and this must influence my ongoing care and treatment… there is no point in basing my care around others, we are all unique.” [PM-9]

The importance of personalised diabetes care was also suggested by participants. They reported that medication prescribing was book-based with medicines prescribed based on local guidelines, as opposed to being discussed with people using shared-decision making and collaborative working principles. In effect, people tended not to be informed of the risks of diabetes medications, with the exception of some common side effects, and thus, were accepting of drugs to improve their diabetes control but at the expense of feeling unacknowledged and dismissed by the medical profession.

> “most doctors just prescribe me medication for diabetes in a book… they do not inform me of options or ask what I may prefer.. I don’t know but involvement in the choices would help me to understand.” [PM-2]

> “I need to care about the review and advice that I benefitted from in education and from the doctor”. [PF-4]

The need for person-centred diabetes care was also reflected in the accounts of participants who reported that consultation times were too brief to identify and accommodate the varied needs of people. One people noted that they only spent 10 minutes in the diabetes clinic and within this time, the doctor had to find and discuss their blood results, review their medication and re-emphasise lifestyle recommendations. Therefore, there was very little time to tailor diabetes advice and care to the individual lives of people and this was perceived to be a problem and one that caused distress among some participants.

> “the time dedicated to you with him is approximately ten minutes, in which he explains the treatment method, the blood tests, and then ends the conversation…” [PM-3]

In turn, distress was a contributor to suboptimal self-management activities and thus, delivering person-centred care offers the opportunity to mitigate stress and optimise treatment adherence. Through varied accounts of people in relation to the interview questions, there was consistent evidence that a person-centred approach could help individuals to increasingly accept the burdensome aspects of diabetes management given that recommendations could be tailored to individuals working and personal lives and routines.

> “When diabetes was overwhelming, this was a problem, however, it was simple to come up with a solution, I needed tailored treatment that would suit my everyday life and routines.” [PM-8]

6.3.4.2 Subtheme 4.2: Desires for and characteristics of formal diabetes programmes and courses

This subtheme relates to the characteristics of diabetes programmes that were desired, preferred or valued by participants. People reported that they wanted greater autonomy over treatment decision making with some desiring to be able to adjust their dose of medication according to blood glucose readings and to be able to monitor their glycated haemoglobin without the need for laboratory testing and a clinic visit.

> “I want to be involved in treatment… I would like to understand so that I can be more dedicated and greater belief in my health.” [PM-2]

One participant indicated that she would like to hear about similar cases and actions, lifestyle changes and other factors that had been of benefit of helping them achieve better control

> “In diabetes programmes, I am looking for cases that are similar to me – the second type – and for cases that are similar to me in other diseases I have” [PF-4]

In addition, the majority of the participants desired additional information regarding how a healthy diet could be achieved within the cultural limits of Saudi life, as well as information regarding the minimal amount of exercise required to improving their glycaemic control. It was also clear that educational content needed to be more focused upon the problem of excess weight and how improving diet and exercise could tackle this problem and in turn, insulin resistance, diabetes control and the risk of diabetes complications.

> “information in the early stages and later was little.. I had to research myself, we need more education about diabetes.” [PM-1]

> “They [diabetes education programmes] should focus on nutrition, type of food, and practicing activity; because some people miss some of these matters”. [PF-4]

One participant indicated that regular updates and information that could help with decision making would be a welcome addition to education and self-management programs.

> “Daily advice regarding food, how to use medicines and others”. [PF-6]

Notably, participants recognised that improved engagement with self-management would reduce the burden being observed by diabetes doctors as there would likely be reduced demand for intensive and frequent input by specialists as people would become their own care provider/advisor. There were also desires for programmes to be established on the grounds of improving general health and wellbeing, as opposed to retaining focus upon meeting strict glycated haemoglobin targets, given that people found care providers to adopt some complacency in their recommendations. As a result, participants believed that a more generic approach would help to optimise the capturing of people' attention as the simple recommendations would highlight how individuals could improve their lives and ability to enjoy various aspects of life.

> "managing our diabetes would help the doctors, they are under pressure, and the hospitals, costs are high and people are too many for the staff." [PM-7]

> "blood glucose targets need to be avoided as strict measures are prone to failure or achievement; one is stress the other is temporary relief from stress." [PM-2]

In terms of programme characteristics, participants desired for self-management education to be provided in brief (short) sessions within groups, in order to sustain individuals' attention and to avoid overwhelming persons with excess information. Group sessions were considered valuable as they would allow persons to share their experiences with others, in order to assist and optimise problem solving of others who were struggling to cope with diabetes and its varied adverse effects upon individual's lives.

> "it is better to gather people in one place every ten days, that is, three times per month." [PM-1]

> "I benefitted from [name of nurse] because she collected a group and was showing us information that was very useful to me, the groups for the health centre, whether it was mixed or not". [PF-3]

One participant highlighted that intensive programmes were necessary to re-enforce the value and important of lifestyle change. The participant suggested that education should be delivered at least three times per month during the first year of diabetes diagnosis and then, reduced thereafter in accordance with increases in self-efficacy, adherence to diabetes recommendations and improvements in glycaemic control. In terms of additional and more specific programme content, participants desired for further information regarding the frequency of meals, as well as portion sizes, healthy snacks and how to regulate or stabilise blood glucose levels via dietary means. Moreover, there were requests for exercise pedometers and other means to tracking physical activity, in order to help individuals meet personalised goals as in the absence of prompts, desires to complete set activities were limited.

> “the education and support should be regular and continue for as long as possible, until the people becomes a doctor… I tend to go through phases of good diabetes control and then bad control… I don’t know when each happens, its unpredictable so I need regular help.” [PM-6]

> “In morning breakfast, then lunch and dinner, it can be complicated and so.. information you say.. is needed to ensure our diets are healthy and can actually achieve our goals for diabetes.” [PM-3]

There was also evidence to support the value of the diabetes multi-disciplinary team with people recognising that the best sources of information regarding lifestyle changes were sourced from specialists ranging from dieticians to physiotherapists. In effect, these health professionals were optimally positioned to guide diabetes care in a way that was personalised to individuals as they had sufficient time and the expertise to tailor interventions to ensure goals were realistic and achievable.

> “we are sent to various persons with different knowledge of diabetes and these should work together to ensure care is working towards the same outcome.” [PM-1]

However, people also suggested that providing such information in-person, whether individually or within groups, would not be ideal for most people diagnosed with diabetes as much information would be lost due to the overwhelming nature of the problem and extent of knowledge needed to self-manage the disease. As a potential solution, participants advocated that in-person education be supported by online content that could be accessed remotely and repeatedly and thereby, used to consolidate learnt information.

> “I advise every diabetic to listen to educational programmes and to be keen to attend them and not to miss them, because this is very important and will increase their education in diabetes and how to deal with diabetes.. however, we also need one-to-one intervention to support people who need additional help.” [PM-3]

Aside from the physical aspects of diabetes management, people also recognised the importance of mental wellbeing with impairments being associated with poor treatment compliance and limited pro-activity in self-care activities. Thus, it can be gleaned that diabetes self-management programmes should also focus upon optimising individual’s mental wellbeing through delivering support and care on how participants can develop coping skills and resilience as to deal with the varied adversities of diabetes throughout the disease course.

> “I explain any psychological condition to me due to diabetes, which negatively affects your control.” [PM-4]

> “through the means of communication available to people such as WhatsApp and programs… wellbeing can be improved and solutions to diabetes problems identified.” [PM-8]

Finally, it was clear that people desired diabetes care to be delivered in dedicated centres away from the busy operations and inconveniences of general hospitals, which were often alienating for some people to attend and the reason for poor clinic attendance. Thus, delivering self-management education at specialist diabetes centres could not only optimise the uptake of most diagnosed people but also facilitate group-based learning and provide multi-disciplinary inputs to optimise both physical and mental health.

> “There must be centres specialised in educating people about various diseases, not only diabetics, as the psychological motivation is very important, so first there must be consistent programs.” [PM-4]

> “After the patient comes to the diabetic centre and gets all the information, the rest is his turn”. [PF-6]

One participant even reported that such programs should be founded upon credible research evidence and the previous successes of initiatives implemented with other countries, in order to have optimal potential in improving the health of persons with diabetes in Saudi Arabia.

> “treatment needs to be related to research… the more the better… other countries are leading in healthcare, Saudi needs to catch up.” [PM-8]

Finally, and in line with theme three, some participants reported that religious events, such as Ramadan and Hajj, were obstructive to their diabetes self-management as individuals were unsure on how to partake in such events without compromising their glycaemic control. Given the pertinence of religious traditions, people were not willing to reframe from attending or engaging in the event activities and thus, there is a clear need for future programs to provide trouble-shooting information for individuals seeking to engage in ongoing religious events.

> “In Ramadan, the situation is different.. in my view, they should balance the calories they gain with practicing activity… [PM-6]

In effect, information is needed to support such traditions in terms of how to avoid marked disturbances to blood glucose during extensive fasting and whether physical activity needs to be diminished in accordance with lower energy intake. In a minority of participants, there appeared to be a relative need for a traditional paternalistic approach to providing diabetes education with people seeking to be told to adherence to specific lifestyle recommendations, as opposed to considering and negotiating upon treatment methods and targets in accordance with persons daily routines and lives. Thus, there were mixed views for a person-centred versus conventional approach to diabetes education.

6.4 Summary of findings and chapter

The purpose of Study 3 was to explore the views, perceptions and preferences of people living with type 2 diabetes mellitus in regard to self-management education. Thematic analysis led to the emergence of four main themes. In the first theme (understanding of type 2 diabetes and the principles of diabetes management and glycaemic targets), comprising two subthemes (understanding of type 2 diabetes as an organic disease entity and understanding of diabetes self-management), it was clear that there was marked variance in people ' level of knowledge and self-efficacy in managing their own health. In effect, most people had poor levels of diabetes knowledge in regard to the causes of diabetes, the impact of diabetes upon long-term health and the factors influencing glucose control, which in turn, impeded the ability to recognise the value of self-management. Self-management in this regard mostly relating to exercise and dietary recommendations but perceived efficacy in improving glucose control being obstructed by views related to the aetiology and irreversibility of diabetes. Moreover, all people failed to identify the connection between obesity and type 2 diabetes, which appeared to fuel conceptions that self-management was of little value to improving physical health. Furthermore, improving exercise levels and dietary intake was recognised as an important part of diabetes management by people but engagement was often insufficient (simple walking or part compliance with healthy eating) to induce meaningful changes in weight and glycaemic control.

Theme two summarised the varied barriers to people engaging with self-management recommendations. The first subtheme (lack of information provision and diabetes education in the early stages following diagnosis) revealed that most people failed to receive enough support and education during the period following diagnosis and this compounded self-care efforts. As a consequence, people acquired information about diabetes from their own sources, such as from friends and family members or the internet, which did not always appear credible or helpful in promoting improvements in physical health. The second subtheme (status and role of professional and social support) built upon the first subtheme by identifying people' experiences of receiving insufficient support from healthcare professionals; support that was needed to overcome the emotional and psychological distress encountered as a result of being diagnosed with diabetes. The third subtheme (inconveniences of diabetes upon quality of life) revealed the marked burden of diabetes upon people' everyday lives and life quality with most participants finding diabetes treatment and lifestyle recommendations to be inconvenient and incongruent with desires to live and prosper.

The third main theme identified that the Saudi Arabian culture contributed to much of the poor compliance of people to diabetes self-management recommendations; adhering to a healthy diet being the foremost issue and insufficient rigour of physical activity and sedentary lifestyles being another issue. Finally, the fourth theme highlighted the views of people regarding preferences for self-management education programs. In most cases, people desired for education to be personalised, culturally sensitive, supportive, encouraging collaborative care and treatment decision making and provided within group-based settings. Group-based education being valued as people had found that sharing information with other people was key to improving problem solving and coping skills.

The following chapter details the secondary analysis of an existing dataset relating to the routine data collected from people living with type 2 diabetes at the KFHM Saudi Arabia.

Chapter 7: Secondary data analysis of routinely collected data on type 2 diabetes (Study 4)

7.1 Overview

This chapter describes Study 4 which was a secondary analysis study of a pre-existing dataset drawn from the hospital records at the KFHM, Saudi Arabia. The dataset comprised information that had been routinely collected from people with T2DM by the diabetes centre for research and quality improvement initiatives. The following chapter describes the types of information in the data set and the methods used to analyse this information to provide answers to questions. The findings of the study provide insight into the demographic and clinical factors of the people group of interest that may be influencing uptake and the effectiveness of structured self-management education programs.

7.2 Aims and Research Questions

Study 4 aimed to identify whether any gaps or uncertainties in the dataset exist as to inform ongoing data collection that may help to benefit the design and implementation of self-management programs in the future. In this study, three research questions were posited: 1), what routine data is currently collected and available for people living with type 2 diabetes? 2) what is the quality of the routine data collected? and 3) what, if any, descriptive analyses can be conducted on routine data to describe the target population? The primary objective of this study was to explore the availability and quality of routinely collected data on people living with type 2 diabetes in KFHM and examine how this might be used and adapted to assess a programme of structured education.

7.3 Methods

7.3.1 Design

This study utilised secondary research in the form of a secondary analysis of pre-existing data, which is congruent with a retrospective type of observational research (Wickham, 2019) as historic data was collected from an electronic database as described in subsection 7.3.2. The secondary methodological approach (Aveyard, 2018) was necessary in view of the ease and convenience of analysing pre-existing data collected by the diabetes centre at KFHM. The benefits of secondary analytical research are similar to those of retrospective studies; ability to rapidly derive information from pre-existing data.

7.3.2 Data Source

The dataset analysed in this study was data that was collected from the diabetes centre electronic records within the KFHM Saudi Arabia over a period of four years from January 2016 to December 2020. The electronic record system was established soon after the inception of the specialist diabetes service for people diagnosed with T2DM. Information that was retrieved comprised demographic and clinical data components including age, gender, date of first clinic visit, dates of ongoing clinic visits, type of diabetes, complications of diabetes, and biophysical measurements, such as glycated haemoglobin levels and body mass index. Data entry into these electronic records was managed by healthcare professionals working for diabetes centre in KFHM who were deemed proficient in ensuring all people data, who granted permission, was uploaded to the database.

7.3.3 Desired Data Components

In an ideal dataset, it would prove useful to collect demographic data including age as this is not only an established risk factor for type 2 diabetes but it can also influence views and perceptions of self-care; older persons tending to prefer directive or authoritative care, whilst younger persons tend to be more accepting and uptaking of self-care activities to improve their own health (Wu *et al.*, 2019). Similarly, gender is also a risk factor for type 2 diabetes, as well as influencing the risk of diabetes related complications and adherence to treatment and self-care activities and thus, was data desired in the pre-existing dataset (Arnetz *et al.*, 2014). Other demographic details, such as ethnicity, marital status, employment status, occupation, and socioeconomic status were also desired due to evidence identifying these factors as influencing the course of type 2 diabetes, treatment uptake and adherence (Khunti, 2019, Shan et al., 2017). Such variables can also help to explain inter- people variances in diabetes control and complication incidence (Khunti, 2019, Shan *et al.,* 2017).

Clinical data required among the dataset in regard to type 2 diabetes and self-management education program development would include anthropometric measures, such as body mass index (BMI) and waist circumference, biomarkers, such as glycated haemoglobin, cholesterol and creatinine, and risk factors for complications, such as high blood pressure and family history of cardiovascular disease. Anthropometric measures are important in T2DM as excess weight is known to induce insulin resistance and cause T2DM in over 70% of cases, as well as increasing the risk of early-onset micro- and macro-vascular complications (Leitner *et al.,* 2017). The majority of interventions prescribed for type 2 diabetes comprise a focus upon achieving weight loss, in persons with overweight or obesity status, given that reductions in weight can reduce insulin resistance and in turn, improve glycaemic control (Watson *et al.*, 2011). Improvements in glycaemic control can mitigate the risk of micro- and macro-vascular complications depending upon the extent of control attained (Leitner *et al.*, 2017). Achieving this outcome through losing excess weight forms the primary objective of lifestyle interventions for type 2 diabetes; self-management education seeks to optimise people self-efficacy and sustenance of engagement with such interventions (Captieux *et al.,* 2018). Therefore, BMI is one of the most important anthropometric measures in type 2 diabetes, particularly as overweight and obesity status are considered reversible or modifiable in most cases, which as noted is a key target of self-management programs as this can improve glycaemic control or induce remission of type 2 diabetes and lower the risk of micro- and macro-vascular complications (Wilding, 2014). The BMI provides the most reliable and universally accepted indicator of weight status given that it accounts for the age and height of individuals (Nuttall, 2015). The measure has been categorised into various groups according to weight status as shown in Table 10.

Table 10: Body mass index categories. (Nuttall, 2015)

BMI (kg/m2)	**BMI term definitions**	**Stage of obesity**
<18.5	Underweight	
18.5–24.9	Healthy weight	
25–29.9	Overweight	
30–34.9	Obese	I
35–39.9	Severely obese	II
40–49.9	Morbidly obese	III
>=50	Very morbidly obese	IV

The waist circumference is another important anthropometric measure in type 2 diabetes as it provides an indication of central adiposity, which is considered a useful indicator of the extent of adipose tissue accumulated around organs and has even been reported to provide greater predictive value for cardiovascular risk, than BMI (Selvaraj *et al.*, 2016). In regard to key type 2 diabetes biomarkers, glycated haemoglobin is considered the most important and useful measure as it provides insight into long-term glycaemic control (Carette & Czernichow, 2017). In addition, a wide body of evidence has shown that the extent of glycaemic control, based on glycated haemoglobin measurements, provides strong predictive utility in informing the risk of acute cardiovascular events, as well as other micro- and macro-vascular complications of type 2 diabetes (Suastika, 2021).

Other clinical measures of value among a type 2 diabetes dataset are also important to understand as these can not only influence the onset and prognosis of complications but may also affect individuals desires and capacity to engage with self-management activities (Adu *et al*., 2019). For example, hypertension is one of the most prevalent and burdensome risk factors for cardiovascular disease, worldwide, and a considerable proportion of people living with type 2 diabetes have or acquire the problem over the life-course. Thus, blood pressure measurements can be useful in informing treatment responsiveness and cardiovascular risk; heightened already by type 2 diabetes itself (Song *et al.,* 2020). Similarly, smoking status, lipid profiles and family history of cardiovascular are also important factors in type 2 diabetes as these in isolation or in combination increase the risk of acute cardiovascular events and chronic micro- and macro-vascular complications (Shan *et al.*, 2017).

Finally, since the information in this data set was collected from populations presenting at one of the major specialist centres in Saudi Arabia, it is anticipated that the demographic and clinical variables contained in a desired dataset would be more representative of the nation as a whole increasing the relevance and likelihood that the findings can be reliably applied to other populations with type 2 diabetes in Saudi Arabia (Steckler & McLeroy, 2008).

7.3.4 Study Population

The study population in the dataset comprised all adults aged greater than or equal to 18 years who received a clinical diagnosis of T2DM during the period of January 2016 to December 2020 and whose data had been entered in the electronic record. Any database entries with missing data components regarding glycated haemoglobin, creatinine and cholesterol levels were excluded from the final dataset, as were people who had type 1 diabetes or gestational diabetes, or who were transferred to other services or recorded as deceased. Data included in the final dataset was also limited to information captured during the first clinic visit as this was necessary to capture representative baseline demographic and clinical information of people who had received a new diagnosis of type 2 diabetes; information that could help to inform ongoing data collection for the purposes of informing self-management education programmes that are usually implemented soon after diagnosis. The date of first clinic visit was a useful indicator of new diagnosis of type 2 diabetes as the first visit is usually arranged within the first 1-2 weeks of diagnosis in KFHM.

Data from a total of 5,668 people living with type 2 diabetes was entered into the central database over the defined four-year period, there were a total of 16,125 visits but as data was limited to incident visits, the visit sample size equalled that of the people sample size; n=5,668. This sample was further reduced to 4,001 people living with type 2 diabetes due to missing data regarding glycated haemoglobin, creatinine and/or cholesterol levels among 1,667 people living with type 2 diabetes (Figure 5below). Among these excluded people, glycated haemoglobin, creatinine and cholesterol data was missing for 49%, 11% and 40% of the sample, respectively.

