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#### **UNIVERSITY OF SOUTHAMPTON**

# FACULTY OF LAW, ART AND SOCIAL SCIENCES School of Management

## A model to evaluate diabetes self-management programmes

by

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## **ABSTRACT**

Self-management has emerged as an approach to enhance quality of care for patients suffering from long term conditions, and to control costs of health services. So far, however, the effects of this approach as adopted by the Saudi healthcare system in the early 1990s remain unclear. Although current models define the concept of self-management, they do not provide a systematic development or an explanatory theory of how self management affects the outcomes of care. The objective of this research is to develop a framework applicable to the evaluation of self-management programmes. The evaluation model is built on patient-related intervention. The effectiveness of these interventions is determined by the levels of patient engagement and effective participation. Therefore, studying factors that influence patients' adherence to self-management activities is crucial to explain the outcomes of these interventions. We apply this framework to the case of diabetes mellitus, one of the most common chronic conditions in Saudi Arabia, causing huge burdens on patients and healthcare providers.

A non-experimental retrospective cross-sectional survey research design has been employed to conduct this research using a self-administered questionnaire. Closed-ended questions were used to measure all study variables related to model construction. One open-ended question was used to investigate barriers to diabetes self-management. A non-probability convenient sample design was used to select diabetes centres participated in this study and a systematic approach for selecting patients in these centres. Research data were collected from five diabetes centres and clinics in the main five regions in Saudi Arabia. Quantitative data were analysed using simple, multiple and logistic regressions, whereas a directed content analysis approach was used to analyse qualitative data.

The results of this study revealed that diabetes self-management improves clinical outcomes and reduces utilization of health services. The theoretical approaches underpinning self-management were based on established models from the field of health psychology. By investigating the effect of self-efficacy patients' beliefs, and locus of control on self-management, we found that these behavioural theories support the core assumptions of self-management. Self-efficacy was the most significant predictor of self-management followed by patient beliefs. Social support, effective communication between patients and health providers in addition to diabetes knowledge were all important factors to positively influence diabetes self-management. However a new construct, misconception of fatalism from the Islamic point of view, was found to play a negative role in diabetes management. The research model also

suggests that diabetes knowledge was influenced by several factors. Education level was the most significant predictor of diabetes knowledge followed by age and diabetes education. It was also found that group education improves diabetes knowledge more than individual education.

This model is a valid tool that could be used to evaluate self-management programmes in other chronic diseases. It can be used as a decision making supporting tool; to identify different components of self-management interventions, and to compare outcomes of programmes. It can also be used to group patients into different categories to facilitate providing tailored services suitable for each group. It could assist health providers to plan new interventions or to refine existing ones by allocating efforts and financial resources toward the most influential factors that affect patients' adherence to self-management activities.

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## **Chapter 1: Introduction**

Over the past few decades, many health plans and organizations have begun to offer new models of care in an attempt to improve the quality of care and to slow the growth of health care costs. The continuing rise in the cost of health care is attributable to a number of factors (MacStravic, 2006). One of these factors is the emphasis on reactive care; the treatment of disease after it has become serious. This approach to health care is usually more expensive and often less effective than proactive care; prevention or treatment after an early diagnosis. A second factor is that people are demanding the best treatment available regardless of the cost. The third factor behind rising health care cost is that people in many countries are living considerably longer than they used to (MacStravic, 2006).

The increase in life expectancy, urbanization, and sedentary lifestyle has led to an increase in the prevalence of chronic disease (Correa-Rotter & Gonzalez-Michaca, 2005). As a result of economic growth and industrialization, the pattern of disease has changed from communicable to chronic disease. Therefore the prevalence of chronic conditions is alarmingly increasing in the developing countries (Yach, 2004). As a major cause of death and disability worldwide, chronic disease accounts for 35 million of the 58 million deaths; (60%) of deaths that occur globally each year (Wanless, 2002).

Diabetes mellitus is one of the most common chronic illnesses affecting people of all ages in all nations (Swerdlow & Jones, 1996), causing a major public health concern associated with substantial morbidity, mortality, health care utilization, and costs (Wagner et al., 2001a). It has been estimated to affect over 135 million people throughout the world, and 300 million are projected to be affected by 2025 (King et al., 1998). King et al. also anticipated that 48% of the increase in prevalence is in developing countries, comparing to 27% in developed countries. Future predictions of costs of diabetes care are as alarming as the future predictions of prevalence. It has been suggested that, unless effective prevention measures are introduced, expenditure dedicated to diabetes and its complications will dominate the health economies of many countries by the end of this century (International Diabetes Federation, 2009).

According to (Fowler, 2008), diabetes, if not properly controlled, can lead to a number of complications. These complications include both macrovascular and microvascular diseases. Macrovascular diseases (damage of large blood vessels) could lead to a number of serious conditions such as stroke, ischemic heart disease, and peripheral vascular disease. Microvascular disease (damage to small blood vessels) can involve a

number of organ systems, including the eyes (retinopathy), nerves (neuropathy), and kidneys (nephropathy).

Within the context of this thesis, diabetes always refers to type 2 diabetes mellitus, which comprises 90% of all diabetes cases worldwide (World Health Organization, 2006). There are three main risk factors for type 2 diabetes. These risk factors include obesity, family history, and older age (Haffner, 1998), which in turn is related to behavioural risk factors such as inactive lifestyles and inappropriate nutrition (Blair et al., 1996). However, these risk factors rarely cause the condition independently as they are strongly correlated in people with diabetes (Amos et al., 1997). Hence, it is common to find that people with type 2 usually have more than one of these risk factors and require a range of treatments for diabetes comorbid conditions such as hypertension and dyslipidaemia which is a condition characterised by abnormal level of lipids and lipoproteins (Beckman et al., 2002).

A key objective in the management of diabetes is the achievement of normal or near normal blood glucose levels, which has been shown to reduce the incidence of micro vascular related complications (United Kingdom Prospective Diabetes Study, 1998). Achieving this specific objective will lead to achieving the general objectives of diabetes management including reduction of symptoms, correcting associated problems, reduction of morbidity, mortality and cost of diabetes care (Alwan, 1994). It will also lead to the prevention or delay of diabetes complications and improvement in the quality of life for patients with diabetes (Alwan, 1994).

Effective management of diabetes requires a comprehensive team approach, involving patients, primary care physicians, diabetes care teams and the support of health systems (Yach et al., 2004). There are many studies that demonstrate the view that appropriate diabetes management has the potential to improve long-term outcomes and health status, however, to date, the overall effect on glycaemic control, in reality, appears modest (Knight et al., 2005). The main reason is the slow implementation of patient care guidelines and recommendations by health providers (Alberti & Zimmet, 1998). Several barriers to guideline adherence and implementation have been recognized (O'Connor, 1998) including patient perception about the seriousness of the disease and the effectiveness of treatment (Anderson et al., 1991), inflexible guidelines (Helseth et al., 1999), and unwillingness of patients to make the required changes in their lifestyle (Wing et al., 1985; Golin et al., 1996).

Diabetes self-management is an approach that ensures patients have the appropriate knowledge, skills and confidence to manage their condition on a daily basis (Lorig &

Holman, 2003). This approach is effective in managing diabetes as it allows patients to identify their problems and develop skills and confidence to solve these problems (Bodenheimer et al., 2002). Consequently it is logical that diabetes self-management programmes focus on improving patients' skills including problem solving, decision making, performing good communication with providers of health services, utilizing preventive services, and taking appropriate actions (Lorig & Holman, 2003).

People with diabetes often find these actions, or self-management behaviour, to be very complex as it requires a high degree of self-care where they are usually asked to make difficult lifestyle changes. These changes include maintaining reasonable body weight, modifying food intake, practicing physical exercise, practicing glucose self-monitoring, and following a medication regimen and other preventive practices (Robiner & Keel, 1997). Health behaviour and health promotion research is evolving in this field to assist patients to cope with their conditions and overcome difficulties they may experience when attempting to change their lifestyle.

Many researchers agree that a minimal level of diabetes knowledge is essential before patients could participate effectively to improve their condition (Rubin et al., 1998; Sadur et al., 1999; Sidorov et al., 2000; Smith et al., 2004; Rothman et al., 2005). It is critical that individuals with diabetes learn all the necessary skills that enable them to manage their disease properly (Kurtz, 1990). Therefore improving diabetes care skills has become one of the essential components of diabetes self-management education programmes. However participants in these programmes should not only learn the diabetes care skills, but also be motivated to maintain these skills and healthy behaviours in order to reduce the risks of diabetes complications.

In Saudi Arabia, however, patient adherence to self-management activities is often below optimal; consequently, diabetes-self management education has become an essential component of diabetes care (Elhadd et al., 2007). Yet little is known about the factors that influence the willingness and ability of Saudi people with type 2 diabetes to self-manage their conditions. In addition to diabetes knowledge, other factors such as patient beliefs, attitudes, confidence, social support, and socio-economic status may also influence whether a person with diabetes is willing or able to make the necessary behavioural changes to improve his or her clinical outcomes (Norris et al., 2002).

In summary, diabetes is a largely self-managed disease, therefore, poor outcomes are expected despite any advanced treatment is received, if patients are unwilling or unable to self-manage their diabetes on a daily basis. This study focuses on this particular issue to address the role of patients with type 2 diabetes mellitus in

managing their condition, to investigate the level of adherence to the treatment regimen, to identify possible factors that may influence their ability and willingness to play their role, and to identify possible outcomes they may achieve in accordance with this role.

#### 1.1 Statement of the Problem

With rapid westernisation and sedentary lifestyle in the past few decades in Saudi Arabia, diabetes has becomes one of the greatest disease burdens in terms of mortality, morbidity and medical care costs (Udezue et al., 2005). The prevalence of diabetes in Saudi Arabia is among the highest in the world and has been estimated at 23.7% (Al-Nozha et al., 2004). It was also estimated by the World Health Organisation (WHO) that the prevalence of diabetes mellitus in the Middle East will be the highest in the world by 2030 showing an increase of 163% compared to the year 2000 (Wild et al., 2004). Diabetes mellitus has become the sixth leading cause of death in Saudi Arabia (WHO, 2006). The prevalence of impaired glucose tolerance, a precursor to diabetes, was as high as 14.1% (Al-Nozha et al., 2004).

Moreover, diabetes mellitus has been found to be associated with higher prevalence of Macro vascular diseases as 28.0% of diabetic patients have high risk of developing cardiovascular diseases (El-Hazmi et al., 1999). It was also found that diabetes was associated with higher prevalence of microvascular diseases with 12.8% for nephropathy (Al-Khader, 2001), 25.3% for retinopathy (Abu El-Asrar et al., 1998) and 56% for neuropathy (Akbar et al., 2000). Diabetic patients account for 3.5% of total inpatient days (Al-Maatouq, 1994), with an estimated annual Cost of \$ 2.2 billion in 2010 and expected to reach \$ 4.8 billion in 2030 to include healthcare for diabetes mellitus and its related complications (Zhang et al., 2010).

Although the effectiveness of intensive treatments for both type 1 and type 2 diabetes patients has been documented in many studies, specifically the Diabetes Control and Complications Trial (DCCT, 1998) and the United Kingdom Prospective Diabetes Study (UKPDS, 1998), unsatisfactory outcomes of diabetes care have long been noted in different health care settings in the Saudi health care system. In a hospital setting only 27% of diabetic patients reached the target level for blood glucose as indicated by HbA1c (Akbar, 2001). In different settings, 77% of diabetic people have poor control (Al-Ghamdi, 2004). Also diabetes mellitus is poorly controlled in 49% of diabetic patients attending Primary Health Care Centres (Azab, 2001). It was also found that a

large number of Saudi patients with diabetes are not achieving the recommended levels of glucose, blood pressure and lipid control and are therefore at high risk for diabetes complications (Eledrisi et al., 2007).

Despite an increasing amount of research worldwide devoted to the self-management of individuals with diabetes, to date there has been no real effort to evaluate self-management programmes in Saudi Arabia. Therefore there is still much to be learned about the effectiveness of this approach for improving diabetes outcomes in the Saudi health care system, and even more to be learned about the factors that influence patient adherence to diabetes self-management activities.

### 1.2 Purpose of the Study

The purpose of this research was to develop a model that can be used to evaluate self-management programmes in general. This model can be used to investigate the role that diabetes self-management may play in improving clinical outcomes and quality of life for people with type 2 diabetes mellitus in Saudi Arabia. Further, the research seeks to elucidate the effect of diabetes self-management on the cost of diabetes care through utilization of health services, mainly because healthcare services are provided free of charge to all Saudi citizens through direct government expenditures. Moreover, this study aims to assess the factors that influence patients' adherence to self-management in order to identify the most appropriate interventions that could enhance patient's adherence to treatment regimens. Consequently decision makers could direct their efforts and allocate financial resources toward the most influential factors.

## 1.3 Significance and Contribution of the Research

In western society, a large number of studies have been carried out to investigate the importance of diabetes self-management in terms of improving clinical outcomes, and reducing risk factors, complications, and cost of diabetes care. However research conducted in this area in Saudi Arabia is not sufficient to explore and identify the success factors for this approach, even though there is an alarming increase in the incidence of diabetes every year. The proven success of such an approach for the management of such a medical complex condition will encourage health care providers to adopt and develop diabetes self-management programmes in different health care settings.

Understanding the factors that influence people's behaviour from the growing literature documenting health promotion interventions that have proven successful in the west, does not necessarily mean that these factors are applicable to different people with different cultures. Therefore conducting this research in Saudi Arabia may lead to a different understanding. Accordingly these interventions aiming to assist patients to change their behaviour may need to be modified in order to be suitable for the Saudi population. In addition, the author argues that misconceiving one of the basic pillars of faith in Islam may play an important role in determining patients' adherence to a treatment regimen. This study will be the first research investigating this factor.

This research was conducted using a new methodological approach by adopting the positivist paradigm to investigate the outcomes of diabetes self-management programmes with notable consideration of the humanistic underlying factors behind these outcomes. The results of this research will determine the most influential factors that affect patient adherence to a treatment regimen, and will combine these factors in a single model that can be used to identify areas where improvement is needed. It may also demonstrate other barriers that have not been considered in the model. Therefore it could be used as a decision-support tool to assess diabetes self-management education programmes, assist in reprioritizing objectives of these programmes, and becomes a base for developing more effective interventions. Moreover it could help decision makers to direct their efforts and allocate financial resources toward the most influential factors.

In addition, this study seeks to contribute to theory building through identifying factors relevant to diabetes clinical care setting and factors relevant to diabetes management in health care. Based on the synthesis of the findings and existing theories, this study proposes a model for improving diabetes management. It also contributes to the existing literature on diabetes management, and seeks to provide suggestions for future research. Although it was applied to managing diabetes mellitus, this research proposes a new model that can be used to evaluate self-management programmes for any chronic condition where the role of patients in managing the disease is significant.

## 1.4 Research Questions and Hypotheses

The main research questions this study aims to answer were:

#### Research question 1

What is the effect of diabetes self-management on clinical outcomes of people with type 2 diabetes mellitus in Saudi Arabia?

To answer this question the following hypothesis was tested:

Research hypothesis 1

Diabetes self-management has a positive effect on clinical outcomes, indicated by its effect on reducing blood sugar levels (the level of glycosylated haemoglobin, HbA1c).

#### Research question 2

How could diabetes self-management contribute to the cost of diabetes care through utilization of health services?

To answer this question the following hypothesis was tested:

#### Research hypothesis 2

Diabetes self-management has a negative effect on utilization of health services indicated by emergency visits, number of admissions and length of stay.

#### Research question 3

What is the effect of diabetes self-management on the quality of life for people with type 2 diabetes mellitus in Saudi Arabia?

To answer this question the following hypothesis was tested:

#### Research hypothesis 3

Diabetes self-management has a positive effect on the quality of life for people with type 2 diabetes mellitus in Saudi Arabia.

#### Research question 4

What are the factors that influence patient adherence to self-management activities? To answer this question, the following research hypotheses were tested:

#### Research hypothesis 4

Patient beliefs have a positive effect on diabetes self-management.

#### Research hypothesis 5

Self-efficacy has a positive effect on diabetes self-management.

#### Research hypothesis 6

Misconception of fatalism has a negative effect on diabetes self-management. However this effect may be mediated by its negative effect on self-efficacy.

#### Research hypothesis 7

Diabetes knowledge has a positive effect on diabetes self-management. However this effect may be mediated by the positive effect of patient beliefs and/or self-efficacy on diabetes self-management.

#### Research hypothesis 8

Social support has a positive effect on diabetes self-management. However this effect may be mediated by the positive effect of self-efficacy on diabetes self-management.

#### Research hypothesis 9

Patient-provider communication has a positive effect on diabetes self-management. However this effect may be mediated by the positive effect of diabetes knowledge on diabetes self-management.

#### Research hypothesis 10

Age has a positive effect on diabetes self-management.

#### Research hypothesis 11

Income has a positive effect on diabetes self-management.

#### Research hypothesis 12

Diabetes severity indicated by diabetes co-morbidity has a negative effect on diabetes self-management.

#### Research hypothesis 13

Diabetes complications have a positive effect on diabetes self-management.

#### Research question 5

What factors are associated with improving diabetes knowledge?

To answer this question, the following hypotheses were tested

Research hypothesis 14

Educational level of patients has a positive effect on diabetes knowledge.

Research hypothesis 15

Duration of diabetes has a positive effect on diabetes knowledge.

Research hypothesis 16

Diabetes education indicated by number of hours of training and type of training affect diabetes knowledge.

Research question 6

How can decision makers use the model?

## 1.5 Organization of the Thesis

This thesis is presented in six chapters as follows:

Chapter one: Introduction. In this chapter self-management, the core concept of the research, was introduced as an approach to improve quality and reduce the cost of managing chronic conditions, followed by a statement of the research problem, the purpose and significance of this research, and finally by stating the research questions and hypotheses.

Chapter two: Background. This chapter presents general background information about chronic conditions including different approaches adopted for managing these conditions. It also includes general background information about diabetes mellitus, about Saudi Arabia, and about the Saudi health care system. Finally it includes an overview of diabetes in Saudi Arabia.

Chapter three: Literature review. Previous studies to demonstrate the effectiveness of this approach are presented. The theoretical assumptions underpinning this research are included to illustrate the factors that influence patient adherence to self management and to construct the research model.

Chapter four: Methodology. This chapter presents the methodological approach for conducting this research, showing the methods for data collection and development of the research instrument. Methods for data analysis are also included in this chapter.

Chapter five: Results. This chapter presents the findings of this research including descriptive analysis and testing of the hypotheses.

Chapter six: Discussion & Conclusion. In this chapter a discussion of these findings is presented, in addition to the research implications, limitations and recommendations for practice and future research.

## **Chapter 2: Background**

The purpose of this chapter is to define chronic diseases, and to describe common approaches for chronic disease management, introducing self-management and providing details about this particular intervention. Diabetes as an example of a chronic disease is the main focus of this study, and thus a general background about diabetes is provided. Background information on Saudi Arabia, the Saudi health care system, and a general overview of diabetes and diabetes management in the Saudi health care system is also presented.

#### 2.1 Chronic Conditions

Chronic Diseases (CDs) or long term conditions (LTCs) are conditions that are usually incurable, prolonged, and do not resolve spontaneously; for example "diabetes, asthma, arthritis, heart failure, chronic obstructive pulmonary disease, dementia and a range of disabling neurological conditions" (Dowrick et al., 2005). Although often not immediately life-threatening, they place substantial burdens on the health, economic status, and quality of life of individuals, families, and communities (World Health Organization, 2005). The World Health Organization (WHO) defines chronic diseases as having one or more of the following characteristics: "they are permanent, leave residual disability, are caused by non-reversible pathological alteration, require special training of the patient for rehabilitation, or may be expected to require a long period of supervision, observation, or care" (World Health Organization, 2005).

Chronic illnesses present a significant cost burden for the global economy (Yach et al., 2004). For example in the UK, long term conditions are a major burden for the economy and for the UK's healthcare system (Mayhew, 2000). There are an estimated 17 million people with long-term conditions where around 80% of GP consultations are related to the care of patients with these conditions who also account for over 60% of hospital bed days, and 66% of emergency admissions (Department of Health, 2004). In the United States, chronic conditions account for about 78% of total U.S. health care costs, 76 percent of all hospital admissions, 88% of all drug prescriptions, and 72% of physician visits (Johnson, 2003).

## 2.2 Management of Chronic Conditions

In many developed countries, there has been a shift in health care from a reactive system which focuses on acute care to a proactive system, which supports the management of chronic disease (Zwar et al., 2006). Chronic disease management is defined as "an intervention designed to manage or prevent a chronic condition using a systematic approach to care and potentially employing multiple treatment modalities" (Weingarten et al., 2002 p 925). A variety of models have been introduced to different health systems in response to the increased prevalence of chronic illnesses including Chronic Care Model CCM, Innovative Care for Chronic Conditions (ICCC), and Kaiser Model (Zwar et al., 2006).

#### 2.2.1 Chronic Care Model (CCM)

The Chronic Care Model (CCM) (Wagner et al., 2001b) is an organizational framework to improve management of chronic disease and a successful tool for improving care at both the individual and population level. This model was developed by Wagner et al to describe the elements essential for improving care of people with chronic conditions by focusing on primary care. The overall aim of the CCM is to develop well-informed patients and a healthcare system that is prepared for them (Wagner et al., 2001b). They described six elements of care for chronic disease.

The first element is self-management support where patients and carers are equipped with the necessary skills and confidence to manage their conditions on a daily basis and also provided with essential tools and resources that assist them to perform their role. The second element is delivery system design, where evidence-based care is provided by a specialised team to provide effective, efficient, and structured services. The third element is decision support where an integrated approach using evidence-based guidelines for clinical practice is used to interact with patients for optimum care. The fourth element is related to the use of clinical information systems by organizing data and using reminders to enhance patient adherence, follow up and feedback. The fifth element is related to the appropriate utilization of community resources such as education programmes, exercise programmes, and social support groups. Finally, the sixth element in Wagner's model is the health care organization where a culture of high quality service is created by identifying values of the organization and also by identifying standards of care (Wagner et al., 2001b).

#### 2.2.2 Innovative Care for Chronic Conditions (ICCC)

This model was developed by the World Health Organization (WHO, 2006) as an expanded version of chronic care model in response to the increasing prevalence of chronic conditions. Adopting the acute episodic care for long times by many health care systems throughout the world was described by the World Health Organization as being inadequate approach for managing chronic conditions. Alternatively the WHO introduced a comprehensive global framework for preventing and managing long term conditions in developed and developing countries (World Health Organization, 2006).

This model describes different components related to four different levels; patients and families, healthcare organizations, community, and policy makers level. The model describes eight essential components for appropriate management of chronic conditions. First, it emphasizes a shift from the acute episodic care to a more comprehensive approach suitable for managing chronic conditions. Second, it places a strong emphasis for the political support and financial resources. Third, it advocates building integrated systems for care to share information and to avoid duplication of services. Fourth, it emphasises cooperation with other government agencies to develop policies aiming to improve health outcomes. Fifth, it also emphasises appropriate utilization of health personnel by training them to use evidence-based guidelines for optimum care. Sixth, it promotes self-management for patients and families. Seventh, it emphasises the role of community for helping patients to engage in healthy activities. Finally the model emphasises prevention and early detection of chronic conditions (World Health Organization, 2006).

#### 2.2.3 Kaiser Model

This model was developed by Kaiser Permanente as a service delivery framework based on Chronic Care Model for supporting people with long term conditions (Wallace, 2005). This model shows three levels of integrated care including the professional services required at each level. People with long term conditions are stratified according to their health status, with intensive management targeting those at highest risk (Feachem et al., 2002).

Unlike Evercare and Pfizer, which are other services delivery models that focus on high risk patients, the Kaiser model focuses on the whole population on three levels of care (Singh & Ham, 2006). The British Medical Association (British Medical Association, 2005) explains the basis of stratification and the level of professional interventions required at each level. In level 1, where the majority of people with chronic conditions

(70-80%) fall, the role of patients is crucial to engage in their own care to control their disease and to prevent or delay its complications. Because the majority of people with chronic illnesses fall into this category, any improvement at this level produces enormous impact. In level 2 disease management using proactive high quality evidence-based care is provided by multidisciplinary teams. Whereas in level 3, people usually develop more than one chronic condition (comorbidities), care becomes more complex and difficult for patients. Therefore more professional care usually arranged by a case manager is provided at this level (British Medical Association, 2005).

The UK has developed National Service Improvement Frameworks for each of the major chronic diseases such as diabetes, asthma and cardiovascular diseases to standardise a framework for delivering services (Department of Health, 2004). An example of the delivery services model is the Evercare programme adopted by the UK National Health Service (NHS). It is an internationally unique health care improvement programme targeting older people and aiming to improve quality whilst reducing cost (Campbell et al., 2005). The successful implementation of this programme has reduced hospitalization by 50% and maintains the same level of mortality rate in a study group comparing to a control group in the United States, by providing an integrated primary care service with advanced nurses working collaboratively with general practitioners (Boaden et al., 2005). The programme began in the UK in April 2003 for a 17-month pilot implementation in nine primary care trusts (National Health Service, 2004).

Another example of a delivery service model is the Expert Patient Programme (EPP). This programme develops the role of the patient in their own care and is a self-management programme for chronic illnesses. It comprises a six-week generic training course for adults in Primary Care. The EPP began in May 2002 and has been considered a success in terms of the number of participating patients and the numbers of courses run (Kennedy et al., 2004).

In Saudi Arabia, however, adopting comprehensive approaches for managing chronic conditions has faced several challenges, mainly due to the lack of appropriate communications between providers of health services (Khoja et al., 1997; Khattab et al., 1999), and poor information systems (Al-Khaldi et al., 2002). Inappropriate implementation of evidence-based guidelines is another barrier for effective management of chronic conditions (Dashash & Mukhtar, 2003). In addition, professional development and lack of skilled personnel remains one of the obstacles for improving health services in Saudi Arabia. (Al-Shammari et al., 1994; Jarallah et al., 1998; Tumulty, 2001).

In summary chronic disease management has been established as a national priority in many countries and is being approached from a "whole systems, whole population" framework. The Wagner model of chronic disease management is generally accepted, and there is a strong focus on achieving improved outcomes and efficiencies through adapting "Kaiser Models" of care. Key features of the Kaiser model with particular relevance to healthcare systems include system integration, changing the role of the patient through building self-management skills, and active case management programmes.

## 2.3 Self-management

Although self-management as a concept was developed in the 1970s in the context of paediatric asthma research, and has a significant importance to the care of patients with long term conditions, it is not well-defined and is often inappropriately understood (Schilling et al., 2002). The nature of chronic disease management necessitates a dynamic and positive approach to encourage patients to move from a passive powerless role to a proactive stance (Lorig & Holman, 2003), and educating patients to establish a sense of control over their conditions (Embrey, 2005). This concept is now frequently used to describe modern care of chronic conditions, whereas self-care conventionally referred to the performance of tasks or activities by patients or families which formerly were performed by professionals (Orem, 1995). Selfmanagement in general is defined as practicing specific behaviours and having the ability to reduce the physical and emotional impact of illness, regardless of the degree to which the individual participates in education programmes or treatment training sessions (Gruman & Von Korff, 1996).

Self-management was regarded as a method for finding better solutions to living with illness. This view was criticised as having a negative perspective in that the focus of self-management was on illness, rather than achieving a wider perspective on health (Hughes, 2004). The emphasis has changed and self-management now plays an integral role in health care of people with long-term conditions. Self-management is now regarded as an intervention in health care which increases a patient's power and responsibility for making decisions, and helps ensure that necessary health-care actions are taken (Embrey, 2006).

According to Corbin and Strauss (1988), people with long term conditions usually face three main challenges. The first is the medical management of the condition such as taking medication, adhering to a specific diet or exercise programme. The second is to maintain this role for long periods while creating a meaningful life. The third is to

manage the emotional consequences to cope with the condition (Corbin & Strauss, 1988). Equipping people with long-term conditions with the necessary skills to cope with these challenges is the core of self-management (Mountain, 2006). To overcome these challenges patients are required to develop certain skills which are considered as components of self-management (Mountain, 2006).

Lorig and Holman (2003) identified five core self-management skills necessary for patients to manage and cope with chronic conditions. First, patients need to practice problem solving skills by themselves on an ongoing basis by defining problems, generating solutions, selecting, implementing and evaluating results. Health professionals need to carry out a needs assessment in order to discover what issues and problems are of most importance to each individual patient. Second is decision making, where patients with long-term conditions need to make important decisions and need to build the confidence to develop a variety of options and confidently select an appropriate decision. Third, they need to develop the skills of how to search for appropriate resources, and how to access and utilize these resources to satisfy their needs. Fourth, they also need to develop appropriate communication with health providers by reporting accurate information, participating and collaborating in making shared decisions. Finally, they need to develop the planning skills by setting goals, preparing action plans, implementing and evaluating their plans (Lorig & Holman, 2003).

Self-monitoring is another concept related to self-management (Wilde & Garvin, 2007), where self-management of a chronic condition usually requires periodic assessment of symptoms and treatments related to the condition. This kind of activity is usually referred to as self-monitoring (Paterson & Thorne, 2000). Therefore self-monitoring is a part of managing many chronic conditions, for example self-testing of blood glucose in diabetes mellitus (Davis & Alonso, 2004) and peak flow monitoring in asthma (Hendricson et al., 1996). Thus, self-monitoring is a component of self-management and can be defined as "awareness of symptoms or bodily sensations that is enhanced through periodic measurements, recordings and observations to provide information for improved self-management" (Wilde & Garvin, 2007).