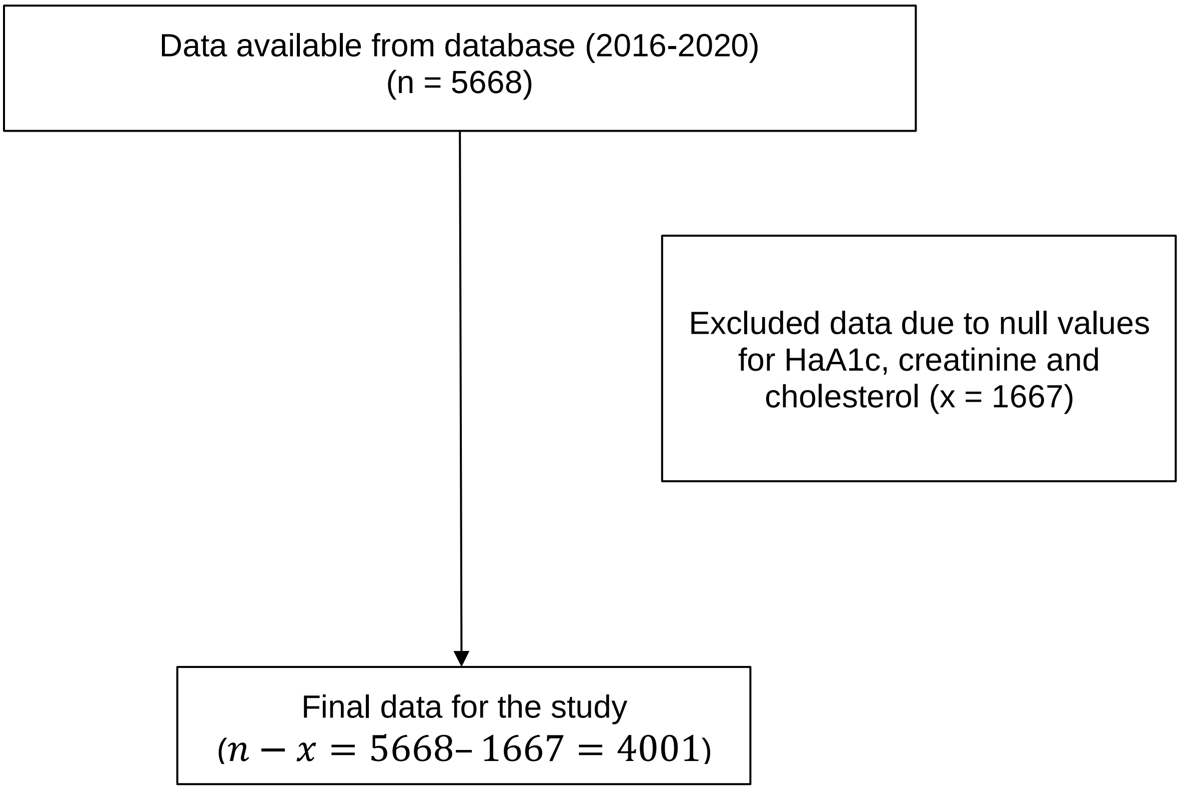


Figure 6: Flow diagram of data cleaning.

7.3.5 Quality of Data

It is important to note that deriving data from electronic health records can increase the risk of issues, such as bias related to missing data and uncertainty regarding the accuracy and reliability of imputed data (Gianfrancesco & Goldstein, 2021), which are factors that may impede confidence and certainty in the findings presented in subsection

7.3. In addition, the validity and reliability of electronic health record data can also depend upon the source of data; when data is people with type 2 diabetes -reported, there can be a risk of response bias, although in this context, data was entered via healthcare professionals and thus, reducing concern for this methodological issue (Rosenman *et al.,* 2011).

The quality of data comprised within the dataset was reviewed in terms of completeness (sufficiency of entered data and missing data) and the number of variables measured and recorded (those considered important or clinically relevant in the management of type 2 diabetes). Evaluating the quality of data held within clinical electronic systems is considered imperative as this factor can influence whether the information can be used to guide ongoing practice or to inform the design, implementation and evaluation of improvement initiatives including self-management education programs (Ostropolets *et al.*, 2021). Authors suggest that the quality of data can be analysed through determining the cohort coverage, the accuracy of data, timeliness and frequency of collection, extent or comprehensiveness of data collected, the storage of data; electronic versus physical data *(*Brazeal *et al.*, 2021). Therefore, the quality of data contained in the diabetes dataset was assessed across these domains, in order to ensure rigour in assessing the data quality, locally.

7.3.6 Statistical Analysis

The data collected from the dataset was analysed using Microsoft Excel and its inbuilt statistics package as this was necessary in view of the data being restricted to analysis within house. However, simple statistical analyses using Microsoft Excel are sufficiently valid to inform health research (Carlberg, 2013). Demographic and clinical data among study people living with type 2 diabetes was analysed using a range of descriptive statistics including means, medians, percentage frequencies and ranges (upper and lower limits). Inferential statistics were not required in this study as no group comparisons were performed (Bland, 2015).

7.3.7 Ethical Considerations and processes

This study received ethical approval following submission of the proposal, which was granted by the College of Veterinary, Medicine and Life Sciences Research Ethics

Committee at the University of Glasgow (approval reference: 200200154) (Appendix 13). In addition, the author was granted approval to access the diabetes center data within KFHM by the General Directorate of Health Affairs for Madinah (approval reference: H-03-M-084) (Appendix 14). Access and storing of data was carried out in accordance with the hospitals data protection policy for the duration of this research study.

Following the retrieval of the required dataset from the hospital, anonymisation of the data was performed prior to data extraction and compilation into the created database via a simple numerical coding system that replaced all identifiable details (name, date of birth and hospital number). Following the extraction and saving of data within an electronic database to permit later analysis, the information technology department were responsible for anonymising people identifiable details and encrypting the data as to prevent unauthorised access and inadvertent loss. Adherence to the data protection policy also ensured that the created database would be saved electronically for a period of time after study completion, in order to permit revisions to the final dataset/analyses. Thereafter, the database would be destroyed after six months. The central database was created using Microsoft Excel with the extraction process being repeated to optimise reliability and minimise the risk of imputation errors. The database could only be accessed using hospital computers that required a dedicated login and thus, data analysis was performed on-site using simple descriptive statistics and graphical representations. Due to the secondary analytical design, it was not deemed necessary to seek the approval of people living with type 2 diabetes to access and analyse the data as people had already been informed and consented to at the time of first data entry that their information could be used for research or quality improvement processes. All people living with type 2 diabetes were initially assured that their personal information would remain confidential through electronic anonymisation methods.

7.4 Results

7.4.1 Overview

This section of the Chapter discusses the key findings of the secondary analysis study and for clarity and ease of interpretation; the results have been structured in accordance with the three central research questions. Question 1 is addressed in subsection 7.3.2, whilst questions 2 and 3 are addressed within subsections 7.3.3 and 7.3.4, respectively.

7.4.2 Research Question 1: What routine data is currently collected and available for people living with type 2 diabetes?

7.3.2.1 Extent of Availability of Demographic and Clinical Data

On review of the dataset (summary in Table 11), demographic information was limited to people age and gender. Thus, other desired information, such as employment status, occupation, marital status, socioeconomic status and educational attainment, was not available for analysis. The limited demographic information may impede insight into the representativeness of the study population but given the large sample size and sufficient four-year period of observation, the applicability of the population is likely to be desirable for populations both within and outside of KFHM. In regards to clinical information, data concerning weight, height, body mass index, glycated haemoglobin, creatinine, lactate dehydrogenase, LDL-cholesterol, HDL-cholesterol, total cholesterol, triglycerides, AST, ALT, microalbumin, vitamin B12, vitamin D and random blood glucose, was available for analysis. Some important clinical data was missing from the dataset that was initially desired, including blood pressure, family history of cardiovascular disease and other clinical risk factors for diabetes related complications. The total cohort of 4,001 people living with type 2 diabetes was subject to some preliminary analyses. In the later subsections 7.3.4.2 and 7.4.3.3, the analysis has been stratified into people with and without diabetes related complications. The descriptive statistics of initial interest have been summarised in Table 11. The mean age of the population in the dataset was 58.0 years (standard deviation [SD] 13.8), whilst the mean weight, height, BMI, glycated haemoglobin, creatinine and cholesterol were 76.8kg (SD 16.4), 164.7cm (SD 7.5), 28.3 kg/m2 (SD 5.8), 151.0 micromole/L (SD 184.5), and 4.3 mmol/L (SD 4.5), respectively.

Table 11:Overall statistical analysis of routine data.

Statistics	**Age**	**Weight (kg)**	**Height (cm)**	**BMI kg/m^2**	**Hb1Ac**	**Creatinine micromol/l**	**Cholesterol (mmol/l)**
Mean	58.0	76.8	164.7	28.3	8.4	151.0	4.3
Standard error	0.2	0.3	0.1	0.09	0.03	2.9	0.1
Median	59.0	75.0	165.0	27.3	8.2	83.0	4.0
Mode	61.0	70.0	160.0	23.4	7.2	74.0	4.0
Standard deviation	13.8	16.4	7.52	5.8	1.8	184.5	4.5
Sample variance	190.7	268.0	56.5	33.2	3.2	34044.9	20.6
Kurtosis	0.5	3.9	-0.09	3.5	-0.1	13.3	707.3
Skewness	-0.2	1.4	0.2	1.4	0.41	3.2	25.4
Range	103	168	46	56.7	15.7	1617	133.6
Minimum	18	32	150	12.5	0	20	0.44
Maximum	87	200	196	69.2	15.7	1637	134
Count	4001	4001	4001	4001	4001	4001	4001
Confidence level (95.0%)	0.4	0.5	0.2	0.2	0.1	5.7	0.1

7.3.2.2 Descriptive Statistics

In terms of gender, of the 5,668 people living with type 2 diabetes in the dataset, there were 58.7% men (n=2,344) and 41.3% of women (n=3,324). The distribution of people living with type 2 diabetes by gender is shown in Figure 6.

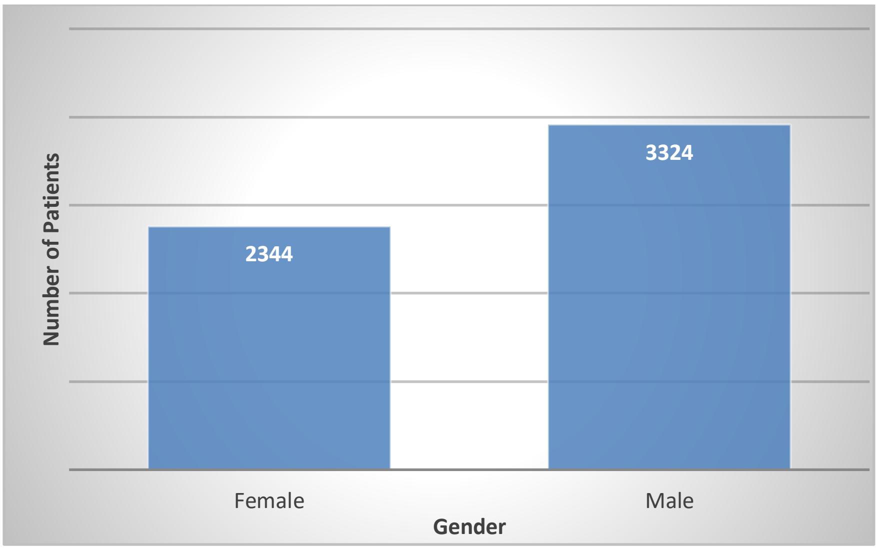


Figure 7: Distribution of people with T2DM by gender.

After the exclusion of data entries with missing critical components of data, as described in subsection 7.3.3.1, the complete data of the remaining 4,001 people living with type 2 diabetes was retained for further analysis. This was based on data collected from people first visits to the diabetes clinic as previously indicated. The proportion of complete versus incomplete data across people has been illustrated in Figure 7.

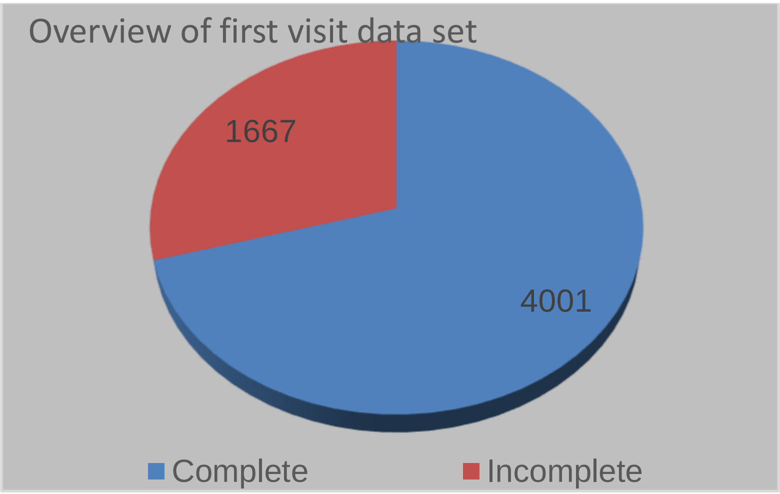


Figure 8: Overview of First Visit Data Set.

Data was then analysed in accordance with people gender; from the 4,001 data entries, the distribution of male and female people living with type 2 diabetes has been shown in Figure 6 above. The proportion of men comprised 59.2% (n=2,368), whilst that for women was 40.8% (n=1,633). Notably, these proportions are similar to those presented earlier in Figure 11and therefore, suggesting that the reduced dataset (due to missing data) can be used to represent the total number of people in the dataset cohort. The mean difference in the proportion of male people living with type 2 diabetes between the initial and refined dataset was 0.5% (58.7% v 59.2%) and for women, the mean difference was 0.6% (41.3% v. 40.8%).

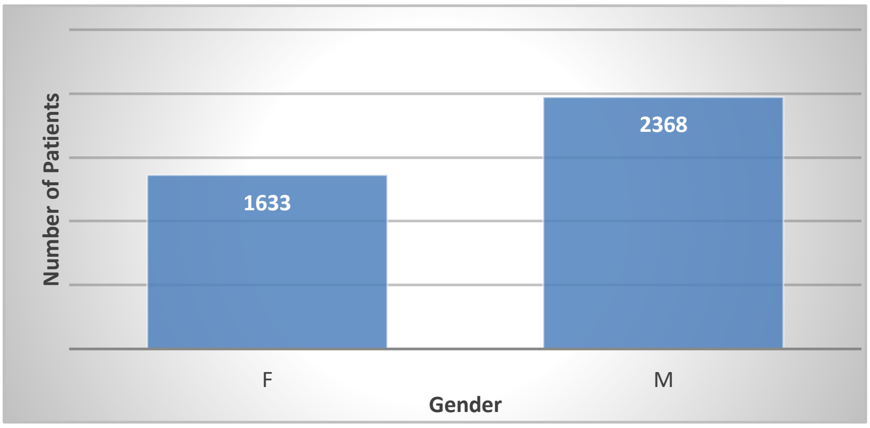


Figure 9: People living with type 2 diabetes with complete routine data and categorised by gender.

The initial analysis of data also revealed that there was annual variance in the proportion of people attending first time clinics as a result of being newly diagnosed with T2DM. These proportions are shown by year over the period of 2016 to 2020 and by gender within Table 12. For all people, the greatest proportion attending first time diabetes clinics was in 2016 (25.4%) and this reduced to 17.6% in 2017 before increasing to stable levels of 21.1% and 22.5% for the years 2018 and 2019, respectively. Notably, in the recent year of 2020, the proportion of people registered on the database following first clinic attendance decreased by almost two-fold from 2016 levels to 13.4%; this is likely to reflect the reduced level of service offered to people living with type 2 diabetes during the COVID-19 pandemic. The proportion of male and female people attending first clinic visits for T2DM remained relatively stable over the four year observation period (range 39.3-44.5% for females and range 55.5-62.1% for males).

Table 12: Analysis of T2DM individuals population data by year of capture.

Year	**Female**		**Male**		**Total**	**Percentage of total**
2016	453	44.5%	564	55.5%	1017	25.4%
2017	289	41.1%	414	58.9%	703	17.6%
2018	320	37.9%	524	62.1%	844	21.1%
2019	361	40.0%	541	60.0%	902	22.5%
2020	210	39.3%	325	60.8%	535	13.4%
Total	**1633**		**2368**		**4001**	**100%**

Data was also analysed in accordance with people age categories. The total age range of people with a complete dataset (n=4,001) was 18-87 years. Due to the large variance in age, the data was categorised into age groups, as recommended by Bland, 2015, to gain insight into the proportion of those within young, middle and older adulthood groups. Therefore, the data was categorised into the following age groups as also shown in Table 13: 18-20, 21-30, 31-40, 41-50, 51-60, 61-70, 71-80 and >80 years. The largest proportion of people (29.3%, n=1,174) fell into the age group of 51-60 years, followed by 61-70 years (27.7%, n=1,109), 41-50 years (15.9%, n=636) and 71-80 years (12.4%, n=495). The smallest proportion of people fell into the youngest age categories of 18-20 years (0.6%, n=25), 21-30 years (2.8%, n=114) and 31-40 years (6.9%, n=277). Overall, more than 73% of people with a first clinic visit for T2DM were aged >50 years. The age group data was also stratified by gender as summarised in Table 13. This shows that 72.4% of men fell within age groups exceeding 50 years, as compared to a slightly higher proportion of women; 75.6%.

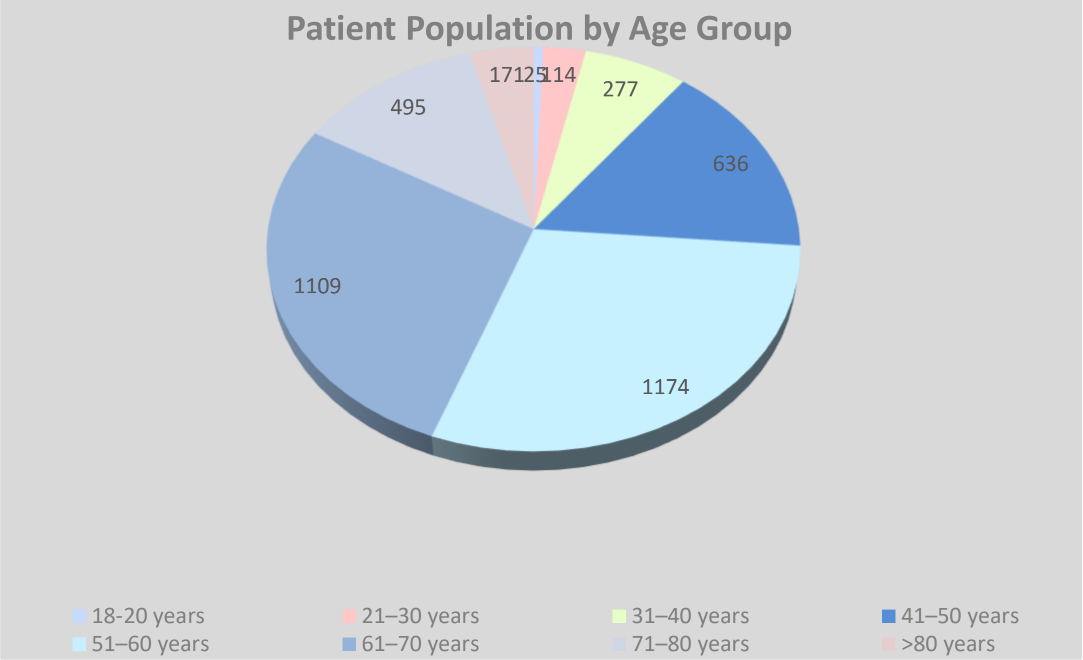


Figure 10: Registered people living with type 2 diabetes by age group categories from 2016 to 2020.

Table 13: Distribution of people living with T2DM by Age.

Age group	**No of male**	**No of female**	**People population by age group**	**Age group by percentage**
18–20 years	15	10	25	0.6%
21–30 years	67	47	114	2.9%
31–40 years	166	111	277	6.9%
41–50 years	405	231	636	15.9%
51–60 years	645	529	1174	29.3%
61–70 years	676	433	1109	27.7%
71–80 years	290	205	495	12.4%
>80 years	104	67	171	4.3%
Total	**2368**	**1633**	**4001**	**100.0%**

The gender and age of the registered patients in the dataset were also analysed to identify any correlations between these demographic variables (Table 14). For female patients (n=1,663), and as previously noted, the data showed that 75.6% of women were aged >50 years, whilst the remaining 24.4% were aged <=50 years. Moreover, the most abundant age group was observed for females aged 51-60 years (32.4%, n=529), whilst the least abundant age groups were 18-20 years (0.6%, n=10) and >80 years (4.1%, n=67).

Table 14: Analysis of 1,633 female registered people living withT2DM.

Age group	**No of people**	**Age groups ≤50 years and ≥ 51 years**	**Percentage of people in each age group to total female population**	**Percentage of people ≤50 years and ≥51 years to total female population**
18–20 years	10	399	0.6%	24.4%
21–30 years	47		2.9%	
31–40 years	111		6.8%	
41–50 years	231		14.2%	
51–60 years	529	1234	32.4%	75.6%
61–70 years	433		26.5%	
71–80 years	205		12.6%	
>80 years	67		4.1%	
Total	**1633**	**1633**	**100.0%**	**100.0%**

For male people (n=2,368), and as previously noted, the data showed that 72.4% were aged >50 years, whilst the remaining 27.6% were aged <=50 years (Table 7.6). Moreover, the most abundant age group was observed for males aged 61-70 years (28.5%, n=676), whilst the least abundant age groups were 18-20 years (0.6%, n=15) and 21-30 years (2.8%, n=67). Therefore, males appeared to observe a later-onset of

T2DM as compared to females due to disparities in the proportion of those attending first time clinics when categorised by age groups (Figure 9).

Table 15: Analysis of 2,368 registered male people with T2DM.

Age group	**No. of people**	**Age groups ≤ 50 years and ≥ 51 years**	**Percentage of people in each age group to total male population**	**Percentage of people aged ≤ 50 years and ≥51 years to total female population**
18–20 years	15	653	0.6%	27.6%
21–30 years	67		2.8%	
31–40 years	166		7.0%	
41–50 years	405		17.1%	
51–60 years	645	1715	27.2%	72.4%
61–70 years	676		28.6%	
71–80 years	290		12.3%	
>80 years	104		4.4%	
Total	**2368**	**2368**	**100.0%**	**100.0%**

The data was also descriptively analysed to identify trends in the BMI and glycated haemoglobin levels (HbA1c) of people with T2DM. This data has been summarised in Tables 16 and 17. Among the total number of people (n=4,001), the mean BMI was 28.3 kg/m2, which was congruent with the overweight category of excess weight (Nuttall, 2015). Notably, the BMI categories are slightly disparate from the internationally accepted classification system due to the nature of data entered onto the local system. The data also revealed that 24.1% (n=966) of people with T2DM observed glycated haemoglobin levels (HbA1c) <7% at first visit, as compared to the remaining 75.9% (n=3,035) of people with T2DM who observed levels >=7%. This implies that as anticipated the vast majority of people with T2DM have poor glycaemic control at first presentation. A fact that further highlights the pertinence of early and intensive intervention, likely via self-management education, in improving the degree of glycaemic control (Ceriello *et al*., 2022). This is discussed further in the discussion chapter.

The majority of people with T2DM (34.6%) with a first visit glycated haemoglobin level <7% (Table 17) observed BMIs within the category of overweight (>25-30 kg/m2), and within the various categories/stages of obesity; BMI >30kg/m2 (30.5%). However, a third of registered patients observed a healthy BMI status (19-25kg/m2; 34.1%). Very few people fell within the underweight classification (<19 kg/m2; 0.7%). The proportion of people with obesity reduced progressively with increasing obesity stage: 17.6% for simple obesity, 7.9% for severe obesity, 4.6% for morbid obesity and 0.5% for very morbid obesity. Among people with a first visit glycated haemoglobin >=7% (Table 18), a third of people (33.8%) also fell within the overweight BMI category (>25-30kg/m2), whilst another third (34.2%) observed healthy weight status (19-25kg/m2) and another third (30.9%) observed obesity statuses (>30kg/m2). Only 0.7% of registered patients were observed to have an underweight BMI status (<19kg/m2). Similar to people with glycated haemoglobin levels <7%, the proportion of those with levels >=7% reduced progressively with increasing obesity stage: 18.6% for simple obesity, 8.0% for severe obesity, 3.7% for morbid obesity and 0.4% for very morbid obesity. This serves to highlight the link between obesity and glycaemic control in people with T2DM.

Table 16: BMI analysis of people with T2DM and HbA1c <7%

BMI	**Number of people**	**Percentage (%)**
<19	7	0.7%
19–25	329	34.1%
>25–30	334	34.6%
>30–35	170	17.6%
>35–40	77	8.0%
>40–50	44	4.6%
>50	5	0.5%
Total	**966**	**100.0%**

Table 17: BMI analysis of people with T2DM with HbA1c ≥7%.

BMI	**Number of people**	**Percentage (%)**
<19	31	1.0%
19–25	1039	34.2%
>25–30	1026	33.8%
>30–35	572	18.9%
>35–40	243	8.0%
>40–50	112	3.7%
>50	12	0.4%
Total	**3035**	**100.0%**

7.4.3 Research Question 2: What is the quality of the routine data collected?

7.4.3.1 Missing Data

Among the total 5,668 people with T2DM in the dataset, 29.4% (n=1,667) had one or more critical missing data components, which included either or more of glycated haemoglobin, creatinine and cholesterol levels. A summary of the missing critical data components are provided in Table 18, which shows the isolated and combined components of data missing in the dataset. The vast majority of missing data was related to glycated haemoglobin (46.1%), followed by cholesterol (37.8%) and creatinine (16.1%). Non-critical data components that were missing from the dataset have not been shown.

Table 18: Missing data from the dataset for the first visits of the registered people with T2DM.

Routine data	**Individual routine data null values**	**Null with respect to HbA1c**	**Null with respect to creatinine**	**Null with respect to cholesterol**	**Null values with respect to entire data set**
HbA1c	817	817	37	104	106
Creatinine	287	37	287	273	
Cholesterol	669	104	273	669	
Total	**1773**				**1667**

In the final dataset, a range of other clinical variables were missing and thus, highlighting further issues with the quality of data collected and specifically, its imputation into the electronic record. A summary of the other missing clinical data has been summarised in Table 19. The missing data shown in Table 19 refers to data components across people with T2DM in regard to the first clinic visit, as data for other visits, was excluded as previously described. The largest proportion of missing data affected the clinical variables of microalbumin (82%, n=4,648), followed by vitamin B12 (72.7%, n=4,122), LDL cholesterol (55.4%, n=3,141), vitamin D (34.6%, n=1,961) and lactate dehydrogenase (33.9%, n=1,924). Clinical data variables with minimal missing data across the cohort included creatinine (5.1%, n=287), AST (5.8%, n=327), ALT (5.3%, n=298) and random glucose (5.6%, n=315).

Table 19: Missing data from routine checks of the 4,001 registered people with T2DM.

Parameters investigated	Total expected data from report	Missing	Percentage of missing data
Hb1Ac	5668	817	14.4%
Creatinine	5668	287	5.1%
LDH	5668	1924	33.9%
LDL cholesterol	5668	3141	55.4%
HDL cholesterol	5668	1360	24.0%
Cholesterol	5668	669	11.8%
Triglycerides	5668	734	13.0%
ASTGOT	5668	327	5.8%
ALT	5668	298	5.3%
Microalbumin	5668	4648	82.0%
Vitamin B12	5668	4122	72.7%
Vitamin D	5668	1961	34.6%
Random glucose	5668	315	5.6%

7.4.3.2 Other Measures of Data Quality

Based on the recommended measures of health data quality as described in the methods section of this report, the data was assessed, in addition to missing data, for cohort coverage, the accuracy of data, timeliness and frequency of collection, extent or comprehensiveness of data collected, the storage of data, electronic versus physical data (Brazeal *et al*., 2021). The data was recorded in electronic format on a central database and thus, avoiding the risk of imputation errors associated with physical approaches to data recording. While it is acknowledged that there could be errors in the data that was entered into the electronic record, it was also noted that this is likely to represent where considerable outliers were identified. Such data was precluded from the remaining analyses in this study.

The cohort coverage was deemed sufficient and representative of the population of people with T2DM being managed in KFHM due to the data of all known people having been uploaded onto the system. It was not clear to the author however, whether any people had been excluded or missed from inclusion on the electronic record, or whether there had been any delays in uploading people data. The accuracy of the data was considered sufficient given that all numerical indices had been documented to one decimal place, which is considered acceptable for health-related measures (Cole, 2015). The comprehensiveness of the data collected on the system was not considered ideal for informing quality improvement initiatives as a range of demographic and clinical variables important in T2DM had not been measured or recorded. Examples of such variables include ethnicity, occupation, blood pressure, personalised glycaemic targets and prescribed drug and non-drug therapy. Finally, the frequency of data collected was identified as being recorded for each clinic visit; therefore, the frequency varied considerably between people with T2DM from 1 to 12 months. Although such variance was recognised, this is likely to be considered appropriate for each people given the convenience for diabetes nurses in uploading data at the end of each clinic.

7.4.4 Research Question 3: What, if any, descriptive analyses can be conducted on routine data to describe the target population?

7.4.4.1 Complete Cohort

Among the entire cohort, 80.3% of people with T2DM observed glycated haemoglobin levels >=7.0%, whilst the remaining 19.7% observed levels <7.0% (Table 20). mean level of glycated haemoglobin was 8.6% and thus, above the threshold of 7.0% that is somewhat indicative of suboptimal glycaemic control. This is important since consensus evidence showing that glycaemic control <7.0% (<53 mmol/mol) reduces the risk of micro-vascular complications and progressive increases above 7.0% increasing the risk of complications (Valensi *et al*., 2019). Therefore, the data shows that the vast majority of people (>80%) observe a heightened risk of diabetes related complications soon after being diagnosed with T2DM.

Table 20: Analysis of Hb1Ac levels of individuals with poor T2DM control.

T2DM control	**Number**	**Percentage**
Hb1Ac <7.0%	505	19.7%
Hb1Ac ≥7.0%	2054	80.3%
Total	**2559**	**100.0%**

Clinical data regarding creatinine levels (an indicator of renal function) was analysed in relation to eliciting information regarding people with T2DM baseline renal function and the likely cautions and contraindications impaired renal function could impose upon pharmacological treatment decision making. The creatinine levels of the cohort were also analysed using descriptive statistics with the data showing that the mean serum concentration was 148.8 micromol/land the range of concentrations being 20-1,637 micromol/l. The creatinine levels were also analysed through stratifying the cohort by gender. Based on local criteria for prescribing metformin, an anti-diabetes medication that is commonly used but can increase the risk of lactic acidosis in people with renal impairment, a threshold creatinine level was defined as 124 micromol/L for women and 133 micromol/L for men to understand the dataset (Holstein & Stumvoll, 2005). This data is shown in Table 21. The data revealed that metformin would be contraindicated in 25.5% of female people and among a similar proportion of men (24.3%). Thus, the drug would be indicated in the remaining 74.5% of women and 75.7% of men. This data highlights the likely treatment needs of the sample included in the cohort; a combination of non-pharmacological and pharmacological therapy based on baseline organ function and glycated haemoglobin levels.

Table 21: Analysis of creatinine level based on recommended use of metformin in people with poor T2DM control

Creatinine level	**Number**	**Percentage**
Female people		
Serum creatinine <124 micromol/L	758	74.5%
Serum creatinine ≥124 micromol/L	260	25.5%
Total female people	**1018**	**100.0%**
Male people		
Serum creatinine <133 micromol/L	1166	75.7%
Serum creatinine ≥133 micromol/L	375	24.3%
Total male people	**1541**	**100.0%**

In regard to total cholesterol levels, the mean serum concentration was 4.1mmol/L, which is 0.4mmol/L below the recommended target of <4.5mmol/L as to reduce the risk of cardiovascular complications (Daniel, 2011). The data for cholesterol has been summarised in Table 22. This shows that 60.9% of the sample observed total cholesterol levels within the <4.5mmol/L target range, whilst the remaining 39.1% of the patients observed cholesterol values exceeding or equal to 4.5mmol/L. Based on the measurable risk factors for micro- and macro-vascular complications, such as high total cholesterol levels, the findings thus far, suggest that the local population of adults with T2DM require intensive support and input to offset the heightened risk of diabetes related complications at baseline; the point soon after T2DM diagnosis.

Table 22: Total cholesterol data analysis for people with T2DM without complications

Total cholesterol level	Number	Percentage
Total cholesterol <4.5%	1559	60.9%
Total cholesterol ≥4.5%	1000	39.1%
Total	2559	100.0%

Other descriptive statistics included measures of LDL-cholesterol, HDL cholesterol and triglycerides, which were important to gain a more complete picture of the average lipid profile of people registered to the local diabetes service. The mean LDL-cholesterol, HDL-cholesterol and triglycerides were 2.5 mmol/L (+/- 4.2), 1.1 mmol/L (+/- 1.5) and 1.8 mmol/L (+/- 4.8), respectively. Evidence recommends that the ideal (low risk of cardiovascular disease) ratio of LDL:HDL-cholesterol is <5:1 and thus, the mean ratio for the cohort was more than desirable, approximating 2.5:1 (Goldberg, 2001). Evidence also suggests that triglycerides should be <1.7 mmol/L to reduce the risk of cardiovascular disease in diabetes but notably the cohort mean fell slightly above this reference limit; 1.8 mmol/L (Goldberg, 2001).

7.4.4.2 People with T2DM without Diabetes Complications

Among people with T2DM who were not found to have a documented diagnosis of a diabetes related complication/s, data was analysed according the level of glycaemic control (<7% and >=7%). Based on the cohort of 4,001 people with T2DM with complete datasets, 21.9% were complication-free at the time of their first visit to the diabetes clinic. The glycated haemoglobin levels were found to range from 4% to 14.1%; the mean level being 7.9%, which is in keeping with poor control (Ceriello *et al*., 2022). The data was also divided into the proportion without diabetes related complications by glycaemic control using the threshold of 7.0% as shown in Table 23. A total of 32.3% of people with T2DM who lacked complications observed glycated haemoglobin levels <7%, whilst the remaining 67.7% observed glycated haemoglobin levels >=7%.

Table 23:Analysis of Hb1Ac levels among people with T2DM but without complications.

	Number	**Percentage**
Hb1Ac <7.0%	284	32.3%
Hb1Ac ≥7.0%	595	67.7%
Total	**879**	**100.0%**

The range of serum creatinine varied from 22.4 to 1,637 micromol/L and thus, indicating marked variation in renal function; low than usual values potentially reflecting people with T2DM with low lean muscle mass and high values likely resulting from chronic renal disease. Based on local criteria for prescribing metformin, an anti-diabetes medication that is commonly used but can increase the risk of lactic acidosis in people with renal impairment, a threshold creatinine level was defined as 124 micromole/L for women and 133 micromole/L for men to understand the dataset (Holstein & Stumvoll, 2005). This data is presented in Table 24. The data revealed that metformin would be contraindicated in 27.1% of females and among a similar proportion of men (27.9%). Thus, the drug would be indicated in the remaining 72.9% of women and 72.1% of men. This data further highlights the likely treatment needs of the sample included in the cohort. This is quite repetitive of the narrative which comes before table 21. In this section, are you mainly relating the serum creatinine to people with T2DM without complications whereas the earlier part/table 21 is people with poor control? It is a little confusing as the two paragraphs come very close together and read as being repetition.

Table 24: Analysis of creatinine levels with respect to recommended use of metformin.

Creatinine level	**Number**	**Percentage**
Females		
Serum creatinine <124 mmol/L	293	72.9%

Serum creatinine ≥124 mmol/L	109	27.1%
Total female	**402**	**100.0%**
Males		
Serum creatinine <133 mmol/L	344	72.1%
Serum creatinine ≥133 mmol/L	133	27.9%
Total male	**477**	**100.0%**

In regard to total cholesterol levels, the mean serum concentration was 4.1mmol/L, which is 0.4mmol/L below the recommended target of <4.5mmol/L as to reduce the risk of cardiovascular complications. The data for cholesterol has been summarised in Table 25. This shows that 61.8% of the sample observed total cholesterol levels within the <4.5mmol/L target range, whilst the remaining 38.2% of people with T2DM observed cholesterol values exceeding or equal to 4.5mmol/L. As with the analysis for the entire cohort in subsection 7.4.3.1, the findings of this subgroup of people who lacked diabetes complications, suggest that more than a third observe an increased risk of complications due to observing cholesterol levels exceeding the recommended threshold (Daniel, 2011).

Table 25: Analysis of total cholesterol data of people with T2DM but without complications.

	Number	**Percentage**
Total Cholesterol <4.5 mmol/L	543	61.8%
Total Cholesterol ≥4.5 mmol/L	336	38.2%
Total	**879**	**100.0%**

7.4.4.3 People with Diabetes Complications

Among people with T2DM who were documented to have one or more diabetes related complication/s, data was analysed similar to the previous section. A total of 561 (14.0%) of people across the entire cohort (n=4,001) with a complete data set were diagnosed with one or more diabetes related complications. A range of complications were noted across 20 diagnostic codes, as shown in Table 26. Among people with T2DM with complications, the most common complication was diabetes-related nephropathy (37.8%), followed by unspecified complications (9.3%), diabetes-related polyneuropathy (11.1%), diabetes-related neuropathy (8.9%) and diabetes-related mononeuropathy (5.8%). The least common complications were skin, soft tissue and musculoskeletal conditions (0.4-0.5%), comorbid ophthalmic disease (0.4%) and diabetes related cardiomyopathy (0.7%).

Table 26: People with T2DM complications at KFHM

T2DM with complications	**No**	**Percentage (%)**
T2DM with nephropathy	212	37.8%
T2DM with other specific complication	74	13.2%
T2DM with polyneuropathy	62	11.1%
T2DM with unspecified complication	52	9.3%
T2DM with neuropathy	50	8.9%
T2DM with mononeuropathy	29	5.8%
T2DM with background retinopathy	17	3.0%
T2DM with foot ulcer	11	2.0%
T2DM with multiple microvascular or other specific nonvascular complications	9	1.6%
T2DM with ketoacidosis	8	1.4%
T2DM with hypoglycaemia	6	1.1%
T2DM with peripheral angiopathy	6	1.1%
T2DM with lactic acidosis, without coma	5	0.9%

T2DM with hyperosmolarity without nonketotic hyperglycaemic-hyperosmolar coma [NKHHC]	5	0.9%
T2DM with cardiomyopathy	4	0.7%
T2DM with cataract	3	0.5%
T2DM with specific skin and subcutaneous tissue complication	3	0.5%
T2DM with advanced ophthalmic disease	2	0.4%
T2DM with specific musculoskeletal and connective tissue complication	2	0.4%
T2DM with multiple complications	1	0.2%
Total	**561**	**100.0%**

7.5 Summary of Results and chapter

This study evaluated the extent and quality of data routinely collected by the local diabetes service in KFHM to determine whether this will be sufficient to informing future evaluations of care quality and self-management education programme effectiveness in the future. This study sought to address three core questions (below).

Research Question 1: What routine data is currently collected and available for people living with type 2 diabetes?

The findings of this study in relation to research question 1 revealed that the current dataset for people living with type 2 diabetes in KFHM comprises a range of key demographic and clinical variables. This includes the level of glycaemic control at the first clinic visit of the participants, cholesterol and measures of renal function. The patterns demonstrated therein, can be used, in part, to help inform the development of future improvement initiatives; as it proposed via a self-management education programme.

Research Question 2: What is the quality of the routine data collected?

In regard to question 2, the study revealed that the quality of data collected was limited to some extent. The representative or cohort coverage of the data was deemed sufficient given that a large number of people with T2DM' data had been recorded; likely all people with a diagnosis of T2DM even despite a large proportion observing missing data for critical clinical variables. A total of 4,001 people with T2DM had complete datasets. It was also identified that the frequency of data collected was ideal (each clinic visit), as was the medium of collection (electronic) and accuracy of numerical variables (one decimal place). However, there was some concern about the comprehensiveness of data collected; a number of key demographic and clinical variables missing that would be considered important in T2DM and self-management education programme development. These include but are not limited to information about blood pressure, any co-existing cardiovascular disease as well as family history of cardiovascular disease and diabetes that could facilitate decisions relating to people risk and therefore inform self-management and other preventive measures.

Research Question 3: What, if any, descriptive analyses can be conducted on routine data to describe the target population?

In regard to the final question, the descriptive analysis of the data revealed that at first clinic visit, a large proportion of people with T2DM observed undesirable glycated haemoglobin, creatinine and cholesterol levels and thus, highlighting the initial intensive needs of the target population group. This data re-enforces the need for informed and optimal management approaches soon after the diagnosis of T2DM as means to improving glycaemic control and lowering complication risk.

The last few chapters have presented the findings from all four studies included in this research study. The following chapter now goes on to discuss these findings in detail.

Chapter 8: Discussion and Conclusion

8.1 Overview

The overall aim of this research study was to understand the factors necessary for achieving culturally sensitive programmes for people living with type 2 diabetes in Saudi Arabia. It aimed to determine the requirements for developing a culturally sensitive structured diabetes education programme for people living with type 2 diabetes in Saudi Arabia. Four studies were conducted to address specific research questions devised to assist with meeting the primary research aim. The MRC's framework for complex interventions (Skivington *et al*., 2021) guided this research for developing and evaluating complex interventions. It used mixed-methods research across multiple phases involving quantitative and qualitative methods to achieve the research objectives. This chapter summarises key findings and discusses them regarding the research questions and relevant literature. This is followed by a review of the research's limitations and the implications and recommendations for education programme development.

8.2 Summary of Findings

8.2.1 Systematic Review (Study 1)

Study 1 comprised a systematic literature review to explore the value of theory-based self-management education programmes with cultural adaptation upon populations with type 2 diabetes. Based on an informed search for relevant literature using key electronic databases, 13 randomised controlled trials comprising a total sample size of 2,215 participants evaluating culturally tailored self-management education programmes for type 2 diabetes were collectively analysed. The results showed that various theories had been used to develop culturally tailored programmes and most studies showed that this enhanced service user engagement with self-management recommendations. All studies evaluated the impact of self-management programmes upon glycaemic control; all but four studies having revealed significant improvements in glycated haemoglobin levels (Vincent, 2009, Babamoto *et al.*, 2009, D'Eramo *et al.*, 2010, Ruggiero *et al.*, 2014). Trials reporting improvements in glycaemic control revealed significant reductions ranging from 0.5-1.6% versus baseline and against controls over a 3-12 month follow-up period (DePue *et al.*, 2013, Gucciardi *et al.*, 2007, Lujan *et al.*, 2007, Osborn, 2010, Prezio *et al.*, 2013, Rosal *et al.*, 2011, Samuel-Hodge *et al.*, 2009, Spencer *et al.*, 2011, Sinclair *et al.*, 2013).