#### 2.4 Diabetes Mellitus

Diabetes is one of the major chronic diseases and a growing public health problem in both developed and developing countries. The World Health Organization defined diabetes as

a metabolic disorder of multiple aetiology characterized by chronic hyperglycaemia with disturbances of carbohydrate, fat and protein metabolism resulting from defects in insulin secretion, insulin action, or both. The effects of diabetes mellitus include long-term damage, dysfunction and failure of various organs (World Health Organization, 1999).

According to the World health Organization, diabetes occurs when "the pancreas does not produce enough insulin, or when the body cannot effectively use the insulin it produces. Hyperglycaemia, or raised blood sugar, is a common effect of uncontrolled diabetes and over time leads to serious damage to many of the body's systems, especially the nerves and blood vessels" (World Health Organization, 2007). The most common diabetes symptoms are an increased urge to urinate, extreme hunger and thirst, weight loss, and fatigue (World Health Organization, 2007).

There are three different types of diabetes; type 1 diabetes (Insulin-dependent diabetes) is usually diagnosed in children and young adults, and was previously known as juvenile diabetes. In type 1 diabetes, "the body does not produce insulin- a hormone that is needed to convert sugar, starches and other food into energy needed for daily life" (ADA, 2007a). It is recognized as an auto-immune disease where the body's immune system destroys the insulin-producing beta cells in the pancreas (Gagliardino et al., 2006).

According to the World Health Organization, type 1 diabetes mellitus "accounts for 10-15% of all people with the disease. It can appear at any age, although commonly under 40, and is triggered by environmental factors such as viruses, diet or chemicals in people genetically predisposed". The essential treatment for people, with type 1 diabetes is insulin, however patients should also follow a careful diet and exercise plan (World Health organization, 2006).

Type 2 diabetes mellitus, non insulin-dependent diabetes mellitus, is the most common form of diabetes, affecting 85-90% of all people with the disease. This type of diabetes, also known as late-onset diabetes, develops when the body becomes resistant to the effects of insulin or when the body produces insufficient amount of insulin to maintain a normal glucose level. Symptoms may not show for many years and, by the time they appear, significant problems may have developed. Type 2 diabetes may be treated by dietary changes, exercise and/or tablets. However insulin might be required in a later stage (World Health Organization, 2006).

The third type is Gestational diabetes which is a temporary form of diabetes develops only during pregnancy. Pregnant women who have never had diabetes before but who have high blood sugar (glucose) levels during pregnancy are said to have gestational

diabetes. The problem however is that 70% of pregnant women with gestational diabetes develop type 2 diabetes in a later stage (Kim, et al., 2002). Gestational diabetes affects about 4% of all pregnant women (Barcelo & Rajpathak, 2001).

#### 2.4.1 Prevalence and Economic Burden of Diabetes

The number of people with diabetes worldwide is 171 million and expected to rise to 366 million by 2030 (Wild et al., 2004). The global prevalence of diabetes was estimated at 4% in 1995 and expected to rise to 5.4% by 2025. This prevalence is higher in developed countries than in developing countries, but the expected increase is higher in developing countries (King et al., 1998). In a recent study however, the prevalence of diabetes worldwide is estimated at 6.4% in 2010 and projected to reach 7.7% in 2030 where five of the top ten world's national prevalence is in the Middle East (Shaw, et al., 2010). This study shows that the number of people with diabetes worldwide is estimated at 284.8 million in 2010 and projected to be 438.7 million in 2030. However there are a substantial number of cases that are not diagnosed for example it was estimated that there are more than 2 million people diagnosed with diabetes in the United Kingdom and approximately 750,000 people with diabetes are not diagnosed (Diabetes UK, 2006).

The increased prevalence of diabetes is associated with substantial cost related to prevention, treatment, complications, and rehabilitation, in addition to the indirect cost related to loss of productivity and premature mortality causing a huge burden to individuals and societies (Barcelo, et al., 2003). The global health expenditure on diabetes accounts for 12% of the total health expenditure with a total cost between \$376 and 672 billion where almost half of the global expenditure will be spent in the United States alone (Zhang, et al., 2010).

#### 2.4.2 Complications of Diabetes

Diabetes, if not properly controlled, can lead to several microvascular and macrovascular complications. According to Fowler (2008), the most common examples of microvascular complications are diabetic nephropathy (kidney disease), retinopathy (eye disease), and neuropathy (nerve disease). Due to the increased prevalence of diabetes and longer survival time for people with diabetes, diabetic nephropathy is considered to be the single leading cause of end-stage renal disease (Mogensen, 2002). Based on data from the UK Prospective Diabetes Study (UKPDS), the 10 years

prevalence of microalbuminuria (an indicator which precedes renal failure) after diagnosis with type 2 diabetes was 25% (Adler, et al., 2003).

Diabetic retinopathy is the second main cause of blindness and partial sight in England and Wales (Bunce, 2006), and in the United States with almost 10,000 new cases every year (Fong, et al., 2004a). Moreover almost all persons with type 1 diabetes and more than 60% of persons with type 2 diabetes will show some degree of diabetic retinopathy within 20 years of diabetes onset, and retinopathy is usually found in about 21% of persons with type 2 diabetes at the time of diagnosis (Fong et al., 2004b). Diabetic neuropathy as an example of microvascular complications is the main cause of foot ulcers which cause about 80% of amputations (Boulton, et al., 2005).

Macrovascular diabetic complications include heart disease, peripheral arterial disease (PAD), and stroke (Fowler, 2008). Although it is not well defined, the role of diabetes on heart problems is by increasing the level of cholesterol, which builds plaques in the arteries causing cardiovascular complications (Fowler, 2008). Cardiovascular complications are the primary cause of death in patients with diabetes, and more than 70% of diabetic patients die of causes related to cardiovascular complications (Laakso, 2001). Diabetes has been specified as an independent risk factor for cardiovascular heart disease, where adult persons with diabetes (24.5%) were significantly more likely than adults without diabetes (6.6%) to have coronary heart disease (Grundy et al., 1999).

Peripheral arterial disease (PAD) is one of the common complication of diabetes. It occurs when "blood vessels in the legs are narrowed or blocked by fatty deposits" (Creager & Anand, 2001). PAD has a significant effect on quality of life, increasing the risk of lower-extremity amputation, and also associated with high risk of strokes and heart attacks, (Steffen, et al., 2008). It is also associated with a substantial economic burden for treatment and rehabilitation (Hirsch, et al., 2008). In persons with diabetes, especially when associated with smoking, 30% will die within 5 years and 70% will die within 15 years after diagnosis of PAD (Creager & Anand, 2001). Another example of macrovascular complications of diabetes is stroke, which is the leading cause of disability and the third leading cause of death in persons with diabetes (McFarlane et al., 2002). The incidence of stroke in persons with diabetes is 3 times higher than in people without diabetes (McFarlane et al., 2005).

#### 2.4.3 Risk Factors for Diabetes

The exact cause of type 2 diabetes is not completely understood, but it is known that the disease has a strong hereditary component, where Individuals who have a parent or sibling with type 2 diabetes have a 10% to 15% chance of developing the disease (Rewers & Hamman, 1995). It was found that the prevalence of diabetes when the father is diabetic was 6.4%, and when the mother is diabetic was 10%, whereas when both of them are diabetic, the prevalence was 14.94%, suggesting a strong association between family history and the occurrence of diabetes (Jali & Kambar, 2006).

In addition to the genetic factor, some environmental and medical factors may increase the risk of getting diabetes. Environmental factors such as inactive lifestyle or poor diet may act as a trigger for someone with a genetic tendency towards type 2 diabetes. The adoption of a more affluent and sedentary lifestyle "characterised by decreased physical activity, greater fat consumption and subsequent obesity" which is contributing to an increase in prevalence of type 2 diabetes (Hu, et al., 2001; Mozaffarian et al., 2009). Obesity is highly correlated with type 2 diabetes (Wild, et al., 2004), and is a serious risk factor where approximately 80% of type 2 diabetics are clinically obese (Gonder-Frederick et al., 2002). There are also medical factors that can be considered as risk factors for diabetes or 'pre-diabetes' conditions. These conditions are impaired glucose tolerance (IGT), impaired fasting glucose (IFG), and insulin resistance which are metabolic stages intermediate between normal carbohydrate metabolism and diabetes (McGarry, 2002).

#### 2.4.4 Diagnosis of Diabetes

Conventionally, the recognised method of diagnosing type 2 diabetes has been via the fasting blood glucose test; however in the late 1990s the World Health Organisation (WHO) revised the diagnostic criteria for diabetes. Additional use of the oral glucose tolerance test (OGTT) was recommended to avoid the possibility of some cases of diabetes being missed when the fasting plasma glucose test is the only diagnostic test undertaken (World Health Organization, 1999). The last revision for the diagnostic criteria was included in the organization's report (2006) and adopted by most countries in the world. Table 2.1 summarises the 2006 WHO recommendations for the diagnostic criteria for diabetes and intermediate hyperglycaemia.

Table 2-1: Diagnostic criteria for diabetes and intermediate hyperglycaemia

Diabetes		
Fasting plasma glucose 2-h plasma glucose*	≥ 7.0 mmol/l (126mg/dl) Or ≥11.1mmol/l (200mg/dl)	
Impaired glucose Tolerance(IGT)		
Fasting plasma glucose 2-h plasma glucose*	< 7.0 mmol/l (126mg/dl) and ≥ 7.8 and <11.1 mmol/l (140mg/dl and 200mg/dl)	
Impaired Fasting glucose (IFG)		
Fasting plasma glucose 2-h plasma glucose*	6.1 to 6.9 mmol/l (110mg/dl to 125mg/dl) and (if measured) <7.8mmol/l (140mg/dl)	
	er ingestion of 75g oral glucose load ed, status is uncertain as diabetes or IGT cannot be excluded.	

Source, WHO, 2006

#### 2.4.5 Prevention of Diabetes

Preventing the onset of type 2 diabetes mellitus has been the focus of medical research for years. Results of several studies demonstrated the possibility of preventing the disease (Eriksson, et al., 1991; Pan et al., 1997; Dunning, 2009). The Finnish Diabetes Prevention Study (2003) was one of the first trials to demonstrate the possibility of preventing diabetes by changing lifestyles. These findings encouraged many countries to adopt this programme which focus on weight loss, exercise, and diet to prevent diabetes. A follow up study for this trial showed 43% reduction in the risk of diabetes for the intensive lifestyle intervention group comparing to a control group (Lindstrom et al., 2006). It was also found that including whole grain food and increasing intake of cereal fibres is associated with diabetes prevention (Krishnan et al., 2007).

#### 2.4.6 Treatment and Management of Diabetes

In addition to the medical treatment, patients with type1 and type 2 diabetes mellitus need to change their lifestyles for optimum management of diabetes. While the only medical option for patients with type 1 is to take insulin, patients with type 2 have more options to use to lower their glucose level (Anselmino, et al., 2009). They also categorised three main classes of medications that can be used to reduce hyperglycaemia. These oral anti-diabetic medications are metiglinides and sulfonylureas, biguanides and thiazolidinediones, and alph- glucosidase inhibitors. These medications act in different ways and can be prescribed based on individual needs.

While Metiglinides and sulfonylureas such as Gliclazide and Glipizide act on the pancreas to stimulate insulin secretion, biguanides and thiazolidinediones such as Metformin and Glucophage are used to increase insulin sensitivity and to slow absorption of insulin in the stomach and intestine (Boccuzzi et al., 2001). In a different way alph- glucosidase inhibitors such as Acarbose act by reducing the breakdown of complex carbohydrates into glucose within the stomach and intestines (Boccuzzi et al., 2001). Even with the use of oral anti-diabetic medications, many patients with type 2 diabetes will need insulin within 6-10 years of diagnosis, to maintain a normal level of glucose (Wright et al., 2002). The importance of intensive insulin therapy has been clearly shown in the UKPDS longitudinal study, where a significant decline in progression of diabetes complications was achieved (UKPDS, 1998).

#### 2.5 Saudi Arabia

Saudi Arabia is located in South West Asia. It is considered as a part of the Arab world which extends to the northern part of Africa. From the political point of view, Saudi Arabia is recognised as a part of the Middle East. It occupies most of the Arabic peninsula with an area of 2.15 million squared kilometres. The borders of Saudi Arabia involves Yemen and Oman in the South, United Arab Emirates, Qatar, Bahrain, Kuwait along the Arabic Gulf coasts in the East, Iraq and Jordan in the North, and the Red Sea in the West. Figure 2.1 shows a map of Saudi Arabia. It was once divided into five main regions, but further restructuring was adopted and now it consists of 13 provinces. Saudi Arabia was established by his majesty King Abdulaziz Al Saud in 1932.

The population of Saudi Arabia is estimated at 25.4 million in 2009 where about 6 million of the population are expatriate (Ministry of Health, 2009). The majority of the population (more than 80%) live in the main cities such as Riyadh (the capital), Jeddah, and Dammam, whereas the rest live in rural areas. The majority of population are in younger age groups whereas only 2.8% of the population are 65 years old or above. Females account for 45.7% of the population (Central Department of Statistics, 2008). It is worth mentioning that the entire Saudi population are Muslims.

The economy of Saudi Arabia is based on oil production. The country is the biggest oil producer in the world, with 12 million barrels exported every day which accounts for about 80% of the government budget. The average monthly gross domestic product per capita was estimated in 2008 at 5904 Saudi Riyals (approximately £1000). The country also possesses more than 20% of the world's oil reserves. However the government is making new plans to diversify the economy by focusing on the private

sector to invest in services, education, tourism and many other sectors (Ministry of Economy and Planning, 2008).



Figure 2-1: Location and a map of Saudi Arabia

Created by NormanEinstein, February 10, 2006

#### 2.5.1 Health System in Saudi Arabia

The Health Department was established by His Majesty King Abduaziz in 1926 to provide the first organized medical care in Saudi Arabia. Because of limited resources, progress in health care was extremely slow, and there were only 300 hospital beds by 1946; however the majority of the population relied on traditional medicine. The Ministry of Health (MOH) was established in 1951 to be the main government agency responsible for health in general, providing free services to the entire population (Mufti, 2000). After World War Two, when oil was discovered in the region, the economic revolution in the country has led to dramatic changes in health services as well as in all other sectors.

Data from the annual statistics report of the Ministry of Health show that in 2005 the total number of hospitals was 324, operating 46,622 beds; the number of beds per 10,000 population was 22.40. The main provider of health services in Saudi Arabia is the Ministry of Health, which provides services to 63% of the population, operating 213 hospitals with a total of 30,020 hospital beds. The second main provider in the public

sector is the Medical Services Division of the Armed Forces (MSD), with a total of 5,062 hospital beds. There are however other governmental providers of health services; the National Guard, the Ministry of the Interior, University Hospitals and others. The Government has encouraged the private sector to participate in providing health services by interest-free loans. There are 94 private hospitals operating 11,135 hospital beds; 21.8% of all hospital beds in the Kingdom are operated by the private sector (Ministry of Health, 2005).

The annual report published by the Ministry of Health in 2008, shows that the annual budget for the ministry was about 30 billion Saudi Riyals (£ 5 billion) which accounts for 6.3% of the annual government budget in 2008. However, health services in the country still suffer many problems that contribute to rising healthcare expenditure (Mufti, 2000). These problems can be summarised in the following points:

- Rapid growth of population and demographic changes: The natural increase rate in Saudi Arabia is 3.6 % annually. In association with this high growth rate, substantial resources are required to satisfy the growing demand for health care. Moreover the improvement of health services has led to a growing number of elderly people who usually consume a greater portion of health resources.
- One of the main factors contributing to rising expenditure is the lack of economic constraints, on the part of the consumer (because services are provided free of charge), or on providers due to a lack of professional control.
- The reimbursement method for private health services has also contributed to the rising cost, where services are paid for on a fee-for-service basis. This method of payment encourages the private sector to provide more curative rather than preventive services.
- Duplication of services, due to the availability of different providers and lack of appropriate coordination and integrated information systems.
- The geographical distribution of the population over an area of more than 2 million square kilometres is another challenge for the government, and also leads to higher expenditures to cover remote areas even if the population size is limited.
- Reliance on foreign human resources has also contributed to the increasing cost of medical services, due to high salaries for medical professionals, increasing travel expenses, high turnover rate, and many other unnecessary expenses.

#### 2.5.2 Diabetes in Saudi Arabia

Due to dramatic changes in the life-styles of the Saudi population in the last few decades as a result of urbanization, and socioeconomic developments, diabetes mellitus is becoming a major medical problem in Saudi Arabia (El-Hazmi et al., 1998) .

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Saudi Arabia has been categorized among the highest prevalence rates of diabetes in the world with a prevalence rate estimated at 16.7% (International Diabetes Federation 2009). Because of the substantial number of people who are not aware of having the disease, undiagnosed cases of diabetes are a critical issue in the country, where a lot of effort is directed towards encouraging people to undergo annual routine health assessment. A comprehensive study demonstrated that the prevalence of diabetes in Saudi Arabia was 25.5% and 19.5% among urban and rural Saudi populations respectively, and 27.9% of diabetic patients among the study population were not aware of having the disease (Al-Nozha et al., 2004). It was found that the prevalence of diabetes in Saudi Arabia is higher among females than males and also among people who live in urban areas than those who live in rural areas (Al-Nuaim, 1997).

One of the main risk factors for diabetes is the high rate of consanguineous marriage which is common in Saudi Arabia (Elhad, 2007). It was reported in a study of the relationship between consanguineous marriage and type 2 diabetes, that the rate of consanguineous marriage was 57.7% of whom 28.4% were first cousin marriage (Elhazmi, et al., 2000). Another risk factor associated with diabetes in Saudi Arabia is obesity resulting from a sedentary lifestyle and uncontrolled diet, where a significant number of diabetic patients were obese (Fatani, et al., 1987; Elhazmi, et al., 2000). Complications of diabetes are usually associated with a greater effect on patients and healthcare providers. Nephropathy was found to be the most prevalent complication of diabetes in Saudi Arabia (32.1%) followed by acute coronary syndrome (23.1), whereas the prevalence of retinopathy was (16.7%) and myocardial infarction was (14.3%) (Alwakeel, et al., 2008). The prevalence of diabetic foot (the most feared complication, especially among older people) was 6.2%, of whom 1.3% had had a foot amputated (Al Turki, 2010).

Diabetes is also associated with a huge burden to the economy of Saudi Arabia. In addition to the indirect cost associated with premature life lost and non-productivity, diabetes is estimated to cost the government \$ 2.2 billion in 2010 and expected to reach \$ 4.8 billion in 2030, which places Saudi Arabia in the second rank among the countries with the highest health expenditures on diabetes as measured by the percentage of national health expenditure on diabetes (21%) in 2010 (Zhang et al., 2010).

Care for many people with chronic conditions in Saudi Arabia has conventionally been reactive chracterised by eppsodic unplanned care which has led to an increase in the use of secondary care, particularly unplanned admissions. However, a great shift toward well organized management of chronic illnesses including diabetes has been

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experienced in the 1990s by introducing the first self-management programme for diabetes due to the increased prevalence and cost burden of this condition to the Saudi economy. The next chapter will introduce the importance, benefits and the influencing factors of diabetes self-management.

# **Chapter 3: Literature Review**

This chapter provides general background information to establish the context of this study, and describes the results of prior research on topics related to the research questions. First, it covers the importance of diabetes self-management as an approach for diabetes care including components of self-management programmes. Second, it shows evidence that support the effectiveness of this approach in the improvement of clinical outcomes, utilization of health services, and quality of life for people with type 2 diabetes mellitus.

The next section outlines the theoretical context underpins self-management. The conceptual and empirical literature addressing factors that influence compliance of patients with self-management activities is reviewed in depth. In addition, this chapter delineates the model developed for this thesis providing a conceptual framework for diabetes self-management. Significant discussion is devoted to the literature that contributed to model development.

## 3.1 Diabetes Self-management

Diabetes self-management has emerged as an effective approach for managing diabetes mainly because adoption of a healthy lifestyle along with following medical advice will lead to better metabolic control of diabetes, which in turn will help in the avoidance of subsequent acute and long-term complications of the disease (Funnell, et al., 2010). Diabetes self-management refers to a full range of activities or behaviours that diabetic patients perform to manage their disease and to promote their health (Heisler & Resnicow, 2008).

To provide comprehensive care, effective management of diabetes requires a team care approach. This team usually includes a diabetes nurse specialist or educator, a dietician, a social worker, a psychologist, the general practitioner and the patient (Mensing et al., 2007). However, the person with diabetes is the most crucial player in the team. For diabetes care to succeed, patients must be able to make informed decisions about how they will live with their illness as over 95% of diabetes management is done by patients themselves (Funnell & Anderson, 2000).

To play this crucial role effectively, people with diabetes need to be equipped with the necessary knowledge and skills through diabetes self-management education (DSME) to enable them to adhere to the recommended behaviours including diet, physical

exercise, medication administration, self-monitoring of blood glucose, and foot selfcare.

#### 3.1.1 Diet

Diet control is a fundamental components of diabetes care, and also the most natural and safe control method of treatment. It is widely accepted that the most suitable diet in the treatment of type 2 diabetes is food that is high in carbohydrates (with low glycaemic index such as pasta and parboiled rice), high in fibre (fruits and vegetables) and low in fat, carbohydrates (with high glycaemic index such as white bread), and sweets (Brekke et al., 2007). Selecting the appropriate type of food is one of the strategies of the medical nutrition therapy, however other strategies include meal preparing and planning strategies, such as preparing a packed lunch, and planning several meals at one time, and dining out strategies, such as selecting restaurants, making sensible food choices, and controlling portions of food (Savoca & Miller, 2001).

One way to encourage responsibility in people with type 2 diabetes to help them take an active role in improving their blood glucose is to provide dietary guidelines (Schafer et al., 1997). For example, guidelines for weight loss or maintenance of a constant weight may include eating six small meals instead of three large meals, no large meal late in the day, a light evening snack, and daily self-monitoring of blood sugar (Downer, 2001). It is also suggested that nutrition recommendations for people with diabetes should be practical and achievable based on individual assessment and desired outcomes (Schafer et al., 1997).

Patient adherence to the recommended meal plans, healthy eating, and adjusting food intake in response to glycaemic level was significantly associated with improvement in clinical outcomes. For example Tan et al. (1997) found that diet education interventions result in significant reduction in HbA1c associated with lower consumption of fat, reduced calories intake and more unpolished rice and high fibre food. Other studies also show improvement in clinical outcomes including HbA1c (Jones et al., 2003), fasting blood glucose (Anderson-Loftin et al., 2002), cholesterol (Gaedi, et al., 2001), and weight loss (Sargard et al., 2005). Adherence to healthy diet can also reduce hospitalization, medication consumption, and overall health care cost (Institute of Medicine, 2000).

#### 3.1.2 Exercise

Physical exercise is one of the usually recommended activities for patients with type 2 diabetes mellitus in addition to diet and medications. Aerobic exercise such as walking, jogging, swimming and cycling were known as the most suitable types of exercise for diabetic patients. However studies showed that the ideal exercise programme should include both aerobic exercises and circuit-type resistance training such as weight lifting to improve glycaemic control and blood circulation and also to reduce cardiovascular complications (Honkola, et al., 1997; Eriksson, 1999).

Several studies investigated the role of exercise in controlling blood glucose for diabetic patients. For example resistance training programme improved clinical outcomes indicated by HbA1c (Baldi & Snowling, 2003). It was also found that combining aerobic and resistance training reduce HbA1c (Cuff, et al., 2003). Adherence to regular exercise is a difficult task for many diabetic patients. Therefore gradual engagement in exercise is usually recommended to improve their adherence for better glycaemic control (Yeater, et al., 1990). It was also found that resistance/balance training has a positive effect on physiological function for older people with type 2 diabetes (Morrison, et al., 2010).

### 3.1.3 Taking Medications

Physicians usually start to prescribe oral medications for patients with type 2 diabetes when diet and exercise is not enough to controls the level of glucose in the blood (Anselmino, et al., 2009; Dunning, 2009). According to the European Society of Cardiology and European Association for the Study of Diabetes, the main classes of oral medications that can be prescribed to reduce hyperglycemia are metiglinides and sulfonylureas which increase insulin supply, biguanides and thiazolidinediones which enhance insulin action, and alpha-glucosidase inhibitors which delay carbohydrate absorption (Anselmino et al., 2009). Some patients need more than one type of these medications if a single one is not sufficient to lower blood glucose.

Adherence to taking medications as prescribed is crucial to improve glycaemic control, and prevent diabetes complications. Several studies investigated the importance of adherence to taking medications as prescribed in terms of clinical outcomes and cost. In most studies, it was found that the level of adherence was acceptable, but becomes worse when combinations of medications were prescribed. For example Rozenfeld, et al. (2008) found that adherent patients had better achievement of glycaemic control

indicated by lower HbA1c. Similar conclusions about the importance of adherence to taking medications in improving clinical outcomes have been reached (Schectman et al., 2002; Pladevall et al., 2004; Lawrence, 2006). It was also found that adherence to taking medications reduces hospitalization (Lau et al., 2004; Rumsfeld, et al., 2006), reduces mortality (Rumsfeld, et al., 2006), and also reduces overall health care cost (Balkrishnan, et al., 2003; Hepke, et al., 2004; Sokol, et al., 2005).

## 3.1.4 Self-monitoring of Blood Glucose

Self-monitoring of blood glucose (SMBG) is one of the fundamental tools for appropriate management of diabetes (National Institute for Clinical Excellence, 2008). NICE guidelines indicate that SMBG requires measuring the level of glucose in the blood using a medical device (glucose meter), reading the results, interpreting these results and taking an appropriate action. This process is essential for the daily management of both type 1 and type 2 diabetes mellitus (Owens, et al., 2004). Therefore patient education for the optimum utilization of this device has become one of the main components of diabetes self-management programmes. It provides immediate information for patients regarding glycaemic control that can assist them to make important decisions related to their diet, exercise, and taking medications and also motivate them for proper engagement in self-management activities (Guerci, et al., 2003; Owens, et al., 2004).

Several studies investigated the role of self-monitoring of blood glucose for improving clinical outcomes for patients with diabetes. It was found that management programmes that include self-monitoring of blood glucose result in significant reduction of HbA1c comparing to other programmes that do not include it (Schwedes, et al., 2002; Jansen, 2006; Martin, et al., 2006; Moreland, et al., 2006). It was also found in a recent study that SMBG result in a modest reduction of HbA1c for patients with type 2 diabetes (Cameron, et al., 2010) who also suggested that the frequent use of blood glucose test strips( more than seven times a week) is not cost-effective for managing type 2 diabetes. Whereas Farmer et al. (2007) did not find convincing evidence that self-monitoring of blood glucose improve glycaemic control when they compared the results of an intervention group (self-monitoring with and without medical consultation for the interpretation and application of results) against a usual care group.

Although the UK government spent £90 million in one year (2001) for providing diabetic patients with devices and strips for self-monitoring of blood glucose (Hoffman, et al., 2002), however these devices positively contributed to their personal care

leading to better quality of life, better clinical outcomes and less hospital admissions (Department of Health, 2006).

#### 3.1.5 Foot Care

Foot care is an important component of diabetes management to prevent serious complications of diabetes. Lack of blood supply to the foot (ischemia) and damage of nerves (peripheral neuropathy) are the main reasons for foot ulcer which is a common complication of diabetes affecting 15% of diabetic patients (Boulton, et al., 1995). Foot ulcer may lead to more serious complications by destroying parts of the tissues, causing gangrene which requires lower extremity amputation (Reiber, et al.; 1998). However these serious complications can be reduced significantly if proper prevention measures were taken (Mccabe et al., 1998).

Although researchers support the importance of preventive measures for foot ulcer, however there is a little agreement on how to achieve this target. On the one hand foot care education programmes were found to be an effective way to reduce the incidence of foot ulcer (Litzelman, et al., 1993; Rith-Najarian et al., 1998), and also reduce the incidence of amputation (Malone, 1989). However, on the other hand foot care education was not found to be an effective way to reduce the incidence of foot ulcer (Peters & Lavery, 2001; Leese et al., 2005). It was also found that an education programme for a high risk group has improved patients' behaviour but was not associated with clinical benefits (Lincoln, et al., 2008). However Singh et al. (2005) suggest that diabetic patients may benefit from foot care education programmes, but screening for patients with high risk of developing foot ulcer is the most recommended preventive measure.

In all cases foot care education emphasizes the role of patients in caring and monitoring their feet on a daily basis. According to the National Institute for Clinical Excellence (2004), the recommended guidelines for foot care include examining (on daily basis) any problems in the feet such as swelling, change in the colour, pain or break in the skin. It also emphasizes the importance of using well fitted shoes, daily hygiene by cleaning, drying, and moisturizing the foot, nail care, and taking appropriate precautions to avoid accidents. Following these guidelines by patients in addition to routine examination by health professionals leads to early detection, diagnoses and treatment of foot problems to prevent serious complications (National Institute for clinical Excellence, 2004).

## 3.2 Diabetes Self-management Programmes

Diabetes self-management programmes can be defined as an organized health intervention that is provided by heath care organizations to promote and educate diabetic patients to self-manage their disease.

Outcome evaluation is one of the basic steps to evaluate health interventions. Outcomes of health interventions include clinical outcomes to reflect quality of care, economical outcomes to reflect cost-effectiveness of the intervention and psychosocial outcomes to reflect the effect of the intervention on the quality of life of participating patients (Bowling, 2002).

To investigate the outcomes of diabetes self-management programmes, a review of the literature has been conducted by searching in two databases specialised in health related articles; Medical Literature Analysis and Retrieval System Online (MEDLINE), and Cumulative Index to Nursing and Allied Health Literature (CINAHL). In both databases the search was conducted using (diabetes AND self-management OR self-care).