Some trials also evaluated cardiometabolic risk factors as outcome measures including blood pressure, body mass index and waist circumference but most studies failed to revealed notable improvements versus baseline levels (Babamoto *et al.*, 2009, D'Eramo *et al.*, 2010, DePue *et al.*, 2013, Rosal *et al.*, 2011, Samuel-Hodge *et al.*, 2009, Vincent, 2009). Furthermore, most trials evaluated the impact of the culturally tailored self-management education programmes upon self-care behaviours and found improvements in healthy eating, physical activity, self-efficacy and adherence to management recommendations for type 2 diabetes (Babamoto *et al.*, 2009, D'Eramo *et al.*, 2010, Gucciardi *et al.*, 2007, Osborn, 2010, Rosal *et al.*, 2011, Ruggiero *et al.*, 2014, Samuel-Hodge *et al.*, 2009, Spencer *et al.*, 2011). Some trials even identified improvements in general health status and psychological wellbeing (Babamoto *et al.*, 2009, D'Eramo *et al.*, 2010). Finally, trials were assessed against the Ecological Validity Framework to assess the extent of cultural adaptation of the self-management education programmes evaluated. Trials were assessed against the eight core domains of the framework including language, persons, metaphors, concepts, contents, goals, methods and context. Based on these ratings, seven trials met 6-8 of the framework criteria for cultural adaptation and thus, were deemed sufficiently culturally sensitive (Babamoto *et al.*, 2009, Gucciardi *et al.*, 2007, Osborn, 2010, Rosal *et al.*, 2011, Samuel-Hodge *et al.*, 2009, Sinclair *et al.*, 2013, Vincent, 2009), whilst the remaining six trials met <6 criteria and thus, were less culturally appropriate for the self-management education programmes (D'Eramo *et al.*, 2010, DePue *et al.*, 2013, Lujan *et al.*, 2007, Prezio *et al.*, 2013, Ruggiero *et al.*, 2014, Spencer *et al.*, 2011).

8.2.2 Qualitative Research (Study 2)

Study 2 (qualitative research) sought to explore the perspectives of healthcare professionals involved in the care of people living with type 2 diabetes in a single Saudi Arabian hospital centre (KFHM) to identify the benefits and challenges in supporting service users to engage with self-management recommendations. The qualitative findings revealed consistent reports of healthcare professionals that self-management programmes would confer meaningful benefits for service users. These benefits specifically include improvements in glycaemic control and decreases in the risk of micro- and macro-vascular complications. Such improvements were perceived to result from the impact of programmes upon empowering people with T2DM to become more responsible for their own health and develop the coping and resilience skills to overcoming challenges throughout the course of type 2 diabetes such as to sustain focus upon enhancing glycaemic control and improving general health status.

The qualitative study also revealed evidence to suggest that group-based education could benefit from mobile health and social media platforms as people living with type 2 diabetes could share information with others to gain support and new problem solving skills to cope with the adversities of the disease. Telehealth also enabled clinicians to provide education in the wake of COVID-19 where access to usual in-person consultations had become more restricted. Moreover, education was also perceived to provide people with emotional and psychological support as to enhance their preparedness and readiness for tackling diabetes and improving glycaemic control. Re-shaping people knowledge of type 2 diabetes and how the disease and complication risks could be mitigated through self-management recommendations was also a key value of the programme reported by physicians as this was perceived to influence long-term self-care behaviours.

Furthermore, correcting misconceptions about the causes of type 2 diabetes and the various factors influencing glycaemic control was also found to influence people engagement with self-care recommendations. The timeliness of providing self-management education was perceived to be of the utmost importance with most participants advocating a balance between early provision soon after diagnosis and delayed provision to enable delivery following individual’s acceptance of type 2 diabetes. The qualitative study revealed factors that facilitate the development and implementation of self-management education programmes for type 2 diabetes. These factors include; multi-disciplinary team working and integrated diabetes care, prioritising education in relation to the most challenging aspects of lifestyle change in type 2 diabetes, cultural sensitivity of educational content, person-centred information provision, delivering care in congruence with family- or support-centred care principles for older people, and using information technology to bolster information provision for younger persons.

In contrast, reported barriers to effective self-management education included a lack of multi-disciplinary team working where some diabetes clinics were purely physician- or nurse-led, poor access to clinics for people living in remote areas, group-based education for females due to cultures that discourage male-female mixing, lack of cultural tailoring of educational content, distrust in Western medicine and the Western medical model, language barriers, lack of person-centred diabetes care, low levels of self-efficacy and self-responsibility among people, lack of standardised or structured education programs for type 2 diabetes, insufficient support and funding at the policy level, inability of older persons to engage in exercise recommendations due to physiological limits, short staffing levels, lack of facilities to deliver education, and a lack of guidelines for self-management education.

8.2.3 Qualitative Research (Study 3)

Study 3 (qualitative research) sought to explore the perspectives of people living with type 2 diabetes, in order to identify the barriers and facilitators of self-management regimes for improving glycaemic control and cardiovascular risk. The qualitative study 3 revealed that most people held various views regarding the causes of type 2 diabetes and in turn, this is likely to have influenced their desires to engage in self-care recommendations. A large proportion of participants viewed type 2 diabetes as a form of punishment from God and thus, perceived their fate to be outside of their own control.

According to the study findings, there are a number of factors that might hinder people’s ability to manage their diabetes. These include a lack of resources, unpleasant feelings, and a lack of care. Inadequacies in environmental resources and support techniques for diabetes self-management were reported by people. There are several ways to help people with diabetes improve both their health and their quality of life. People who work in healthcare have an important role to play in educating people about diabetes self-management, supporting treatments, and encouraging them to engage in protective behaviours. Importantly, very few participants reported upon the relationship between type 2 diabetes and obesity and thus, highlighting a global lack of knowledge regarding type 2 diabetes and how the pathological process can be modified through simple lifestyle initiatives. This was even despite people being knowledgeable of some of the serious complications of type 2 diabetes, although such participants had already received ongoing surveillance for potential or established complications.

The majority of people recognised that improved adherence to healthy eating and physical activity were key to improving diabetes control but this co-existed with various barriers. The most common barriers hindering engagement with self-management recommendations included a lack of information and education soon after diagnosis, lack of support from healthcare professionals and support networks, beliefs that diabetes could not be controlled or cured, and the adverse impact of self-management activities upon daily routines and other life priorities. The qualitative research revealed a broader range of factors influencing self-care among people living with type 2 diabetes, which revolved around culture. In this regard the Saudi Arabian culture was found to be unsupportive of the lifestyle recommendations desired in type 2 diabetes and consequently, generating an internal conflict in people with T2DM in regard to conveying desirable life acts.

Overall, people with T2DM adhering to traditional cultural values and traditions found it markedly challenging to adhere to a healthy diet, increase physical activity levels, reduce sedentary behaviour and attain a healthy sleeping pattern. In addition, the study explored the views of people with T2DM regarding the desired means to delivering self-management education. This identified that person-centred education and culturally tailored information were the two most advocated approaches desired among participants.

8.2.4 Secondary Data Analysis (Study 4)

Finally, study 4 (descriptive quantitative research) evaluated the extent and quality of data routinely collected by the local diabetes service in KFHM to determine whether this will be sufficient to informing future evaluations of care quality and self-management education programme effectiveness in the future. This study sought to address three core questions: 1), what routine data is currently collected and available for people living with type 2 diabetes) what is the quality of the routine data collected? and 3) what, if any, descriptive analyses can be conducted on routine data to describe the target population? A secondary analysis of the pre-existed dataset was undertaken over a four year retrospective period (2016-2020) with the results analysed using descriptive statistics. Data from a cohort of 5,668 people with T2DM was analysed, although this was reduced to 4,001 due to missing data for some pre-defined variables; glycaemic haemoglobin levels, creatinine and/or cholesterol levels. Demographic information was not sufficiently extensive; limited to people age and gender, and whilst some important clinical data was captured (weight, height, body mass index, glycated haemoglobin, creatinine and renal function, lipid profiles, liver function and vitamin levels), other important data was missing including blood pressure, family history of cardiovascular disease and other risk factors for diabetes-related complications. This suggested that the current dataset is not positioned to permit future evaluation of diabetes care quality and outcomes. Of the data that was analysed statistically, the mean age, weight, body mass index, glycated haemoglobin, creatine and cholesterol were 58 years, 76.8kg, 28.3 kg/m2, >7.0%, 151.0 microm/L, and 4.3 mmol/L, respectively. Notably, more than 80% of people with T2DM observed glycated haemoglobin levels in excess of 7.0% and thus, being indicative of suboptimal glycaemic control; a problem potentially attributed to a lack of exposure to standardised self-management education programmes. The remaining data also revealed that a large proportion of people with T2DM observed heightened risk factors for diabetes-related complications. The most common established complications were neuropathy, nephropathy, and retinopathy and foot ulceration.

8.3 Evaluation of findings in the context of existing research

This main subsection of the discussion is concerned with evaluating the key findings of the research studies given that study four (the secondary data analysis) was primarily conducted to help tailor local diabetes service processes for evaluating care quality and intervention effectiveness.

Foremost, the systematic review identified that culturally-tailored self-management education programmes conferred a meaningful decrease in glycated haemoglobin levels after 3-12 months follow-up of 0.5-1.6% (DePue *et al.*, 2013, Gucciardi *et al.*, 2007, Lujan *et al.*, 2007, Osborn, 2010, Prezio *et al.*, 2013, Rosal *et al.*, 2011, Samuel-Hodge *et al.*, 2009, Spencer *et al.*, 2011, Sinclair *et al.*, 2013). The extent of reduction in glycated haemoglobin is similar and even superior to evidence about the efficacy of conventional recommended therapies for type 2 diabetes including lifestyle modification and anti-hyperglycaemic drugs. Intensive glycaemic control confers a 6-12% reduction in the risk of cardiovascular-related mortality or severe micro- or macro-vascular complications, a 10% reduction in the risk of myocardial infarction, stroke and cardiovascular death (composite outcome), a 18-24% reduction in non-fatal myocardial infarction and a 2-12% reduction in stroke versus less stringent controls (Boussageon *et al.*, 2017). Communicating this information to people forms an integral part of education initiatives, particularly as the information is individually significant due to its existential threat to life and thus, offering a means to stimulating behavioural change in the form of compliance with self-care measures for type 2 diabetes (Kayyali *et al.*, 2019).

Twelve studies were included in the review and again excess, inter-study heterogeneity was observed due to differences in education and population characteristics, duration of follow-up and assessment measures. Despite this, significant improvements in glycated haemoglobin were observed for the intervention groups in 60% of included studies, as compared to their respective usual care controls. While the review of Mikhael *et al.* (2020) did not include any studies in Saudi Arabia this simply highlights a paucity of research in said setting; a problem due to the current lack of advocation of self-management education programmes in national guidelines (Al Slamah *et al.*, 2020). However, it is expected that self-management education programmes in Saudi Arabia would yield a similar impact upon glycaemic control to that reported elsewhere, particularly if the interventions are culturally tailored.

Some studies have investigated the impact of education upon various type 2 diabetes outcomes in Saudi Arabia but the authors had delivered interventions that were largely disparate to the principles and expectations of contemporary self-management education conditions. For example, Asmary and Alharbi (2013) conducted an uncontrolled quasi-experimental study to explore the impact of an intensified person-centred intervention comprising multi-disciplinary team support with educational elements to improve understanding into the importance of lifestyle behaviours in type 2 diabetes. The results showed that glycated haemoglobin levels improved markedly from

10.5% at baseline to 8.6% at six months follow-up, representing a mean significant improvement of 1.9% (p<0.001). However, this was based on a small cohort of adults and was in relation to a multi-factorial intervention including drug and non-drug treatments and thus, it is not clear how much of the variance effect education may have accounted for in the effect reported.

It is also important to highlight that in the completed systematic review, there was marked inter-study variation in the impact of culturally tailored education upon glycaemic control (0.5-1.6%) but this was likely due to the lack of homogeneity across studies in relation to the content, duration and intensity of the educational interventions. In addition, variation in the extent of cultural tailoring of the education programmes is also likely to have influenced the impact upon glycaemic control outcomes. In the systematic review, the extent of cultural tailoring of the educational interventions was assessed against the Ecological Validity Framework, which is one of the available and valid means to assessing the cultural appropriateness of clinical interventions (Perera *et al.*, 2020). The review found variances in cultural appropriateness across studies with seven trials meeting 6-8 of the framework criteria (Babamoto *et al.*, 2009, Gucciardi *et al.*, 2007, Osborn, 2010, Rosal *et al.*, 2011, Samuel-Hodge *et al.*, 2009, Sinclair *et al.*, 2013, Vincent, 2009) and the remaining six trials meeting <6 criteria (D'Eramo *et al.*, 2010, DePue *et al.*, 2013, Lujan *et al.*, 2007, Prezio *et al.*, 2013, Ruggiero *et al.*, 2014, Spencer *et al.*, 2011). The latter trials were deemed less culturally tailored than the former trials. Indeed, some minor trends in the extent of cultural tailoring of the educational programmes and glycaemic control outcomes are identifiable. In this regard, most trials meeting 6-8 criteria of the Ecological Validity Framework observed mean reductions in glycated haemoglobin of 0.5-0.6% (Gucciardi *et al.*, 2007, Osborn, 2010, Rosal *et al.*, 2011, Samuel-Hodge *et al.*, 2009), whilst only one of such trials observed a more marked reduction of 1.1% (Spencer *et al.*, 2011). However, trials that were rated as meeting <6 criteria of the Ecological Validity Framework and thus, deemed less culturally tailored, reported more meaningful reductions in glycated haemoglobin; two trials observing reductions of 0.5-0.8% (Babamoto *et al.*, 2009, D'Eramo *et al.*, 2010) and two trials reporting 1.0-1.6% reductions (DePue *et al.*, 2013, Prezio *et al.*, 2013).

The two qualitative research studies provided useful insight into the perceived value, factors influencing uptake and desired characteristics of self-management education programs in the local Saudi diabetes service. Interviews with healthcare professionals identified perceptions around the timing of education provision with most advocating delivery early following the diagnosis of type 2 diabetes, in order to instigate lifestyle changes and healthy behaviours from an early stage as to optimise glycaemic control and minimise complication risk. Indeed, evidence has shown that delays in attaining reasonable glycaemic control can not only reduce the likelihood of attaining remission, in persons where obesity is the dominant factor driving insulin resistance, but it can also lead to a poorer prognosis with a course of hyperglycaemia that is less responsive to available drug treatments (Paul *et al.*, 2015).

Although some healthcare professionals were less supportive of early education following diagnosis of type 2 diabetes due to concerns regarding information overload and psychological distress in affected people, the evidence appears to support the need for early education and treatment intensification, in order to promote the best possible outcomes (Paul *et al.*, 2015). The potential issue of information overload and related distress could be mitigated or overcome by educators employing support measures simultaneous to information delivery. Indeed, most self-management education programme curricula advocate the importance of support; both educator delivered and wider support from people' relatives and loved ones given that this is necessary to promote acceptance of type 2 diabetes and uptake and adherence to critical self-care measures in both the short- and long-term (Captieux *et al.*, 2018). These observations feed into the implications and recommendations of the research findings for education programme development in the local diabetes service, which are detailed in the conclusion of this chapter.

Very few studies have explored the views of healthcare professionals regarding the perceived benefits of self-management education programmes for type 2 diabetes. In a recent qualitative study conducted in Saudi Arabia but in a different region of Qassim to the research reported herein, Al Slamah *et al.* (2020) explored the views of a multi-disciplinary team of healthcare professionals working with people living with type 2 diabetes. This included doctors, nurses, nutritionists and educators, which is a similar diversity of professionals to those interviewed in this research. The findings revealed a similar set of views regarding the problem of unhealthy lifestyle behaviours of people prior to receiving a type 2 diabetes diagnosis and how this tended to influence a poor course of diabetes with suboptimal glycaemic control and difficulties in attaining remission. Some participants alluded to the value of education for these people in helping to transition unhealthy cognitions and behaviours surrounding lifestyle habits early in the course of diabetes, in order to improve outcomes, which is in keeping with the findings reported in this research. However, participants in the study of Al Slamah *et al.* (2020) did not elaborate upon the timing of education provision, which precluded insight into whether healthcare professionals held views regarding the potential adverse impact of information overload. The cited authors also found various barriers to the development and delivery of self-management education, which are important to consider and compare to the barriers identified by health professionals in this research. The identified barriers included insufficient resources and support at the policy level, lack of Western education programmes, such as DESMOND and DSME, being piloted in the local setting, poor people uptake and adherence, and self-care recommendations that were disparate or insensitive to the culture and social traditions of service users.

Indeed, the interviews with healthcare professionals and people living with type 2 diabetes in this research also identified that a lack of support from the Ministry of Health, lack of formal self-management education programme piloting in Saudi Arabia and the disparities between diabetes management expectations and culture were perceived obstructions to education programme development and impact. One of the most consistently reported cultural barriers to people compliance with self-care measures to improve glycaemic control was the Saudi Arabian diet; a diet high in calories with excess fat and added sugar, which poses clear difficulties for service users in losing weight that is the key driver of insulin resistance in type 2 diabetes (Hardy *et al.*, 2012). In addition, Al Slamah *et al.* (2020) also revealed problems regarding the relative lack of physical activity and exercise in people living with type 2 diabetes. This was also shared by the perceptions of healthcare professionals in this research and simply highlights the perpetuating issue of physical inactivity and erroneous perceptions among people with T2DM that low-intensity activity, such as walking, is sufficient to control diabetes.

Evidence has shown that persons with excess weight and associated metabolic syndrome or type 2 diabetes are required to engage in moderate to intensive physical activity on a regular basis, in order to attain meaningful weight loss; >5-10% of initial body weight (Wilding, 2014). Such extent of body weight reduction is necessary to observe meaningful decreases in insulin resistance and in turn, this can improve glycaemic control and in some cases, lead to remission of diabetes (Ryan and Yockey, 2017). In addition, meaningful reductions in body weight can also improve other cardiovascular risk factors, such as elevated blood pressure, dyslipidaemia and subclinical inflammation, which can also improve overall health status by reducing the risk of acute and chronic cardiovascular events (Apovian *et al.*, 2019).

Aside from these common barriers, the research in this thesis helped to advance knowledge in the field by recognising a wider and more in-depth range of factors influencing the potential of self-management education programmes in benefitting service users in Saudi Arabia. Specifically, this research found that people tended to believe that type 2 diabetes was a result of God and a punishment for prior misdeeds; this was not identified in the study of Al Slamah *et al.* (2020). While this is challenging, there might be a place for attempting to correct causative misconceptions of diabetes in future education programmes. People with lower levels of literacy and knowledge of diabetes and self-management had worse health outcomes, therefore it is critical that effective health education be delivered at their level of education and comprehension of the condition. Measures that might be of benefit include public enlightenment through radio, television and social media based platforms.

This research also suggests that supplementing and supporting disease education with people with T2DM forums and social media could help to benefit the learning and cognitive behavioural change process as service users could share problems and solutions to such problems with one another, in order to promote improved health behaviours and glycaemic control on a meaningful level. Notably, the value of telehealth in type 2 diabetes, among other chronic diseases, has been growing in popularity due to advances in information technology and the simplicity and convenience of accessing health information (Robson & Hosseinzadeh, 2021). A recent meta-analysis of telehealth in type 2 diabetes showed that online interventions, that mostly comprised initiatives with an educational focus, were associated with 0.2% reductions in glycaemic haemoglobin (p=0.04), as compared to no-intervention controls (Robson & Hosseinzadeh, 2021). Thus, in combination with self-management programmes, telehealth could help to further improve diabetes outcomes for service users in Saudi Arabia.

This may be an important supportive step in overcoming the resistance and hesitancy in engaging in group-based education identified among people living with type 2 diabetes in this research, particularly as females who are discouraged from mixing with males due to cultural restrictions, may be able to communicate safely and anonymously with others via online forums. It was interesting that more women indicated that they had spent a lot of time looking for online and other telehealth interventions that kept them from interacting in public places. This raises the question of the differences in levels of knowledge, attitudes and practice among women relative to men in the country, a pattern that is worth exploring further in future research. In addition, it points to the possibility that the self-management training and diabetes education needs of Saudi women might differ from those of their male counterparts.

However, while the interest in the use of other source of health information is a positive development, the integration and uptake of telehealth to support type 2 diabetes management in Saudi Arabia will have to consider and overcome the various barriers to mobile health reported among the wider literature; mostly funding, conformity of information technology with health systems and ensuring equity in access to mobile health (Alaboudi *et al.*, 2016). The interviews with healthcare professionals also revealed that education was important in providing emotional and psychological support, in order to mitigate the distress of the diagnosis of type 2 diabetes and the burden of the disease upon their future lives.

This finding was also unique to the evidence of Al Slamah *et al.* (2020) and importantly, highlights the wider value of education; mitigating distress being essential in type 2 diabetes given the strong associations between the disease and adverse mental health problems (Ducat *et al.*, 2014). In Saudi Arabia, the culture discourages discussions about mental health among lay persons as this tends to be associated with stigma due to misconceptions of the cause and consequences of mental health problems(Alattar *et al.*, 2021).This further re-enforces the value of this research is contributing vital information that is likely to be key in developing a successful self-management education programme. Finally, the qualitative research presented in this report identified perceptions of healthcare professionals that people living with type 2 diabetes had little self-motivation and self-efficacy in exerting efforts to improve their physical health status.

This is not an uncommon observation in people living with type 2 diabetes; evidence from an international perspective has found that attaining cognitive behavioural change as to improve the lifestyle behaviours of service users can be markedly challenging (Hackett *et al.*, 2018). In addition, failure to achieve behavioural change is often cited as the core reason for poor outcomes in type 2 diabetes, particularly as much of the burden is considered reversible or modifiable through reductions in weight and insulin resistance (Van Rhoon *et al.*, 2020). Attaining cognitive behavioural change in persons in Saudi Arabia may even be more challenging when education initiatives fail to acknowledge and account for person-valued needs including culture and traditional beliefs (Alodhayani *et al.*, 2021).

8.4 Research Limitations

Although the findings of this research have provided useful insight into the requirements for developing a culturally tailored self-management education programme for people living with type 2 diabetes in Saudi Arabia, the evidence should be considered in view of some limitations. In regard to study one (the systematic review), the search for key literature may have been insufficiently extensive and thus, risked missing one or more key studies from inclusion in the narrative synthesis. This risk may have been increased by the restriction criteria used to permit evidence filtering and selection. In this regard, studies were limited to randomised controlled trial design, English language, peer-review and publication in the past 20 years. Therefore, the exclusion of non-randomised or non-controlled evidence could have increased the risk of searching bias, as could the preclusion of non-English studies, particularly as the evaluation of some culturally tailored education programmes for diabetes may have been published in various native languages.

Other limitations to the systematic review include the various methodological issues detected across the informing studies based on the Cochrane risk of bias tool. Three of thirteen trials observed a high risk of bias, whilst six observed an unclear risk of bias. This meant that only four trials observed a low risk of bias and therefore, the key findings reported may be subject to issues of invalidity and suboptimal applicability. Due to the characteristics of cohorts included across studies that evaluated culturally tailored education programmes for type 2 diabetes, applicability ratings were not feasible to derive given the primary aim to evaluate the impact of such programmes upon clinically important outcomes to inform the local development of a novel education programme. However, the outcomes of the review also observed limitations related to the relatively short follow-up periods of studies included in the synthesis. This clouded insight into the long-term efficacy of culturally tailored self-management education programmes upon type 2 diabetes.

In studies 2 and 3 (qualitative research), further methodological limitations were identified, although these were balanced against strengths of the research to ensure informative evidence was generated to assist in education programme development. First, the participants who participated in the interviews were sampled using convenience and purposive methods, that whilst being suited to qualitative research for capturing subjects likely to provide rich accounts of information, the methods also increase the risk of selection bias. This is in addition to the sampling strategy capturing a low sample of the target groups and as a result, generating little diversity in characteristics, which limits representativeness and applicability to other diabetes services in Saudi Arabia. This is demonstrated in part by the relatively lower number of female participants in comparison to their male counterparts. However, it must also be recognized that cultural and religious beliefs limit the extent to which women would be able to interact with individuals outside their families, particularly of the opposite gender (Austin *et al,* 2011). This might indicate that women might have different diabetes self-management needs as well as different personal preferences for how they can access diabetes education and self-management training programmes. There would therefore potentially be a benefit to the facilitation of single gender educational and interview sessions to ensure that the views, perceptions and needs of all patients are fully explored and addressed. Furthermore, there is a wide range of health professionals involved in the provision of care for people living with type 2 diabetes. As a result, there might be a benefit to research that examines the views and perceptions of health professionals involved in care throughout the people progression through the diabetes care service.

However, the emphasis was on deriving evidence applicable and relevant to the local context to permit education programme development for the self-management of type 2 diabetes. Second, applicability was further restricted to the local context given the single-centre and single-service design. Third, data was collected via semi-structured interview process as this encouraged the use of open and closed ended questions to ensure sufficiency in the responses gathered regarding experiences and views of self-management education. However, as with all qualitative research studies, the interview process may have been prone to researcher subjectivity; unconscious and conscious biases that influence actions and behaviours during interviews that may influence participants responses in terms of response extent and truth validity (Noble and Smith, 2015).

Moreover, the direct presence of the researcher could have also increased the risk of interview bias as respondents may have felt pressured into providing responses to suit the perceived expectations of the interviewer (Pannucci and Wilkins, 2010). Although this risk is unlikely to have occurred among the health professional group, it is a plausible risk for the service user group as lay persons are more disconnected from the moral and ethical responsibilities that demand objectivism and professionalism during contributions to research (Medical Research Council, 2012). However, the risk of interviewer bias is hoped to have been minimised by the use of a topic guide, which helped to standardise the interview questions and process across subjects and thereby, diminish subjective influences. Despite this, the interviews were conducted in Arabic and later translated into English to permit data analysis and therefore, a minor risk of bias related to translational errors may have occurred. However, such risks should have been negligible due to the fluency and credentials of the translator.

The qualitative data was analysed using the standard process of thematic analysis and various techniques to enhance trustworthiness of the findings were applied to optimise credibility, dependability and confirmability. Such techniques included data saturation, member checking, investigator triangulation, and author reflexivity. These methods were considered sufficiently extensive as to minimise the risk of various qualitative biases in the findings presented.

In the final study (secondary analysis of pre-existing data), the study comprised a secondary-analytical design and this co-exists with various quality issues related to missing data and the quality and extent of data variables available to permit informed analysis (Johnston, 2014). Due to having no control over the variables of interest to the research, the study was limited to the data available and as a result, issues regarding selection, confounding, information and imputation biases (Pannucci and Wilkins, 2010). Indeed, the analysis of the data revealed that missing data components were a key problem, as was the extent of data collected; this was insufficient as to prove useful for evaluating ongoing care quality and the effectiveness of novel diabetes education programmes. However, determining the extent and quality of the pre-existing dataset was the purpose of the study and as a result of the findings, implications and recommendations for revising the database have been described in the following subsection.

8.5 Implications and Recommendations for Education Programme Development

Despite some limitations to the research, the findings have some important implications for the development of a self-management education programme for type 2 diabetes in the local Saudi Arabian centre. These implications are detailed in this section along with recommendations for programme development. First, it is clear from the evidence of the systematic review and the wider literature that theory based, culturally tailored education programmes are effective for improving clinically important outcomes in type 2 diabetes. Given the marked influence of culture upon the cognitions and health behaviours of local service users, it is imperative that culturally adapted education is introduced into routine diabetes care provision. This will be particularly important for persons who receive a new diagnosis of type 2 diabetes as it is intuitive and evidence-based to find that instigating early changes in health behaviours is key to attaining stringent glycaemic control from the outset and subsequently, achieving a more favourable prognosis. Conforming to the cultural nuances of persons in Saudi Arabia is also key given that most resistance factors to adhering to self-management measures were found to arise from aspects of culture. Thus, it is important that the education programme is tailored to the specific local culture among service users resident within the catchment area of Madinah. The Ecological Validity Framework could be used to inform how the education programme can be tailored to suit the cultural needs of the local service users. This may be crucial to accommodating the various surface and deep aspects of culture that are valued by people living with type 2 diabetes and can lead to adverse effects upon health behaviours when such aspects are neglected in disease education. One of the means by which this can be achieved is by the fostering active service user participation in the development of the education programme. In addition to providing valuable insights into the impact of their cultural, religious and social views on their health and health-related behaviours; it also helps to ensure that these programmes address the specific needs and preferences of these service users (Al-Khashan *et al,* 2012). Therefore, it is important that the education programme considers and incorporates all eight core domains of the Ecological Validity Framework; language, persons, metaphors, concepts, contents, goals, methods and context. The findings from studies 2 and 3 revealed more about the cultural barriers in Saudi Arabia that are major contributers to misconceptions about type 2 diabetes, highlighting the importance of the use of a cultural adaptation framework such as the Ecological Validity Framework. Most people believe that diabetes is caused by eating too much sugar, curses or punishment from God according to their cultural beliefs. The framework provides a guideline to how intervention programmes should adopt to cultural sensitive treatment. This will require the education to adopt the local language and any colloquialisms and regional variations, to ensure the use of symbols and metaphors that align with the local culture. This allows for congruence between the ethical values conveyed between educators and people living with type 2 diabetes, to ensure person-orientated goals account for cultural factors and account for wider influences of culture in the educational content. Although the use of the Ecological Validity Framework should assist in developing a culturally suited program for service users, developers should also employ the principles of person-centeredness as this may be key to unlocking additional efficacy and motivation among people living with type 2 diabetes in improving health behaviours and self-care efforts.

To support the development of the education programme, the diabetes service is likely to require support in the form of funding from the local health organisation. In addition, following a pilot of the education programme and evaluation in research, upscaling the initiative to permit integration across other diabetes services will prove invaluable. However, this will require much greater support and funding from the Ministry of Health but the initial investment costs are unlikely to outweigh the likely benefits and costs saved in the future. Thus, the local diabetes service will need to act as the incident and role model centre in Saudi Arabia to offer the first evidence-based culturally tailored diabetes education program to help enhance self-care among people living with type 2 diabetes. This should co-exist with a regional and national awareness campaign to help other diabetes service users and health professionals involved in the care of such people to improve their knowledge and understanding of the value of self-management education.

There are also some key recommendations for revision of the current database managed by the local diabetes service. These revisions are important to help improve the quality and extent of data captured regarding type 2 diabetes, which will be essential to internal evaluations of care quality and the effectiveness of the self-management education programme. First, it is important that the database collects a broader range of variables concerning people demographics and clinical characteristics. Specifically, data entry components are needed for people ethnicity, family history of type 2 diabetes and cardiovascular disease, systolic and diastolic blood pressure, co-morbidities, prescribed medications, diabetes-related complications with date of onset and severity/staging, and attendance at clinic visits and educational programmes with dates. Second, it is important that the quality of data entered into the database is improved, in order to eliminate or reduce the issues with missing data variables. Therefore, it is recommended that several database champions are nominated within the diabetes department who will then be provided with the responsibility to ensure quality in the data entered. Such champions will also be responsible for extracting and analysing data to permit future service evaluations and clinical audits during the educational interventions for type 2 diabetes. This is in addition to being able to encourage and facilitate active staff engagement and dedication to ensuring the accuracy of information being entered at each crucial point during the people living with type 2 diabetes visit. Finally, it is important that healthcare professionals working in the local diabetes service ensure people anthropometric and clinical biomarkers are measured on a regular basis and in accordance with guidelines to ensure up-to-date and temporal data is available to upload onto the database.

8.6 Conclusion

In conclusion, the design and implementation of self-management education programmes for people living with type 2 diabetes is acknowledged to play a major role in facilitating behavioural change that can improve outcomes and the control of the condition in affected individuals. Self-management education programmes and/or interventions have been discovered to be effective in bringing out positive change in people living with the condition. However, while existing programmes have been discovered to be effective, most of these programmes are based on models that were developed for use in Westernised, largely Caucasian environments. This highlights the need for cultural adaptation to make these programmes of relevance in population with differing cultures and practices such as Saudi Arabia.

As demonstrated by the systematic review, culturally sensitive, theoretically driven self-management interventions can produce significant improvements in HbA1c as well as people knowledge of diabetes, risks and management. This is important since glycaemic control is directly related to people risk of acute hyperglycaemic events as well as risk of micro- and macro-vascular complications that cause a significant proportion of the burden of type 2 diabetes (Boussageon *et al*., 2017). It is therefore evident that the communication of relevant information to people living with type 2 diabetes is vital for people education (Kayyali *et al*., 2019). While there are studies examining the impact of education on diabetes outcomes in Saudi Arabia, these studies were based on the provision of general information relating to diabetes (Al Hayek *et al,* 2013; Asmary & Alharbi, 2013). There are very few if any studies examining the impact of culturally adapted self-management educational interventions in Saudi Arabia type 2 diabetes populations. However, the findings of the review highlight the fact that there is a potential place for such programmes in the future.

In-depth interviews with both health care professionals and people living with type 2 diabetes provided insight into the perceived value of self-management education as well as factors that could potentially hinder or encourage the uptake of self-management education amongst affected populations. HCPs were united in recognising the importance of education in encouraging the move to healthier lifestyles and behaviours as a means of achieving glycaemic control in affected populations. This leads to questions about the timing and the content of such education programmes. In view of the need for urgent action to avoid the development of acute or chronic complications arising from poor glycaemic control, it would be expected that education be provided as early as possible. However, it was thought that this would represent an information overload for people living with type 2 diabetes and it was recommended that information be provided gradually over time. This appeared to echo the people views which highlighted that they were often in a state of psychological shock after their diagnosis and indicated that they would require some time to accept this diagnosis. However, it was also suggested that information overload and distress can be reduced by providing people with suitable support including but not limited to educator and family support.

In addition, the importance of education about dietary and physical activity recommendations cannot be overemphasised since people living with type 2 diabetes and professionals acknowledged that one of the major cultural barriers to compliance with self-care was the nature of the Saudi Arabian diet (Hardy *et al.,* 2012). There are some barriers including the relative lack of resources directed towards diabetes care as well as the disparity between the expectations of diabetes management training programmes and local cultural and religious expectations. This is in additional to the largely fatalistic perception of diabetes as a punishment from God and the impression that there is little or nothing that can be done to mitigate the circumstances. This raises the question of encouraging active participation of religious leaders as a means of increasing population knowledge and understanding of the condition. Furthermore, while it is recognised that there might be religious and cultural issues relating to mixed male and female gatherings for group education sessions, there might be a role for male- and female- only group sessions that allow for the exchange of ideas and experiences that might serve to encourage the adoption of healthy behaviours and lifestyles.

Finally, this research also showed that supplementing and supporting disease education with people forums and social media could help to benefit the learning and cognitive behavioural change process as service users could share problems and solutions to such problems with one another, in order to promote improved health behaviours and glycaemic control on a meaningful level. in view of the ongoing COVID-19 pandemic and potential future infectious epidemics and pandemics, many self-management programs have transitioned to utilise telehealth to support education provision. Although such approaches have proven effective in enhancing self-care and glycaemic control for some populations, it has not been clear whether the use of information technology would be acceptable or effective for ethnic minority groups (Mackenzie *et al.*, 2021). For some ethnic minorities and subgroups who hold preferences for one-to-one or individually delivered education, such as females of Saudi Arabian ethnicity, telehealth may prove beneficially for this subgroup due to the approach being congruent and sensitive to their preferences (Abdullah, 2018). However for other groups, engagement with self-care may depend upon views and attitudes towards information technology, as well as competence in using technology and access, affordability and availability of technology (Mackenzie *et al.*, 2021, Gal *et al.*, 2020).

In type 2 diabetes management review, studies evaluated in-person self-management education programs and thus, it cannot be assumed that delivery of education via telehealth would be as effective as the findings reported herein. At present, the accepted curricula for self-management education for type 2 diabetes, as detailed within the American Diabetes Association guidelines, appears too broad to inform the development of culturally sensitive education programs; these need to be revised for specific ethnic groups to optimise program design and effectiveness (Beck *et al.*, 2017). This may help to improve diabetes outcomes on a much larger and more equitable scale. However, it must be recognised that there is a role for the use of social media and other forms of Telehealth options to leverage on the education and information provided through routine face-to-face and group interventions aimed at ensuring that all people are able to make educated, fully informed health and health-related decisions.

The importance of funding from local health authorities and ministries of health cannot be overemphasised. This will be of particular importance when the results of the pilot of the intervention are being up scaled for inclusion in other diabetes services. There is also a need for revision to the management and nature of information being collected by the local diabetes services. It is acknowledged that there is a lot of the information currently in the database (HbA1c; BMI, lipid levels) is vital as a means of determining severity of type 2 diabetes at initial diagnosis as well as response to treatment. Data entry components such as ethnicity, family history of type 2 diabetes, the presence of diabetes-related complications, as well as people attendance at clinics and self-management education programmes would greatly facilitate evidence-related decision making. The nomination of database champions in each of the affected departments would work well towards to achieving this aim.

Furthermore, in recognition of the fact that many research studies conduct follow-up of people living with type 2 diabetes for a maximum of 12 months, it is acknowledged that there might be a need to ensure that any research study follows up the people to determine if the impacts of these programmes are sustained in the medium- and the long-term. Currently, most people living with diabetes and pre-diabetes do not get any kind of structured diabetes education. According to the National Standards for DSME programmes, future recommendations concerning education programmes for type 2 diabetes are established. Documenting the program's structure, purpose, and objectives might help the future education programmes for people living with type 2 diabetes run more smoothly and effectively. The demographic features of the population, such as ethnicity and literacy, must be taken into account. It is recommended that the organization acknowledge and promote excellent DSME as an important component of diabetes care in the target community by improving access to educational programmes for people. In addition, a written curriculum based on current data and recommendations for DSME outcomes should be developed. The sections of the curriculum offered to the participant will be determined by their specific need.

It is also recommended that more research should be undertaken to investigate how people perceive and engage with the intervention programmes developed. The benefits associated with the structured education programmes are investigated through conducting interviews and people questionnaires. Recommendations are made to probe how cultural background affects education programmes in self-management for people living with type 2 diabetes. This means longitudinal studies over the course of 12, 24, and 36 months that highlight both the changes in people views and beliefs as well as the changes in measures of their clinical health and well-being. It is anticipated that the identification of these changes over time would also help with the design and implementation of suitably, culturally adapted type 2 diabetes self-management programmes for people living with the condition in Saudi Arabia.

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Appendices

Appendix 1. Letter of Invitation to Participate in Study

University of Glasgow | College of Medical, Veterinary & Life Sciences

Letter mail: Invitation to Participate in Study

Subject: Invitation to participate in an interview-based research study relating to your preferences, needs and experiences towards the current situation of self-management and culturally appropriate self-management education programmes for people with T2D in Saudi Arabia.

Dear Sir/Madam,

You are being invited to participate in an interview-based research study that will be conducted by Bandar Alhumaidi, PhD candidate at the college of Medicine, Dentistry and Nursing at the University of Glasgow in United Kingdom. The researcher want to know what the types of support people want and need, and he want to know the changes that must be made to existing programs to make them suitable for people with type 2 diabetes who live in Saudi Arabia.

Please read the participants information sheet carefully provided and reply if you may consider participating. When we receive your reply to take part in the study the researcher will get in touch with you by telephone to discuss further details and to answer any questions you may have. Further details about the study can be found in the participant information sheet or you can contact or if you have any questions.

Thank you for your consideration.

Yours sincerely

Appendix 2. Healthcare professional participant information sheet (Study 2)

University of Glasgow | College of Medical, Veterinary & Life Sciences

INFORMATION SHEET PROFESSIONALS' PARTICIPANT

1.Study title

Developing a culturally appropriate self-management education program for adults with type 2 diabetes in Saudi Arabia.

2.Invitation paragraph

We would like to invite you to participate in a research study that will be conducted by Bandar Alhumaidi, PhD candidate at the college of Medicine, Dentistry and Nursing at the University of Glasgow. Before you decide whether you want to participate, it is important that we explain why the research is being done and what it will involve for you. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information.

3.What is the purpose of the study?

Self-management has been characterised as a key feature of contemporary healthcare systems (Sadler et al., 2014). Supporting self-management by people with chronic conditions is now an accepted and important part of reducing the disease burden and health service use associated with chronic disease in many countries (Fuller et al., 2008). Many researchers have examined the effectiveness of selfmanagement education programmes and reported positive results in terms of improving several factors associated with diabetes complications such as glycaemic control, blood lipids, knowledge, body weight and quality of life. In addition, selfmanagement education programmes have been found to significantly reduce hospitalisations among people with type 2 diabetes (Koproski et al., 1997). Although there is a prevalence of T2DM in Saudi Arabia, the self-management programmes have yet to be developed and deployed to serve this population. Research shows that little work has been done in Saudi Arabia in the area of self-management programmes to help people living with type 2 diabetes better control their illness. In addition, despite the fact that healthcare professionals play a key role in integrating self-management educations programmes into routine diabetes care, there is also a lack of studies exploring their views on such interventions. This study investigates the perception of health care professionals (HCPs) towards culturally appropriate self-management education programmes, specifically for people with type 2 diabetes in Saudi Arabia.

4.Why have I been invited to participate?

The main reason for including you in this research study is because you are staff members in the diabetes health care team and you have experienced the work with people with type 2 diabetes mellitus.

5. Do I have to take part?

To participate in this research study it is your choice. If you agree to take part, you will be asked to complete a questionnaire. You will be able to complete the questionnaire privately, or with the help of the researcher. By signing the consent form, you would be confirming your willingness to take part. You are free to withdraw at any point while taking part in the study.

6. What will happen to me if I take part?

If you decide to take part in this study, You will be asked to participate in an interview with researcher. You will be involved in an interview in order provide a deeper understanding towards culturally appropriate self-management education programmes, specifically for people with T2D in order to enable them engaging with diabetes self-management education programmes. the efficacy of the support they receive from health care professionals as well as families and friends The interview it will take approximately 30 minutes to an hour and will be scheduled at a date that is convenient to you.

7.What are the possible disadvantages and risks of taking part?

There are no foreseeable risks in taking part in this study. However, the study will take up some of your time.

8.What are the possible benefits of taking part?