In Medline the search was limited to full text studies between January 2000 and December 2009. The number of studies retrieved was 702 titles. By reviewing the titles 601 were excluded for not being related to type 2 diabetes or being medical or pharmaceutical studies. 101 studies remain for further investigation. In CINAHL, however the same search was conducted but limited to full text studies available between January 2000 and February 2010, and the term diabetes in the title. The total number of studies retrieved was 510. After applying the same exclusion criteria, the number of studies remaining for further investigation was 98 titles.

Both 101 studies from Medline and 98 studies from CINAHL were retrieved to an Endnote library. By discarding duplications, the total number of studies remaining was 123 studies. The abstracts and the full texts if necessary have been reviewed to include studies that involve a specific intervention related to self-management. Studies were excluded if they did not involve an intervention, systematic reviews, descriptive studies, and studies that showed irrelevant outcomes for the purpose of this study. For example some studies measured diabetes knowledge or changes in patients' behaviour as outcomes. These studies were excluded at this stage. The main reason for excluding these studies is that these outcomes were used to evaluate diabetes self-

management educations which for the purpose of this research are not considered as outcomes. Rather the outcomes in this research result from actual activities performed by patients. The outcomes of performing these activities are the focus of this study at this stage. However most of the excluded studies were considered when investigating the factors that influence diabetes self-management activities. After the application of inclusion and exclusion criteria shown above, 28 studies remained for further investigation. Table 3.1 summarizes these studies.

Table 3-1: Summary of studies included in the review

No	Author, date, and country	Method	Intervention	Main results
1	Balamurugan et al (2006) USA	Comparative pre- post trial	12 hours of group education on nutrition and self-management	After one year HbA1c declined Less hospital admissions, emergency visits, and outpatient visits
2	Berg & Wadhwa (2002) USA	historical control comparison	Diabetes disease management programme in a community based setting	Symptoms of hyperglycaemia decreased Significantly lower hospitalization and facility visit Lower emergency visits, physician visits Lower cost
3	Brown et al (2007) USA	Randomised controlled trial	Self-management education and support group to promote health beliefs	Improved health beliefs led to reduction in HbA1c
4	Davies et al (2008) UK	Cluster randomized controlled trial	structured group education programme	After one year, no significant difference for HbA1c, but weight loss, better knowledge and lower depression in the intervention group
5	Farmer (2007) Germany	randomised controlled trial	self-management oriented group intervention	Mean HbA <sub>1c</sub> and fasting blood glucose concentrations were reduced Better psychological outcomes
6	Griffiths et al (2005) UK	Randomized controlled trial	Expert Patients Programme. A lay led education programme to support self-care	No significant reduction in utilization of services. No improvement in quality of life Self-efficacy and health behaviour improved
7	Keers et al (2005) Netherlands	Pre-post trial	Intensive programme to educate patients with prolonged self- management problems using a multidisciplinary team	Significant improvement in HbA1c Significant decrease in diabetes related cost Improved diabetes related distress
8	Kennedy et al (2007) UK	pragmatic randomized controlled trial	Expert Patients Programme. A lay led generic courses to support self-care	No reductions in routine health services utilization, better quality of life. Small reduction in cost. 70% probability of cost effectiveness in terms of quality adjusted life year.
9	Kirk et al (2001) UK	Randomized controlled trial	exercise consultation and standard exercise information	Positive effect on quality of life Increased patients sport activities

10	Kuijer et al (2007) Netherlands	Pre-post trial Then-test method	A short intervention to enhance quality of life and based on proactive coping theory and self- regulation theory	No significant effect on self-care, self efficacy or quality of life
11	Kulzer et al (2007) Germany	Randomized Controlled Trial	Self-management oriented programme delivered to a group	No significant difference in HbA1c Fasting blood glucose and BMI improved No significant improvement in knowledge or negative well being
12	Liebman et al (2007) USA	Cross-sectional	Culturally appropriate self-management activities were implemented over a course of 3 years	Improvement in glycaemic control indicated by HbA1c
13	Lorig et al (2009) USA	Randomized Controlled Trial	Community-based peer-led diabetes self-management programme	No significant change in HbA1c, on utilization measures, but improvement in depression, behaviour, self-efficacy was observed
14	Richardson et al (2008) UK	Randomized Controlled Trial	Expert Patients Programme, a lay-led self-care group involving six weekly sessions	reduced cost of around 27 pounds per patient and 0.020 gain in quality adjusted life years (one week of perfect health per year)
15	Samuel-Hodge et al (2008) USA	cross-sectional analysis	church-based diabetes education programme	Improvement in psychological adaptation and coping outcomes
16	Samuel-Hodge et al (2009) USA	randomized controlled trial	culturally appropriate, church-based intervention using patients visits, group sessions, phone contact to enhance self-management	Significant improvement in knowledge and quality of life Reduction in HbA1c
17	Scain et al (2009) Brazil	randomized controlled trial	structured education group (8-hour )programme in a hospital setting	Significant reduction in HbA1c in the intervention group. significant improvement in other clinical outcomes (blood pressure weight and total cholesterol)
18	Siminerio et al (2006) USA	Evaluation research to compare hospital and community based programmes	Applying element of chronic care model to evaluate self-management programmes.	Improvement in HbA1c, increasing in recognized programmes and number of patients participating in community based vs hospital based programmes
19	Siminerio et al 2005 USA	Pre-post trial	Self-management education programme based on element from chronic care model in a rural practice setting	Significant improvement in all clinical measures including HbA1c Improvement in knowledge and empowerment
20	Steed et al (2005) UK	randomized controlled trial	theoretically based self-management programme	Improved patients beliefs, behaviour and quality of life Reduction in HbA1c
21	Steinhardt et al (2009) USA	Pre-post trial	Diabetes Coaching Program, 4 weekly class sessions devoted	significant improvements in diabetes empowerment, HbA1c, BMI total cholesterol, low-density

			to resilience education and diabetes self- management + 8 weekly support group	No significant improvement in, fasting blood glucose perceived stress, and high-density lipoprotein
22	Tang et al (2005) USA	Pre-post trial	Community-based, ongoing self-management intervention to enhance self-care behaviour. 24 weekly sessions	No significant improvement in HbA1c Other clinical outcomes significantly improved(BMI, total cholesterol, H&L density lipoprotein) Improved self-care behaviour
23	Tankova et al (2001) Bulgaria	Pre-post trial	5 days structured teaching programme related to diabetes self- care	Improve quality of life Reduced HbA1c Incidence of diabetic ketoacidosis decreased
24	Thompson et al (2007) USA	Pre-post trial	diabetes management education based on trans-theoretical model of change in primary care	Reduction in HbA1c whereas the improvement in other clinical outcomes was not significant
25	Thoolen et al (2008) Netherlands	Randomized Controlled Trial	a brief self- management course using elements from proactive coping and self-regularity theory	No clinical outcomes were measured but, the programme shows improvement of proactive coping and self-efficacy
26	Utz (2008) USA	Randomized Controlled Trial	a culturally tailored education programme for African American in a community centre to compare groups and individual sessions	Both groups improved in HbA1c, and satisfaction with better achievement in individually tailored group
27	Wangberg (2008) UK	Randomized Controlled Trial	Internet-based intervention to improve self-efficacy	Improvement in self-efficacy which function as a moderator for self-care Insignificant improvement in HbA1c
28	Williams et al (2007) USA	randomized controlled trial	patient-cantered, computer-assisted diabetes care intervention in primary care	Increased patient's perception that their autonomy was support and satisfaction Improve clinical outcomes

Although these interventions vary in terms of the components and durations of education sessions, however they all aim to enhance self-management of patients with diabetes. Measuring the outcomes of these programmes is essential to judge the successfulness of these interventions to improve diabetes care. One of the most important aspects of these outcomes is the clinical improvement of patients participating in these interventions which is an indicator of the quality of care provided and effectiveness of participants' engagement.

Clinical outcomes refers to the analysis of dataset related to the condition of patients participating in a specific intervention by identifying a set of clinical indicators to measure the health condition before and after the intervention (Masella, et al., 2004). Table 3.1 shows that the most common indicator for measuring the clinical outcomes was the glycosylated haemoglobin (HbA1c) which measures the average level of blood

glucose in the last 8-12 weeks. Data from the United Kingdom Prospective Diabetes Study (UKPDS) demonstrate that a 1% drop of glycosylated haemoglobin (HbA1c) is associated with significant reductions in risk of diabetes-related deaths (21%), myocardial infarction (14%), and micro vascular complications (37%) (Stratton et al., 2000).

All studies in table 3.1 measured clinical indicators as outcomes for specific interventions related to diabetes self-management except studies number (6, 8, 9, 10, 14, 15, and 25) mainly because not only patients with diabetes were involved in the interventions but also patients with other chronic conditions. Of the remaining 21 studies, 17 studies demonstrated improvement in clinical outcomes indicated by significant reduction in HbA1c for patients with diabetes as a result of participating in self-management interventions (1, 2, 3, 5, 7, 12, 16, 17, 18, 19, 20, 21, 23, 24, 26, 27, and 28). However, 3 studies showed no significant differences in HbA1c (4, 11, 13). Only one study showed a slight improvement in HbA1c but this was not significant (22), whereas significant improvements were reported for other clinical indicators including body mass index, total cholesterol, low-density lipoprotein and high-density lipoprotein.

Economic evaluation of health interventions deals with inputs and outputs of a specific intervention and usually conducted when different options are available (Awasthi, 2000). Cost benefit analysis, cost effectiveness, and cost utility analysis are tools to conduct complete economic evaluation. Cost is one of the important outcomes in diabetes research, and has been measured to evaluate different types of interventions in diabetes management. Cost as an outcome in diabetes management programmes can be measured either directly through direct medical costs or through utilization of health services, for example hospitalizations or number of admissions, length of stay, and number of emergency visits, or indirectly through work loss or restricted activity days (Epstein & Sherwood, 1996). It can also be indirectly calculated through quality-adjusted life years which is a measure of the burden of disease in terms of quantity and quality of life lived (National Institute for Health and Clinical Excellence, 2008). However for the purpose of this research cost was assessed through utilization of health services in a simple form due to lack of information.

According to Williams (2000), the terms need, demand, and utilization are conceptualized differently to analyse the behaviour of patients in health care systems. Need is often defined as professionally assessed or clinically identifiable justification for using health care services for example laboratory tests requested by physicians. Demand is defined as the patients' attempts to obtain services. While patients may attempt to obtain services that clinicians may find unnecessary, clinicians may request

services that patients reject. The need and demand for health services produced the term "utilization" as a concept used to evaluate necessary and unnecessary services (Williams, 2000). Necessary services are usually determined by clinical guidelines, policies and procedures.

Table 3.1 shows that 7 studies of the total 28 studies included in the review conducted economic evaluation of the intervention (1, 2, 6, 7, 8, 13, and 14). Of these, 5 studies used utilization of health services as a measure of cost where significant reductions in utilization of health services were reported in two studies (1, and 2), and no reductions in utilization of health services were reported in two studies (6, and 13). Three studies used direct medical cost, reported significant decrease in cost (7, and 14), and a small reduction in cost (8). Quality adjusted life years as an indirect cost was reported in two studies (8, and 14) which showed a 70% probability that the intervention was cost effective if the quality adjusted life year value was £20,000 (8), and a gain of 0.020 in quality adjusted life years which is equivalent to one week of perfect health per year (14).

Quality of life has emerged as a crucial outcome measure for health interventions to evaluate the effect of these interventions, treatment and services on patients' well-being (Vaapio, et al., 2009). Quality of life is a multidimensional concept that includes several aspects of people's lives such as physical, mental, emotional and social functioning, life satisfaction, family/marital well being, and environmental factors (World Health Organization Quality of Life Group, 1998). Therefore Health Related Quality of Life (HRQOL) is concerned with these aspects of life for patients suffering a specific condition. Although there is no "gold standard" to measure diabetes-specific quality of life, developing such an outcome measure is essential mainly because improving clinical outcomes for diabetic patients is meaningful only to the extent that it affect their physical and emotional well being (Rubin, 2000).

Table 3.1 shows that quality of life has been investigated as an outcome measure in 16 studies (4, 5, 6, 7, 8, 9, 10, 11, 13, 15, 16, 20, 21, 23, 25, and 28). Although these studies used different measures, but these measures incorporate quality of life as a broad multidimensional construct. 12 studies reported improvement in quality of life or components of quality of life. Diabetes self-management has led to lower depression (4, and 13), better psychological outcomes (5), improved distress (7), improved psychological adaptation and coping outcomes (15, and 25), improved patients satisfaction (28), and also led to improvement in overall quality of life (8, 9, 16, 20, and 23).

On the other hand 4 studies reported no improvements in quality of life or its related aspects as an outcome of diabetes self-management programmes (6, 10, 11, and 21) where diabetes related stress did not improve after 8 months of the programme (21), No significant differences were found between the intervention groups in relation to the negative well-being, however both groups were involved in self-management programmes with different educational approaches (11). No improvement in overall quality of life has been reported in two studies (6, and 10).

This review provides evidence that diabetes self-management programmes improve clinical outcomes, improve quality of life and reduce overall health care cost. Several systematic reviews and meta analyses in the literature provide similar supporting evidence. In a meta analysis of chronic disease self-management programmes conducted by Chodosh (2005) to assess the effect of these programmes on clinical outcomes, the authors reviewed 26 studies on diabetes, the results of 20 comparison studies reported HbA1c outcomes. These studies demonstrated a statistically and clinically significant pooled effect size of -0.36 (95% CI, -0.52 to -0.21) in favour of the intervention group comparing to a control group or usual care. The negative effect size indicates a lower HbA1c level in the treatment group and the effect sizes of -0.36 indicates a reduction of HbA1c of 0.81% (Chodosh et al., 2005). In addition Urbanski et al. (2008) reviewed five systematic reviews to conclude that diabetes self-management education programmes were cost-effective, whereas Fisher et al. (2007) conducted a systematic review to investigate the effect of self-management programmes on quality of life, coping and negative emotions to conclude that the remarkable achievements of these interventions provide a base to expand in these programmes for healthy coping with diabetes.

In summary diabetes self-management programmes improve clinical outcomes, reduce health care cost, and improve quality of life. Thus, diabetes self-management has a positive effect on clinical outcomes (research hypothesis1), has a negative effect on utilization of health services indicated by emergency visits, number of admissions and length of stay. (research hypothesis 2), and has a positive effect on quality of life (research hypothesis 3). Figure 3.1 illustrates these relationships.

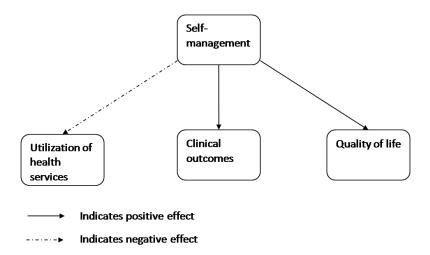


Figure 3-1: Outcomes of self-management programmes

Achieving these promising outcomes requires effective engagement of patients in self-management. However in practice, patient adherence to the recommended treatment guidelines is often below optimal due to the inability or unwillingness of patients to perform self-management activities. Therefore it becomes essential to investigate the factors that influence patients' ability to engage effectively in these activities by enhancing the factors that positively affect self-management and eliminating or reducing the effect of the factors that negatively influence self-management.

## 3.3 Theoretical Framework

One of the basic requirements for effective self-management is the ability and willingness of patients to change their behaviour. Thus it is very crucial to consider theoretical approaches to diabetes management as theory-based approaches are more likely to be effective at changing behaviour and maintaining behaviour change (Elder et al., 1999). In addition it is also important to specify and test the critical assumptions that trigger patients engagement in self-management by grounding intervention in theoretical principles that regulate patients behaviour (Rothman, 2004). Theoretical approaches also provide conceptual and analytical answers that explain the success or failure of a specific intervention (Bartholomew, 2001).

The Health Belief Model (HBM), self-efficacy theory, and locus of control theory have all been applied with varying success to research for explaining, predicting, and influencing behaviour (Rosenstock et al., 1988). In application to health behaviour, these theories have been used to explain patients' engagement in self-management,

following healthy behaviour, using preventive measures engaging in screening programmes, and many other applications.

### 3.3.1 Health Belief Model

The Health Belief Model (HBM), which is the main conceptual framework guiding this study, is one of the first, and most commonly used theoretical frameworks to predict and explain health-related behaviours (Aalto and Uutela, 1997). It was originally developed by Rosenstock et al in the 1950s to explain people's lack of participation in health prevention, and diseases early detection programmes. This model has been developed and modified to a large extent for application to various types of health behaviours (Janz & Becker, 1984).

According to Rosenstock et al.(1988), behaviour is explained by the HBM as a result of combination of attitudes related to four concepts: perceived susceptibility which refers to an individual's view of the likelihood of experiencing or being susceptible to a potentially harmful condition (threat), perceived seriousness which is concerned with how threatening the condition is, perceived benefits which focuses on the effectiveness of specific behaviours in reducing the threat of the condition, and finally perceived barriers which relate to the negative aspects of the anticipated behaviour. Thus, the model predicts that individuals will take preventive actions if they perceive themselves to be susceptible to a condition or a problem, if they believe that this problem is serious enough to be avoided, if they believe that the required action will reduce or eliminate the threat, and if they believe that the benefits of taking action is more important or outweigh the costs or expected barriers (Rosenstock et al., 1988).

Another component of the HBM is cues to action which refers to the factors that motivate individuals to perform healthy behaviour when expected benefits are considered (Rosenstock, 1988). This healthy behaviour is triggered by advice from others such as health professionals, family member and friends, or by personal observation from mass media, newspapers or magazines. The health belief model also includes demographic variables, knowledge, and interactions between patients and health professionals which are all considered predictors of health behaviour. The model was expanded for better explanation of the role of patients in adherence to a treatment regimen after being diagnosed with a specific illness (Janz & Becker, 1984).

Janz and Becker (1984) reviewed 29 studies related to the health belief model published during the period from 1974 to 1984, the findings suggested that perceived barriers was the most powerful dimension of the model to predict health behaviour, whereas perceived severity showed weak association with patients health behaviour.

Therefore, they criticised the limitations of the HBM in predicting and explaining health behaviour indicating that it is "a psychosocial model; as such, it is limited to accounting for as much of the variance in an individual's health behaviour as can be explained by their attitudes and beliefs" (Janz & Becker, 1984).

In application to diabetes, the health belief model (or some of its dimensions) was tested in a considerable amount of research. The general findings of these studies were that the model was adequate to explain and to predict patients adherence to treatment regimen where perceived severity was found to be the strongest predictor of adherence (Cerkoney & Hart, 1980; Harris & Linn, 1985), while the perceived benefits was the strongest predictor of adherence to treatment regimen (Brownlee-Dtiffeck et al., 1987; Bond et al., 1992).

Aalto and Uutela (1997), augmented the model to include self-efficacy, locus of control, and social support, and was labelled the extended health belief model (EHMB). Gillibrand and Stevenson (2006), investigated within the theoretical framework of the extended health belief model (EHBM), the experience of young people with diabetes. The results of this study demonstrated the importance of family support to control diabetes. It also showed that internal locus of control and high levels of self-efficacy predicted the benefits of compliance with treatment regimen outweighing the costs of doing such activities. Finally they concluded that the model explained 12 percent of the variance in young people's compliance with self-management. Moreover, Searle et al. (2007) concluded in their study to assess the relationship between illness beliefs and coping in patients with type 2 diabetes, that emphasis on beliefs about diabetes is more beneficial to improve self-care than manipulating patients' coping cognitions.

In summary, the Health Belief Model is adequate to explain patients' behaviour, and provides empirical evidence in its utility to predict self-care for patients with diabetes. Patients' beliefs in the effectiveness of treatment including medications, diet, exercise and self monitoring of blood glucose to control diabetes and its complications play a major role to determine their adherence to treatment regimen. Thus, patients' beliefs have a positive effect on diabetes self-management (research hypothesis 4).

### 3.3.2 Self-efficacy

Diabetes is one of the diseases that place a high level of demand on patients to monitor and self-manage their disease. It also requires engagement in self-care activities for long time. Therefore patients need to have a high level of confidence in their ability to perform self-management activities and maintain this confidence for a long time. Social cognitive theory, developed by Bandura (1977) states that individuals

tend to perform activities that they feel they can cope with, and tend to avoid to perform activities that they feel they cannot manage (Bandura, 1977). Self-efficacy is one of the fundamental concepts of social cognitive theory and was defined as the belief in one's abilities to organize and execute what is required to produce a desired outcome (Bandura, 1977).

Bandura demonstrates that self-efficacy is influenced by four important sources of information. The most important source is enactive mastery experiences, which refer to what the person has experienced or accomplished her/ him-self. The second in importance is vicarious experience, which refers to the observation of what others have experienced. Then, verbal persuasion, which refers to information verbally received from parents, teachers, friends, doctors, etc. The fourth and the least important among these sources of information is physiological and affective states, which refers to the self-evaluation of the physical and emotional factors that influence the individual' beliefs in his or her ability to achieve something (Bandura, 1977).

Enactive mastery experiences strengthen the individual's confidence that he or she is able to perform similar activities in the future. Therefore any failure to accomplish these activities will be attributed to different situational factors rather than one's ability (Bandura, 1977). However, vicarious experience (model); cannot be relied upon solely as the effect on beliefs can be annulled by perceived personal failure. The greater the assumed similarity the more influential is the models' successes and failures (Bandura, 1977).

While verbal persuasion is easy to provide; advice and suggestion by other reliable persons can be effective, but mastery expectation developed by verbal persuasion is also easily lost, so it can be used in addition to other sources (Bandura, 1986). Emotional arousal derived from physiological cues such as heart beat and breathing pattern, is used by individuals to judge their degree of anxiety and readiness to act. Higher levels of anxiety serve as negative feedback that can erode self-confidence and performance, especially for complex tasks (Bandura et al., 1999).

Self-efficacy theory has two cognitive components; the perceived efficacy belief (efficacy expectation), and outcome expectancy (Bandura, 1986). Perceived efficacy refers to an individual's confidence to maintain a specific behaviour in a challenging situation, whereas outcome expectancy refers to an individual's beliefs that a specific behaviour will produce a desired outcome (Bandura, 1986). According to Sigurdardottir (2005) enhancing self-efficacy requires assisting patients to overcome barriers that

prevent healthy behaviour especially for those with low efficacy. For example health professionals, through education programmes, may identify reasonable changes in patients' lifestyles that they can cope with. They could also break down difficult tasks into smaller ones that can be achieved. Regular feedback for patients about their achievements in controlling their disease can also enhance self-efficacy.

Self-efficacy demonstrated the potential to explain the adoption of new health-related behaviours, the avoidance of risky lifestyle behaviours (Shannon et al., 1990), and maintenance of behaviours associated with chronic illness in general (Lorig, 1996). In application to diabetes self-management, several studies found that patients who have higher levels of self-efficacy have been more successful in performing self-care activities and have better health outcomes (Hurley and Shea, 1992; Rubin et al., 1993; Anderson et al., 1995; Corbett, 1999; Bernal et al., 2000; Senecal et al., 2000; Johnston-Brooks et al., 2002; Gastal et al., 2007; Trief et al., 2009; King et al., 2010).

To assess the relationship between self-efficacy, autonomous self-regulation, and self-care, Senecal et al (2000), confirmed that self-efficacy was significantly more associated with adherence, whereas autonomous self-regulation was significantly more associated with life satisfaction, emphasising that more focus should be put on increasing self-efficacy through self-management interventions. Similarly, Nakahara et al., (2006) found that self-efficacy directly reinforced adherence, and adherence had a direct association with HbAc1. It was also found that Self-efficacy is a significant predictor of adherence to management plans; therefore increasing confidence in patients' ability for self-management activities was necessary to improve diabetes self-care adherence (Kavanagh et al., 1993; Nobel & Norman, 2003).

The focus of diabetes research has been on educational interventions to improve knowledge of diabetes, and self-care behaviour including improving skills and compliance behaviour to improve diabetes outcomes (Brown et al., 1992). However, within the last few decades, the focus for diabetes research has gradually extended to recognize the significance of psychosocial factors such as social support (Brody et al., 2008) and cognitive factors such as self-efficacy theory (Anderson et al., 1995; King et al., 2010).

In summary, self-efficacy as a fundamental concept in social cognitive theory explains patients' adherence to treatment regimen. Those with higher confidence in their ability to perform self-management activities (perceived efficacy) and those who have higher beliefs that performing these activities will improve their health (outcome expectancy)

are more likely to participate effectively in self-management. Thus, self-efficacy has a positive effect on diabetes self-management (research hypothesis 5).

### 3.3.3 Locus of Control

The concept of locus of control (LOC) was developed from the Social Learning Theory by Rotter in 1954 (Rotter et al., 1972). It was developed to describe the role of reinforcement in behaviour. This theory assumes that the role of reinforcement is crucial in the acquisition and performance of both knowledge and skills. In this theory, behaviour is determined by the value of the goal and the expectancy that a given behaviour will lead to a desirable outcome. Perceived control of reinforcement is described as the way individuals view the connection between their behaviour and the occurrence of reward or punishment. When the reinforcement for behaviour is perceived to be directly related to individual's own behaviour or characteristics, this is labelled Internal Control. In contrast when the reinforcement for behaviour is not perceived entirely dependent upon individual's own behaviour or perceived to be the result of fate, chance or luck, this is labelled External Control (Rotter et al., 1972).

Individuals who have an internal locus of control are more likely to take responsibility for their own actions, and attempt to exercise more control over their environment, therefore LOC might be associated with people's health related behaviours including prevention, diagnosis and treatment (Wallston et al., 1978). Health locus of control can be conceptualized by identifying health related behaviours. Individuals who believe that they are primarily in control of their health are of internal locus of control, whereas those who believe that their health is controlled by others are of external locus of control. Externals who blame powerful others such as family, doctors and other health professionals labelled powerful others locus of control, and externals who blame chance are labelled chance locus of control (Wallston et al., 1978).

Those described as internals are more likely to engage in screening behaviours such as screening for breast and cervical cancer (Murray & McMillan, 1993; Williams-Piehota et al., 2004; Rowe et al., 2005) and to engage in healthy behaviours such as regular physical exercise (Duffy, 1997), and eating health food (Callaghan, 1998). Internals are also more likely to avoid risky health behaviours such as smoking (Strickland, 1978) and alcohol consumption (Callaghan, 1998). However other studies found weak associations between health related LOC and theses behaviours for example smoking and alcohol consumption (Calnan, 1989), and for physical exercise (Rabinowitz et al., 1992). In a recent study, Bailis et al. (2010) found the health locus of control is related

to age where the strength of internal LOC increased in younger people and decreased in older people suggesting that the threshold occurs at age 42.

On the other hand, Wallston (1991, and 1992) demonstrated that these beliefs fall on a continuum; that is individuals are never entirely internal or external. Therefore, health locus of control (HLC) may not be stable, and was found to be related to health domain but not to any specific health behaviour. In addition, patient's beliefs and self-efficacy were better predictors of health related behaviour than HLC. However, Steptoe and Wardle (2001) justified the inconsistent findings and the weak association between locus of control and health related behaviours as it may be because of small samples and over-reliance on correlations as measures of association. In their study, they selected a sample of 7115 students from 18 European countries to assess the relationship between locus of control and ten related health behaviours (physical exercise, smoking, alcohol consumption, breakfast, tooth-brushing, seat belt use, and consumption of fruit, fat, fibre and salt). They used multivariate logistic modelling to find a high association between locus of control and health behaviour.

Because LOC and HLOC affect numerous health behaviours, they may also have an effect on diabetes self-management. Many studies have examined the relationship between LOC and diabetes management. Because previous research has suggested that internals are more likely to perform a range of health promoting behaviours (Strickland, 1978), it appears that internals would engage in self-management activities. According to Knight et al. 92006), patients with an internal LOC are more likely to take preventive measures by maintaining healthy behaviour, while those with beliefs in 'powerful others' tend to avoid regulating or organizing their treatment, unless it is specified and monitored by a health professional. By examining the relationship between diabetes-specific health locus of control and glycosylated haemoglobin for adults with type 1 diabetes, Stenström and Andersson (2000), found that internals had better glycaemic control than people with more external locus of control.

Similar results have been reported when using education programmes to enhance patient's internal locus of control. For example Howorka (2000) showed that outpatient group training for 'Functional Insulin Treatment' (selective insulin dosages for eating, fasting or correcting hyperglycaemia) resulted in a measurable improvement of patients' perceived control over diabetes and their self-efficacy (Howorka et al., 2000). In their study, De Weerdt et al. (1990) used Fishbein & Ajzen's attitude-behaviour theory, to assert that diabetes education should first aim at improving peoples' level of knowledge and health locus of control, and second at a positive attitude to active self-

care. They also found in their study that attitude was the most important determinant of active self-care, while adequate knowledge and a low orientation towards powerful others were prerequisites for a positive attitude (de Weerdt et al., 1990).

Fatalism as an external locus of control is defined in Webster's Dictionary as "a doctrine that events are fixed in advance so that human beings are powerless to change them". However this concept is differently conceptualized in the literature. Powe and Weinrich (1999) define fatalism as a complex psychological cycle characterized by perceptions of hopelessness, worthlessness, meaninglessness, powerlessness, and social despair, whereas (Straughan and Seow, 1998), defined fatalism as "a belief that some health issues are beyond human control." In Islam however fatalism is conceptualised differently. It is called "Qadaa and Qadar" divine will and predestination which is one of the essential components of faith in Islam.