Taking part in this research will not have any benefits for you . But your opinions will inform further research in the area and hopefully help us to develop programmes that aid people with type 2 diabetes to get the help and support that they need to better manage this lifelong condition. We hope that it will help the development of a tool to reduce some of the complications that can happen if people struggle to get good control of their diabetes. We will be able to refund travel expenses up to £20 and we will provide £30 as a token of our appreciation to any person who takes part.

9.Will my taking part in this study be kept confidential?

Yes, All the information about your participation in this study will be kept confidential and transcripts will be anonymised. You will be given a unique identification number, only the researcher will be able to access your information. Any publication of the information will be completely anonymous with no way of identifying individual participants. In addition, all the audio-recordings from focus groups will be destroyed.

10.What will happen to my data?

During and subsequent to the study, the terms and condition of the General Data Protection Regulation (GDPR), as agreed by the European Parliament and Council and implemented in 2018, will be strictly adhered to. Only the investigators will have access to the data and all personal details will be stored securely. Neither the names of individuals nor those of involved organisations will be disclosed. Identity codes will be substituted and these will be known only to the researcher. Audio records of focus group discussions and semi-structured interviews will be destroyed once they have been transcribed. They too will be destroyed via a password-protected computer accessible only to the researcher. The records will not have been emailed or transferred via a memory stick. All documentation of the study will, again, be stored for

10 years in a locked cabinet in a locked room in the Nursing and Health Care School at the University of Glasgow, in accordance with university policy.

11.What will happen to the results of the research study?

We hope that the results of this study will be helpful for further research in this area and they will be submitted for publication in academic journals and written up as part of a PhD thesis. Should you wish to know the results of the study then we will send you a summary of the main findings once the research is complete.

12.Who is organising and funding the research?

This study is part of PhD project currently undertaken by Bandar Alhumaidi that funding scholarship from the Royal Embassy of Saudi Arabia's Cultural Bureau in London.

13.Who has reviewed the study?

The research has been reviewed by Madinah health affairs ethics committee and the University of Glasgow, college of medical& veterinary and life science ethics committee for none clinal research.

14.Contact for Further Information

If you have any further questions at this time then you can contact;
Bandar Alhumaidi
Email:
Tel:

Thank you for taking time to read this and for thinking about taking part.

Appendix 3. People living with type 2 diabetes participant information sheet in English and Arabic language (Study 3)

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PARTICIPANT INFORMATION SHEET

1.Study title

Developing a culturally appropriate self-management education program for adults with type 2 diabetes in Saudi Arabia.

2.Invitation paragraph

I would like to invite you to participate in a research study that will be conducted by Bandar Alhumaidi, PhD candidate at the college of Medicine, Dentistry and Nursing at the University of Glasgow in United Kingdom. Before you decide whether you want to participate, it is important that we explain why the research is being done and what it will involve for you. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information.

3.What is the purpose of the study?

Living with a chronic condition like diabetes is a lifelong commitment that can be quite challenging. People with diabetes need support, good quality information and help with the demands of managing diets, lifestyles and medication (different tablets and injections) that might be used as treatments. Currently not all people have access to the information, support and training they need to become effective in managing their diabetes. Self-management programmes are one way to get better support and information about diabetes and encourage people to be in control over managing their diabetes. We want to know what people with type 2 diabetes think about self-management and what kinds of support would best help them to self-manage. We particularly want to know what changes need to be made to existing programmes to make them suitable for people with type 2 diabetes who live in Saudi Arabia.

4.Why have I been invited to participate?

We are looking for people aged 18 and above who have type 2 diabetes who would be interested in taking part in interview. You have been identified because you are registered with the Diabetes Centre in KFHM. By participating, you will help us to understand how we can better support people living in Saudi Arabia who have type 2 diabetes to self-manage.

5.Do I have to take part?

You do not have to take part. If you do agree to take part, you will be asked to sign a consent form to confirm you wish to take part before you start in the study, but you can withdraw at ANY time you want and you can do so without giving a reason. If you withdraw from the study all the data collected will be removed up till the point of data analysis where it will not be possible to remove individual’s information. Declining to take part or withdrawing from the study will NOT have any effect on the care you receive from your doctor.

6.What will happen to me if I take part?

If you decide to participate in this study, males will be asked to participate in an interview with the researcher. Females will be asked to participate in an interview with female nursing staff (SA), who is working at the diabetes centre .The interview will focus on participants' preferences, needs and experiences toward the current selfmanagement status and culturally appropriate self-management education programs for people with T2D in the Kingdom of Saudi Arabia. The interview will take place at the Diabetes Centre, take about 30 minutes to an hour, and it will be scheduled on a date convenient for you. All of the interviews will be audio-taped so we do not lose any of the valuable ideas or views that are expressed during the sessions. If at any stage there are issues you do not feel comfortable discussing please let us know and we will address this immediately.

7.What are the possible disadvantages and risks of taking part?

There will be no risk to your health from participating in this study. Blood work or lab investigations will NOT be needed before, during or at the end of your participation in this study. This study is not likely to cause anxiety or harm. However, some people may find it difficult to talk about their disturbing experiences. If you do wish extra support in dealing with your emotional needs after the interview, the researcher can refer you to healthcare professionals for help and support in this matter (with your permission). We understand that the importance of your time and some conflicts with your schedule may occur due to participation in interview. Therefore, we try to organize a suitable time for you and this can be done during the day from 9 AM until 4 PM.

8.What are the possible benefits of taking part?

Participation in this research may not have any benefits to your health. But your opinions will inform more research in the region and we hope you help us to develop culturally appropriate programs that help people with type 2 diabetes get the help and support they need to better manage this lifelong condition. Also, talking about some experiences may be beneficial and therapeutic for some participants

9.Will my taking part in this study be kept confidential?

Yes, all the information about your participation in this study will be kept confidential and transcripts will be anonymised. You will be given a unique identification number, only the researcher will be able to access your information. Any publication of the information will be completely anonymous with no way of identifying individual participants. In addition, all the audio-recordings from interviews will be destroyed.

10.What will happen to my data?

During and subsequent to the study, the terms and condition of the General Data Protection Regulation (GDPR), as agreed by the European Parliament and Council and implemented in 2018, will be strictly adhered to. Only the investigators will have access to the data and all personal details will be stored securely. Neither the names of individuals nor those of involved organisations will be disclosed. Participants will be given a unique identification number which will be known only to the researcher. Audio records of interview will be destroyed once they have been transcribed. Transcripts of the interviews will be stored on a password-protected computer accessible only to the researcher. The records will not have been emailed or transferred via a memory stick.

All documentation of the study will be stored for 10 years in a locked cabinet in a locked room in the Nursing and Health Care School at the University of Glasgow, in accordance with university policy.

11.What will happen to the results of the research study?

We hope that the results of this study will be helpful for further research in this area and they will be submitted for publication in academic journals and written up as part of a PhD thesis. Should you wish to know the results of the study then we will send you a summary of the main findings once the research is complete.

12.Who is organising and funding the research?

This study is part of PhD project currently undertaken by Bandar Alhumaidi at the University of Glasgow, UK and is funded through a scholarship from the Royal Embassy of Saudi Arabia's Cultural Bureau in London.

13.Who has reviewed the study?

The research has been reviewed by Madinah health affairs ethics committee and the University of Glasgow, college of medical& veterinary and life science ethics committee for non clinal research.

14.Contact for Further Information

If you have any further questions at this time then you can contact;

For male participant	For female participant
Bandar Alhumaidi	Souad Aljohani
Email: Tel:	Email: Tel:

Thank you for taking time to read this and for thinking about taking part.

University of Glasgow | College of Medical, Veterinary & Life Sciences

استمارة المعلومات للمشاركين في الدراسة

عنوان الدراسة :

تطوير برنامج تعليمي مناسب ثقافيًا للإدارة الذاتية للبالغين المصابين بداء السكري من النوع 2 في المملكة العربية السعودية

فقرة الدعوة:

أود أن أدعوكم للمشاركة في دراسة بحثية أنا بندر الحميدي طالب دكتوراه في كلية الطب وطب الأسنان والتمريض في جامعة غلاسكو في المملكة المتحدة. قبل أن تقرر ما إذا كنت تريد المشاركة، من المهم أن نشرح سبب إجراء البحث وما الذي سيتضمنه بالنسبة لك. يرجى تخصيص بعض الوقت لقراءة المعلومات التالية بعناية ومناقشتها مع الآخرين إذا كنت ترغب في ذلك. اسألنا إذا كان هناك أي شيء غير واضح أو إذا كنت ترغب في مزيد من المعلومات.

ما هو الغرض من الدراسة؟

العيش مع حالة مزمنة مثل مرض السكري هو التزام مدى الحياة يمكن أن يمثل تحديًا كبيرًا. يحتاج مرضى السكري إلى الدعم ومعلومات جيدة النوعية والمساعدة في متطلبات إدارة الحميات الغذائية وأنماط الحياة والأدوية (أقراص وحقن مختلفة) التي يمكن استخدامها كعلاجات. في الوقت الحالي، لا يستطيع جميع المرضى الوصول إلى المعلومات والدعم والتدريب الذي يحتاجونه ليصبحوا فعالين في إدارة مرض السكري لديهم. تعد برامج الإدارة الذاتية إحدى الطرق للحصول على دعم أفضل ومعلومات عن مرض السكري وتشجيع الأشخاص على التحكم في إدارة مرض السكري لديهم. نريد أن نعرف ما يفكر فيه مرضى السكري من النوع الثاني حول الإدارة الذاتية وأنواع الدعم التي من شأنها أن تساعدهم بشكل أفضل على الإدارة الذاتية. نريد بشكل خاص معرفة التغييرات التي يجب إجراؤها على البرامج الحالية لجعلها مناسبة للأشخاص المصابين بداء السكري من النوع الثاني الذين يعيشون في المملكة العربية السعودية.

لماذا دعيت للمشاركة؟

نحن نبحث عن الأشخاص الذين تزيد أعمارهم عن 18 عامًا والذين يعانون من مرض السكري من النوع 2 ويرغبون في المشاركة في مقابلة. لقد تم التعرف عليك لأنك مسجل في مركز السكري في مستشفى الملك فهد. من خلال المشاركة، ستساعدنا على فهم كيف يمكننا تقديم دعم أفضل للأشخاص الذين يعيشون في المملكة العربية السعودية والذين يعانون من داء السكر النوع الثاني لإدارة أنفسهم.

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هل يجب أن أشارك؟

ليس عليك المشاركة. إذا وافقت على المشاركة، سيُطلب منك التوقيع على نموذج موافقة لتأكيد رغبتك في المشاركة قبل بدء الدراسة، ولكن يمكنك الانسحاب في أي وقت تريد ويمكنك القيام بذلك دون إبداء الأسباب. إذا انسحبت من الدراسة، فستتم إزالة جميع البيانات التي تم جمعها حتى نقطة تحليل البيانات لأنه لن يكون من الممكن إزالة معلومات الفرد. لن يكون لرفض المشاركة في الدراسة أو الانسحاب منها أي تأثير على الرعاية التي تتلقاها من طبيبك.

ماذا سيحدث لي إذا شاركت؟

إذا قررت المشاركة في هذه الدراسة، فسيُطلب من الذكور المشاركة في مقابلة مع الباحث (بندر الحميدي). سيُطلب من الإناث المشاركة في مقابلة مع طاقم التمريض (سعاد الجهني)، التي تعمل في مركز السكري، ستركز المقابلة على تفضيلات المشاركين واحتياجاتهم وتجاربهم تجاه وضع الإدارة الذاتية الحالي وبرامج تعليم الإدارة الذاتية المناسبة ثقافياً للأشخاص الذين يعانون من داء السكر النوع الثاني في المملكة العربية السعودية. ستتم المقابلة في مركز السكري، وتستغرق حوالي 30 دقيقة إلى ساعة ، وسيتم تحديد موعدها في موعد مناسب لك. سيتم تسجيل جميع المقابلات بالصوت حتى لا نفقد أيًا من الأفكار أو الآراء القيمة التي تم التعبير عنها خلال الجلسات. إذا كانت هناك أية مشكلات لا تشعر بالراحة في مناقشتها في أي وقت، فيرجى إخبارنا وسنقوم بمعالجتها على الفور.

ما هي العيوب والمخاطر المحتملة للمشاركة؟

لن يكون هناك خطر على صحتك من المشاركة في هذه الدراسة. لن تكون هناك حاجة لعمل أي فحوصات مخبرية قبل أو أثناء أو في نهاية مشاركتك في هذه الدراسة. من غير المحتمل أن تسبب هذه الدراسة القلق أو الأذى. ومع ذلك ، قد يجد بعض الأشخاص صعوبة في التحدث عن تجاربهم المزعجة. إذا كنت ترغب في الحصول على دعم إضافي في التعامل مع احتياجاتك العاطفية بعد المقابلة ، يمكن للباحث أن يحيلك إلى متخصصي الرعاية الصحية للحصول على المساعدة والدعم في هذا الشأن (بإذن منك). نحن نتفهم أن أهمية وقتك وبعض التعارضات مع جدولك الزمني قد تحدث بسبب المشاركة في المقابلة. لذلك نحاول تنظيم وقت مناسب لك ويمكن القيام بذلك خلال النهار من الساعة 9 صباحًا حتى 4 مساءً .

ما هي فوائد ممكنة من المشاركة؟

قد لا يكون للمشاركة في هذا البحث أي فوائد لصحتك. لكن آرائك ستفيدنا في المزيد من الأبحاث في المنطقة ونأمل أن تساعدنا في تطوير برامج مناسبة ثقافيًا تساعد الأشخاص المصابين بداء السكري من النوع 2 في الحصول على المساعدة والدعم الذي يحتاجون إليه لإدارة هذه الحالة مدى الحياة بشكل أفضل. كما أن الحديث عن بعض التجارب قد يكون مفيدًا وعلاجيًا لبعض المشاركين.

هل ستبقى مشاركتي في هذه الدراسة سرية؟

نعم، ستبقى جميع المعلومات المتعلقة بمشاركتك في هذه الدراسة سرية وستكون النصوص مجهولة المصدر. سيتم منحك رقم تعريف فريدًا، ولن يتمكن سوى الباحث من الوصول إلى معلوماتك. سيكون أي نشر للمعلومات مجهولة المصدر تمامًا دون أي وسيلة لتحديد المشاركين الأفراد على سبيل المثال سيتم تنقيح أي إشارة إلى المعلومات التي يمكن تحديدها من النصوص وأي معلومات منشورة من الدراسة. بالإضافة إلى ذلك، سيتم إتلاف جميع التسجيلات الصوتية من المقابلات. الحالة الوحيدة التي سيتم فيها نقل المعلومات المتعلقة بك إلى فريقك السريري هي إذا تم تحديد أي مشاكل تتعلق بالسلامة. ستتم مناقشة هذا الأمر معك والحصول على موافقتك على نقل المعلومات.

ماذا سيحدث لبياناتي؟

أثناء الدراسة وبعدها، سيتم الالتزام الصارم بشروط وأحكام اللائحة العامة لحماية البيانات. سيتمكن المحققون فقط من الوصول إلى البيانات وسيتم تخزين جميع التفاصيل الشخصية بشكل آمن. لن يتم الكشف عن أسماء الأفراد أو المنظمات المعنية. سيتم منح المشاركين رقم تعريف فريدًا يكون معروفًا للباحث فقط. سيتم تدمير التسجيلات الصوتية للمقابلة بمجرد نسخها. سيتم تخزين نصوص المقابلات على جهاز كمبيوتر محمي بكلمة مرور لا يمكن الوصول إليه إلا الباحث. لن يتم إرسال السجلات عبر البريد الإلكتروني أو نقلها عبر شريحة ذاكرة. سيتم تخزين جميع وثائق الدراسة لمدة 10 سنوات في خزانة مقفلة في غرفة مقفلة في كلية التمريض والرعاية الصحية في جامعة غلاسكو وفقًا لسياسة الجامعة.

ماذا سيحدث لنتائج الدراسة البحثية؟

نأمل أن تكون نتائج هذه الدراسة مفيدة لمزيد من البحث في هذا المجال وأن يتم تقديمها للنشر في المجلات الأكاديمية ويتم كتابتها كجزء من أطروحة الدكتوراه. إذا كنت ترغب في معرفة نتائج الدراسة، فسوف نرسل لك ملخصًا بالنتائج الرئيسية بمجرد اكتمال البحث.

من يقوم بتنظيم وتمويل البحث؟

هذه الدراسة جزء من مشروع الدكتوراه الذي يقوم به حاليا طالب الدكتوراه بندر الحميدي في جامعة غلاسكو بالمملكة المتحدة ويتم تمويلها من خلال منحة دراسية من جامعة طيبة بالمدينة المنورة والملحقية الثقافية بسفارة المملكة العربية السعودية في لندن.

من قيم هذه الدراسة؟

تمت مراجعة البحث من قبل لجنة أخلاقيات البحث بالإدارة العامة للشؤون الصحية بالمدينة المنورة و لجنة أخلاقيات البحث بجامعة غلاسكو في المملكة المتحدة.

الاتصال للحصول على مزيد من المعلومات

إذا كانت لديك أي أسئلة أخرى في هذا الوقت، فيمكنك الاتصال؛

للمشاركين من الذكور الباحث (بندر الحميدي)

البريد الإلكتروني:

هاتف:

للمشاركين من الإناث طاقم التمريض)سعاد الجهني(

البريد الإلكتروني:

هاتف1

شكرًا لك على الوقت الذي استغرقته في قراءة الاستمارة والتفكير في المشاركة.

Appendix 4: Interview guide for healthcare professional

Interview questions

1.Questions regarding the experience of supporting people living with type 2 diabetes. What are the issues? How could things be improved?

- What do you think about the diabetes knowledge level of your people living with type 2 diabetes?
- Is your people living with type 2 diabetes ‘knowledge and understanding about T2D sufficient to live well?
- What kind of support do you think people living with type 2 diabetes need?
- What kind of diabetes information should you provide to people living with type 2 diabetes?
- What do you think about the diabetes care you provide to your people living with type 2 diabetes? Is it adequate? Is it based on the current guidelines?

2.Questions Regarding experiences and perceptions in providing self-management education program in the Saudi context.

- What is your understanding of self-management? How relevant is it for the people living with type 2 diabetes you see?
- What kinds of self-management support do you currently offer?
- What have been your experiences in offering self-management programmes for people with diabetes.?
- What kinds of things stop or make it difficult for self-management support/education from being offered to people in Saudi?
- What kinds of things might help self-management support/education to happen more consistently in the Saudi context?
- How should diabetes self-management care look in the Saudi context?
- Do you think Saudi culture can be a barrier to implementing self-management programmes for people with diabetes?
- Do you think implementing a self-management programme within Saudi culture would be helpful for people with diabetes?

- What kinds of things stop or make it difficult to apply for a self-management programme from being offered to people in Saudi?
- What kinds of things might help and facilitate applying for a self-management programme in the Saudi context?

Appendix 5: Interview guide for people with type 2 diabetes

Interview Questions

1. Questions Regarding knowledge and perceptions of diabetes, in relation to self-management advice for managing diabetes.

- What do you understand about T2D?
- Could you describe your experiences when you were newly diagnosed to have T2D by HCPs, did you receive sufficient information about the disease?
- What do you understand about the term diabetes self-management? What do you think about it?

2.Questions Regarding Current practices relating to diabetes selfmanagement.

- What kind of treatment are you presently receiving from your doctor in order to control your diabetes?
- What do you think about the diabetes care provided by your HCPs?
- How do you feel about it?
- What kind of diabetes information should your HCPS provide to you?

3.Questions Regarding motivations and difficulties relating to diabetes selfmanagement.

- What do you think are the worries or troubles, if any, that people with diabetes have?
- How has diabetes affected your life and family?
- How are they involved in helping you to manage your diabetes?
- What kind of support do you need related to your diabetes?

4.Questions Regarding experiences and perceptions of people with type 2 diabetes in relation to self-management education and barriers to accessing care.

- Can we talk about your experiences of receiving self-management support from HCPs?
- Do you ever attend a health education session about diabetes?

- What should people living with type 2 diabetes do to manage their condition?
- What do you actually do to manage your condition?
- Where do you find help and advice when you need to manage your diabetes?
- Overall what did you think about the self-management programmes?- How do you think they might help you to manage your diabetes?
- Was there anything you looked for in these programmes? If so what? What features would you like to see? What would make these programmes culturally appropriate?
- Finally, are there any further comments or suggestions?

Appendix 6. Healthcare professional demographic questionnaire

ID				
Age	**25-34**	**35-44**	**45-54**	**55-60**
Gender	**Male**	**Female**		
What is your role in looking after people living with type 2 diabetes ?	**Physicians**	**Diabetes Nurse**	**Dietician**	**Other**
How much experience do you have to help manage people living with type 2 diabetes ?	**1-2 years**	**3-4 years**	**5-9 years**	**10 and above**
What is the highest level of educational qualification that you have completed	**Technical Degree**	**Bachelor**	**Higher Degree**	
What is your ethnic background?				
Have you ever been involved in delivering education programmes to help manage people living with type 2 diabetes ?	**Yes**	**No**		

Appendix 7. People living with type 2 diabetes’ demographic questionnaire

<table>
<tr><td>ID</td><td></td></tr>
<tr><td>Age</td><td><table><tr><td>18-29</td><td>30-39</td><td>40-49</td><td>50-59</td><td>60 and above</td></tr><tr><td></td><td></td><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>Gender</td><td><table><tr><td>Male</td><td>Female</td></tr><tr><td></td><td></td></tr></table></td></tr>
<tr><td>Marital Status</td><td><table><tr><td>Single</td><td>Married</td><td>Divorced</td><td>Widow</td></tr><tr><td></td><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>What is the highest level of educational qualification that you have completed?</td><td><table><tr><td>Primary</td><td>Secondary</td><td>University and above</td><td>None</td></tr><tr><td></td><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>How is your diabetes managed?</td><td><table><tr><td>Diet</td><td>Tablets</td><td>Insulin</td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>How long have you had diabetes? (in years)</td><td><table><tr><td>Please specify the number of years ....</td></tr></table></td></tr>
</table>

Do you suffer any of the following complications of diabetes?	**Heart disease**	**Kidney problems**	**Stroke**	**Anxiety**	**Depression**
Do you suffer any of the following conditions?	**High blood pressure**	**High level of cholesterol**	**Other conditions**	**None**	
Have you been involved in any diabetes education sessions?	**Yes**	**No**			
If yes, please were these sessions	**Group**	**Individual**	**Both**		

Appendix 8. Ethical approval for qualitative study from University of Glasgow

Dear Dr Lisa Kidd

MVLS College Ethics Committee
Project Title *Developing a culturally structured self-management education program for people with type 2 diabetes in Saudi Arabia.*
Project No

The College Ethics Committee has reviewed your application and has agreed that there is no objection on ethical grounds to the proposed study.

We are happy therefore to approve the project, subject to the following conditions.

- Project end date as stipulated in original application.

- The data should be held securely for a period of ten years after the completion of the research project, or for longer if specified by the research funder or sponsor, in accordance with the University's Code of Good Practice in Research: (http://www.gla.ac.uk/media/media_227599_en.pdf)

- The research should be carried out only on the sites, and/or with the groups defined in the application.

- Any proposed changes in the protocol should be submitted for reassessment, except when it is necessary to change the protocol to eliminate hazard to the subjects or where the change involves only the administrative aspects of the project. The Ethics Committee should be informed of any such changes.

- For projects requiring the use of an online questionnaire, the University has an Online Surveys account for research. To request access, see the University's application procedure at https://www.gla.ac.uk/research/strategy/ourpolicies/useofonlinesurveystoolforresearch/.

- You should submit a short end of study report to the Ethics Committee within 3 months of completion.

Yours sincerely

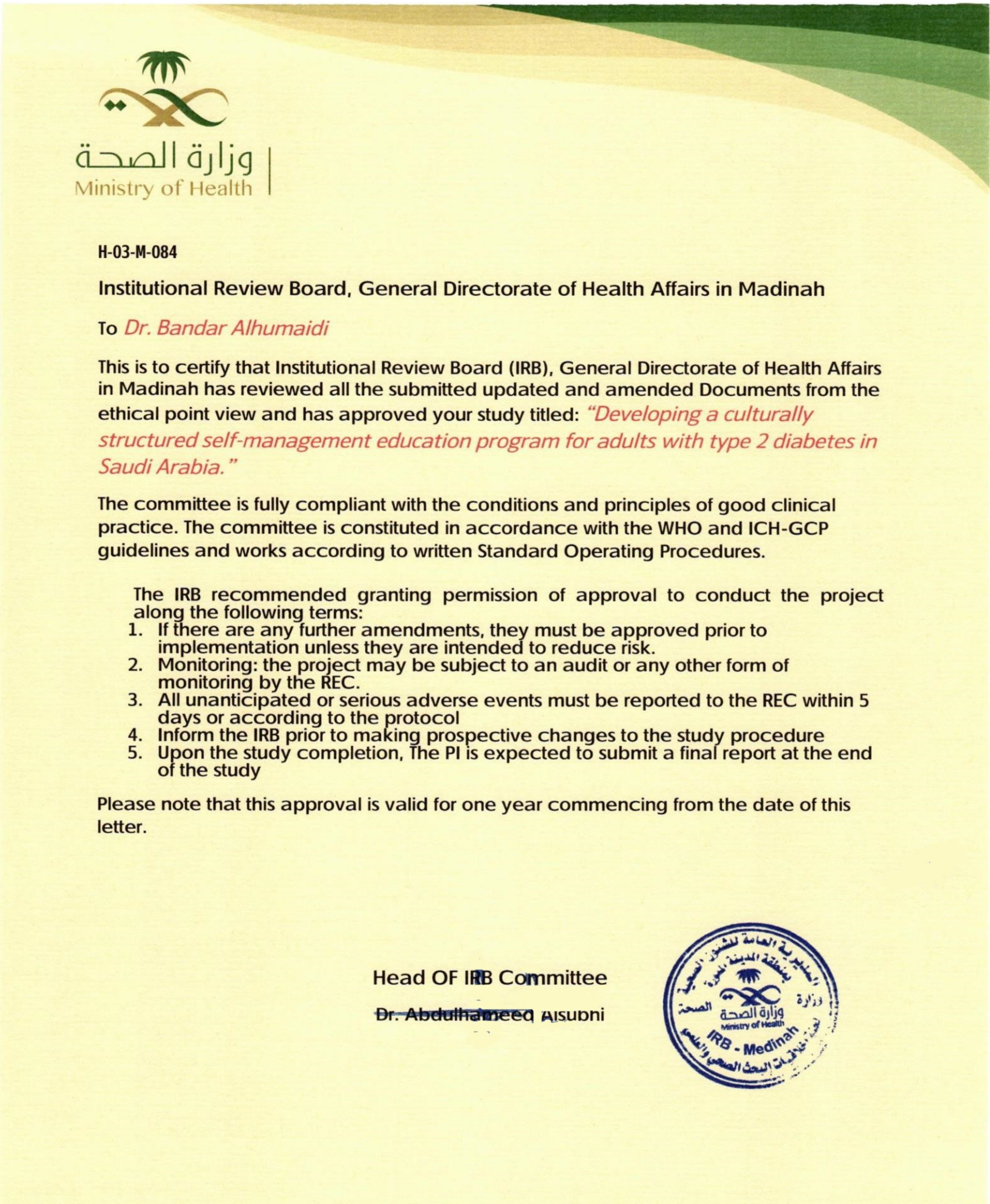
Terry Quinn
FESO, MD, FRCP, BSc (hons), MBChB (hons)
Senior Lecturer / Honorary Consultant

College of Medicine, Veterinary & Life Sciences
Institute of Cardiovascular and Medical Sciences
New Lister Building, Glasgow Royal Infirmary
Glasgow
G31 2ER
terry.quinn@glasgow.gla.ac.uk
Tel –

Dr Terry Quinn

The University of Glasgow, charity number SC004401

Appendix 9. Ethical approval for qualitative from ministry of health in Saudi Arabia



وزارة الصحة
Ministry of Health

H-03-M-084

Institutional Review Board, General Directorate of Health Affairs in Madinah

To *Dr. Bandar Alhumaidi*

This is to certify that Institutional Review Board (IRB), General Directorate of Health Affairs in Madinah has reviewed all the submitted updated and amended Documents from the ethical point view and has approved your study titled: *"Developing a culturally structured self-management education program for adults with type 2 diabetes in Saudi Arabia."*

The committee is fully compliant with the conditions and principles of good clinical practice. The committee is constituted in accordance with the WHO and ICH-GCP guidelines and works according to written Standard Operating Procedures.

The IRB recommended granting permission of approval to conduct the project along the following terms:

1. If there are any further amendments, they must be approved prior to implementation unless they are intended to reduce risk.
2. Monitoring: the project may be subject to an audit or any other form of monitoring by the REC.
3. All unanticipated or serious adverse events must be reported to the REC within 5 days or according to the protocol
4. Inform the IRB prior to making prospective changes to the study procedure
5. Upon the study completion, The PI is expected to submit a final report at the end of the study

Please note that this approval is valid for one year commencing from the date of this letter.

Head OF IRB Committee

Dr. Abdulhameed Alsubhi

وزارة الصحة
Ministry of Health

Hospital : King Fahad	**Medina , KSA**
Date 31 December 2019	**IRB Approval Form**

Institutional Review Board King Fahad Hospital – Medina

To :Bandar Al- Humaidi

This is to certify that departure research committee King Fahad Hospital – medina al Munawarh has reviewed all submitted updated and amended documents from the ethical point of view your study (ADCARE) titled **Developing a Culturally Structured Self – Management Education Program for adults with Type 2 Diabetes in Saudi Arabia**

All the updated documents received by the committee below have been reviewed and approved. The committee is fully compliant with the conditions and principles of good clinical practice . the committee is constituted in accordance with the WHO and ICH – GOP guidelines and works according to written standard operating procedures.

Below are the list of IRB members that reviewed and approved the above mentioned documents , kindly to know that only those IRB members who are independent of the investigator and sponsor vote / provide opinion on trial related matter:

Se. No	Name	Role in Ethics Committee	Qualification	Attendance
1	**Dr. Abeer Al- Harbi**	**Chairman**	**Consultant Chest & Sleep Medicine**	**Vacation**
2	**Dr. Ghassan Al-Sisi**	**Member**	**Consultant General Medicine & Head of Dept**	**No**
3	**Dr. Ahmed Al- Hujaili**	**Member**	**Consultant anatomic pathology & nephropathology**	**Yes**
4	**Dr. Kawther Basher**	**Member**	**Consultant Internal medicine MRCP**	**No**
5	**Dr. Mafaten al- chaoali**	**Member**	**Patient safety director MD , M. Sc infection control**	**Yes**
6	**Dr. Fadwa Al- Oufi**	**Member**	**Consultant medicine & transplant infectious diseases**	**Yes**

The REC recommended granting permission of approval to conduct the project along the following terms :

1- If there are any further amendments , they must be approved prior to implementation unless they are intended to reduce risk .
2- Monitoring : the project may be subject to an audit or any other form of monitoring by REC .
3- All unanticipated or serious adverse events must be reported to the REC within 5 days or according to the protocol
4- Inform the IRB prior to making prospective changes to the study procedure
5- Upon the study completion , the PI is expected to submit a final report at the end of the study .

Please note that this approval is valid for any year commencing from the date of this letter .

Head Of IRB Committee King Fahad Hospital	**Medical Director**
Dr. Abeer Al- Harbi	**Dr. Badr Al- Hamayeed**

Dr. Abeer Alharbi MD
Consultant Chest/Sleep Medicine
King FAHAD Hospital, Madinah
Madinah - KSA

Appendix 10. Consent form of the interview for participants

Title of Project: Developing a culturally structured self-management education program for people with type 2 diabetes in Saudi Arabia.

Name of Researcher: Bandar Alhumaidi

Your Consent	**Please initial box**
I confirm that I have read and understood the Participant Information Sheet version 2 dated 01/07/2020 and have been given time to consider whether or not I wish to take part.	
I have had the opportunity to think about the information and ask questions and understand the answers I have been given.	
I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my legal rights being affected.	
I understand that all data and information I provide will be kept confidential and will be seen only by study researchers and regulators whose job it is to check the work of researchers.	
I agree that my name, contact details and data described in the information sheet will be kept during the project so that the researcher can contact me and can send me a copy of the study findings. I understand that any personally identifiable information that is collected during the project will be destroyed 2 months after it is completed.	
I agree to my interview being audio recorded.	
I understand that the recorded interview will be transcribed word by word and the transcription stored for up to 10 years in University archiving facilities in accordance with Data Protection policies and regulations.	
I understand that my information and things that I say in an interview may be quoted in reports and articles that are published about the study, but my name or anything else that could tell people who I am will not be revealed.	
I agree to take part in the above study.	

Name of participant ____________ Date ____________ Signature ____________

Researcher ____________ Date ____________ Signat ____________

Appendix 11. Summary of coding descriptions (Study 2)

Code name/label	Theme/subtheme	Example of evidence/ quotations	Description of code content/meaning
1: Emphasis upon patients in acquiring the means to becoming their own doctors	Informing subtheme 1.1 [Care provider views and perceptions of patients' needs] of Theme 1 [Perceptions of the value of self-management programmes]	"patient is the one who controls and participates in the decision-making about his health condition, the medications he needs, and the diet with the doctor" [MPD-14]	Clinicians viewed self-management as transferring responsibility for care and outcomes to patients themselves
2: Improving service efficiency	Informing subtheme 1.1 [Care provider views and perceptions of patients' needs] of Theme 1 [Perceptions of the value of self-management programmes]	"the number of useless visits will decrease" [MPN-12]	Professionals recognised that self-management had potential to improve service efficiency – patient throughout and costs
3: Improving clinical outcomes	Informing subtheme 1.1 [Care provider views and perceptions of patients' needs] of Theme 1 [Perceptions of the value of self-management programmes]	"the evidence is my attempts to implement the program inside the clinic in the educational aspect, with repeated visits, there are remarkable results with a clear progression of patients 'cases within a period of three months" [FPD-2]	Clinicians also believed that self-management could improve clinical outcomes and anecdotes supported meaningful improvements in glycaemic control
4: Improving mental wellbeing	Informing subtheme 1.1 [Care provider views and perceptions of patients' needs] of Theme 1 [Perceptions of the value of self-management programmes]	"will achieve several positive aspects, including relieving pressure and awareness and mental health of the patient" [MPD-1]	Clinicians also found that education leading to improve diabetes control conferred positive effects upon emotional, psychological and mental wellbeing.
5: Approach to diabetes care	Informing subtheme 2.1 [Medium and purpose of information and education delivery] of Theme2 [Role of information provision and patient education in addressing knowledge and awareness regarding type 2 diabetes self-management]	"I teach him the correct information, and this patient will have another patient with him, and therefore the more of this thing, the more this thing will be continuous, the errors will be corrected" [FPN-9]	Physicians approaches to treating patients with diabetes often did but not always involved self-management.
2: In-person versus remote care	Informing subtheme 2.1 [Medium and purpose of	"the patient was effective benefit from the experience that is still benefiting from it	Meeting service user demands was not always feasible via the traditional clinic

	information and education delivery] of Theme 2 [Role of information provision and patient education in addressing knowledge and awareness regarding type 2 diabetes self-management]	during the Corona pandemic, and the method is present in the form of lectures through the Zoom program that include both theoretical and practical side in addition to dialogue to ask patients' problems" [FPD-2]	setting and required remote consultations via video conferencing software and other methods to enhance learning.
3: Care satisfaction and positive service experiences	Informing subtheme 2.1 [Medium and purpose of information and education delivery] of Theme2 [Role of information provision and patient education in addressing knowledge and awareness regarding type 2 diabetes self-management]	"The most important step is for the patient to feel that he is a participant in making the decision and not the doctor gives orders" [MPD-14]	Professionals reported that patients were generally satisfied with trialling self-management and positive experiences predominated at follow-up clinics
4: Happiness secondary to better health and mental wellbeing	Informing subtheme 2.1 [Medium and purpose of information and education delivery] of Theme2 [Role of information provision and patient education in addressing knowledge and awareness regarding type 2 diabetes self-management]	"we prepare the person psychologically, because it is a new thing in his life, he will take needles every day, meaning this is a new thing in his life" [MPN-7]	As a result of service users finding content in engaging in self-management, positive effects upon general health status and mental wellbeing were reported
5: Awareness of impact of self-management upon relieving health system pressures	Informing subtheme 2.1 [Medium and purpose of information and education delivery] of Theme2 [Role of information provision and patient education in addressing knowledge and awareness regarding type 2 diabetes self-management]	"this almost did not take us time to understand the disease and how he can control his disease without resorting to a doctor except in emergency cases" [MPN-7]	Professionals also reported that patients recognised that value of self-management in reducing pressures upon secondary and tertiary diabetes services
6: Information provision to optimise knowledge and awareness	Informing subtheme 2.2 [Importance of timing in optimising uptake and sustaining engagement with Type 2 diabetes self-management] of Theme 2 [Role of information provision	"From what I have noticed that the majority of patients do not know what is the meaning of diabetes" "the first thing is to correct the patient's information, the first thing that must be known" [FPN-9]	Clinicians were concerned with providing information about diabetes at specific windows of opportunity following diagnosis

	and patient education in addressing knowledge and awareness regarding type 2 diabetes self-management]		
7: Pressure to deliver information and education soon after diagnosis	Informing subtheme 2.2 [Importance of timing in optimising uptake and sustaining engagement with Type 2 diabetes self-management] of Theme 2 [Role of information provision and patient education in addressing knowledge and awareness regarding type 2 diabetes self-management]	“It is better to activate the concept of self-management in the first visits to the patient and before the symptoms of the disease appear, which allows the doctor to provide them with information about the disease and how to avoid complications and deal with them” [MPD-1]	Clinicians felt that it was important to provide education at the time of diagnosis, in order to optimise adherence to management strategies and to prevent tendencies to adopting unhealthy coping strategies
8: Perceptions that delayed education would compound diabetes outcomes	Informing subtheme 2.2 [Importance of timing in optimising uptake and sustaining engagement with Type 2 diabetes self-management] of Theme 2 [Role of information provision and patient education in addressing knowledge and awareness regarding type 2 diabetes self-management]1	“self-control is also an excellent step… we are looking to teach them before they have diabetes” [MPD-1]	Clinicians also thought that failure to provide education in the immediate post-diagnosis period would ultimately worsen outcomes over time
9: Prioritising the type of information to be exchanged at different disease time-points	Informing subtheme 2.2 [Importance of timing in optimising uptake and sustaining engagement with Type 2 diabetes self-management] of Theme 2 [Role of information provision and patient education in addressing knowledge and awareness regarding type 2 diabetes self-management]1	“first visit; no, possibly second or third visit, the patient can benefit fully after the third visit” [MPN-7]	Some clinicians recognised that information had to be provided at key clinical time points to help support patients in consolidating new information about diabetes
10: Need to improve inter-disciplinary and inter-agency working	Informing subtheme 3.1 [Integration of diabetes care services and inter-agency working] of Theme 3 [Factors	“We must have a full team that includes a consultant endocrinologist, a specialist in diabetes, education and nutrition, so that the patient knows all the necessary	Respondents reported that there was a need to improve the standardisation of diabetes care across departments and

	influencing the adoption and availability of self-management programmes]	information"… there is no complete team here, as the presence of the team is very important for patients" [MPN-6]	services, in order to promote and monitor self-management
11: Developing educational strategies based on multi-disciplinary and multi-agency inputs	Informing subtheme 3.1 [Integration of diabetes care services and inter-agency working] of Theme 3 [Factors influencing the adoption and availability of self-management programmes]	"patient needs the participation of more than one party to achieve a high level of education that serves this group to support them, such as the nutrition aspect, for example" [FPD-2]	Professionals noted that multi-disciplinary team working was key to sustaining uptake and recommendations of self-management as a key diabetes care approach
12: Education to optimise knowledge and awareness	Informing subtheme 3.3 [Barriers to self-management programs for patients with type 2 diabetes] of Theme 3 [Factors influencing the adoption and availability of self-management programmes]	"We are trying to make patients reach the level that they only visit the clinic for cumulative analysis every six months, so that they can establish the level of sugar using treatments and how to deal with symptoms of high blood sugar and how to avoid them" [MPN-6]	Clinicians were also concerned with providing patients with education on how to cope with diabetes-related problems.
13: Time pressures limiting the extent of information/education	Informing subtheme 3.3 [Barriers to self-management programs for patients with type 2 diabetes] of Theme 3 [Factors influencing the adoption and availability of self-management programmes]	"The information about type 2 diabetes was not spread enough to avoid the disease or reduce complications, due to the lack of time and the high pressure on the clinics" [FPD-2]	Clinicians encountered time related pressures that limited the duration of patient consultations and in turn, compounded the ability to provide information/education
14: Short staffing limiting the time spent with individual patients	Informing subtheme 3.3 [Barriers to self-management programs for patients with type 2 diabetes] of Theme 3 [Factors influencing the adoption and availability of self-management programmes]	"diabetes service is short staff… we need more resources to help improve care" [FPN-1]	This problem exacerbated time pressures in being able to provide patients with all the information required about diabetes and its management approaches
15: Impact of negative experiences of self-	Informing subtheme 3.3 [Barriers to self-management	"so someone must be educated with them, I cannot teach a patient over the age of 65,	Some professionals reported self-management to be unacceptable to

management upon wider diabetes care practices	programs for patients with type 2 diabetes] of Theme 3 [Factors influencing the adoption and availability of self-management programmes]	I teach him alone, there must be his son with him or his family” [FPN-9]	patients or ineffective in improving diabetes outcomes.
16: Generational influences of self-management acceptability	Informing subtheme 3.2 [Cultural acceptability of self-management] of Theme 3 [Factors influencing the adoption and availability of self-management programmes]	“young people can change the way they eat and their lifestyle, but the elderly do not have this ability to change” [MPN-8]	Some professionals held beliefs that traditional paternalistic approaches to diabetes care were ideal, albeit not being based on research evidence
17: Cultures supportive of patient education	Informing subtheme 3.2 [Cultural acceptability of self-management] of Theme 3 [Factors influencing the adoption and availability of self-management programmes]	“but regarding group discussion, many patients don’t respond to it”… “obstacles are related to culture in Saudi Arabia, and it is not administrative, but the problem is in the people themselves, such that the females must be alone” [MPN-8]	Professionals recognised that overarching cultures were important in influencing how they approached diabetes care
18: Limited education of lay population regarding the principles of self-management	Informing subtheme 3.2 [Cultural acceptability of self-management] of Theme 3 [Factors influencing the adoption and availability of self-management programmes]	“the patient searches for someone who understands and listens to him during his visit to the clinic” [FPD-2]	Poor awareness of self-management among the general population impeded uptake and acceptance of the approach by patients with diabetes
19:Acknowledgement of variances in and influences of culture upon health	Informing subtheme 3.2 [Cultural acceptability of self-management] of Theme 3 [Factors influencing the adoption and availability of self-management programmes]	“a good culture, succeeds in educating patients”…. “I do not think now the Saudi society is an educated society, and we accept change” [FPD-3]	Clinicians recognised that culture was highly influential upon service users risk of ill health and in utilising the principles of continuous quality improvement to help introduce novel management initiatives
20: Language barriers among non-native Saudi persons	Informing subtheme 3.2 [Cultural acceptability of self-management] of Theme 3 [Factors influencing the adoption and availability of	“it is possible to make publications about the disease in several languages to educate patients more broadly” [MPD-1]	It was clear that sufficient education materials were available for persons who spoke Arabic but not for those fluent in foreign languages.