In Islam, the belief in Qadar (predestination) is one of the basic principles of faith without which a person's belief is not complete (Al-Ashqar, 2005). In his book, Al-Ashqar clearly explains this concept showing that it is one of the complex concepts that many people misunderstand or may be led astray when they explain it. Prophet Muhammad (peace be upon him) said "Eeman (faith) is to believe in Allah, His angels, His books, His messengers, and the last day, and to believe in divine destiny both the good and the evil thereof". There are several verses of the holy Quran that mentioned qaddar:

"Verily, We have created all things with qaddar[ Divine preordainments of all things before their creation as written in the Book of Decrees-Al-Lauh al \_mahfooz]" Quran 54:49

- " .. And the command of Allah is a decree determined." The Holy Quran 33:38
- "... but [you met] that Allah might accomplish a matter already ordained [in His knowledge]..." The Holy Quran 8:42

Fatalism in Islam is indicated by the belief Qadda and Qaddar where qadda refers to the previous knowledge according to which Allah created all things and ruled by it from eternity, and qaddar (predestination) refers to when creation follows that which has already been decreed.

The belief in Qadar requires the belief of four essential components or pillars. First, belief that the knowledge of Allah is all-encompassing. Second, belief that Allah has

written in Al-Lauh al-mahfooz (the preserved tablet) everything that will come to pass until the day of Resurrection. Third, belief in the irresistible will and perfect power of Allah so what he wills happens and what he does not will does not happen. Fourth, belief that Allah has created everything that exists and that Allah has no partner in His creation.

Islamic scholars mentioned several benefits of this belief. It makes a person persist in his adherence to the straight path, so that he/she is not reckless at times of ease, and does not fall into despair when calamity strikes. It is also a relief for people who suffer problems or experience sad events to know that these things are happening by the decree of Allah so they do not panic or despair, rather they seek the rewards of Allah and bears it with patience to bring contentment and tranquillity to their hearts.

"Who when affected with calamity say, Truly to Allah we belong and truly, to Him we shall return, they are those who are blessed and will be forgiven, and they are those who receive His Mercy and it is they who are the guided ones} The Holy Quran 2: 156-157

However through the early ages of Islam some Muslims misconceived this pillar extremely and moderately. One of the extreme views was a group that denied predestination and the other believed that people are compelled to do what they do and have no freedom of choice. In direct refutation to these claims, early Islamic scholars used evidence from the Holy Quran, Prophet Muhammad (Peace be upon him) sayings, and rational evidence to eliminate these schools of thought with a great success that these thoughts are rarely followed. The moderate misconception of this pillar was the claim that belief in qadar (predestination) implies lack of interest in taking action or seeking the means to an end, leading to laziness, not taking appropriate precautions, and inappropriate striving. However the text of the Holy Quran and prophet sayings are full of commands to pursue the prescribed means in different areas of life (Al-Ashqar, 2005).

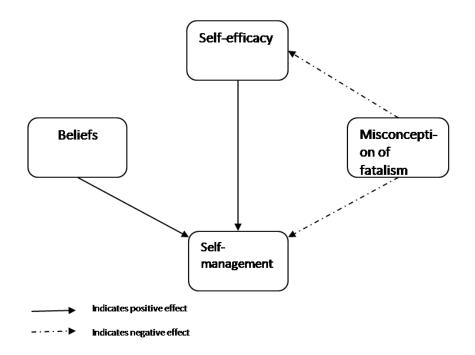
Few studies have investigated the effect of fatalism on diabetes self-management. According to Egede and Bonadonna (2003), most studies that investigated this role derived the construct of fatalism from locus of control theory. However it appears that fatalism play a negative role in diabetes self-management; more fatalist beliefs is associated with lower adherence to treatment regimen and poorer diabetes outcomes (Schlenk & Hart, 1984; Peyrot & Rubin, 1994; Schwab et al., 1994; Tillotson & Smith, 1996). Although no studies have been conducted to assess the effect of fatalism from the Islamic point of view on diabetes self-management, the author argues that this

factor may contribute to ineffective diabetes care and inappropriate adherence to treatment regimen. This study is the first one to investigate the effect of fatalism from the Islamic point of view on diabetes self-management.

Locus of control, self-efficacy, and the health belief model are the main theories explaining and predicting health behaviour with some similar and related aspects. Self-efficacy and outcome expectancy are the two primary determinants of health behaviour (Bandura, 1986) where outcome expectancy is the same construct as the perceived benefit in the health belief model. However the difference in self-efficacy is that patients need to belief that the required action will lead to a desired outcome but they also need to belief in their ability to do the required action. Locus of control also linked to self-efficacy in that internals have high self-efficacy and externals have low self-efficacy (Waller & Bates, 1992).

In summary, locus of control theory denotes a context of outer- or inner-directed behaviour in different situations faced by patients in daily life. Those of internal locus of control claim responsibility of these situations and its consequences, while those of external locus of control place responsibility on others such as health professionals, luck or fate. Fatalism (divine will and predestination) is one of the basic pillars of faith in Islam. Misconceiving fatalism may lead to inappropriate management of chronic conditions. Thus, misconception of fatalism has a negative effect on diabetes self-management. However this relationship may be mediated by its negative effect on self-efficacy (research hypothesis 6). Figure 3.2 illustrates the relationship between self-efficacy, beliefs, misconception of fatalism, and self-management.

Figure 3-2: The relationship between beliefs, self-efficacy, misconception of fatalism and self-management



## 3.4 Diabetes Education and Knowledge

Patient education is the cornerstone in self-management programmes for patients with chronic illnesses. Although traditional patient education and self-management education programmes aim to improve patient knowledge, they differ in the way they approach this improvement and the use of patient knowledge to achieve the desired behaviour change to improve outcomes. According to Bodenheimer et al. (2002) the difference between these two types of patient education is that in the traditional education, patients are taught information and technical skills about the disease, problems are seen as a result of inappropriate control of the disease, education is disease specific and all information is related to the disease, and based on the assumption that disease knowledge creates behavioural change that produces better outcomes, whereas in self-management education, patients are taught how to act on problems which they have experienced and may or may not be related to the disease, education provides problem-solving skills relevant to the consequences of chronic disease in general, and generally based on the assumption that the higher the confidence of patients in their ability to perform a healthy behaviour (self-efficacy) the better the outcomes will be. In addition traditional education focuses on delivering

knowledge and technical skills to patients to enable them to follow medical advice, while self-management education is premised on the goal of empowering patients to take active control of their conditions and apply problem-solving skills to meet new challenges (Bodenheimer et al 2002). Thus, in self-management education, the emphasis shifts toward patients as principal caregivers, yet the role of professionals remains of great importance to provide their patients with necessary information and assistance to perform self-management activities (Von Korff et al., 1997).

This distinction is reflected in the methods by which each of these interventions is delivered: patient education is taught through a conventional didactic approach and self-management education through participatory learning techniques (Coulter &, Ellins, 2006). Norris et al. (2001) classified various types of interventions in diabetes education. Improvements in diabetes knowledge have been reported in all types of interventions; for example providing patient with didactic knowledge or information (Wise et al., 1986; Korhonen et al. 1983; Brown et al., 1992), Collaborative, knowledge, and information interventions (Falkenberg et al., 1986; Vinicor et al., 1987; Fernando, 1993; de Weerdt et al., 1991; D'Eramo-Melkus et al., 1992; Ridgeway et al., 1999), life style interventions including exercise and diet (White et al., 1986; Heller et al., 1988; Agurs-Collins et al., 1997; Hawthorne & Tomlinson, 1997), and skills teaching interventions including self-monitoring of blood glucose (Jones, 1990; Barth et al., 1991; Kruger & Guthrie, 1992).

In addition to diabetes education, there are other factors that may influence diabetes knowledge for example duration of diabetes and education level. Duration of diabetes or the period of time since patients were diagnosed with diabetes is a significant predictive factor for diabetes knowledge; longer duration of diabetes is associated with increased diabetes knowledge (McClean et al, 2001). It was also reported that higher diabetes knowledge was significantly correlated with higher education level and longer duration of diabetes (Rothman et al., 2005b). Similarly, using multivariate analysis to assess the relationship between demographic factors and diabetes knowledge in patients with type 2 diabetes mellitus, it was found that age, years of schooling, duration of treatment, and sex were independent determinants of the knowledge score, specifically significant to years of schooling and duration of diabetes showing a strong correlation between observed and predicted scores (Murata et al., 2003).

Although most studies support the hypothesis that longer duration of education programmes and that higher patient educational level produce more improvement in

diabetes knowledge, there is little agreement on whether individual or group education lead to better results for diabetic patients. While group education was found more effective (Rickheim et al., 2002, Deakin et al., 2005) tailored educational intervention was found to be more effective (Campbell et al., 1994; Brug et al., 1999), though a combination of group and individual education produces optimum results (Gucciardi et al., 2007).

Diabetes self-management education (DSME) is an essential component for diabetes management, and can be defined as is the ongoing process of facilitating the knowledge, skill, and ability essential for diabetes self-care (Funnell et al., 2008) This process incorporate the needs, goals, and life experiences of people with diabetes and is guided by evidence-based standards to support informed decision-making, self-care behaviours, problem-solving and active collaboration with health providers to improve health, clinical and psychosocial outcomes (Funnell et al., 2008). On the other hand, diabetes knowledge refers to the individual's available resources of information and skills about diabetes symptoms, treatment (diet, exercise, medication administration), and complications, and is comprised of accumulative life experience in addition to informal and formal diabetes education required to support proper self-management (Speight, et al., 2001). Therefore diabetes knowledge is considered as a main product of diabetes education through which patients are equipped with the necessary information and skills that facilitate their engagement in diabetes self-care management (Dunn et al., 1990; Carlson & Rosenqvist, 1991; Agurs-Collins et al., 1997).

Although a few studies reported no significant relationship between diabetes education and patient knowledge (Carlson & Rosenqvist, 1991; Coates & Boore, 1995), the vast majority of studies support the significant positive effect of diabetes education on diabetes knowledge and self-care. Deakin et al. (2005) reviewed the literature to assess the effect of group based training for self-management on various outcomes. They reviewed 11 studies involving 1532 participants. The results of the meta-analyses reported improved diabetes knowledge at 12-14 months (SMD 1.0; 95% CI 0.7 to 1.2; P < 0.00001). Similarly Norris et al. (2001) reviewed 72 studies and found that most studies measuring changes in diabetes knowledge reported improvement with education. In addition Corabian and Harstall (2001), found in their review that knowledge and skill performance were improved, and that this improvement was positively correlated with longer duration of education programmes. In general the level of improvement depends on several factors such as duration of education

programmes, individual or group education, educator's interpersonal skills, and nature of intervention.

Knowledge about diabetes facilitates patient engagement in self-care and is considered a prerequisite for effective self-management (De Weerdt et al., 1990). In general structured diabetes education that emphasizes both knowledge and self-care behaviours assumes a causal path from learning to changed patient performance, and from altered behaviour to changes in clinical and psychosocial outcomes (Mazzuca et al., 1986). Moreover, Valk et al. (2002), reviewed the literature to assess the effect of diabetes education and foot care behaviour. They found that foot care knowledge and behaviour of patients was positively influenced by patient education in the short term. Similarly Rubin et al. (1993) claimed that knowledge could be affected by an educational and coping skills training programme resulting in increased self monitoring of blood glucose and adjustment of insulin. Adequate diabetes knowledge has been also found to be a strong predictor of self-management even though there was only a weak relationship between knowledge and clinical outcomes (Dunn et al., 1990; Bradley, 1995; Coates & Boore, 1996; Speight & Bradley, 2001). This weak relationship was explained by Rothman et al. (2005b) by assuming that knowledge is not always associated with patient behaviour. They also assumed that there might be other factors influencing clinical outcomes such as diabetes duration.

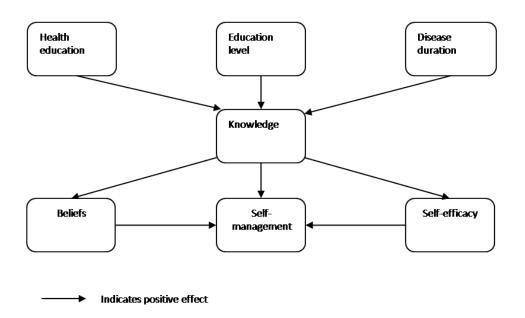
However, knowledge about diabetes has been found to be insufficient by itself to guarantee most advantageous clinical outcomes (Arseneau et al., 1994). As in other chronic medical conditions, knowledge is one component of effective selfmanagement. The other components include behavioural skills, cognitive problemsolving abilities, and a sense of efficacy to overcome any difficulties or barriers which might hinder optimal disease outcome (Hill-Briggs, 2003). In addition, Norris et al (2001) found in their meta-analysis of 31 randomized controlled trials of self-care education for adults with Type 2 diabetes that (HbA1c) improved immediately after intervention, but that this benefit declines over time. Therefore, there is a need for tools that can support and encourage long-term changes as well as facilitate retrieval of information and communication with peers and health care professionals, based on theoretical frameworks that are generally recommended for long term behavioural changes (Wangberg, 2008). This recommendation concurs with the findings of Skinner et al. (2003) who compared a group diabetes education based on four theories (selfregulation theory, self-determination theory, social learning theory, and dual process theory) through a workshop designed to provide self-management education for

people with newly diagnosed type 2 diabetes. They concluded that self-management education that is grounded in an empowerment philosophy and psychological theory is pleasurable for both patients and professionals and is effective to improve patient beliefs and enhance behavioural changes (Skinner et al., 2003).

Patients may not believe that they might benefit from a particular activity, therefore they are less likely to perform it. In this case their knowledge of the importance of that activity is questionable. In the same sense patients' confidence in their ability to perform a task might be affected by the level of skills they have learnt to perform such a task. Thus, improving patients' confidence in their ability to perform self-care management (self-efficacy) and their beliefs in the effectiveness of this performance in improving their conditions (beliefs) is a very important function of diabetes education. In a community-based diabetes education intervention Chapman-Novakofski and Karduck (2005), demonstrated that the programme resulted in a positive effect on knowledge, health beliefs, and self-reported behaviours, and that this improvement in knowledge can be influential in moving individuals to an action or maintenance stage and in improving self-efficacy. Xu et al. (2006) found that knowledge indirectly affected diabetes self-management through patients' beliefs in treatment effectiveness and self-efficacy.

In summary, diabetes knowledge is positively influenced by diabetes education, duration of diabetes and educational level. Improvements in diabetes knowledge, improves diabetes self-management. However this improvement in self-management may be a result of the improvements in patients' confidence in their ability for self-management and/or may be a result of the improvements in their beliefs in the effectiveness of self-management activities to improve their conditions. Thus, diabetes knowledge has a positive effect on diabetes self-management. However this effect may be mediated by the positive effect of patient beliefs and/or self-efficacy on diabetes self-management (research hypothesis 7). On the other hand educational level of patients has a positive effect on diabetes knowledge (research hypothesis 14), duration of diabetes has a positive effect on diabetes knowledge (research hypothesis 15), and length of diabetes education has a positive effect on diabetes knowledge (research hypothesis 16). Figure 3.3 illustrates these relationships.

Figure 3-3: The effect of knowledge on self-management and factors influencing knowledge



## 3.5 Social Support

Managing diabetes mellitus requires a life-long commitment to recommended treatment guidelines which necessitates making changes in lifestyle patterns, therefore the social surrounding of people living with diabetes becomes an important factor in this process. Social support is an essential aspect of diabetes care and has received greater attention in the last three decades. Although the term is not clearly defined, social support is often understood in a general sense but arguments arise in details (House, 1981). It involves the provision of love, trust, empathy, caring, tangible services, help, suggestions, advice, and information (House, 1981; Shumaker & Brownell, 1984). Different forms of social support have been identified, these forms according to Taylor (1999) include informational support where patients are provided with advise and education, financial support for medications or diabetes-related needs, emotional support by expressing affection, acceptance, or approval, instrumental support by providing assistance with self-management activities, affirmation support by validating and appreciating patients 'efforts to self-manage their conditions.

Several studies in the literature have assessed the relationship between social support and self-management considering clinical and psychosocial outcomes. Some studies showed that providing excessive social support by assuming extreme responsibilities for patient behaviour (for example strict restrictions on food intake, and treatment

regimen) may have a negative impact, in particular psychological distress (Fisher et al., 1997; Penninx, et al., 1998). However the majority of studies demonstrated the positive impact of social support on diabetes self-management and outcomes. Brown and Hedges (1994), estimated a linear model to predict metabolic control in diabetes. A direct positive relationship between social support and metabolic control has been reported in the results of this study. However this relationship was only marginal (Schafer et al., 1986) and social support had no implications for HbA1c even though it predicted health-promoting behaviour (McDonald et al., 2002). Thus it was suggested that there are a range of predisposing factors influencing metabolic control beside social support, for example diabetes knowledge, socioeconomic status, and self-care activities (McDonald et al., 2002).

Gallant (2003) has conducted a review of the literature to investigate the effect of social support on self-management of chronic disease. The author reviewed 22 quantitative, and 7 qualitative studies of which diabetes was the most common disease. The results of this review showed that particularly for diabetes, there were a positive modest effect for social support on chronic diseases self-management, especially for diabetes. Out of six studies that showed a high level of social support related to a high level of self management, five studies were about diabetes. This positive relationship was also demonstrated in a recent study conducted by Tang et al (2008) to assess the effect of social support on quality of life and self-care behaviour among African Americans. The findings of this study suggested that social support plays a role in diabetes-specific quality of life and self-management practices, and that social support includes multiple dimensions that differentially influence specific diabetes health-related outcomes and behaviours (Tang et al., 2008).

There are various sources of social support, family, friends, work, and community. Family support was found to be the most important source of social support for people with type 1 diabetes (La Greca, & Bearman, 2002) and the strongest predictor of treatment compliance among patients with type 2 diabetes (Glasgow & Toobert, 1989). The results of this study reported that exercise-specific support accounted for 34% of the variance in exercise adherence. Similarly Wang and Fenske (1996) reported that multiple sources of social support, including family, friends, and diabetes support group were related to better compliance with treatment regimen among patients with type 2 diabetes. The results of this study indicated that social support accounted for 17% of the variance in illness-related self-care practice, concluding that this factor cannot be ignored in explaining self-management behaviour in patients with type 2 diabetes (Wang & Fenske, 1996). It was also found that the absence of supportive

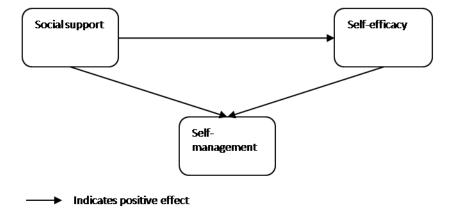
behaviour of the family members was associated with poorer outcomes (Schafer et al., 1986). Although family support is very important to all patients with diabetes to self-manage their disease, women reported more support from friends whereas men reported more support from family (Kvam, & Lyons, 1991). Friends and family support positively impacts self-management efforts of individuals with diabetes by providing emotional and instrumental support to help them adhere to a self-care regimen (Toljamo & Hentinen, 2001).

Social support positively influences various aspects of diabetes self-management. It improves the individual's knowledge, awareness, and understanding of the disease and its complications (Jennings et al., 1987; Maxwell et al., 1992; Zrebiec & Jacobson, 2001). It facilitates patient engagement in self-care (Orem, 1995), and also improves adherence to treatment plans and compliance with self-care activities for patients with diabetes (Garay-Sevilla et al., 1995; Oren et al, 1996; Tillotson & Smith, 1996; Robison, 1993; Toljamo & Hentinen, 2001), for weight control (Wierenga, 1994), and for women with gestational diabetes (Ruggiero et al., 1990). Thus, social support eventually yields positive clinical and psychosocial outcomes (Fukunishi et al., 1998; Maxwell et al., 1992; Oren et al, 1996; Robison, 1993; Zrebiec & Jacobson, 2001) and reduces the risk of diabetes complications and deaths (Zhang et al., 2007). Testing a contextualecological model of factors relevant for glycaemic control in patients with diabetes mellitus, Brody et al (2008), found that psychological functioning among adults with diabetes and support persons was associated with the instrumental and emotional support they received from their support persons for diabetes self-management. Support, in turn, was linked indirectly with glycaemic control through encouragement of glucose monitoring (Brody et al., 2008).

In other studies where self-efficacy was included, it was found that when the effects of self-efficacy were controlled for, social support was no longer a significant independent predictor of self-care. Thus, self-efficacy plays the role of a mediator between social support and self-management (Williams & Bond, 2002). In addition (Skinner & Hampson, 1998), found that family support was a significant predictor of all self-management activities; however for dietary self-management this relationship was partially mediated by the perceived efficacy of treatment to control diabetes. These results concur with the assumption of self-efficacy theory that social support is one of the environmental factors that influence the development of self-efficacy (Bandura, 1986), which in turn improve self-management as it was illustrated previously. Self-efficacy was also found to be a mediating variable for the relationship between non supportive parental behaviours and adherence to blood glucose monitoring for adolescents with type 1 diabetes mellitus (Ott et al., 2000).

The role of self-efficacy as a mediator between social support and self management in other chronic illnesses and health prevention measures has been investigated in several studies. It was found that self-efficacy partially mediated the relationship between family social influence and physical activity, with self-efficacy mediating 36.4% of the total effect (Shields et al., 2008). Self-efficacy perceptions mediated the relationships between social support and both trauma and general distress (Benight et al., 1999). It also served as a mediator in the influence of social support on exercise behaviours to improve health and well-being (Duncan & McAuley, 1993). Similarly it mediated the influence of family support on preventive behaviour of patients with osteoporosis (levers-Landis et al., 2003), and on adherence to treatment regimen for patients with acquired immune deficiency syndrome (AIDS) (Simoni et al., 2002). In summary social support play an important role in improving self-management activities of patients with type 2 diabetes mellitus. Thus, social support has a positive effect on self-management. However this effect may be mediated by the positive effect of self-efficacy on self-management (research hypothesis 8). Figure 3.4 illustrates these relationships.

Figure 3-4: The relationship between social support, self-efficacy and self-management



## 3.6 Patient-Provider Communication

Patients with diabetes play a crucial role in managing their disease by self-monitoring and adhering to treatment regimen as prescribed by health professionals. This process requires setting goals and improving problem solving skills (Glasgow & Anderson, 1999; Anderson & Funnell, 2000; Griffin, 2001). Therefore it is extremely important that health professionals help their patients to identify reasonable goals for behaviour

change that they can achieve and encourage them to maintain these changes for long time to avoid emotional burnout (Hoover, 1983; Charman, 2000). The process of interaction between health professionals and patients is referred to as patient-provider communication. It involves listening, asking questions, explaining information, showing respect for patient concerns, and more importantly sharing goal setting and decision making (Ong et al., 1995).

Ong et al. (1995) identified three different purposes of communications. The first purpose is creating a good inter-personal relationship; which is an important purpose of communication especially for care of long-term conditions. Having a good relationship was viewed by some researchers as meaning having a good "bedside manner", for example making personal remarks, giving patients compliments, conveying interest, friendliness, honesty, a desire to help, devotion, a non-judgemental attitude and a social orientation, however other researchers consider that the importance of a good relationship between patients and their physicians is determined by the therapeutic qualities (Irwin et al., 1989). The second purpose was the exchange of information; which includes information giving and information seeking (Ong et al., 1995). The third purpose was medical decision-making; traditionally the ideal patient-physician relationship was paternalistic: physicians direct care and make decisions about treatment; however this approach has shifted in the last few decades toward shared decision-making (Brock & Wartman, 1990; Siminoff & Fetting, 1991).

Effective patient-provider communication is often associated with better self-management and improved outcomes. Stewart (1995) reviewed the literature to assess the effect of patient-physician communication on a patient's emotional health, symptom resolution, function, physiological measures (blood pressure and blood sugar level) and pain control in different medical conditions. The results of this review reported that 16 studies out of 21 showed positive relationships, 4 showed no significant negative relationships, and one study was inconclusive. The review also found that positive provider interactions may promote greater adherence self-efficacy, which is associated with better compliance with medications for patients with acquired immune deficiency syndrome (Johnson et al., 2006). Specifically for chronic conditions, Kaplan et al. (1989) assessed the effect of patient-physician interactions on the outcomes of chronic diseases; the results reported that better health and better behaviour were consistently related to specific aspects of patient-physician communication.

For patients with diabetes patient-provider communication is even more important, due to the complexity of the patients' role in managing their disease, especially when

diabetes is associated with other co-morbid conditions such as hypertension and dyslipidaemia (a condition characterised by abnormal levels of lipids and lipoproteins in the blood). The importance of this communication is to assist patients to develop their understanding of their role to manage diabetes, help them to cope with the illness, and participate in decision making related to goal setting and behaviour change. Several studies supported the importance of positive communication to improve diabetes self-care; for example, Piette et al. (2003) identified two dimensions of providers' communication, general and diabetes-specific. When they measured patients' assessments of the two dimensions against self-reported foot care, and adherence to hypoglycaemic medications, dietary regimen, and exercise, they found that general and diabetes-specific communication reports were only moderately correlated but both dimensions of communication were independently associated with self-management (Piette et al., 2003).

Similarly Heisler et al. (2007) found that both dimensions of communication, providers' provision of information and efforts to actively involve patients in treatment decision-making, were associated with better overall diabetes self-management. Providing information on foot care and taking medications was more important than sharing decisions, however sharing decisions was more important for glucose monitoring, diet and exercise (Heisler et al., 2007). It was also found that communication with health care providers, knowledge of diabetes, and the consequences of poor glycaemic control were the three major themes affecting adherence to treatment regimen among which appropriate communication was the most important factor (Matthews et al., 2009).

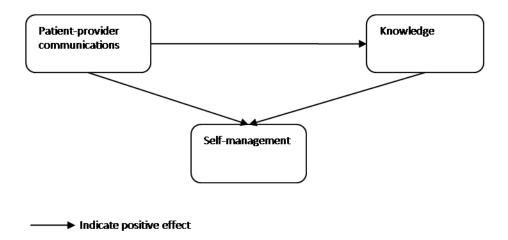
In another study Maddigan et al. (2005) found that positive perceptions of the patient-provider relationship had a significant direct impact on adherence to diet, exercise, and diabetes management attitudes. The direct path from management attitudes to exercise was also significant. They concluded that patient-provider relationship and exercise adherence appeared to be key constructs in the model. Health related quality of life in people with type 2 diabetes was positively associated with exercise adherence, which was related to a positive communication between patient and health professionals. Adherence to diet was also related to a positive patient-provider communication (Maddigan et al., 2005).

On the other hand, Golin et al. (1996) introduced a model for the determinants of adherence to diabetes self-care that include the effects of patient participation in medical decision making. In this model, they suggest three ways that patient participation can affect adherence to self-care: 1) it may have a direct effect; 2) it may

affect adherence to self-care indirectly by affecting patients' understanding of their treatment regimen (knowledge), and 3) perceived omissions of participation can affect adherence to self-care indirectly through an effect on patient satisfaction. Similarly Heisler et al. (2002) investigated the relevance importance of physician communication, participatory decision making, and patient understanding in diabetes self-management; they found that higher scores in provider decision making style and provider communication were each associated with higher self-management assessments. When modelled together, provider communication remained a significant independent predictor of self-management but provider decision making style became not significant. However when they added understanding (knowledge) to the model, it diminished the unique effect of provider communication in predicting self-management. Thus, understanding (knowledge) was strongly and independently associated with self-management (Heisler et al., 2002). These results indicate the importance of diabetes knowledge in explaining the effect of positive patients-provider communication on diabetes self-management.

In summary, effective patient- provider-communication positively influenced diabetes self-management; however this improvement may be explained by the improvement in diabetes knowledge as a result of effective communication. Thus, patient-provider communication has a positive effect on self-management; however this relationship may be mediated by the positive effect of diabetes knowledge on diabetes self-management (research hypothesis 9). Figure 3.5 illustrates these relationships.

Figure 3-5: The relationship between patient-provider communication, knowledge and self-management



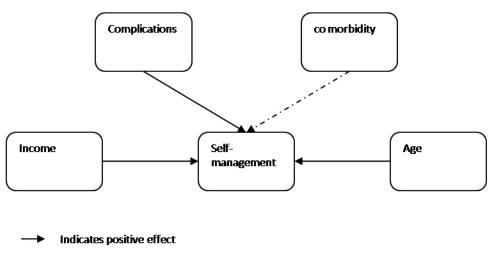
## 3.7 Demographic and Disease Related Factors

In addition to the above mentioned factors that affect diabetes self-management, there are also other demographic, socio-economic and clinical factors that influence the ability and willingness of patients to effectively engage in self-management activities. It was found that age and income play an important role in determining the level of engagement where older and higher income patients tend to adhere to treatment regimen better than younger and lower income patients (Glasgow, et al., 2001).

On the other hand the severity of the disease indicated by complications and co morbidity (other chronic conditions with diabetes) also play a role in determining their level of engagement. It was found that comorbidity plays a negative role, where patients who have more than one chronic condition find it difficult to adhere to the treatment regimen of different diseases (Kerr et al., 2007) whereas when the complications of diabetes appear, patients tend to adhere better to the treatment regimen (Kravitz, et al,1993).

Thus, age has a positive effect on self-management (research hypothesis 10), income has a positive effect on diabetes self-management (research hypothesis 11), co morbidity has a negative effect on diabetes self-management (research hypothesis 12), and diabetes complications have a positive effect on diabetes self-management (research hypothesis 13). Figure 3.6 illustrates these relationships.

Figure 3-6: Demographic and disease related factors influencing self-management

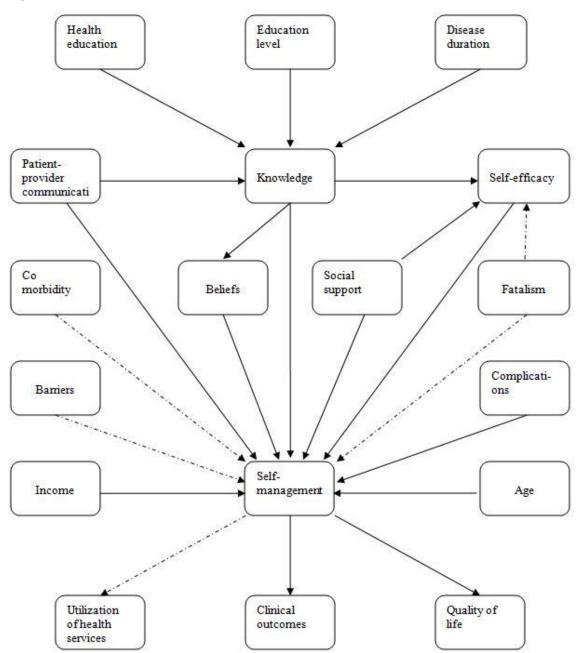


- · ▶ Indicates negative effect

In addition to these factors that influence patients ability and willingness to perform self-management activities, there are usually barriers that prevent or reduce efficient participation of patients in these activities. Wdowik et al. (1997) conducted a qualitative research to identify these barriers. The findings of their study suggest two different types of barriers. Firstly, personal barriers including stress, financial problems, diet management constraints, time management, and hypoglycaemic reactions. The other type was psychosocial barriers which were grouped into three categories; issues related to social support, issues related to motivators, and issues related to inconveniences of diabetes management. It was also found that barriers to appropriate self-care increase when patients suffer more than one chronic condition (Bayliss et al., 2003). These barriers have negative effects on diabetes self-management, therefore it is essential to incorporate any possible barriers in self-management education programmes to assist patients in expecting and dealing with these barriers.

Considering the clinical, socio-economic, and psychosocial outcomes of self-management, the factors that influence self-management, and the factors that influence patients' knowledge, it becomes possible to evaluate patients-related aspects of self-management programmes. Figure 3.7 illustrates the proposed model for evaluating self-management programmes.

Figure 3-7: Research model



- → Indicates a positive effect
- · · → Indicates a negative effect

Figure 3.7 shows the integrated model for evaluating self-management programmes. It provides a comprehensive framework relevant to cover most aspects related to patients involved in these programmes. This model is unique in that it does not only show the outcomes that most clinicians are concern about, but also shows the underlying factors behind these outcomes. It is also unique in that it shows how these factors are related to each other for the purpose of providing a clear picture to find areas where improvements are needed and ways for achieving these improvements. For example if self-efficacy was found to be a problem that prevents some patients from taking the required actions, we can use the model to find that we need to improve their knowledge and to enhance the level of social support provided to these patients.

In health behaviour research, studies usually focus on the factors that influence self-management, whereas in health education research, studies usually focus on methods for improving patients' knowledge to produce optimum improvements in their behaviour or optimum outcomes. However, this research is the first one that combines all these factors together to enhance patients' knowledge, behaviour, and ultimately to improve the outcomes of care. This combination enables us to use the model as an evaluation tool, and evaluation per say is one of the most important functions of management. Therefore clinicians, health mangers, and decision makers could all use the model for different purposes.

This model is intended to be used to evaluate diabetes self-management programmes in Saudi Arabia where 100% of citizens are Muslims. Therefore it was essential to include in the model one of the important factors that we argue has an important effect on patients' willing to self-manage their condition. Considering this factor that has not been investigated before also add to the integrated nature of this model in an attempt to consider all possible factors that may influence patients' ability to do the required actions to manage their disease.

# **Chapter 4: Methodology**

This chapter aims to show in detail the methodological approach used for this research and the justification for adopting the research methodology. It also defines the research methods and the process of data collection in addition to data management and analysis.

### 4.1 Introduction

Diabetes self-management programmes have been providing sophisticated diabetes care to the Saudi population since the early 1990s. These programmes have been successful in introducing a new concept in diabetes care. However, there is not sufficient data to assess the effectiveness of these programmes as a cost containment strategy or to assess their effectiveness in providing high quality diabetes care. The aim of this research is to present a framework for the evaluation of self-management programmes. The evaluation model was built on a patient-related intervention. The effectiveness of these interventions is affected by levels of patient engagement and effective participation. Thus studying factors that influence patient compliance with self-management activities was crucial to explain the outcomes of these interventions.

Most evaluation studies (see table 3.1) used experimental designs, specifically randomised control trials (RCT), in order to eliminate bias and spurious causality. RCTs are considered to be the most reliable form of scientific evidence (Lachin, 1988). To evaluate the effectiveness of diabetes self-management programmes in a randomised trial, eligible participants are assigned at random either to an intervention group or to a control group. While the control group uses the existing services as if the programme does not exist, the intervention group is engaged into a defined programme for evaluation.

The second common type of research is the quasi-experimental design, specifically a "before and after" design where outcomes are measured on participants before the programme is implemented and after the implementation of the programme (Babbie, 2007). In this type of research, the researcher usually measures certain parameters before an intervention and then after the intervention. The difference between these measurements is taken to be the impact of the intervention. Research based on similar assumptions takes the position that holds that the goal of knowledge is simply to describe the phenomena that we experience (Clark, et al, 2007).

According to Rubin and Rubin (2005), a paradigm can be defined as an ideological stance or a system of beliefs about the nature of the world, and eventually when applied to research, a paradigm is the assumptive base from which knowledge is produced. Therefore the researcher's paradigmatic position is determined by her/his understanding of the nature of knowledge and realty (Broom & Willis, 2007). Philosophically, researchers make claims about the nature of knowledge which is referred to as epistemology, and claims about reality which is referred to as ontology, but the practical process for studying these claims is known as methodology (Creswell, 2002).

There are two main research paradigms or philosophies; these are the positivism and the phenomenological or what is called interpretivism. They can be considered as the two extremes of a continuum along which the features and assumptions of one paradigm are replaced by the other (Collis & Hussey, 2003). These assumptions include epistemological assumption about the relationship between the researcher and what is being researched, ontological assumptions about the nature of reality, axiological assumptions about the role of values, and methodological assumptions about the process of research (Creswell, 2002).

In application to social science research, positivism argues that the methods of inquiry for natural sciences are applicable to social sciences, and separates the values of the social actors from the facts that are found by this inquiry (Williams & May, 2000). To maintain an objective stance, positivists believe that only phenomena that can be observed and measured can be regarded as knowledge (Collis & Hussey, 2003). This belief reflects the broad tradition of thought that reality is constant and exists whether we are conscious about it or not (Giddens, 1987). Different quantitative methods have emerged from this research paradigm including retrospective cohort, cross-sectional designs, and experimental designs, and randomized control trials which are very common in health research (Broom& Willis, 2007). The main characteristics of this type of research are the focus of deduction, confirmation, theory testing, explanation, prediction, standardised data collection, and statistical analysis (Johnson & Onwuegbuzie, 2004).

On the other hand, phenomenologists argue that reality is constructed rather than being constant and could not be objectively measured, as individuals construct their own reality by associating meaning with certain events or actions (Bryman, 2001). They minimize the distance between the researcher and what is being researched by different forms of participative inquiries, assuming that researchers have values that affect what is recognized as a fact (Collis & Hussey, 2003). Different qualitative

methods have emerged from the phenomenological research paradigm including indepth, semi structured or unstructured interviews, focus groups, and observations (Broom& Willis, 2007). The main characteristics of this type of research are the focus on induction, discovery, exploration, theory generation, and qualitative analysis (Johnson & Onwuegbuzie, 2004).

However, many researchers use a different class where the researcher mixes or combines qualitative and quantitative research approaches, methods, or concepts into one single study. This approach move beyond the paradigm debate offering a logical and practical alternative based on inquiries that include induction (discovery of pattern), deduction (testing of theories), or abduction (uncovering and relying on best explanation for results). Thus it helps to bridge a schism between qualitative and quantitative research approaches (Onwuegbuzie & Leech, 2004).

According to Green et al. (1989) mixed methods serve different purposes; *triangulation* where the consistency of findings are tested using different instruments, *complementarity* where the results of one method are clarified by using another method, *development* where the subsequent methods of the research process are shaped by the results of the other method, *initiation* where the results obtained by one method stimulate new research questions or challenges, and *expansion* where richness and detail is added to the study by exploring specific features of each method (Green et al., 1989).

For this particular study, neither the positivist nor the interpretivist approaches would serve our research purpose. Research based on the positivist approach assumes that a specific programme has improved patient behaviours and outcomes regardless of cultural and demographic differences between patients. This approach also considers a programme as a standardized and fixed intervention that is applied to inactive individuals (Clark, et al, 2007). Therefore such an approach usually fails to explain the variations in the outcomes of these programmes. It also fails to explain how different elements of the programme affect a specific behaviour or a desired outcome (Clark, et al, 2007). These methodological issues reflect the philosophical tenet of positivism, which emphasize the focus on observable phenomena and poorly conceptualize the social and individual context. It also reflects the assumption that individuals are rational decision makers who need to gain knowledge about their disease to change their behaviour accordingly, whereas human behaviour is more complex than this assumption (Clark, et al, 2007).

On the other hand, in the extreme view of interpretivism, reality is considered to be determined by an individual's mind. This assumption contradicts the nature of medical disciplines, whose main goals are to eliminate disease and injuries that have a reality beyond individual's beliefs and perceptions (William, 2003). Although an interpretivist approach could clearly view the content of self-management programmes through the perspective of individuals, it cannot offer any meaningful way to measure the impact of these programmes. In addition this approach does not account for the scientific evidence-based support for self-management programmes (Clark, et al, 2007). This assumption cannot be accepted mainly because accepting it means that the inherited knowledge that can be used for improving diabetes care is very limited.

Therefore, knowledge claims for this specific inquiry involve that absolute truth cannot be achieved especially when people's beliefs, perceptions and attitudes are involved, but claims to truth can be compared and discussed on a rational basis to identify what can be considered as truth (Bhaskar, 1998). This is the basic assumption of one of the most common post positivism philosophies, which is critical realism. This philosophy was developed in response to the limitation of positivism and interpretivism (Clark, et al, 2007).

While recognizing that it is not possible to be positive about claims when studying human behaviour, realist philosophy reflects a deterministic approach (Creswell, 2002), where cause and effect relationships are identified, but it also considers underlying factors that may explain these relationships. Thus, similar to the construction of the model in this study, research outcomes are extended beyond behavioural change and biological measures towards process-focused factors (Archer & Tritter, 2000). It also reflects a reductionist approach in that a broad concept such as self-management is reduced into a variable that can be measured and tested based on a deductive approach where theories can be tested (Creswell, 2002).

According to Clark et al. (2007), critical realism assumes that various objects, structures, and practices that make up reality, exist independently of whether their existence is understood or observed; therefore it is crucial to differentiate between experience and research inquiry which are both fallible and socially specific phenomena. It also posits that phenomena operate in open systems; therefore several factors can affect human behaviour and programme outcomes. This approach examines the complexity of these systems in order to understand, realize and optimise outcomes by not only exploring what works for whom but also when and why (Clark, et al, 2007). Therefore researchers should use different methodological approaches using

quantitative and qualitative methods as necessary to examine such complex systems (Sayer, 2000).

Thus for this study a cross-sectional survey was designed to collect quantitative data by using a self-administered questionnaire. Closed-ended questions were used to measure most of the study variables that contributed to the construction of the model. The responses to these questions are amenable to statistical analysis to test the model, which includes both systemic and individual factors. However, one open-ended question was included in the questionnaire to generate qualitative data about personal barriers to compliance with diabetes self-management activities. This question serves the purpose of triangulation, in that any information arising either explicitly or implicitly can fit in the model, and can be considered as a support to the model. Alternatively, emergent issues may appear that can be considered to extend or modify the model, or to make suggestions for future research. The methodological contribution of this research is the use of the positivist approach to investigate the outcomes of diabetes self-management programmes with notable consideration of the humanistic underlying factors behind these outcomes.

## 4.2 Research Design and Method

A non-experimental retrospective cross-sectional survey research design has been employed to conduct this research using a self-administered questionnaire. Experimental and quasi-experimental designs are not suitable for the nature of this research, mainly due to the focus of this research on human behaviour which is not subject to experimental manipulation or randomisation. A survey can be defined as a research method in which a sample of subjects is drawn from a population and asked to answer questions that can be used to make inferences about the whole population. This research is a retrospective or (ex post facto) because it involves asking respondents questions about things which happened in the past, relating to their behaviour and their disease history. It also involves questioning them about their current attitudes and beliefs which may have influenced that behaviour or specific disease outcomes.

A cross-sectional survey is one of the most common research methods used in the social sciences (Babbie, 2007). When the survey's data collection tool is administered at one point of time or short period of time and only once to a specified sample of respondents, it is referred to as a cross-sectional study (Nardi, 2006). Similar to the purpose of this research, it can be used to describe a phenomenon of interest and analyse associations between variables to estimate specific population parameters

(Bowling, 2005). Although this type of research design has limitations if it is used to infer causality, mainly because of the difficulty to define the directions of the cause and the effect (Calnan, 2007), however, using well established theoretical bases, and the increasing sophistication of statistical techniques made it possible to overcome such limitations (Bowling, 2005).

According to Kate (2006), using a cross-sectional survey has many advantages especially when compared to longitudinal studies. It takes relatively little time to be conducted and also cost less than other types of research. Cross-sectional surveys can provide good estimates of the outcome(s) of interest, if an appropriate sample from the whole population is used. It also avoids loss to follow-up and provides useful information for health planning, understanding disease aetiology and prognosis, testing and generating research hypotheses (Kate, 2006).

This study can be categorised as an evaluation study, where according to Babbie (2007), evaluation is the process of determining whether an intervention has produced the intended results. As the research model suggests, the intervention is self-management and the results are improving clinical outcomes and quality of life of patients and reducing the cost of health services.

### 4.3 Research Instrument

For the purpose of collecting data, a widely used tool for collecting survey data was used. The self-administered questionnaire is a very popular tool for data collection because it allows covering a large number of respondents (even if they are spread over different regions) in shorter times and at less cost than any other method (Babbie, 2007). A questionnaire can be defined as a set of questions presented on a form to be completed by respondents (persons who are asked these questions) in respect of a research project (Bryman 1988). A questionnaire is self-administered when respondents are asked to complete it on their own.

According to Nardi (2006), a self-administered questionnaire is a good tool for data collection when measuring variables with several different values of response categories that would take a long time to be read in interviews and phone surveys. It is also more suitable for measuring sensitive information that might be difficult to be expressed by respondents face to face. Therefore it allows respondents to be more candid about the information they provide. It also allows measuring unobservable phenomena such as beliefs and attitudes from a large sample of respondents (Nardi 2006).

To guide the empirical study of this research, a structured questionnaire was designed. Closed-ended questions were used to measure most study variables; the response categories for most questions were determined in advance. Closed-ended questions do not provide as much data compared to open-ended questions. However they are easier and quicker to complete by respondents, and are also easier for coding and analysis. Closed-ended questions were used to measure most of the variables involved in the construction of the research model. However one open-ended question was used to generate qualitative data regarding barriers to diabetes self-management.

### 4.3.1 Measurement and Coding of Study Variables

The purpose of this section is to move from concepts of study variables that have been conceptualised and discussed in details in chapter 2 and chapter 3 of this thesis, into more specific research procedures that will lead to empirical observations to represent these concepts in the real world. This process is called Operationalization (Babbie, 2007). Operationalization is the process of finding the best empirical counterpart for a specific concept (Ruane, 2005), through which the abstract concepts are translated into concrete measurable variables.

### **Self-management**

Self-management is the core concept of this research. The concept has been discussed in details in chapter two of this thesis. One of the basic aspects of self management is the actual activities performed by patients or self-care activities. In application to diabetes these activities as shown earlier in chapter three, involve five important activities (diet, exercise, taking medications, self-monitoring of blood glucose, and foot care) that are usually recommended by health providers for the optimum care for people with type 2 diabetes mellitus.

For the purpose of measuring self-care, patients were asked about their performance in complying with these five activities during the last seven days. This measure was adopted and modified from the famous Summary of Diabetes Self-Care Activities (SDSCA). This measure was introduced by Toobert et al (2000) with demonstrated validity and reliability.

These five activities are diet, taking medications as prescribed, exercise, self-monitoring of blood glucose, and foot care. Therefore the questions used to measure self-care activities were as follow:

- On how many of the last seven days have you followed your diabetes diet as it was recommended?
- On how many of the last seven days have you taken your medications as they were prescribed by your physician?
- On how many of the last seven days have you participated in at least 30 minutes of physical exercise?
- On how many of the last seven days have you tested your blood sugar by yourself?
- On how many of the last seven days did you check and take care of your feet?

Respondents have the chance to tick on the box corresponding to each question, ranging from zero if they have not complied on any day, up to 7 if they complied every single day. The answers were coded according to the number of days of compliance for each of these activities.

#### **Clinical Outcomes**

One of the most useful measures in diabetes research is the glycosylated haemoglobin (HbA1C). This laboratory test has become established as the monitoring test of choice to evaluate medium term control of diabetes (Reynolds, et al, 2006). This measure was introduced in the early 1980s and has contributed significantly to appropriate management of diabetes (Kilpatrick, 2004). HbA1C shows the average level of glucose in the blood in the last two to three months, which is the lifespan of the red blood cells (Kilpatrick, 2004). Therefore it gives a reliable measure of blood glucose over a long period of time (Goldstein, et al, 1986).

In the United Kingdom, the recommended target for HbA1C is between 6.5 to 7.5%, aiming toward the lower end if patients are at risk of developing macrovascular diseases (Kilpatrick, 2004). The required target in the United States and in Saudi Arabia is 7% or less as recommended by The American Diabetes Association (ADA, 2000) and (Akbar, 2001) respectively.

HbA1C has been used in several studies as a measure of diabetes control, for example the United Kingdom Prospective Diabetes Study (UKPDS, 1988) and the Diabetes Control and Complication Trial (DCCT, 1993). In this research, HbA1c was used to assess diabetes control as an outcome of diabetes self-management. It is the only measure in the research questionnaire that is not reported by patients, as a registered

nurse was assigned in each centre to record the result of this lab test on the top of the questionnaire as it appears in appendix B.

#### **Quality of Life Scale**

Measuring quality of life as an outcome of health interventions has become a matter of great importance, mainly to ensure that the focus of interventions is on patients rather than on diseases (Higginson & Carr, 2001). Therefore the heart of this measure is to capture the personal and social aspects of a patient's life. Although it is crucial to consider these aspects, numerical measurement of quality of life is not widely used in clinical practice (Carr, et al, 1996). Furthermore, even if it was used, it does not affect clinical decision making in practice (Higginson & Carr, 2001).

In application to diabetes, the measure aims to assess people's perception of the impact of diabetes on their quality of life. Therefore various aspects of the personal and social lives of respondents were considered. These aspects were adopted and modified from the individualized questionnaire measure of the perceived impact of diabetes on quality of life. This questionnaire was developed by Bradley et al. (1999). A scale of five statements on a Likert scale was used to measure this variable.

According to Dawes (2008), the Likert Scale is named after the inventor Rensis Likert in 1931. It is widely used in surveys when researchers attempt to measure constructs that cannot be measured directly such as perceptions, attitude and beliefs. Therefore, a multi-item scale is developed to measure the construct of interest. Participants will need to respond for each statement by checking one of the usually five specified response categories. The most common response categories are strongly agree, agree, neutral, disagree, and strongly disagree. When the items are summed together it is called a Likert scale but if they are dealt with separately they are called Likert items (Dawes, 2008).

For the purpose of measuring the quality of life in this research, the following five statements were used:

- If I do not have diabetes, my employment/ career opportunities would be
- If I do not have diabetes, my social relationships would be
- If I do not have diabetes, my sex life would be
- If I do not have diabetes, my sporting holiday/ leisure opportunities would be
- If I do not have diabetes, my future hopes and expectations would be

The response categories for each of these statements were as follow:

- A great deal better, this response category was coded 1.
- Better, this response category was coded 2.
- The same, this response category was coded 3.
- Worse, this response category was coded 4.
- A great deal worse, this response category was coded 5.

As the codes indicate, the higher the value for each item, and ultimately for the summative scale, the better the quality of life for respondents.

#### Utilization of Health Services

In addition to improving the clinical outcomes for people with diabetes, one of the primary objectives of self-management programmes is to reduce the cost of health services. Therefore it is crucial to assess the effect of this approach on the cost of health services. In health systems where medical services are based on insurance, researchers normally assess the cost in monetary terms, usually by referring to claims from insurance companies for those enrolled in a self-management programme and comparing it to the claims of those who are not enrolled in that specific programme. However this common approach is not feasible to be applied in this research, because health services are provided free for all citizens in Saudi Arabia through direct government expenditure.

An alternative approach is to measure the effect of the programme on utilization of health services. This approach is based on the assumption that people with type 2 diabetes who are actively participating in self-management programmes are less likely to visit emergency rooms and are less likely to be admitted to hospital for diabetes and diabetes-related problems. This approach has been used in several studies to investigate the effect of self-management on cost reduction. For example Lorig et al. (2001) investigated the affect of self-management programmes of some chronic conditions on utilization of health services using emergency visits, outpatient visits, number of times hospitalised, and number of days in hospital.

To measure utilization of health services, three aspects were considered; emergency visits, number of admissions and length of stay. In the research questionnaire respondents were asked if they have visited the emergency room in any hospital for diabetes or diabetes related problems in the last 12 months. The response categories for this question were (yes) and (no). Those who answered yes (Yes), were asked a secondary question about the number of times they visited the emergency room. If the

answer was (no), it was coded 0, and if the answer was (yes), the response for the secondary question is recorded.

Another question asked respondents if they had been admitted to any hospital for diabetes or diabetes related problems in the last 12 months. The response categories for this question were (yes) and (no). For those who answered (yes) to this question, two secondary questions were asked; the number of admissions and the length of stay in the hospital(s) for all these admissions, in days. If the answer was no, it was coded 0, and if the answer was yes, the responses for the secondary questions were recorded. Therefore the utilization of health services was measured using the number of admissions x (length of stay per admission) + Number of emergency visits.

### **Self-Efficacy Scale**

Self-efficacy reflects the level of confidence of a person in her/his ability to perform a task (Bandura, 1977). The required task in this study is the set of self-management activities described earlier in this chapter. Therefore the purpose of this measure is to assess the level of confidence of people with type 2 diabetes mellitus to perform self-management activities (diet, exercise, taking medications, self-monitoring of blood sugar, and foot care).

Bijl et al. (1999) developed a scale to measure the level of self-efficacy for patients with type 2 diabetes mellitus. This scale assesses the belief of patients in their ability to execute a required course of action. With an internal consistency for the 20 scale items of alpha= .81 and test retest reliability of r=.79(p less than .001), the scale was considered valid and reliable. This scale was summarised and modified by using six Likert items to measure self-efficacy as following:

- Do you think you are able to check your blood glucose by yourself?
- Do you think you can follow your recommended diet most of the time?
- Do you think you can follow your recommended diet while dinning outside in occasions?
- Do you think you are able to examine and take care of your feet?
- Do you think you are able to do physical exercise on regular bases?
- Do you think you are able to take your medications as prescribed?

This response category for these questions were as follow:

- Yes definitely, this response category was coded 5
- Probably yes, this response category was coded 4

- May be yes may be no, this response category was coded 3
- Probably no, this response category was coded 2
- Definitely no, this response category was coded 1

As these codes indicate the higher the value for each item, and ultimately for the whole scale reflects better confidence of patients for their ability to perform self-management activities.

#### **Patients Beliefs Scale**

According to the health belief model, patients should believe that they are susceptible to a particular threat, and that this threat is serious enough to be avoided (Aalto and Uutela, 1997). They should also believe that the required action will lead to avoiding the threat and that the perceived benefits would outweigh the barriers that prevent them from taking the required action. Therefore the basic component of the health beliefs model is that patients should believe that the required action will lead to the desired outcome.

In application to diabetes, the threat is uncontrolled blood glucose that may lead to serious complications and the required actions are self-management activities. The aim of this measure is to assess the importance of self-management activities specifically (diet, exercise, self-monitoring of blood glucose) in controlling the level of glucose in the blood. It also aims to assess the importance of all these activities in addition to foot care to prevent future complications of diabetes.

The following nine Likert items were used to measure patients' beliefs:

- Following diabetes diet is important to control the level of blood glucose
- Following diabetes diet is important to prevent diabetes complications
- Doing physical exercise is important to control the level of blood glucose
- Doing physical exercise is important to prevent diabetes complications
- Self-monitoring of blood glucose is important to control its level in the blood
- Self-monitoring of blood glucose is important to prevent diabetes complications
- Taking medications as prescribed is important to control the level of blood glucose
- Taking medications as prescribed is important to prevent diabetes complications
- Checking and taking care of your foot is important to prevent diabetes complications

The response categories for these statements were as follow:

- Strongly disagree, this response category was coded 1
- Disagree, this response category was coded 2
- Not sure, this response category was coded 3
- · Agree, this response category was coded 4
- · Strongly agree, this response category was coded 5

These codes indicate that the higher the value for each item and ultimately for the whole scale, the stronger the belief that the required action will lead to the desired outcome.

#### **Fatalism Scale**

Fatalism is one of the basic pillars of faith in Islam (Al-Ashgar, 2005). It basically reflects the belief that future events are predetermined by Allah and all Muslims should accept what Allah has planned for them. However Muslim as clearly stated by Prophet Mohammad (peace be upon him) should always take all necessary precautions and do every possible effort to maintain their well being. Therefore it was crucial to distinguish between the absolute belief and that the belief does not hinder the necessary actions.

Six items were developed to measure this variable; the first three statements consider the absolute belief without including actions and the last three statements include a specific action to be taken in each item as follow:

- All believers should accept whatever Allah has meant for them.
- Whatever illness I will have, Allah has already planned it.
- Whatever future complications result from my disease is definitely happening.
- I do not need to try to improve my health because I know it is up to Allah to improve it.
- When I am sick I give my burdens to Allah without doctors having to do anything.
- If Allah wants me to have a good health in the future that will happen without having to take care of myself.

The response category for these statement were as follow:

- Strongly agree, this response category was coded 5
- Agree, this response category was coded 4
- Do not know, this response category was coded 3
- Disagree, this response category was coded 2
- Strongly disagree, this response category was coded 1

These codes indicate that the higher the values for the first three items, the stronger the belief is. However for the last three items higher values reflects higher level of misconception of fatalism.

### Social Support Scale

Social support is a multidimensional concept (Goodall, 1991). To assess social support for chronic illnesses, Glasgow et al. (2000), developed a scale to measure different segments of support; support from doctors and health care team, from family and friends, personal support, from neighbourhood, from community, from media and policy, and from community organisations. From these segments, support from family and friend was the most appropriate type of support to meet the purpose of this research in terms of applicability.

The overall instrument, and subscales, had in general moderate to high test-retest reliability, acceptable internal consistency, good construct validity, and moderate concurrent and prospective criterion validity (Glasgow, et al, 2000). This scale was shortened and modified to suit diabetes and used to assess the level of social support for self-management of patients with type 2 diabetes mellitus. Five Likert items were used to measure this variable as follow:

- To what extent have your family and friends listened carefully for what you had to say about your illness?
- To what extent have your family and friends encouraged you to commit to your treatment plan?
- To what extent have your family and friends bought and cooked food that suits your diet?
- To what extent have your family and friends praised you for your commitment to your treatment plan?
- To what extent have your family and friends reminded you to take your medications on time?

The response categories for these questions were as follow:

- Not at all, this response category was coded 1
- A little, this response category was coded 2
- A moderate amount, this response category was coded 3
- A lot, this response category was coded 4
- A great deal, this response category was coded 5

These codes indicate that the higher the values for each question and ultimately for the whole scale, the higher the level of social support.

#### Patients-Providers communications scale

Appropriate communication between patients and providers of health services is essential in the management of chronic conditions including diabetes (Ong et al. (1995). Through appropriate communication, clinicians provide their patients with the necessary information and encouragement they need to cope and manage their conditions. Therefore it was crucial to assess the perception of individuals regarding the communication process.

Stewart et al. (1999) developed the interpersonal processes of care questionnaire (IPC) that was designed to assess different aspects of patients-provider communication such as explanation of the condition, necessity of required tests, and disease prognosis. This measure was shortened and modified to suit diabetes to evaluate the level of communication between patients and providers. Five Likert items were used to measure this variable as follow:

- How often did your doctor talk to you using medical terms that you do not understand?
- How often did your doctor listen carefully to what you had to say about your medical problems?
- How often did your doctor answer your questions and concerns about diabetes?
- How often did your doctor explain why a test was being done and what were the results?
- How often did your doctor explain to you how to take your medications?

The response categories for these questions were as follow:

- Never, this response category was coded 1 except for the first question it was coded 5
- Rarely, this response category was coded 2 except for the first question it was coded 4
- Sometimes, this response category was coded 3
- Often, this response category was coded 4 except for the first question it was coded 2
- Always, this response category was coded 5 except for the first question it was coded 1

These codes indicate the higher the value for each question and ultimately for the whole scale, the better the communication between patients and providers.

#### Measuring diabetes Knowledge

The assessment of diabetes-related knowledge is essential for appropriate evaluation of diabetes management. It is also an important tool to evaluate the outcome of diabetes education programmes. Diabetes knowledge refers to the ability of patients with diabetes to understand relevant information to their condition including diet, exercise, self-monitoring of blood glucose, taking medications and foot care.