	self-management programmes]		
21: Policy level barriers	Informing subtheme 3.3 [Barriers to self-management programs for patients with type 2 diabetes] of Theme 3 [Factors influencing the adoption and availability of self-management programmes]	“building a partnership between the Ministry of Health and the universities so that there are training and educational and awareness programs” [MPDT-5]	There were consistent reports that poor support and funding for diabetes education at the policy level had negative downstream effects upon care.
22: Policy drivers of diabetes care	Informing subtheme 3.3 [Barriers to self-management programs for patients with type 2 diabetes] of Theme 3 [Factors influencing the adoption and availability of self-management programmes]	“improving the integration of diabetes care and diabetes care quality requires more support and funding and resources from the government” [FPN-4]	Professionals recognised that issues or support at the health policy level influenced the ability to provide high quality diabetes care and in adopting new management strategies
23: Clinical drivers of diabetes care	Informing subtheme 3.4 [Standards and guidelines regarding self-management approaches to type 2 diabetes care]of Theme 3 [Factors influencing the adoption and availability of self-management programmes]	“the Ministry of Health needs to consolidate diabetes services and introduce large-scale self-management programs to help improve outcomes on a meaningful level” [MPDT-5]	Participants also reported that the provision of diabetes care was driven by clinical targets and clinically-orientated treatment goals
24: Lack of diabetes guideline specificity	Informing subtheme 3.4 [Standards and guidelines regarding self-management approaches to type 2 diabetes care]of Theme 3 [Factors influencing the adoption and availability of self-management programmes]	“there are no universal guidelines to help guide diabetes care… these need to be developed specifically to the Saudi context” [MPN-6]	Limited advocation of education within diabetes guidelines impeded the universal use of information provision to optimise outcomes.
25: Poor adherence to guideline recommendations among care providers	Informing subtheme 3.4 [Standards and guidelines regarding self-management approaches to type 2 diabetes care]of Theme 3 [Factors	“I have witnessed different diabetes practices, some intensive input from different health professionals in diabetes, others being solely managed by a general practice doctor, guidelines need to	Some clinicians noted that there were marked practice variances in treatment approaches, which was due to limited use of national guidelines for diabetes.

	influencing the adoption and availability of self-management programmes]	promote multi-disciplinary diabetes care and within each specialty, self-management" [MPD-1]	

Appendix 12. Summary of coding descriptors (Study 3)

Code name/label	Theme/subtheme	Evidence/ Quotations	Description of code content/meaning
1: Dominant focus on blood sugar levels	Informing subtheme 1.1 [Understanding of type 2 diabetes as an organic disease entity] of Theme 1 [Understanding of type 2 diabetes and the principles of diabetes management and glycaemic targets]	“move away from a little from sugary drinks and sweets that contain a high proportion of sugar” [PM-2]	Broad knowledge regarding blood sugars but little correlation with other aspects of diabetes
2: Adjusting blood sugar levels to meet set parameters	Informing subtheme 1.1 [Understanding of type 2 diabetes as an organic disease entity] of Theme 1 [Understanding of type 2 diabetes and the principles of diabetes management and glycaemic targets]	“I control its percentage so that it should not exceed 120, 125 at most, I don’t let its percentage rise above that” [PM-3]	Focus upon meeting stringent acute targets as opposed to improving long-term control and the lifestyle measures needed to achieve this
3: Understanding of complication risk	Informing subtheme 1.1 [Understanding of type 2 diabetes as an organic disease entity] of Theme 1 [Understanding of type 2 diabetes and the principles of diabetes management and glycaemic targets]	“diabetes can be more dangerous than the Coronavirus, it can and control your internal organs - the heart, kidneys, nerves, and many other things” [PM-5]	Most participants feared diabetes complications and could name the organ systems usually affected. Complications were also seen as serious as COVID-19.
4: Understanding of the causes of type 2 diabetes	Informing subtheme 1.1 [Understanding of type 2 diabetes as an organic disease entity] of Theme 1 [Understanding of type 2 diabetes and the principles of diabetes management and glycaemic targets]	“my mother is diabetic, and my brothers most of them have it.. we have an inheritance to diabetes” [PM-2]	Some participants reported that diabetes was due to genetics (inheritance) but there were no clear correlates with excess weight.
5: Overarching purpose to alter blood sugar levels and diabetes control	Informing subtheme 1.2 [Understanding of diabetes self-management] of Theme 1 [Understanding of type 2 diabetes and the principles of diabetes management and glycaemic targets]	“reduce high sugar and improve diet.. better sugars” [PM-8]	Most individuals were concerned with controlling blood sugars.
6: Lack of awareness and knowledge of self-management principles	Informing subtheme 1.2 [Understanding of diabetes self-management] of Theme 1 [Understanding of type 2 diabetes and the principles of diabetes management and glycaemic targets]	“but the media and the Ministry of Health are categorically neglect diabetes” [PM-5]	Few participants recognised the value of education in diabetes management and reported health bodies to neglect prioritising this approach.
7: Education provision	Informing subtheme 1.2 [Understanding of diabetes self-management] of Theme 1 [Understanding of type 2 diabetes and	“education to learn about diabetes and how exercise, diet, change sugar in blood” [PM-5]	Similarly, few participants did not recognise how education could be used to induce self-care activities to control diabetes.

	the principles of diabetes management and glycaemic targets]		
8: Adjusting lifestyle habits	Informing subtheme 1.2 [Understanding of diabetes self-management] of Theme 1 [Understanding of type 2 diabetes and the principles of diabetes management and glycaemic targets]	“diabetics need to follow is to balance between walking and eating, to know their burning rate per day, and to balance it with the calories they eat” [PM-6]	Most participants reported upon the need to consume a healthy diet and engage in regular physical activity; to an extent more than usual.
9: Extent of information provision	Informing subtheme 2.1 [Lack of information provision and diabetes education in the early stages following diagnosis] of Theme 2 [Barriers to diabetes self-management]	“They did not provide me with anything, not information or services” [PM-1]	There was very poor information and education in the early stages following diabetes diagnosis.
10: Extent of education provision	Informing subtheme 2.1 [Lack of information provision and diabetes education in the early stages following diagnosis] of Theme 2 [Barriers to diabetes self-management]	“first time I visited a diabetic doctor, he told me: You are a diabetic patient, and this is your treatment, and goodbye” [PM-9]	Education was almost completely lacking for participants included in the study with seldom reports of having received formal education from members of the multi-disciplinary team.
11: Professional support	Informing subtheme 2.2 [Status and role of professional and social support] of Theme 2 [Barriers to diabetes self-management]	“I follow up with a doctor who wrote me a medicine, but I changed it… I go to a specialist doctor and I noticed a big difference with him” [PM-1]	There were marked variances in the supportiveness of diabetes health professionals; some being inspiring and engaging, whilst others adopted a paternalistic position.
12: Non-professional supports	Informing subtheme 2.2 [Status and role of professional and social support] of Theme 2 [Barriers to diabetes self-management]	“No one helps me; I take care of myself because sugar is considered in society as a normal thing.. I rely on family” [PM-6]	Most participants relied upon their own initiatives to learn about and manage diabetes, although some sought the support of family and friends.
13: Dietary effects	Informing subtheme 2.3 [Inconveniences of diabetes upon quality of life] of Theme 2 [Barriers to diabetes self-management]	“two things, first: burning calories, movement and walking, and at times in food” [PM-7]	Diet was a major component of participants lives and the restrictions due to diabetes were seen as a marked inconvenience.
14: Other lifestyle effects	Informing subtheme 2.3 [Inconveniences of diabetes upon quality of life] of Theme 2 [Barriers to diabetes self-management]	“My friends and close mates advised me not to care about that and to eat and not to give the matter any concern and to deal normally as I am still young” [PM-3]	Participants also reported that diabetes impact almost all other aspects of their everyday lives including work and personal relationships.
15: Emotional burden	Informing subtheme 2.3 [Inconveniences of diabetes upon quality of life] of Theme 2 [Barriers to diabetes self-management]	“No, by God, I could not control it, so far I struggling with it” [PM-9]	There was an overwhelming sense that diabetes and the management approaches incurred an emotional burden upon individuals due to the varied stressors of coping with the disease.
16: Dietary limits underpinned by culture	Informing subtheme 3.1 [Cultural beliefs and traditions that promote unhealthy dietary intake] of Theme 3 [Cultural	“I know what the dinner system is there, it is known to be high in	The Saudi culture was centred around food traditions and gatherings, which detracted persons from complying with a healthy diet.

	mediators of type 2 diabetes self-management]	calories, sugars, and carbohydrates” [PM-2]	
17: Impacts of dietary restrictions	Informing subtheme 3.1 [Cultural beliefs and traditions that promote unhealthy dietary intake] of Theme 3 [Cultural mediators of type 2 diabetes self-management]	“the diabetic gets tired a lot because he is not able to eat all the foods, but the patient should not deprive himself” [PM-1]	Dietary restriction was associated with poor sleep and impaired enjoyability and contentedness in life.
18: Acceptability of physical exercise	Informing subtheme 3.2 [Cultural beliefs and traditions that promote a sedentary lifestyle] of Theme 3 [Cultural mediators of type 2 diabetes self-management]	“some people are busy in the morning with work hours” [PM-7]	Most participants found increasing physical activity difficult and had little free-time to engage in meaningful exercise.
19: Rigour of physical activity	Informing subtheme 3.2 [Cultural beliefs and traditions that promote a sedentary lifestyle] of Theme 3 [Cultural mediators of type 2 diabetes self-management]	“the majority of people who suffer from diabetes are retired and have free time.. this patient can benefit from walking” [PM-5]	Similarly, there was an emphasis upon walking as the main mode of activity but little reports of the intensity and duration of exercise needed to promote weight loss.
20: Person-centred diabetes care	Informing subtheme 4.1 [Provision of personalised diabetes care] of Theme 4 [Perceived views of desired approaches to self-management education]	“we are human, sometimes there is some kind of transgression, you know human beings, but it always goes back to the line and pays attention” [PM-2]	Some participants recognised that individualising diabetes care was key to improving their compliance with management recommendations.
21: Individualising treatment plans	Informing subtheme 4.1 [Provision of personalised diabetes care] of Theme 4 Perceived views of desired approaches to self-management education]	“Some doctors give medication from the book and it is not based on your actual condition” [PM-1]	Building on the former subtheme, participants reported that more detailed and personalised treatment plans were necessary to improve their glycaemic control and to reduce their risk of complications in the future.
22: Support for self-management programs	Informing subtheme 4.2 [Desires for and characteristics of formal diabetes programs and courses] of Theme 4 Perceived views of desired approaches to self-management education]	“I advise every diabetic to listen to educational programs and to be keen to attend them and not to miss them, because this is very important and will increase their education in diabetes and how to deal with diabetes” [PM-3]	Most participants were accepting of self-management programs as they recognised the importance of education in acquiring the knowledge and skills needed to improve their health status.
23: Characteristics of self-management programs	Informing subtheme 4.2 of Theme 4 Perceived views of desired approaches to self-management education]	“it is better to gather patients in one place every ten days, that is, three times per month” [PM-1]	Participants tended to prefer education in group based settings and held no extreme preferences regarding content or educationalists. However, it was emphasised that the content should be accessible via online mediums following the programs to permit repeated access to consolidate information learnt.

Appendix 13. Ethical approval for secondary data study from university of Glasgow

University of Glasgow

Dr Lisa Kidd

MVLS College Ethics Committee

An analysis of the scope, quality and potential utility of routine data collected for people with type 2 diabetes in King Fahad Hospital in Saudi Arabia. 200200154

The College Ethics Committee has reviewed your application and has agreed that there is no objection on ethical grounds to the proposed study. We are happy therefore to approve the project, subject to the following conditions

- Project end date as stipulated in original application.
- The data should be held securely for a period of ten years after the completion of the research project, or for longer if specified by the research funder or sponsor, in accordance with the University's Code of Good Practice in Research: (http://www.gla.ac.uk/media/media_227599_en.pdf)
- The research should be carried out only on the sites, and/or groups defined in the application.
- Where a questionnaire collects sensitive or protected information, the Data Protection Impact Assessment should be discussed with the data office.
- Any proposed changes in the protocol should be submitted for reassessment, except when it is necessary to change the protocol to eliminate hazard to the subjects or where the change involves only the administrative aspects of the project. The Ethics Committee should be informed of any such changes.
- For projects requiring the use of an online questionnaire, the University has an Online Surveys account for research. To request access, see the University's application procedure at https://www.gla.ac.uk/research/strategy/ourpolicies/useofonlinesurveystoolforresearch/.
- You should submit a short end of study report within 3 months of completion.

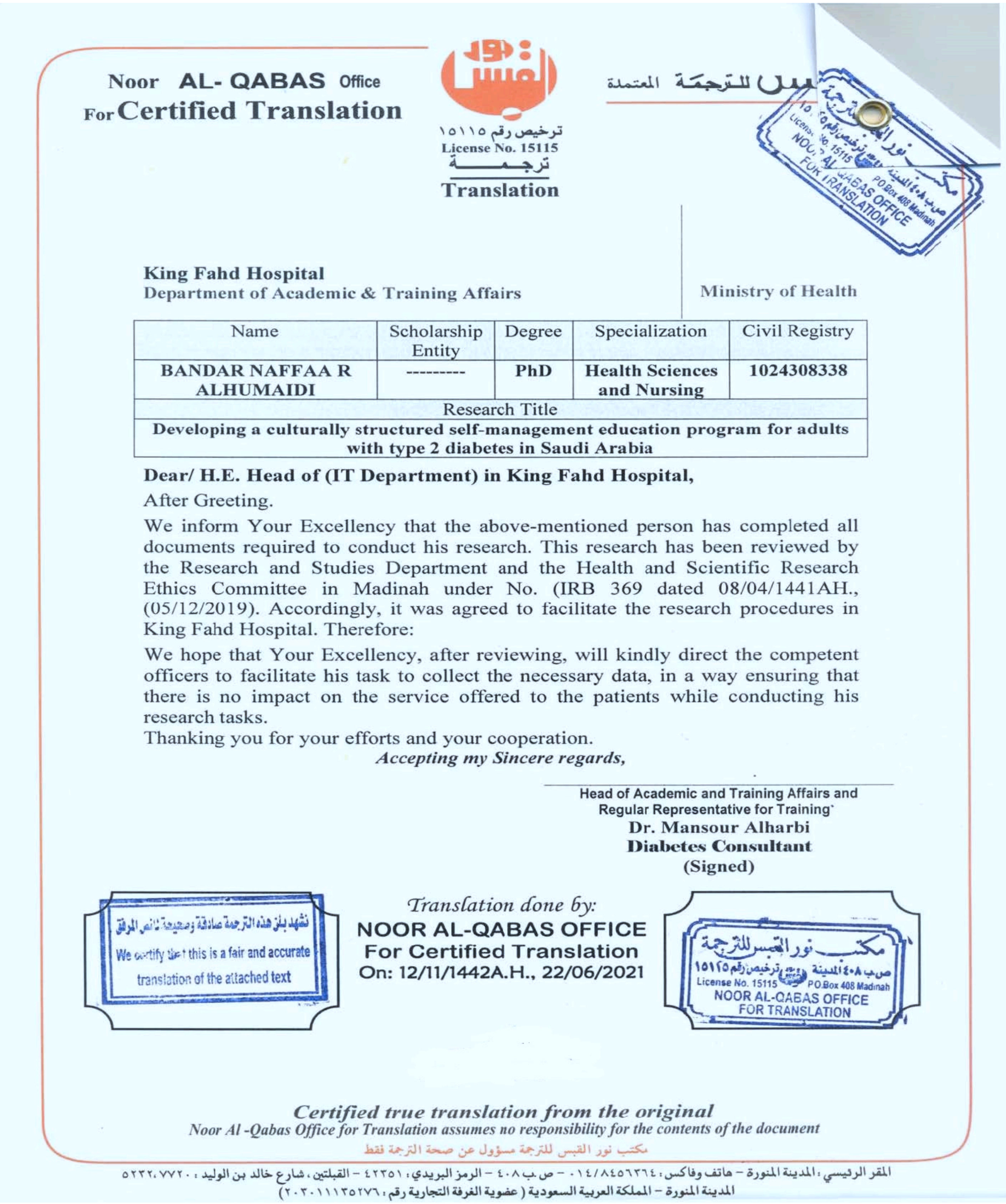
Yours sincerely

Terry Quinn
FWSO, FESO, MD, FRCP, BSc (hons), MBChB (hons)
Reader / Honorary Consultant

College of Medicine, Veterinary & Life Sciences
Institute of Cardiovascular and Medical Sciences
New Lister Building, Glasgow Royal Infirmary
Glasgow G31 2ER
terry.quinn@glasgow.gla.ac.uk Tel
–

Dr Terry Quinn

Appendix 14. Ethical approval for secondary data study from ministry of health in Saudi Arabia



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King Fahd Hospital
Department of Academic & Training Affairs

Ministry of Health

Name	Scholarship Entity	Degree	Specialization	Civil Registry
BANDAR NAFFAA R ALHUMAIDI	---------	**PhD**	**Health Sciences and Nursing**	**1024308338**
Research Title				
Developing a culturally structured self-management education program for adults with type 2 diabetes in Saudi Arabia				

Dear/ H.E. Head of (IT Department) in King Fahd Hospital,

After Greeting.

We inform Your Excellency that the above-mentioned person has completed all documents required to conduct his research. This research has been reviewed by the Research and Studies Department and the Health and Scientific Research Ethics Committee in Madinah under No. (IRB 369 dated 08/04/1441AH., (05/12/2019). Accordingly, it was agreed to facilitate the research procedures in King Fahd Hospital. Therefore:

We hope that Your Excellency, after reviewing, will kindly direct the competent officers to facilitate his task to collect the necessary data, in a way ensuring that there is no impact on the service offered to the patients while conducting his research tasks.

Thanking you for your efforts and your cooperation.

Accepting my Sincere regards,

Head of Academic and Training Affairs and
Regular Representative for Training
Dr. Mansour Alharbi
Diabetes Consultant
(Signed)

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Madinah
Organizational Planning and Transformation
Research and Studies Department

Ministry of Health

Name	Scholarship Entity	Degree	Specialization	Civil Registry
BANDAR NAFFAA R ALHUMAIDI	---------	**PhD**	**Health Sciences and Nursing**	**1024308338**

Research Title
Developing a culturally structured self-management education program for adults with type 2 diabetes in Saudi Arabia

Dear/ H.E. Director of King Fahd Hospital,

Peace, mercy and blessings of Allah be upon you!

We inform Your Excellency that the above-mentioned person has completed all documents required to conduct his research. This research has been reviewed by the Research and Studies Department and the Health and Scientific Research Ethics Committee in Madinah under No. (IRB 369) dated 08/04/1441 AH., (05/12/2019). Accordingly, it was agreed to facilitate the research procedures in the health facilities affiliated to the Health Affairs Directorate in Madinah. Therefore:

We hope that Your Excellency, after reviewing, will kindly direct the competent officers to facilitate his task to collect the necessary data, in a way ensuring that there is no impact on the service offered to the patients while conducting his research tasks. Note that the Ministry of Health guarantees his rights in the research results through the data sharing agreement that has been concluded by and between the Researcher and Research and Studies Department in Madinah.

Accepting my Sincere regards,

(sealed)
Research and Studies Department, Directorate of Planning and Development, Ministry of Health

(Signed)
Dr. Yasmine Talal Aljohani
Director of Research and Studies Department
Chairman of the Health and Scientific Research Ethics Committee

Asrar Jan

Code: 300/275- Research-Madinah@moh.gov.sa – No. 1795106- Date: 07/10/1442 AH. (19/05/2021)
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