The Michigan Diabetes Research centre (MDRC) developed a series of valid and reliable tests for diabetes knowledge that can be used by researchers to assess the ability of patients with diabetes to understand information relevant to their condition. The original test contains 23 questions, but it was shortened to ten questions and modified to suit the Saudi culture. Patients were asked to select the right answer for each of the ten multiple choice questions. These questions are:

- 1) Which of the following is high in carbohydrates:
  - a) Baked chicken
  - b)Swiss cheese
  - c) Baked potato
  - d)I don't know

The correct answer (c) was coded 1, and all other answers were coded 0

- 2) Eating food lowers in fat decreases your risk for:
  - a) Nerve disease
  - b) Kidney disease
  - c) Heart disease
  - d)I don't know

The correct answer (c) was coded 1, and all other answers were coded 0

- 3) Which is the best method for testing blood glucose?
  - a) Urine testing
  - b) Blood testing
  - c) Both are equally good
  - d)I don't know

The correct answer (b) was coded 1, and all other answers were coded 0

4) Self-monitoring of blood glucose is:

- a) The key to determining the right amount of medication
- b)Important to see the effect of diabetes control such as diet and exercise
- c) Both a and b
- d)I don't know

The correct answer (c) was coded 1, and all other answers were coded 0

- 5) The action of diabetes pills:
  - a) Lower blood sugar
  - b)Increase insulin secretion
  - c) Increase insulin sensitivity
  - d)All above
  - e) I don't know

The correct answer (d) was coded 1, and all other answers were coded 0

- 6) Low blood glucose may be caused by
  - a) Too much insulin
  - b)Too little insulin
  - c) Too much food
  - d)I don't know

The correct answer (a) was coded 1, and all other answers were coded 0

- 7) For a person in good control, what effect does exercise has on blood glucose?
  - a) Lowers it
  - b) Raises it
  - c) Has no effect
  - d)I don't know

The correct answer (a) was coded 1, and all other answers were coded 0

- 8) In general, fit patients with diabetes should exercise for
  - a) I hour once a week
  - b) 20 to 30 minutes 3 to 5 times a week
  - c) 1 hour every day
  - d)I don't know

The correct answer (b) was coded 1, and all other answers were coded 0

- 9) Which of the following is usually not associated with diabetes?
  - a) Vision problems
  - b) Nerve problems
  - c) Lung problems

d)I don't know

The correct answer (c) was coded 1, and all other answers were coded 0

- 10) The best way to take care of your feet is to:
  - a) Look at and wash them every day
  - b) Massage them with alcohol every day
  - c) Buy shoes a size larger than usual
  - d)I don't know

The correct answer (a) was coded 1, and all other answers were coded 0. The total score for diabetes knowledge was obtained by the sum of scores of the ten questions. In addition to diabetes duration all previous variable were measure on a scale/interval level.

In addition to the above mentioned scales, other important variables were measured. Demographic variables including gender, age, region, social status, educational level, and income of participants were included in the questionnaire. Also other variables related to the history of the disease were measured. These variables include the duration of diabetes, complications of diabetes and comorbidity with diabetes. The response categories for diabetes complications include eye problems, kidney problems, nerve problems, heart diseases, and foot problems. For diabetes comorbidity, the two most common health problems usually associated with diabetes were included as response categories; high blood pressure, high level of cholesterol, both of them, or none of them.

To assess diabetes education programmes, it was essential to measure some information about diabetes education sessions. This information comprises on one hand the duration of diabetes education sessions and on the other hand the type of education participants have experienced, including group education, individual sessions or both. Table 4.1, summarises all study variables, codes, response categories, and levels of measurements for each variable. Appendix B shows the research questionnaire.

Figure 4-1: Levels of measurements of study variables

Scale/interval level				
variables	Code name	Measurement	Scale	
Glycosylated haemoglobin	HbA1c	Laboratory test, recorded by a nurse		
Diabetes duration	DD	Self reported		
Utilization of health services	UT	Self reported. Number of admissions x length of stay per admission) + Number of emergency visits		
Diabetes self management	DSM	Self reported responses to 5 items concerning the level of compliance with various activities for managing diabetes in the last seven days	0 = not at all 1 = 1 days 2 = 2 days 3 = 3 days 4 = 4 days 5 = 5 days 6 = 6 days 7 = 7 days	
Quality of life	QOL	Self reported responses to 5 items concerning how various aspects of life would be	1 = a great deal better 2 = better 3 = the same 4 = worse 5 = a great deal worse	
Patient's beliefs	PB	Self reported responses to 9 items concerning beliefs in the importance of various self-management activities	1 = Strongly disagree 2 = Disagree 3 = Do not know 4 = Agree 5 = Strongly agree	
Self efficacy	SE	Self reported responses to 6 items concerning ability to take care of oneself	1 = Definitely not 2 = Probably no 3 = Maybe yes, maybe not 4 = Probably yes 5 = Definitely yes	
Fatalism	FAT	Self reported responses to 6 items concerning faith	1 = Strongly disagree 2 = Disagree 3 = Do not know 4 = Agree 5 = Strongly agree	
Patients- providers communications	PPC	Self reported responses to 5 items concerning communication with doctors about diabetes. First item with reversed codes	1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always	
Social support	SS	Self reported responses to 5 items concerning the support provided by families	1 = Not at all 2 = A little 3 = A moderate amount 4 = A lot 5 = A great deal	
Diabetes knowledge	DK	Self reported responses to a test of 10 questions about diabetes	0 = minimum 10 = maximum	
Diabetes education	DE	Self reported. (Number of sessions x Number of minutes per session)/60		

٨٥٥	AGE	Solf reported age	1 - Loss than 20 years
Age	AGE	Self reported age	1 = Less than 30 years 2 = 30-39 years
			3 = 40-49  years
			4 = 50-59 years
			5 = 60 years or more
Educational level	EL	Self reported educational level	1 = Illiterate
Educational level	LL	Sen reported educational level	2 = Primary
			3 = Intermediate
			4 = Secondary
			5 = Bachelor
			6 = Post graduate
Monthly income	INC	Self reported income	1 = Less than 4000
Monthly income	IIVC	Sen reported income	2 = 4000-8000
			3 = 9000-13000
			4 = 14000-18000
			5 = 19000 or above
	1		3 - 13000 01 05000
		Nominal variables	
Gender	SEX	Self reported gender	1 = Male 0 = Female
Geographic	REG	Self reported area of country	1 = Middle
region			2 = Eastern
			3 = Northern
			4 = Western
			5 = Southern
Social status	STAT	Self reported marital status	1 = Single
			2 = Married
			3 = Divorced
			4 = Widow
Co-morbidity	COMB	Self reported medical conditions in addition	0 = None
		to diabetes	1 = High blood pressure
			2 = High cholesterol
			3 = Both
Complications	СОМР	Self reported complications:	0 = No
		Retinopathy	1 = Yes
		Nephropathy	
		Neuropathy	
		Heart disease	
	<del> </del>	Foot problems	
Form of diabetes	FORM	Self reported form of diabetes education	0 = None
education attended	1		1 = Group
	1		2 = Individual
			3 = Both

Finally, to measure barriers to diabetes self-management, an open-ended question was placed at the end of the questionnaire. This question aims to generate qualitative data where respondents could have the chance to express in their own word the difficulties and the barriers that prevent them from doing any of the self-management activities. This question was expressed in this form:

Please mention in the space below (or on the back of this page if you need more space) any barriers that prevent you or reduce your ability to follow your treatment plan including diet, exercise, taking medications, checking blood glucose, and/or taking care of your feet.

#### 4.3.2 Validation of Research Instrument

One of the important criteria by which the adequacy of a research instrument is assessed is its validity (Babbie, 2007). Validity refers to the extent to which an

empirical measure adequately reflects the real meaning of a considered concept (Babbie 2007). That is the degree to which an instrument is measuring what it is supposed to measure. There are several aspects that can be considered to evaluate the validity of an instrument. These aspects include face validity, content validity criterion-related validity, and construct validity.

Face validity and content validity of the research instrument were validated at this stage by a group of colleagues and a group specialist recruited for this purpose from King Khalid University and Armed Forces Hospital Southern Region. Face validity refers to the general appearance of the instrument to domain experts, and whether it could be suitable to measure the research variables. The opinions of colleagues with expertise in this field were considered to primarily validate the research instrument.

Content validity refers to the extent to which a measure covers the range of meanings included within a concept (Babbie, 2007) by assessing whether questions or items in each scale are relevant to measure that specific variable and also to check if they are sufficient to capture the phenomena in concern. In application to this research, the fatalism scale was reviewed by two staff members of the Islamic studies department in King Khalid University. The scale was subject to some modifications, especially to emphasise the acceptable and not acceptable aspects of fatalism.

All the other scales were reviewed by a team of specialists in the Armed Forces Hospital. In addition to the research author, the team consists of a general practitioner with a special interest in diabetes, a pharmacist, a diabetes educator, a registered nurse and a social worker. During a team meeting, the whole questionnaire (except the fatalism scale) was reviewed and each item was subject to discussion to reach an agreement about the final research instrument in appendix B.

### 4.3.3 Translation of the Research Instrument

Accurate translation of the research instrument is very important to ensure that the validity of research instrument is not affected. Therefore the most common translation technique (translation-back translation method) was used. This method was developed by Brislin (1970), where the original questionnaire is translated to the target language by a bilingual person. Then a second bilingual person translates the document back into the original language. Then the two translators negotiate any differences.

The same procedure was adopted for translating the research instrument of this study. The research questionnaire was developed in English. Two professional translators

working in the translation department of the Armed Forces Hospital Southern Region with long experience in translating medical reports agreed to translate the research questionnaire. The first participant translated the questionnaire from English to Arabic, and the second participant translated it from Arabic to English. The final Arabic version of the research questionnaire is in appendix C.

### 4.4 Data Collection

This section explains the research process for collecting data, the sampling process, data management and cleaning. In addition it explains in detail the statistical techniques used for the quantitative analysis of research data, methods for qualitative analysis and the process for obtaining ethical approval.

#### 4.4.1 Ethical Considerations

Based on the requirements of the Research Governance Office (RGO) in the University of Southampton, a research protocol that explains the purpose of the research and methods for data collection and the research instrument was sent to the host organization. This protocol was submitted with an Arabic version of the research questionnaire to the Medical Services Division in Riyadh for the purpose of granting ethical approval. The Research and Ethics Committee of the Armed Forces Hospital Southern Region approved the research protocol on 26/10/2008, and this approval was accepted by all other participating centres, except in the western region where another application was considered to the Research Ethics Committee in King Fahad Armed Forces Hospital. The approval was granted on 29/03/2009. The RGO reviewed the ethical approvals to sponsor the research study. Appendix A shows ethical approvals and sponsorship.

Prior to conducting the research, every possible effort was made to guarantee confidentiality of data. Appropriate measures were considered to protect human subjects. The first sheet of the questionnaire is an addressed letter from the researcher to every participant, explaining the purpose and procedures of the research. The second sheet is a consent form which every participant had to sign before any data was collected. By signing the consent form participants agree to participate in the study, know their right to withdraw at any time, and that their lab results will be recorded. Appendix B shows the addressed letter and the consent form.

#### 4.4.2 Sampling

Identifying the research population, how this population can be accessed, and the eligibility criteria is a basic step in collecting survey data. The target population for this survey was Saudi people with type 2 diabetes mellitus who received regular treatment in diabetes centres or clinics that provide diabetes self-management education programmes. The target population was accessible in diabetes centres and clinics in different settings. Patients were eligible for participation in this survey, if they were twenty one years old or above, and had been diagnosed with type 2 diabetes mellitus for more than one year.

Sampling is the process of selecting a segment of the population to represent the entire population (Babbie, 2007). Sampling designs can be categorised into two groups; probability and non-probability. For the purpose of collecting data from representative samples to increase the likelihood of generalisation of research outcomes, two sampling strategies needed to be adopted; one was to select a sample from diabetes centres or clinics operating in Saudi Arabia that provide special care for patients with diabetes including self-management education programmes. The second strategy was used to select participants within these centres.

Saudi Arabia is a large country where several providers of health services work independently from each other (Mufti, 2000). There are five main regions in the country; Middle region, Eastern region, Western region, Northern region, and Southern region. The sampling target was to select one centre from each region. There are, however, limited choices, for example in the southern region, only two centres provide diabetes self-management education programmes. It was not possible to define a sample frame to identify a list of all diabetes centres or clinics that provide self-management education programmes. Such a list is one of the fundamental requirements to draw a probability sample. For this reason a non-probability convenience sample design was used to select diabetes centres participating in this study, based on two simple criteria, ease of access and willingness to participate.

One way to increase the ability to generalise the results of a specific study is to select samples from two or more different sites (Polit & Hungler 1999). Several centres were contacted by the author and finally the following five centres were selected: the diabetes centre in the Armed Forces Hospital (southern region), the diabetes centre in King Fahad Armed Forces Hospital (western region), the diabetes clinic in Dirab National Guard Primary Care Centre (Middle region), King Fahad Medical Complex (eastern region), and finally, North West Armed Forces Hospital (northern region).

To avoid selection bias, research assistants were asked to recruit participants in general diabetes clinic who come for regular checkups (usually every three months) and met the selection criteria based on a systematic approach, by asking every second patient arriving at the reception to participate in the study. Two hundred copies of the research questionnaire were given to each centre; thus a total of one thousand questionnaires were distributed to all participating centres.

#### 4.4.2 Data Collection Process

The research assistants were trained to follow a specific procedure for data collection. When patients arrived at reception, they were asked if they were willing to participate in the study after briefly explaining its purpose. If they agreed to participate, a full description of the procedure was described with a letter from the researcher and a consent form to be sought. When a blood sample was collected for analysis (which is a routine practice in these clinics), patients wait for the results before being seen by their doctors. During the waiting time, participants filled in the research questionnaire and kept it until their lab results were ready. These results were then recorded on the top of each questionnaire by a registered nurse. The completed questionnaires were placed in a specially designed box for the purpose of data protection and confidentiality.

### 4.4.3 Data Management

The final number of returned questionnaires was 479 (equivalent to a response rate of 47.9 %). These data were entered into the most widely used software for survey analysis - Statistical Package for Social Sciences (SPSS, version 17). The statistical analysis of data using SPSS required the measurement levels of the variables to be defined as scale/interval, ordinal, or nominal (Field, 2009). The 12 scale/interval level variables shown in (table 4.1) consisted of numerical attributes based on units of measurement corresponding to equal intervals between successive points on fixed scales.

Responses to variables measured using Likert type scales such as self-efficacy, patients beliefs, and quality of life are not strictly measured at the scale/interval level mainly because a response coded as 5 is not exactly five times greater than a response coded as 1. Although considered to be controversial, numerically coded responses based on Likert type scales are commonly used in statistical analysis as if they are measured at the scale/interval level. It is assumed that the intervals between each point on the scale

are approximately equal for the purposes of statistical analysis (Tabachnik & Fidell, 2007).

Three ordinal variables (age, income, and educational level) consisted of mutually exclusive groups of attributes that could be logically ranked into an implicit numerical order based on a value judgment. Each attribute was coded with a unique numeric label to identify its rank with respect to the others (Table 4.2).

Six nominal variables (gender, region, social status, co morbidity, complications, and type of diabetes education) consisted of mutually exclusive groups of qualitative attributes that could not be ranked into a logical numerical order. Each attribute was coded with a number, but only as a convenient label. The numbers assigned to each attribute did not represent their relative ranks in a hierarchy (Table 4.3).

#### 4.4.4 Data Cleaning

Data cleaning is an essential process to improve the quality of data in preparation for statistical analysis (Field, 2009). It refers to the process through which errors are corrected, duplications, and extreme values (outliers) are removed and missing values are handled. The preliminary screening of data identified numerous outliers (extreme values) and missing values (null responses). Therefore it was crucial to perform this process because the inclusion of cases with a substantial number of missing values and outliers could bias the statistics to such an extent that the conclusions drawn from the data might be distorted (Tabachnik & Fidell, 2007).

All variables measured at the scale/interval level (Table 4.1) were checked for missing values and outliers. Univariate outliers were identified as data with Z scores or standardized residuals (deviations from the mean divided by the standard deviation) greater than  $\pm$  2.5. Multivariate outliers were identified as having Mahalonobis d² (distance) statistics with p values < .001 (Hisham, 2008). Accordingly, 67 cases containing missing values and outliers were excluded from the analysis.

It is considered that the statistical analysis performed on the cleaned data using SPSS was not biased by cases that were not representative of the majority of the research population. The statistics were based on 412 (86%) of the 479 patients whose responses were within the normal range (within  $\pm$  2.5 standard deviations of the mean values of each variable).

## 4.5 Quantitative Data Analysis

The aim of the statistical analysis was to explore the relationships between the variables listed in Table 4.1 based on the conceptual model outlined in Figure 3.7, to test the research hypotheses by testing whether:

- DSM improves clinical outcomes (indicated by HbA1c).
- DSM reduces utilization of health services.
- Diabetes self-management (DSM) has a positive effect on quality of life (QOL)
- Self efficacy (SE) has a positive effect on DSM.
- Patient's beliefs (PB), has a positive effect on DSM.
- Fatalism (FAT) has a negative effect on DSM.
- Diabetes knowledge (DK) has a positive effect on DSM; alternatively the effect of DK on DSM is mediated by the positive effect of DK on SE and on PB.
- Social support (SS) has a positive effect on DSM; alternatively, the effect of SS on DSM is mediated by SE.
- Patient-provider communication (PPC) has a positive effect on DSM; alternatively, this effect is mediated by DK.
- Income (INC) and age has positive effects on DSM.
- Diabetes duration (DD) diabetes education (DE) and education level (EL) have positive effects on diabetes knowledge (DK).

#### 4.5.1 Frequency Distribution

All demographic and disease related variables including gender, age, social status, educational level, income, and clinical information were summarized using frequency distributions. The aim was to describe the demographic characteristics of the population and their medical history. The null hypothesis that the sex ratio was 1:1 was tested using a Chi-Square ( $\chi^2$ ) goodness of fit test. The null hypothesis was rejected if the p value of the  $\chi^2$  statistic was < .05.

Frequency distributions were also constructed to summarise all the other study variables listed in Tables 4.1.

### 4.5.2 Reliability Analysis

Internal consistency reliability refers to how strongly a group of variables are interrelated and hang together as a construct (Field, 2009). A construct is a consistent underlying theme concerning the attitudes, knowledge, behaviour, and beliefs of

people that can be extracted from a group of responses to a survey instrument (Allen & Yen, 2002). Reliability analysis, involving the computation of Pearson's correlation coefficients and Cronbach's alpha was performed in order to determine if reliably measured constructs could be extracted from the groups of variables collected to measure diabetes self-management (DSM), quality of life (QOL), patients beliefs (PB), self-efficacy (SE), fatalism (FAT), patients-providers-communications (PPC), and social support (SS).

The use of Cronbach's alpha was justified because it is the simplest and most widely used statistic applicable to analyze the internal consistency reliability of constructs extracted from instruments devised for educational, economic, behavioural, and clinical assessments (Hogan et al., 2000; Cronbach & Shavelson, 2004). The identification of a reliably measured construct using Cronbach's alpha is equivalent to the extraction of a single factor or dimension using factor analysis (Gorsuch, 1983). Since reliably measured constructs could be identified and extracted from the data using only Cronbach's alpha, factor analysis was not considered necessary for the purposes of this study.

According to Allen and Yen (2002), values of alpha increase when the correlations between the responses increase so that if alpha = 1, a cluster of items is a perfectly reliable and consistent measure of a construct. However, alpha = 1 is rarely, if ever, encountered, due to sampling error. This study followed the general rule that the value of Cronbach's alpha should be at least 0.6 before reliability can be considered as "adequate" and 0.8 or over before reliability can be considered as "good" (Allen & Yen, 2002). When a group of inter-correlated responses has been shown to be reliably measured by Cronbach's alpha  $\geq$  0.6 then the scores can reasonably be aggregated to formulate a new composite variable in order to measure a named construct (Allen & Yen, 2002).

The summation of a group of scores helps to reinforce the systematic components of the construct or the consistent theme that it aims to measure. It also to cancel out the non-systematic components or the sampling error associated with inconsistent responses (Allen & Yen, 2002). Accordingly, in this study, groups of significantly correlated, consistently and reliably measured responses that comprised the constructs of DSM, QOL, PB, SE, FAT, PPC, and SS were summated to formulate composite variables that could be used in correlation and regression analysis.

## 4.5.3 Correlation and Regression Analysis

#### Linear regression

The aim of linear regression analysis was to construct models of the form:

$$Y = \beta_0 + \beta_i X_i \pm \epsilon$$

Where: Y = the predicted average value of the dependent variable;  $\beta_0$  = the intercept (the theoretical predicted value of the dependent variable when all the predictor variables are zero);  $\beta_i$  = the partial regression coefficient for predictor variable  $X_i$ ; i = the number of the predictor variable,  $\epsilon$  = residual error. Partial regression coefficients can only be numerically compared with each other when they are measured on the same scale. Because the regression coefficients of the predictor variables of this study were measured using different scales,  $\beta$  weights (standardized regression coefficients) were used to numerically compare the relative importance of multiple regression coefficients. The  $\beta$  weight of a regression coefficient  $\beta_i = S_{xi}/S_{y}$  where  $S_{xi}$  = standard deviation of  $S_{y}$ ,  $S_{y}$  = standard deviation of  $S_{y}$  (Neter et al., 1996).

Linear regression analysis using the method of least squares assumes that the dependent variable is normally distributed and is measured at the scale/interval level. The predictor variables must be measured at the scale/interval or ordinal level or be nominal variables coded numerically in rank order of magnitude. Nominal categories coded with more than two numerical values such as the geographic region, cannot be used as predictor variables in regression analysis because they do not represent a numerical hierarchy. Dummy binary codes using 0 or 1 were used to represent each category of the nominal variables in table 4.1. It is essential to compute the unique estimator of the regression coefficients using the rule that the number of codes equals the number of categories in the variable minus one (Neter et al., 1996).

Regression analysis assumes that the residual error; the differences between the predicted and observed values should not deviate from normality (Tabachnik & Fidell, 2007). Therefore, the standardized residuals were visualized using frequency distribution histograms. One of the basic assumptions of linear regression models is the linearity between the dependent variable and one or more of the independent variable(s) or predictors. Linearity refers to the consistency between the average change of the dependent variable in response to a unit change in the independent variable (predictor), and can be tested using the correlation coefficient (Pearson's r). The null hypothesis that there is no correlation between the variables was rejected if the if the p value of Pearson's correlation coefficient was < .05. A significant zero order correlation between a dependent and a predictor variable does not imply a

meaningful relationship between them, since the correlation may be confounded by the influence of a third variable, called a mediating variable.

Several mediating variables were proposed in this study including self efficacy, patient's beliefs and social support (Figure 3.7). Partial correlation analysis is the most appropriate method to identify mediating variables (Tabachnik & Fidell, 2007). The partial correlation coefficient measures the strength of the relationship between two variables when the influence of the mediating variable is removed or controlled. Partial correlation analysis was performed in this study, controlling for self efficacy, patient's beliefs, and other variables, to determine if any correlative relationships involving diabetes self management practices were confounded by mediating variables. The decision rule was to conclude that a variable was acting as a mediator if the partial regression coefficient declined substantially in value relative to the zero order correlation coefficient (Tabachnik & Fidell, 2007).

According to Field (2009), for regression analysis to work properly there must be homogeneity of variance; the variability in the dependent variable should be the same with respect to each predictor variable. Non-homogeneity of variance invalidate confidence intervals and tests of hypothesis mainly because of the bias of the standard errors. There is no formal statistical test for homogeneity of variance in regression analysis, but it can be visualized graphically using the scatter plots where the predicted values and the residuals can be observed (Tabachnik & Fidell, 2007). If the residuals were randomly and evenly scattered around the mean value (zero), then homogeneity of variance was concluded. However, non-homogeneity of variance was concluded if the scatter plots show a specific geometric shape that indicate a systematic variation of the variance (a curve, a line, or a cloud).

The regression coefficients, t statistics and p value are all important components of regression analysis. The null hypothesis that the regression coefficient is zero was tested using the p value of the t statistics. If the p value was < .05, then the null hypothesis was rejected. if the p value was > .05, then it was concluded that the regression coefficient was not zero. The R² value in the regression analysis indicate how much of the variations in the dependent variable was explained by the variations of the independent variable(s) or predictors. It measures the effect size of the independent variable on the dependent variable. This effect was considered significant if the p value of the F statistics is less than 0.05 (Field, 2009).

When the independent variables in multiple linear regression are strongly correlated, collinearity occurs. One of the assumptions of multiple linear regression model is that

the independent variables should not be collinear. Therefore it is essential to identify and eliminate collinearity which affect the regression statistics (Field, 2009). The effect of collinearity on regression statistics occurs because the value of the standard error increase which in turn lead to a reduction in the significance level of the regression coefficients. Consequently, even if the  $R^2$  and F statistics are significant and even if the independent variables are linearly related to the dependent variable, the regression coefficients of collinear independent variables (predictors) may not be statistically significant at the .05 level. Variance Inflation Factor (VIF) was used to measure collinearity in this study. If VIF statistics was  $\geq 3.3$ , then collinearity was indicated (Tabachnik & Fidell, 2007).

An independent sample t-test was used to compare means in two groups. This test assumes normality and equality of variance, but is relatively robust with respect to slight departure from the assumptions, particularly when the sample size is large (Field, 2009). The null hypothesis of no significant difference between means was rejected if the p value of the t statistic was < .05.

#### **Binary logistic regression**

The recommended target for the level of HbA1c as a measure of clinical outcome in patients with Type 2 diabetes is 7% or lower. To perform logistic regression analysis, the dependent variable (HbA1c) was categorized into two groups: those patients who were successful in achieving the target (7% or lower) were coded as 1, and those patients who failed to achieve the target (7.1% or higher) were coded as 0. Binary logistic regression was performed to predict the log odds or logistic function of the event using the equation:

$$\log_{e}(\pi/1 - \pi) = \beta_{0} + \beta_{1}X_{1} + .... + \beta_{n}X_{n}$$

Where  $\pi$  = the predicted probability of a patient achieving the target; X = the vector of the independent or predictor variable X;  $\beta_0$  = a constant; and  $\beta_1$ .... $\beta_n$  = the regression coefficients (or  $\beta$  coefficients) corresponding to n predictor variables (Hosmer & Lemeshow, 2000). The odds ratio for each independent variable was computed from the log odds to predict the ratio of the probability that the patient achieved the target over the probability that the patient did not achieve the target.

According to Hosmer and Lemeshow (2000), the odds ratio of an event is interpreted as if it qualitatively behaves the same as the probability of the event. This implies that as the predicted odds ratio increases, so the probability of a patient achieving the target increases. The model contained the five self-management activities (diet, exercise, taking medications, self-monitoring of blood sugar, and foot care) as independent variables. The null hypothesis was tested that each  $\beta$  coefficient was not

significantly different from zero. The alternative hypothesis was that the  $\beta$  coefficient was significantly different from zero. The decision rule was to reject the null hypothesis and accept the alternative hypothesis if the computed significance level (p value) of the coefficient, based on the magnitude of the Wald Chi-square test statistic, was less than the prescribed significance level of p < .05.

#### 4.5.4 Sample Size

Regression analysis requires a large sample size in order to generate stable coefficients and exhibit sufficient power to reject false null hypotheses (Field, 2009). The minimum number of cases required to construct a regression model varies with respect to the effect size and the number of predictor variables in the model (Cohen, 1988). Assuming a medium to large effect size, the number of cases required to construct a model with up to 8 predictor variables is 107 cases. Therefore the sample size of 412 patients used in this study was more than adequate to provide sufficient statistical power for the purposes of regression analysis.

### 4.5.5 Statistical Significance and Practical Importance

One of the important issues to be considered when reporting the research results is the significance of these results using the *p* value (Field, 2009). However it has been reported that many medical and other researchers misinterpret and misuse p values (Altman et al., 1983; Cohen, 1994; Suter; 1996; Cline, 2004). For example, if the prescribed significance level is .05, then a p value of .046 may be interpreted as significant whereas a p value of .054 may be interpreted as not significant; however, a simple dichotomous comparison of p values does not provide any useful information about the meaningfulness of data. Neither does the magnitude of the p value signify the practical or clinical importance of the results.

Statistical significance and practical importance are not equivalent, and cannot be used interchangeably. If a p value < .05 is interpreted as significant this does not imply that the results are practically important. If a p value > .05 is interpreted as not significant this does not imply that the results have no practical importance. It is possible that different p values may reflect differences in sample size rather than differences in effect size (Altman et al, 1983). If the sample size is large enough, then the results of a statistical test may be significant at p < .05 even though the effect size is small, and the data have little practical importance. On the other hand, if the sample size is too

small, then a statistical test may not have enough power to be significant at p < .05 even if the effect size is large, and the data are practically important.

Therefore it is essential for researchers when reporting the results, to include sample sizes and effect sizes, and not just depend on p values to interpret the results (Altman et al., 1983; Thomson, 1998; Cline 2004). Accordingly the effects sizes, denoted by  $R^2$  for regression analysis and Cohen's d for t tests, were computed in this study.  $R^2$  values > 10% were considered to represent a substantial effect size (Cohen, 1988). Cohen's d was computed as the difference between two means divided by the pooled standard deviation. Cohen's  $d \le .2$  indicated a small effect, d values between .3 and .7 indicated a moderate effect, whereas  $d \ge .8$  indicated a large effect (Cohen, 1988). For binary logistic regression, Cox & Snell  $R^2$  value was computed to measure the effect size. Cox & Snell  $R^2$  is a version of the coefficient of determination to measure the effect size for logistic regression based on the log-likelihood of a model and the log-likelihood of the original model, and the sample size (Fields, 2009).

## 4.6 Qualitative Data Analysis

One of the widely used techniques to analyse qualitative data is content analysis (Hsieh & Shanon, 2005). It can be defined as a systematic process for analyzing textual information in a way that allows for making inferences about this information (Webber, 1990). The main focus of qualitative content analysis is to determine the characteristics of the language for the purpose of finding the contextual meaning of text that could be Content analysis is generated from different sources including openended questions (Kondracki & Wellman, 2002). By using categories to represent explicit or implicit meaning of a text, the goal of content analysis is to provide a better understanding of a phenomenon (Downe-Wamboldt, 1992).

Hsieh and Shanon (2005) defined three approaches for content analysis in health research; conventional content analysis, summative content analysis, and directed content analysis. These approaches differ in terms of the origin of the code, coding scheme, and trustworthiness. While in conventional analysis the coding categories are generated from data, in the directed approach, the research theoretical grounding guides the process of coding. In summative analysis, however, two stages of analysis are conducted; first stage involves counting and comparing key words in a text (manifest analysis), then a second stage for interpreting the underlying meaning of the text (latent analysis).

Abdullah Alshehri Methodology

The directed content analysis approach was adopted for the purpose of analysing qualitative data generated from the open-ended question regarding barriers to diabetes self-management. The main reason for adopting this approach is the consistency between the purpose of finding the barriers to diabetes self-management and the goal of directed analysis which is to conceptually validate and extend a conceptual framework (Hsieh & Shanon, 2005). Therefore, predetermined codes derived from the constructed model were used to categorize responses from 123 participants who answered the open-ended question. If it was not possible to categorise the response into one of the predetermined categories- a new code was given to that specific response. Responses that were possible to fit with the predetermined categories were handled as supportive to the model, whereas new categories were handled as emergent issues.

### **Chapter 5: Results**

This chapter begins with a description of the socio-demographic profile of study participants and disease related information. Then it examines the relationships between the study variables for the purpose of testing the research hypotheses. It also shows how the model fits the observed data and finally it describes various barriers that prevent appropriate compliance with diabetes self-management activities.

### 5.1 Demographic Information

Data for this research were collected from diabetes centres and clinics in the main five regions in Saudi Arabia. It was processed using SPSS (version 17). Descriptive analysis for the demographic data was conducted to describe the sample of this research. About two thirds of patients were males. The deviation from a 1:1 sex ratio was statistically significant ( $\chi^2$  = 39.9; p < 0.001). The age distributions of males and females were similar. Only about 4% of the patients belonged to the younger age-group < 30 years old. About 59% were in the 40-59 years age-group, and 24% were > 60 years old (Table 5.1). 407 respondents reported their geographic locations; the majority (25.4%) were from the central region and the minority (16.3%) were from the western region of the country (Table 5.2).

Table 5-1: Percentage distribution of age and gender

		C	Gender		
		Female	Male	Total	
Age (years)	Less than 30	1.5%	2.8%	4.3%	
	30-39	3.3%	9.1%	12.4%	
	40-49	8.4%	19.7%	28.1%	
	50-59	12.7%	18.5%	31.1%	
	60 or more	9.1%	14.9%	24.1%	
Total		34.9%	65.1%	100.0%	

Table 5-2: Geographic regions of patients

Region	Percent
Central	25.4
Eastern	21.4
Northern	16.5
Western	16.3
Southern	20.4
Total	100.0

86.4% were currently married, 6.5% were widowed and 6.7% were single. 27.8% were illiterate, 18.7% had primary education, 12.8% had intermediate education, 23.6% had secondary education, 15.8% were graduates and 1.2% had post graduate qualifications. 23.4% had a monthly income less than 4000 Saudi Riyals (SR), 44.0% had income between 4000 and 8000 SR, and 32.6% had an income of 9000 SR or more per month (£1=  $\pm$  6 SR). The average monthly gross domestic product per capita was estimated in 2008 at 5904 Saudi Riyals (approximately £1000).

### 5.2 Diabetes Duration, Comorbidity and Complications

The patients had been diagnosed with diabetes mellitus for 2 to 30 years with a mean of 10.24 years (standard deviation = 6.16). The distribution of diabetes duration deviated slightly from normality and was skewed to the right (Figure 5.1).

25 20 15 10 5 Diabetes duration (years)

Figure 5-1: Distribution of diabetes duration

About 29% of patients reported that they did not have high blood pressure or high cholesterol and 14.1% reported they had both. 56.7% had either high blood pressure or high cholesterol (Table 5.3). 47.1% reported no complications of diabetes whilst 52.9% reported from 1 to 4 complications (Figure 5.2). The prevalence of retinopathy, nephropathy, neuropathy, heart disease and foot problems were 37.6%, 5.8%, 10.7%, 11.4% and 15.0%, respectively.

Table 5-3: Comorbidity

Co-morbidity	Percent
None	29.2
High blood pressure	33.4
High level of cholesterol	23.3
Both	14.1
Total	100.0

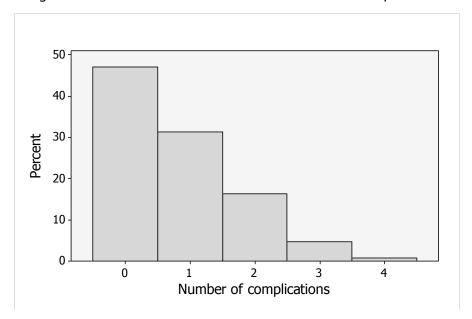


Figure 5-2: Distribution of the number of diabetes complications

#### 5.3 Diabetes Education

32.6% of the patients did not attend any diabetes related educational programmes. 37.4% attended group education and 23.6%, individual level education. 6.4% had attended both individual and group level education. Most of the patients (54.7%) had received 5 or less hours of diabetes education, but only 5% received 10 or more hours. The level of diabetes education varied with respect to the ages of patients, since the younger patients (less than 40 years old) received proportionally less diabetes education than the older patients (Table 5.4). This implies that age must be considered in the analysis of the factors associated with diabetes education.

Table 5-4: Percentage distribution of hours of diabetes education with respect to the ages of the patients

Hours of diabetes education		Age (years)						
	Less than 30	30-39	40-49	50-59	60 or more			
None	1.8%	2.5%	9.7%	8.9%	9.7%	32.6%		
0.1-5 hours	1.0%	6.9%	16.5%	19.6%	10.7%	54.7%		
5.1-10 hours	0.8%	0.0%	1.3%	2.0%	3.6%	7.6%		
10 or more hours	0.8%	1.5%	0.8%	1.0%	1.0%	5.1%		
Total	4.3%	10.9%	28.2%	31.6%	24.9%	100.0%		

### 5.4 Percentage Distributions of Study Scales

#### Diabetes self management (DSM) activities

The percentage distribution of DSM practices is recorded in Table 5.5. It shows that 78% of the patients were very regular in taking their prescribed medications on all the seven days a week. About a half of the patients had diabetic diet on 5 to 7 days per week whilst 13.3% did not follow their diet on all seven days. Regularity of exercising was very poor. 31.8% of the patients did not attempt exercise on even a single day. Only 12.9% maintained a daily exercise schedule. 22% tested their blood sugar and 23% examined their feet every day; however, 33% of the patients did not do daily self-testing of blood sugar, and 26.7% did not examine their feet even once.

Table 5-5: Percentage distribution of diabetic self management (DSM) practices

Item	Numbe	r of day	s confo	rming to	the DSM	practice			
		0	1	2	3	4	5	6	7
DSM1	Healthy eating pattern	13.3	1.7	5.8	10.4	12.1	21.8	11.7	23.1
DSM2	Conforming to taking medications	1.7	0.2	0.2	0.7	0.2	8.3	10.4	78.2
DSM3	At least 30 minutes of exercise	31.8	8.5	14.1	11.2	12.4	6.1	3.2	12.9
DSM4	Self testing of blood sugar	31.3	9.7	11.7	10.4	7.8	3.9	3.2	22.1
DSM5	Checking and taking care of feet	26.7	12.6	12.1	8.5	8.0	5.8	3.4	22.8

The average number of days for compliance with diet was 4.34 of the last seven days, 6.55 for compliance with taking medications, 2.59 for doing exercise, 2.88 for self-monitoring of blood sugar, and 3.04 for foot care. These results indicate that the best level of compliance was with taking medications and the poorest level was with doing exercise.

The matrix of Pearson's correlation coefficients (Table 5.6) provides evidence to conclude that all of the responses to items concerning DSM practices were significantly and positively correlated with each other at the .05 level.

Table 5-6: Matrix of Pearson's correlation coefficients between DSM practices

	DSM1	DSM2	DSM3	DSM4
DSM2	.215*			
DSM3	.408*	.180*		
DSM4	.188*	.143*	.415*	
DSM5	.224*	.176*	.430*	.505*

<sup>\*</sup> Significant at p < .05

The value of Cronbach's alpha = .679 reflected the high level of inter-correlation between the items and indicated that DSM was a consistently and reliably measured construct.

#### Patient beliefs (PB)

The percentage distributions of patient beliefs concerning diabetes are presented in Table 5.7. About half the patients were of the opinion that taking medications as prescribed is extremely important in controlling blood glucose levels and for preventing diabetic complications. More than 90% of the patients considered that diabetic diet, exercise, self-monitoring of blood glucose and checking of feet were important. On the other hand more than 10% of respondents did not consider doing exercise important for controlling blood glucose and preventing future complications.

Table 5-7: Percentage distribution of patient's beliefs about diabetes

Item		Not at all	Not	Fairly	Very	Extremely
		important	important	important	important	important
PB1	Diabetic diet controls blood					
	glucose level	0.7	1.5	24.3	46.6	26.9
PB2	Diabetic diet prevents diabetic					
	complications	1.0	1.7	23.4	53.0	20.9
PB3	Exercise controls blood glucose					
	level	1.2	9.9	30.9	39.8	18.3
PB4	Exercise prevents diabetic					
	complications	1.0	9.1	36.4	39.1	14.5
PB5	Self- monitoring of blood glucose					
	necessary for controlling blood					
	glucose level	0.5	3.5	26.9	44.7	24.4
PB6	Self- monitoring of blood glucose					
	necessary for preventing diabetic					
	complications	0.5	6.3	26.2	43.4	23.5
PB7	Taking medications is important					
	for controlling blood glucose level	0.0	0.5	6.4	40.7	52.5
PB8	Taking medications is important					
	for preventing diabetic					
	complications	0.0	0.2	6.6	41.0	52.1
PB9	Checking and taking care of foot					
	help prevent diabetic complications	0.2	2.7	29.3	38.1	29.6

The matrix of Pearson's correlation coefficients (Table 5.8) provides evidence to conclude that all but two of the responses to items concerning patients beliefs were significantly and positively correlated with each other at the .05 level. The value of Cronbach's alpha = .831 reflected the very high level of inter-correlation between the items and indicated that patients beliefs was a consistently and reliably measured construct.

Table 5-8: Matrix of Pearson's correlation coefficients between patient's beliefs

	PB1	PB2	PB3	PB4	PB5	PB6	PB7	PB8
PB2	.692*							
PB3	.699*	.577*						
PB4	.381*	.486*	.720*					
PB5	.093	.299*	.116*	.330*				
PB6	.022	.260*	.087	.327*	.793*			
PB7	.256*	.211*	.226*	.263*	.291*	.238*		
PB8	.298*	.193*	.221*	.240*	.313*	.218*	.839*	
PB9	.503*	.335*	.551*	.519*	.112*	.132*	.397*	.478*

<sup>\*</sup> Significant at p < .05

#### Self efficacy (SE)

The percentage distributions of the abilities of the patients to perform various diabetic related activities are recorded in Table 5.9. 57% of the patients were sure about their ability to check blood glucose levels. About 7% expressed their inability to follow diabetic diet, and 47% did not think they would be able to follow a diabetic diet while dining out. Less than half of the patients were confident about their ability to examine and take care of their feet. Three quarters were definitely confident of their ability to follow medication as prescribed.

Table 5-9: Percentage distribution of self efficacy

Item		Definitely	Probably no	Maybe yes	Probably	Definitely
		not		maybe no	yes	yes
SE1	Check blood glucose	7.8	7.8	6.3	21.4	56.8
SE2	Follow diabetic diet	2.5	4.2	30.1	33.3	29.9
SE3	Follow diabetic diet while dining out	13.8	32.8	27.4	12.4	13.6
SE4	Examine and take care of feet	2.0	6.6	20.3	27.9	43.3
SE5	Regular physical exercise	8.1	17.2	22.1	21.8	30.9
SE6	Taking medication as prescribed	2.2	0.2	4.6	18.0	75.0

The matrix of Pearson's correlation coefficients (Table 5.10) provides evidence to conclude that all but one of the responses to items concerning self efficacy were significantly and positively correlated with each other at the .05 level. The value of

Cronbach's alpha = .814 reflected the very high level of inter-correlation between the items and indicated that self efficacy was a consistently and reliably measured construct.

Table 5-10: Matrix of Pearson's correlation coefficients between self efficacy items

	SE1	SE2	SE3	SE4	SE5
SE2	.405*				
SE3	.234*	.488*			
SE4	.543*	.588*	.368*		
SE5	.512*	.631*	.414*	.681*	
SE6	.289*	.314*	.085	.451*	.296*

<sup>\*</sup> Significant at p < .05

#### Fatalism (FAT)

The percentage distributions of the faith related beliefs (fatalism) of the patients are recorded in Table 5.11. There was an obvious difference in the distributions of FAT1, FAT2, and FAT3 (concerning the will of Allah when human actions were not involved) to which the majority of patients agreed, and FAT4, FAT5, and FAT6 (where a specific action was involved) to which the majority of patients disagreed.

The matrix of correlation coefficients (Table 5.12) reflected this dichotomy. FAT4, FAT5, and FAT6 were significantly inter-correlated with each other at the .05 level but they were not all correlated with FAT1, FAT2, and FAT3. The value of Cronbach's alpha = .597 reflected the relatively low level of inter-correlation between the six items indicating the variations in responses when specific actions were involved. Nevertheless, .597 rounds up to the threshold level of 0.6 required to consider fatalism as a reliably measured construct for the purposes of this study.

Table 5-11: Percentage distribution of fatalism (faith related beliefs)

Item		Strongly disagree	Disagree	Do not know	Agree	Strongly agree
FAT1	Should accept whatever Allah has meant for them	0.0	0.0	0.0	1.7	98.3
FAT2	Whatever illness I will have, Allah has already planned it	0.0	0.0	7.6	15.4	77.0
FAT3	Future complications result from my disease is definitely happening	1.0	11.2	20.9	32.1	34.8
FAT4	Need not try to improve my health because I know it is up to Allah	14.8	63.5	17.3	2.9	1.5
FAT5	When I am sick I give my burdens to Allah without doctors having to do anything	22.4	70.3	4.6	1.5	1.2
FAT6	If Allah wants me to have a good health in the future that will happen without having to take care of myself	21.5	49.3	19.8	9.0	0.5

Table 5-12: Matrix of Pearson's correlation coefficients between faith-related beliefs (fatalism)

	FAT1	FAT2	FAT3	FAT4	FAT5
FAT2	.152*				
FAT3	.004	.361*			
FAT4	.022	.113*	.311*		
FAT5	023	.077	.175*	.370*	
FAT6	.005	.069	.269*	.507*	.255*

<sup>\*</sup> Significant at p < .05

#### Patient-provider communication (PPC)

Table 5.13 presents the responses of the patients regarding patient-provider communication. The proportions who answered "often" or "always" for questions concerning the doctor listening carefully, answering questions and concerns about diabetes, explaining why a test was being done, what were the results, and how to take medications were very high at 79.5%, 75.6%, 67.9% and 82.0%, respectively. It is important to note, however, that 53% of the patients reported that the doctor talked to them using medical terms they could not understand.

Table 5-13: Percent distribution of Patient-Provider Communication (PPC)

		Never	Rarely	Sometimes	Often	Always
Item						
PPC1	Doctor talk to you using medical terms that you do not understand	6.8	6.3	33.6	29.4	23.8
PPC2	Doctor listen carefully to what you had to say about your medical problems	2.0	3.2	15.4	44.4	35.1
PPC3	Doctor answer your questions and concerns about diabetes	0.7	2.0	21.7	35.4	40.2
PPC4	Doctor explain why a test was being done and what were the results	0.2	3.4	28.5	33.6	34.3
PPC5	Doctor explain to you how to take your medications	0.2	1.7	16.0	34.7	47.3

The matrix of Pearson's correlation coefficients (Table 5.14) provides evidence to conclude that all but two of the responses to items concerning patient-provider communication were significantly and positively correlated with each other at the .05 level. The value of Cronbach's alpha = .720 reflected the high level of inter-correlation between the items and indicated that patient-provider communication was a consistently and reliably measured construct.

Table 5-14: Matrix of Pearson's correlation coefficients between items concerned with patient-provider communication

	PPC1	PPC2	PPC3	PPC4
PPC2	.002			
PPC3	.072	.651*		
PPC4	.151*	.491*	.627*	
PPC5	.163*	.452*	.634*	.556*

<sup>\*</sup> Significant at p < .05

#### Social support (SS)

Table 5.15 presents the distribution of the responses regarding social support. Less than 23% of the patients reported that they never or rarely got family support with respect to listening carefully, encouraging exercise or eating healthy diet, buying or cooking suitable food, or reminding to take medications. A larger proportion (42%), however, was never or rarely praised for commitment to their treatment plan.

Table 5-15: Percentage distribution of items concerning social support (SS)

		Never	Rarely	Sometimes	Often	Always
Item						
SS1	Family listen to you carefully when you talk about your disease	3.6	7.0	24.8	41.3	23.3
SS2	Family encourage you to exercise or to eat healthy diet	2.9	9.2	38.4	26.0	23.4
SS3	Family buy or cook food that suite your diet	8.6	14.7	39.6	24.7	12.5
SS4	Family praise you for your commitment to your treatment plan	18.5	23.8	31.6	13.4	12.7
SS5	Family remind you to take your medications in the right time	2.7	4.6	19.5	31.4	41.8

The matrix of Pearson's correlation coefficients (Table 5.16) provides evidence to conclude that all of the responses to items concerning social support were significantly and positively correlated with each other at the .05 level. The value of Cronbach's alpha = .774 reflected the high level of inter-correlation between the items and indicated that social support was a consistently and reliably measured construct.

Table 5-16: Matrix of Pearson's correlation coefficients between items concerned with social support

	SS1	SS2	SS3	SS4
SS2	.573*			
SS3	.279*	.429*		
SS4	.311*	.460*	.608*	
SS5	.421*	.483*	.246*	.272*

<sup>\*</sup> Significant at p < .05

#### Quality of life (QOL)

The responses of the patients regarding their quality of life are presented in Table 5.17. The percentages of people who considered that their career opportunities, social relationships, sex life, leisure and future hopes would have been (worse or great deal worse) if they did not have diabetes were less than 4%. Between 23% and 30% perceived that their quality of life would have been a great deal better if they did not have diabetes.

Table 5-17: Percentage distributions of items concerned with quality of life (QOL)

Item	If did not have diabetes	Great deal better	Better	Same	Worse	Great deal worse
QOL1	Employment- career opportunities would be	28.7	19.0	49.6	2.2	0.5
QOL2	Social relationships would be	28.2	29.7	38.6	3.5	0.0
QOL3	Sex life would be	30.4	28.8	37.8	3.1	0.0
QOL4	Sporting holiday/leisure opportunities would be	23.3	40.0	34.2	2.7	0.7
QOL5	Future hopes and expectations would be	28.3	21.1	46.2	3.7	0.7

The matrix of Pearson's correlation coefficients (Table 5.18) indicates that all of the responses to items concerning quality of life were significantly and positively correlated with each other at the .05 level. The value of Cronbach's alpha = .910 reflected the very high level of inter-correlation between the items and indicated that the reliability of the measure of quality of life was good.

Table 5-18: Matrix of Pearson's correlation coefficients between items concerned with quality of life

	QOL1	QOL2	QOL3	QOL4
QOL2	.703*			
QOL3	.617*	.717*		
QOL4	.545*	.693*	.637*	
QOL5	.696*	.745*	.631*	.740*

<sup>\*</sup> Significant at p < .05

#### Diabetic knowledge

The responses of the patients to the questions intended to assess diabetes knowledge are presented in Table 5.19. Over 80% obtained correct answers for 5 of the 10 questions. The questions that were answered correctly by less than 50% of the patients concerned the types of food that were high in carbohydrates and the frequency for exercise.

Table 5-19: Percentages of patients who obtained correct answers in a test of diabetic knowledge

	Question	Percent (correct answer)
DV1	M/high of the fallenting is high in south the dyster	40.0
DK1	Which of the following is high in carbohydrates	48.0
DK2	Eating food lower in fat decreases your risk for	85.8
DK3	Which is the best method for testing blood glucose	66.1
DK4	Self-monitoring of blood glucose is	62.0
DK5	The action of diabetes pills	66.7
DK6	Low blood glucose may be caused by	81.5
DK7	For a person in good control, what effect does exercise have on blood glucose	81.5
DK8	In general- fit patients with diabetes should exercise for	44.0
DK9	Which of the following is usually not associated with diabetes	81.6
DK10	The best way to take care of your feet is to	81.0

#### Construction of composite variables

Cronbach's alpha values ranging from about 0.6 to about 0.9 indicated that the multiple responses used to measure the variables diabetes self management (DSM), patients beliefs (PB), self-efficacy (SE), fatalism (FAT), patients-providers-communication (PPC), social support (SS), and quality of life (QOL) (Table 5.20) were significantly inter-correlated. It is concluded that each of these seven variables reliably and consistently measured an identifiable construct. The values of Cronbach's alpha justified the summation of the multiple responses to formulate composite variables for purpose of statistical analysis.

Table 5-20: Construction of composite variables

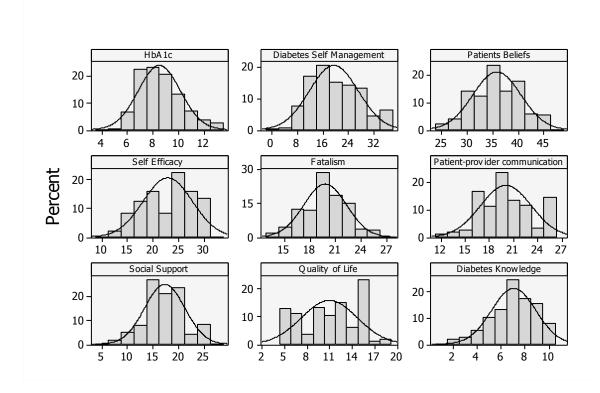
Composite variable		Summated multiple responses	Cronbach's
			alpha
DSM	Diabetes self management	DSM1 + DSM2 + DSM3 + DSM4 + DSM5	0.679
PB	Patient's beliefs	PB1 + PB2 + PB3 + PB4 + PB5 + PB6 + PB7 + PB8 +	0.831
		PB9	
SE	Self efficacy	SE1 + SE2 + SE3 + SE4 + SE5 + SE6	0.814
MF	Fatalism	FAT1+FAT2+FAT3+FAT4+FAT5+FAT6	0.597
PPC	Patient provider	PPC1+PPC2+PPC3+PPC4+PPC5	0.720
	communication		
SS	Social support	SS1+SS2+SS3+SS3+SS4+SS5	0.774
QOL	Quality of life	QOL1+QOL2+QOL3+QOL4+QOL5	0.910
DK	Diabetes knowledge	Correct answers to	not
		DK1+DK2+DK3+DK4+DK5+DK6+DK7+DK8+DK9+DK	applicable
		10	

Diabetes knowledge (DK) was based on a test which did not aim to measure a construct. Reliability analysis was therefore not applicable. The measure of diabetic knowledge of the each patient was taken as the total number of correct answers out of the 10 questions.

#### Distribution of scale/interval level variables

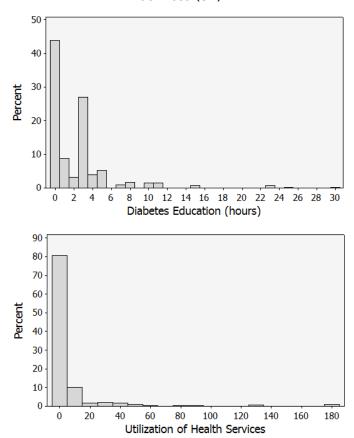
The frequency distributions of HbA1c, and the composite variables DSM, PB, SE, FAT, PPC, SS, QOL, and DK deviated from perfect normality but were generally mound-shaped, which was sufficiently normal for purposes of statistical analysis. No transformations were considered necessary to normalize these distributions (Figure 5.3)

Figure 5-3: Frequency distributions of HbA1c, diabetes self-management, beliefs, self-efficacy, fatalism, patients-provider communication, social support, quality of life, and diabetes knowledge



The frequency distributions of the variables diabetes education (DE) and utilization (UT), however, were highly skewed to the right (Figure 5.4). The skewness was caused by the large mode at zero on the left hand side. 32.6% of patients had no diabetes education at all (Table 5.4) whilst 44% had 0 to 1 hours of diabetes education. 45.4% did not use the health services (emergency and/or admission), and for 80.9% of the patients the utilization of the health services was rated as 0 to 10 in the measurement index. These highly skewed distributions could not be normalized using logarithmic or square root transformations.

Figure 5-4: Frequency distributions of Diabetes education (DE) and utilization of health services (UT)



Consequently, for purposes of statistical analysis, diabetes education was converted to a binary categorical variable where 0 = patient had no diabetes education, 1 = patient had some diabetes education. Utilization of health services was also converted to a binary categorical variable where 0 = patient did not use health services, 1 = patient did use heath services.

#### **HbA1c statistics**

The average HbA1c was 8.43% (above the recommended target of 7% or less), with a standard deviation of 1.58. The minimum value was 4.8% and the maximum value was 12.7%.

### 5.4 Testing research hypotheses

This section aims to investigate the relationships between the study variables based on the constructed model. However other relationships between study variables were considered in the analysis, based on their significance and the size of the effect.

#### 5.4.1 Outcomes of Diabetes Self-management

# Relationship between diabetes self-management (DSM) and the quality of life (QOL)

QOL was significantly correlated with DSM (Pearson's  $r = -.235 \, p < .001$ ). Figure 5.5 illustrates the fitted regression line. The linear regression statistics are provided in Table 5.21.

Figure 5-5: Relationship between DSM and QOL (fitted regression line  $\pm$  95% prediction intervals)

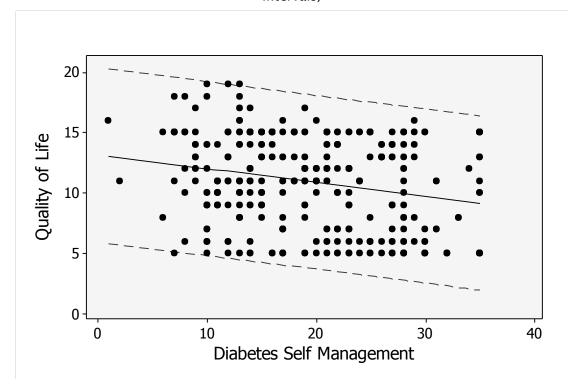


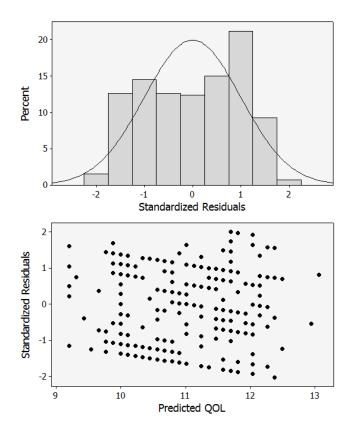
Table 5-21: Prediction of quality of life (QOL)

	Un standardized Coefficients			Significance
β Standard Error t		t statistic	р	
Intercept	13.17	.504	26.09	.000*
DSM	114	.024	-4.75	.000*

<sup>\*</sup> Significant at p < .05

The regression equation is  $Y = 13.17 - .114 \, X$  where Y = QOL, X = DSM. The model predicted that the QOL score (where a high score = better QOL and a low score = worse QOL) declined with respect to the DSM score (where a low score = low compliance and a high score = high compliance). Consequently, as the level of compliance with various diabetes self-management activities in the last seven days increased, the quality of life got worse. The p value of the t statistic indicated that DSM was a statistically significant predictor of QOL at p < .001. The  $R^2$  value = 0.55 indicated that 5.5% of the variability in QOL was explained by the variability in DSM, a low effect size. The results of ANOVA (F = 22.53 p < .001) indicated that this proportion was statistically significant. The model did not violate the assumptions of regression with respect to residual normality and homogeneity of variance (Figure 5.6).

Figure 5-6: Distribution of residuals for the prediction of quality of life (QOL)



5.5%, however, is only a small effect size, suggesting that the relationship between DSM and QOL, although statistically valid and significant, may not be practically important. It is concluded that diabetes self-management has a small negative effect on quality of life.

## The relationship between diabetes self-management (DSM) and clinical outcome (HbA1c)

HbA1c was negative correlated with DSM (Pearson's r = -.567 p < .001). Figure 5.7 illustrates the fitted regression line. The linear regression statistics are provided in Table 5.22.

Figure 5-7: Relationship between HbA1c and DSM (fitted regression line  $\pm$  95% prediction intervals)

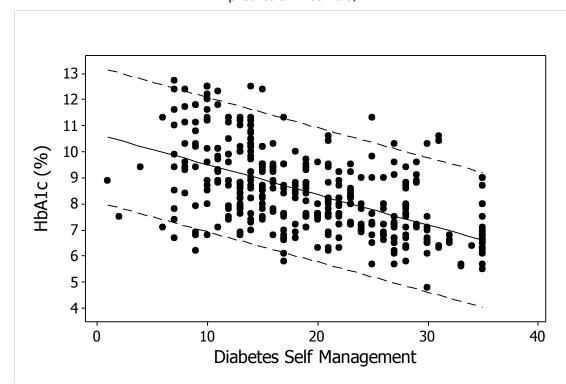


Table 5-22: Prediction of HbA1c

	Un standardized		Significance	
β Standard Error		t statistic	p	
Intercept	10.67	.175	60.77	.000*
DSM	116	.008	-13.72	.000*

<sup>\*</sup> Significant at p < .05

The regression equation is Y = 10.67 - .116 X where Y = HbA1c, X = DSM. The model predicted that HbA1c (where a low value = a clinically better outcome and a high value = a clinically worse outcome) declined with respect to the DSM score (where a low

score = low compliance and a high score = high compliance). Consequently, as the level of compliance with various diabetes self-management activities in the last seven days increased, the clinical outcome improved. The p value of the t statistic indicated that DSM was a statistically significant predictor of HbA1c at p < .001. The  $R^2$  value = 0.321 indicated that 32.1% of the variability in HbA1c was explained by the variability in DSM, a substantial effect size. The results of ANOVA (F = 188.34 p < .001) indicated that this proportion was statistically significant.

Visual examination of the distributions of the residuals (Figure 5.8) indicated that the model did not appear to violate the assumptions of regression with respect to residual normality and homogeneity of variance.

It is inferred that the relationship between DSM and HbA1c was not only statistically valid and significant, it may also be clinically important, since 32.1% is a large effect size. It is concluded that a high level of diabetes self management improves the clinical outcome. This very significant finding is potentially of great interest to clinicians.

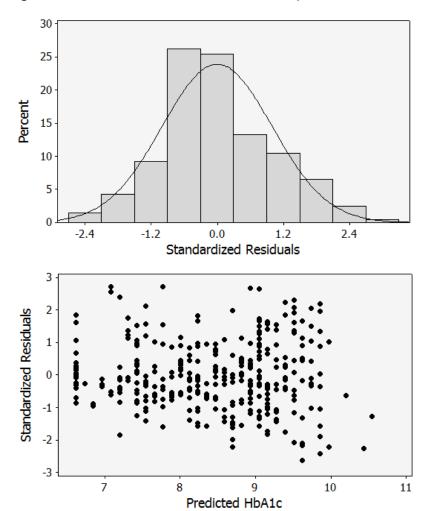


Figure 5-8: Distribution of residuals for the prediction of HbA1c

#### Achieving the recommended Level of HbA1c

The recommended level of HbA1c is 7% or lower. To predict the probability that a patient will achieve this target, a binary logistic regression was conducted using HbA1c (categorized variable) as a dependent variable and the five self- management activities as predictors. 20.3% of the patients achieved the target (7% or lower HbA1c) and 79.7% did not achieve the recommended target. The results of binary logistic regression analysis to predict the log odds of a patient achieving the target are presented in Table 5.23.

Table 5-23: Model to predict the log odds of a patient achieving the target of 7% or less HbA1c

	β coefficient	Standard Error		Degrees of freedom	p value	Odds Ratio
DSM1	.022	.073	.087	1	.769	1.022
DSM2	.161	.200	.649	1	.420	1.175
DSM3	.166	.067	6.183	1	.013*	1.181
DSM4	.233	.060	15.357	1	.000*	1.263
DSM5	.154	.062	6.154	1	.013*	1.166
Constant	-4.483	1.332	11.334	1	.001*	.011

<sup>\*</sup> Significant at p < .05

The model was defined by the equation:

$$\log_{e}(\pi/1 - \pi) = -4.483 + .022 \text{ DSM1} + .161 \text{ DSM2} + .166 \text{ DSM3} + .233 \text{ DSM4} + .154 \text{ DSM5}$$

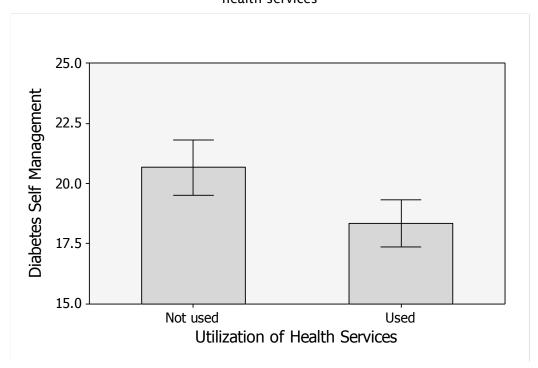
Where  $\pi$  = the predicted probability of a patient achieving the target; DSM1 = healthful eating pattern; DSM2 = conforming to medications; DSM3 = exercise; DSM4 = self testing of blood sugar and DSM5 = checking and taking care of feet. The binary logistic regression model predicted that the probability of achieving the target increased if the patient performed all five self management activities; and the Cox & Snell R² value = 18.6% indicated a substantive effect size; however, the Wald Chi Square statistics indicated that  $\beta$  coefficients for DSM1 and DSM2 were not significantly different from zero at the .05 level. Cox & Snell R² value is defined in section (4.5.5). The three diabetes self-management activities with  $\beta$  coefficients greater than zero at the .05 level were DSM3, DSM4, and DSM5, with odds ratios ranging from 1.166 to 1.263. The most important predictor, with a  $\beta$  coefficient of .233 and an odds ratio of 1.263 was DSM 4 i.e., the self-monitoring of blood sugar.

## The relationship between diabetes self-management (DSM) and the utilization of health services (UT).

The mean DSM score = 18.34 (standard deviation = 7.38) was lower for the 225 patients who did not use health services compared to the DSM score = 20.67 (standard deviation = 7.94) for the 187 patients who did use health services (Figure 5.9). A one-tailed independent samples t test assuming equal variances was used to test the null

hypothesis that there was no difference between the DSM scores. The alternative hypothesis was that the mean DSM score was lower for patients who used the health services compared to those who did not. The null hypothesis was rejected (t statistic = 3.08 p = .001) and the alternative hypothesis was accepted.

Figure 5-9: Mean  $\pm$  95% confidence intervals of DSM with respect to utilization of health services



The effect size measured for t test by Cohen's d (section 4.5.5). Cohen's d = 0.304, was moderate indicating that the results were not only statistically significant, but may also have some practical importance. It is concluded that those patients who frequently complied with diabetes self-management activities used the health services significantly less than patients who did not comply.

#### 5.4.2 Factors influencing diabetes self-management

The relationship between diabetes self-management (DSM) income, age, self efficacy (SE), patients' beliefs (PB) fatalism (FAT) diabetes knowledge (DK) social support (SS) and patient-provider communication (PPC)

A matrix of Pearson's correlation coefficients (Table 5.24) was constructed to identify linear relationships between the variables.

Table 5-24: Matrix of Pearson's r coefficients between variables

Age	Diabetes Self Manageme nt 192*	Age	Income	Patients Beliefs	Self Efficacy	Fatalism	Patient Provider Comm.	Social Support
Income	.023	206*						
Patients Beliefs	.411*	153*	.084					
Self Efficacy	.636*	099	.045	.518*				
Fatalism	228*	091	.014	262*	360*			
Patient Provider Comm.	.248*	.063	056	.329*	.361*	541*		
Social Support	.302*	051	.069	.347*	.452*	046	.322*	
Diabetes Knowledge	.292*	.184*	.150*	.280*	.239*	041	.055	.066

<sup>\*</sup> Significant at p < .05

At the .05 level, DSM was negatively correlated with age and fatalism, positively correlated with patients' beliefs, self efficacy, patient-provider communication, social support and diabetes knowledge, but not correlated with income. Patients' beliefs and self efficacy were significantly correlated with all the other variables at the .05 level. Age was correlated with income, patients' beliefs and diabetes knowledge. Patient-provider communication was correlated with fatalism and social support. Diabetes

knowledge was correlated with DSM, age, income, patients' beliefs, and self efficacy (Table 5.24).

Table 5-25: Partial correlation coefficients to identify mediating variables

Correlation between	Controlling for:	Partial correlation coefficient
Diabetes knowledge and DSM (Pearson's r = .292)	Self efficacy	.170
Diabetes knowledge and DSM (Pearson's r = .292)	Patients beliefs	.193
Social support and DSM (Pearson's r = .302)	Self efficacy	.016
Fatalism and DSM (Pearson's r =228)	Self efficacy	006
Patient- provider communication and DSM (Pearson's r = .248)	Diabetes knowledge	.240
Patient provider communication and DSM (Pearson's r = .248)	Self efficacy	.029
Patient provider communication and DSM (Pearson's r = .241)	Patients beliefs	.150

Partial correlation analysis (Table 5.25) provided evidence to indicate that self efficacy acted as weak mediator between DSM and diabetes knowledge since the partial correlation coefficient decreased by about 0.1 relative to the zero-order Pearson's r coefficients. Self efficacy was, in comparison, a very strong mediator between DSM and social support, since the partial correlation coefficient declined to almost zero, indicating that most of the correlation between DSM and social support could be accounted for by self efficacy. For a similar reason, it was concluded that self efficacy mediated strongly between fatalism and DSM. Diabetes knowledge was not considered to be a significant mediator between patient provider communication and DSM since the partial coefficient decreased by only .008 relative to Pearson's r. Self efficacy was, in comparison, a very strong mediator between DSM and patient-provider communication, since the partial correlation coefficient declined to almost zero, indicating that most of the correlation between DSM and patient-provider communication could be accounted for by self efficacy. The decline in the partial regression coefficient by about 0.1 compared to Pearson's r indicated that patient's beliefs was a weak mediating variable between DSM and patient-provider communication.

Multiple linear regression analysis was performed (Table 5.26) to predict DSM using age, patients beliefs, and self efficacy as predictor variables. Income was excluded since it was not correlated with DSM (Table 5.24). Fatalism, patient-provider communication, social support, and diabetes knowledge were also excluded from the model, because the correlations between these variables and DSM were controlled by patient's beliefs and/or self efficacy (Table 5.25).

Variables	Un-standardized Coefficients		Standardized Coefficients		Significance p value	Collinearity VIF
	β	Standard Error	β weight			
Intercept	-2.944	2.678		-1.099	.272	
Age	-1.005	.279	144	-3.599	.000*	1.025
Patient's Beliefs	.163	.075	.101	2.180	.030*	1.382
Self Efficacy	.892	.073	.565	12.160	.000*	1.382

Table 5-26: Model to predict diabetes self-management DSM

The multiple regression model defined using un-standardized coefficients was:

$$Y = -2.944 - 1.005 X_1 + .163 X_2 + .892 X_3$$

The model defined using standardized coefficients (B weights) was:

$$Y = -2.944 - .144 X_1 + .101 X_2 + .565 X_3$$

Where Y = DSM,  $X_1$  = Age (ordinal categories),  $X_2$  = Patients beliefs,  $X_3$  = Self efficacy. The p values of the t statistics indicated that age, patients' beliefs, and self efficacy were statistically significant predictors of DSM at the .05 level, but the intercept was not significantly different from zero.

The model predicted that the average DSM declined with respect to age, but increased with respect to patients' beliefs and self efficacy. Since the three predictor variables were measured on different scales,  $\beta$  weights are necessary to interpret their relative importance. The largest  $\beta$  weight was 0.565 for self efficacy, implying that self efficacy was the most important predictor of DSM. For every standardized unit increase in self efficacy the DSM increased by .565 standardized units. The R² value = .432 adjusted for the number of predictor variables in the model indicated that 43.2% of the variability in DSM was explained by the variability in the predictor variables, which was a substantial effect size. The results of ANOVA (F = 92.976 p < .001) indicated that this proportion was statistically significant.

Using Variance Inflation Factor (VIF) as a measure of Collinearity (section 4.5.3), the VIF statistics less than 3.3 inferred that the predictor variables were not collinear. Visual examination of the standardized residuals (Figure 5.10) indicated that they did not deviate from normality. The even distribution of the residuals around their mean (zero) value indicated that the variance in the dependent variable was homogeneous.

<sup>\*</sup> Significant at p < .05

Evidence is provided to imply that the model did not violate any of the theoretical assumptions of multiple regression analysis.

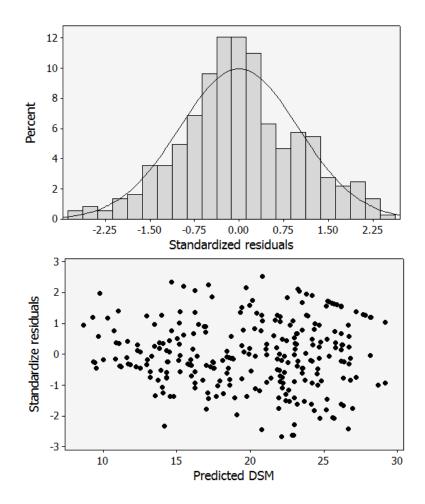


Figure 5-10: Distribution of residuals for the model to predict DSM

It is concluded that those patients who have higher level of compliance with various diabetes self-management activities were the younger age group who believed in the importance of these activities and exhibited a high level of confidence in their ability to perform these activities. This model was not only statistically valid and significant, but it may also have some practical importance, since the effect size indicated by  $R^2 = 43.2\%$  was high.

## The relationship between diabetes self-management (DSM) gender, and the geographic region of patients

The gender and geographic regions of the patients were added to the multiple regression model described in Table (5.26). Gender was defined as 0 = Female, 1 = Male. The five geographic regions were originally coded 1 to 5 (Table 1) which could

not be used in regression analysis because they did not represent a numerical hierarchy. The five geographic regions were represented by four binary categories. A dummy value of 1 was used to indicate that a patient came from a particular region. A dummy value of 0 was used to indicate that the patient did not come from a particular region. The regression statistics for the model with the inclusion of gender and geographic regions are presented in Table 5.27.

There was no Collinearity when gender and geographic location were included in the model, indicated by VIF statistics < 3.3. Evidence was provided to indicate that gender was not a significant predictor of DSM at the .05 level. The partial regression coefficient for the Middle region was significant at p < .05. The  $\beta$  weight predicted that DSM increased by .130 standardized units when the patient was from the Middle region. The partial regression coefficients for the other regions were not significantly different from zero at the .05 level. The adjusted R² value increased from 43.2% to 44.6% when gender and geographic region were added to the model. It is concluded that gender contributed nothing and geographic region contributed only a little to the prediction of DSM.

Table 5-27: Model to predict DSM including gender and geographic region

Variables Un-standardiz Coefficients			Standardized Coefficients	t statistic	Significance p	VIF
	β	Standard Error	β weight			
Intercept	-4.204	2.983		-1.409	.160	
Age	897	.289	128	-3.100	.002*	1.088
Patients Beliefs	.156	.077	.096	2.025	.044*	1.440
Self Efficacy	.916	.080	.572	11.409	.000*	1.603
Gender	815	.654	051	-1.246	.214	1.077
Middle Region	2.295	.901	.130	2.548	.011*	1.658
Eastern Region	1.138	.960	.061	1.186	.237	1.712
Northern Region	.642	.989	.032	.649	.517	1.517
Western Region	1.210	1.013	.058	1.195	.233	1.484

<sup>\*</sup> Significant at p < .05

#### The relationship between the severity of diabetes and DSM

The severity of diabetes, indicated by co-morbidity and clinical complications, were added to the model described in Table 5.26. The four co-morbidity categories were originally coded with values from 1 to 3 (Table 1) but these codes could not be used in

multiple regression analysis because they did not represent a numerical hierarchy. The four co-morbidity categories were represented by three binary categories. A dummy value of 1 was used to indicate that a patient had high blood pressure or high cholesterol. A dummy value of 0 was used to indicate that the patient did not have high blood pressure or high cholesterol. The multiple regression statistics for the model including co-morbidity and complications are presented in Table 5.28.

There was no Collinearity when co-morbidity and complications were included in the model, indicated by VIF statistics < 3.3. Evidence was provided to indicate that co-morbidity and complications were not significant predictors of DSM. The partial regression coefficients to predict DSM with respect to no co-morbidity, high blood pressure, high cholesterol, retinopathy, nephropathy, neuropathy, heart disease, foot complications, and total number of complications were not significantly different from zero at the .05 level. The adjusted R² value remained at 44.6% when co-morbidity and complications were added to the model. It is concluded that co-morbidity and complications did not significantly influence the variability in DSM.

Table 5-28: Model to predict DSM including co-morbidity and clinical complications

Variables	Un-standardized Coefficients		Standardized Coefficients	t statistic	Significance p	Collinearity VIF
	β	Standard Error	β weight			
Intercept	-2.782	2.889		963	.336	
Age	-1.035	.324	148	-3.192	.002*	1.374
Patients Beliefs	.171	.076	.106	2.255	.025*	1.404
Self Efficacy	.903	.075	.573	12.047	.000*	1.436
No co-morbidity	855	1.115	052	766	.444	2.912
High Blood Pressure	-1.627	1.122	102	-1.449	.148	3.132
High Cholesterol	442	1.225	024	361	.719	2.872
Nephropathy	.332	1.556	.010	.213	.831	1.534
Neuropathy	488	1.074	019	454	.650	1.090
Heart Disease	-1.849	1.272	081	-1.453	.147	1.956
Foot complications	526	1.141	026	461	.645	1.944
Number of complications	.517	.693	.069	.747	.456	5.478

<sup>\*</sup> Significant at p < .05

#### 5.4.3 Factors influencing diabetes knowledge

## The relationship between diabetes knowledge, diabetes duration, diabetes education, educational level, and age

A matrix of Pearson's correlation coefficients (Table 5.29) was constructed to identify linear relationships between the variables. All the variables were significantly correlated with each other at the .05 level except for diabetes duration with diabetes knowledge, and diabetes education with age. Multiple linear regression analysis was performed (Table 5.30) to predict diabetes knowledge using diabetes education, educational level, and age as predictors. Diabetes duration was excluded since it was not correlated with diabetes knowledge (Table 5.29).

Table 5-29: Matrix of Pearson's correlation coefficients

	Diabetes	Diabetes	Diabetes	Educational
	knowledge	duration	education	level
Diabetes duration	084			
Diabetes education	.193*	139*		
Educational level	.285*	230*	.320*	
Age	215*	.430*	039	456*

<sup>\*</sup> Significant at p < .05

The multiple regression model defined using un-standardized coefficients was:

$$Y = 6.977 + .431 X_1 + .234 X_5 - .227 X_3$$

The model defined using standardized coefficients (B weights) was:

$$Y = 6.977 - .113 X_{1} + .199 X_{2} - .140 X_{3}$$

Where Y = Diabetes knowledge,  $X_1$  = Diabetes education (0 = no diabetes education, 1 = some diabetes education),  $X_2$  = Educational level (ordinal),  $X_3$  = Age (ordinal). The p values of the t statistics indicated that diabetes education, educational level, and age were significant predictors of diabetes knowledge at the .05 level, and the intercept was significantly different from zero.

Table 5-30: Model to predict Diabetes knowledge

			Standardized	Т	Significance	Collinearity
			Coefficients			VIF
	β	Standard	β weights			
		Error				
Intercept	6.977	.448		15.582	.000*	
Diabetes education	.431	.201	.113	2.147	.032*	1.134
Educational level	.234	.069	.199	3.395	.001*	1.409
Age	227	.090	140	-2.517	.012*	1.264

<sup>\*</sup> Significant at p < .05

The model predicted that diabetes knowledge increased if the patient had some diabetes education, increased with respect to the educational level, but decreased with respect to age. Since the three predictor variables were measured on different scales,  $\beta$  weights are necessary to interpret their relative importance.

The largest  $\beta$  weight was 0.199 implying that educational level was the most important predictor of diabetes knowledge. For every standardized unit increase in educational level the diabetes knowledge increased by .199 standardized units. The R² value = .105 adjusted for the number of predictor variables in the model indicated that 10.5% of the variability in diabetes knowledge was explained by the variability in the predictor variables. R² was only just above the threshold level of 10% to conclude a substantive effect size. The results of ANOVA (F = 15.340 p < .001) indicated that this proportion was statistically significant.

The VIF statistics less than 3.3 inferred that the predictor variables were not collinear. Visual examination the standardized residuals (Figure 5.11) indicated that their distribution was relatively normal. The even distribution of the residuals around their mean (zero) value indicated that the variance in the dependent variable was homogeneous. Evidence is provided to imply that the model did not violate any of the theoretical assumptions of multiple regression analysis.

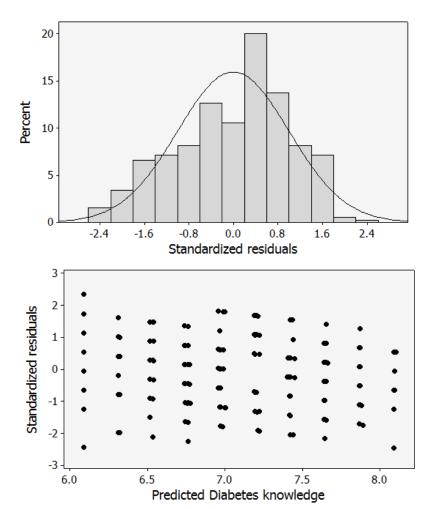


Figure 5-11: Distribution of residuals for the model to predict diabetes knowledge

It is concluded that patients with high score in diabetes knowledge were the younger age group who had attended diabetes education sessions and have higher level of education. This model was statistically valid and significant, but is not a very precise predictor of diabetes knowledge, since the effect size indicated by  $R^2 = 10.5\%$  was relatively low in comparison to the other models constructed in this study.

## The effects of gender, geographic region, and form of education on Diabetes knowledge

Multi-factorial ANOVA was performed to determine the effects of three independent variables, the gender, the geographical region, and the form of diabetes education received on the mean diabetes knowledge of 371 patients (Table 5.31). There were no significant interactions between the independent variables at the .05 level so the interaction terms are excluded from Table 5.31.

Table 5-31: Multi-factorial ANOVA on the factors affecting diabetes knowledge

	Type III	Degrees				Effect
	Sum of	of	Mean		Significance	size
Source	Squares	Freedom	Square	F statistic	р	η 2
Gender	1.207	1	1.207	.399	.528	.001
Geographical region	25.141	4	6.285	2.075	.084	.022
Form of education	78.222	3	26.074	8.608	.000 *	.067
Error	1093.466	361	3.029			
Total	19929.000	370				

<sup>\*</sup> Significant at p < .05

Gender and geographic region had no significant effects on the mean diabetes knowledge of patients at the .05 level indicated by p = .528 and p = .084 respectively (Table 5.31); however the form of education had a significant effect, indicated by F (3, 361) = 8.608 p = .000. The effect size was low, indicated by  $\eta^2 = .067$ . Dunnet's T3 post-hoc test for the pair-wise comparison was used to compare the mean values, because it is applicable when the sample sizes in each group are unequal (Field, 2009). The post-hoc test indicated that the mean diabetes knowledge of the patients who received group education was significantly higher at the .05 level than those who received no education, individual education, or both group and individual education. The clear difference in diabetes knowledge of those who received group education relative to other forms of education is visualized in Figure 5.12.

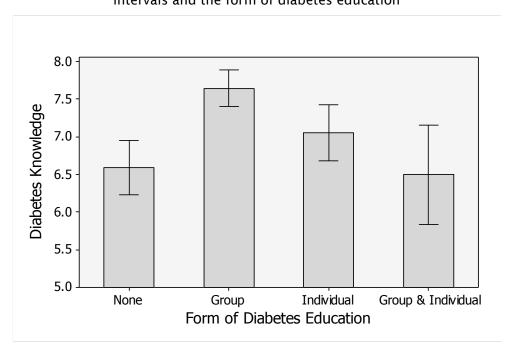


Figure 5-12: Relationship between mean diabetes knowledge  $\pm$  95% confidence intervals and the form of diabetes education

#### 5.5 Fitness of the Model to the Observed Data

The goodness of fit of a regression model to the observed data is indicated by the effect size, reflected by the magnitude of the R<sup>2</sup> value, a measure of the proportion of the variance in the dependent variable that is explained by the variance in the predictor variable(s). The R2 values are provided for all of the regression models. The R2 value = 0.55 indicated that 5.5% of the variability in QOL was explained by the variability in DSM, a low effect size. The R<sup>2</sup> value = 0.321 indicated that 32.1% of the variability in HbA1c was explained by the variability in DSM, a substantial effect size. The R2 value = .432 adjusted for the number of predictor variables in the model to predict DSM indicated that 43.2% of the variability in DSM was explained by the variability in the predictor variables, which was a substantial effect size. The adjusted R2 value increased from 43.2% to 44.6% when gender and geographic region were added to this model. It is concluded that gender contributed nothing and geographic region contributed only a little to the prediction of DSM. The R<sup>2</sup> value = .105 adjusted for the number of predictor variables in the model indicated that 10.5% of the variability in diabetes knowledge was explained by the variability in the predictor variables. R<sup>2</sup> was above the threshold level of 10% to conclude a substantive effect size. The binary logistic regression model predicted that the probability of achieving the target increased if the patient performed all five self management activities; and the Cox & Snell R<sup>2</sup> value = 18.6% indicated a substantive effect size:

In general high R<sup>2</sup> values indicated that the effect sizes were substantial, implying that the observed data were an overall good fit to the model. The only aspect of the model that did not have a substantive goodness of fit to the observed data was associated with the relationship between diabetes self-management (DSM) and quality of life (QOL).

## 5.6 Barriers to diabetes self-management

Analysis of the open-ended question to investigate possible barriers to diabetes self-management revealed several aspects that patients find as barriers to appropriate management of their conditions. A total of 123 respondents answered this question. The number of barriers for not complying with treatment plan ranged from one to four barriers. Table 5.32 shows these barriers, how often these barriers were reported and the specific self-management activity these barriers were associated with if reported.

Table 5-32: Barriers to compliance with treatment plan

barriers	frequency	Percentage	Associated with
Events and banquets are not conducive to dieting	25	16.5	Diet
Some habits do not help to follow the diet	18	11.8	Diet
Inability to walk	10	6.6	Exercise
Difficult to exercise	8	5.3	Exercise
Laziness and lethargy	14	9.2	Exercise
Lack of time	9	5.9	Not specified
Lack of time to exercise	3	2.0	Exercise
Lack of care and encouragement by family	17	11.2	Not specified
Lack of appropriate places for walking	4	2.6	Exercise
Lack of interest in following diet	4	2.6	Diet
Blood testing is painful	3	2.0	Self-monitoring of blood sugar
Difficulty of blood self testing	2	1.3	Self-monitoring of blood sugar
Lack of instrument	4	2.6	Self-monitoring of blood sugar
Unwillingness to exercise	13	8.6	Exercise
Priorities of life (work, taking care of family)	18	11.8	Not specified
Total	152	100	

Table 5.32 shows that more than 30 % of reported barriers were related to compliance with diet, 27.7 % of reported barriers were related to compliance with exercise, and 5.9 % were related to self monitoring of blood glucose. The rest of reported barriers were not associated with a specific self-management activity, however the associations of some of these barriers were clear within the context of the reported statements.

More than 28% of the reported barriers to compliance with diet regimen were related to traditional habits. Most of these habits (16.5%) concerned with the difficulty to follow diet regimen when dining out, especially during events and banquets. The others were concerned with traditional habits of eating types of food that are not suitable for diabetes. Following habits that are not consistent with beliefs indicates low self-efficacy.

More than 11% of reported barriers were related to lack of encouragement, motivation, care and support from family and/or friends. All these barriers indicate the importance of social support as one of the main factors that influence compliance with diabetes self-management activities.

More than 27% of reported barriers were related to difficulties in doing physical exercise. These difficulties were associated with fatigue after exercise, laziness and lethargy. Other responses include unwillingness to exercise mainly because of the belief that exercise is not important for managing diabetes or because of the weather or lack of facilities. These barriers indicate the importance of knowledge and patients beliefs as predictors of self-management. Knowledge is essential for patients to help them choose physical activities that are suitable for them and also to increase the level of awareness about the importance of physical activities to reduce blood sugar.

About 20% of reported barriers were related to time management. These barriers include lack of time, work, and family commitments such as family demands or raising children. Appropriate time management appears as an emergent issue which people need not only for managing their chronic conditions but also for all other aspects of life.

These barriers in general are considered as internal or personal barriers. There are however other external barriers which affect compliance with self-management activities. These external barriers include system-related barriers such as access to the system to refill medications, lack of self-testing instruments and replacements. System-related barriers are beyond the scope of this research.

### 5.7 CONCLUSIONS

Cronbach's alpha values  $\geq 0.6$  confirmed that the scale/interval level variables were reliably measured. Statistical models were constructed using the reliably measured scale/interval variables in addition to ordinal and nominal categorical variables. The

models did not violate theoretical assumptions with respect to residual normality or homogeneity of variance, and so they were assumed to reflect unbiased statistical relationships between the variables. A causal explanation of the observed relationships is necessary. Correlation between variables, expressed in terms of correlation coefficients and regression models, are often confused with <u>causality</u>, although a statistically significant correlation between variables does not directly imply a cause and effect relationship. An empirically observed correlation between variables is an essential, but insufficient, condition to conclude causality. Causation requires more than statistical analysis, it requires factual inter-dependence. Nevertheless, if a correlation between variables is found to be non-random (i.e., not due to chance, as indicated by a significance level of < 0.05 for a correlation or regression coefficient) then it may be intuitively inferred that some type of causal mechanism is operative (Holland, 1986).

Statistical evidence at the .05 level was provided to infer that:

- Diabetes self-management has a large positive effect on clinical outcomes indicated by the negative effect on HbA1c (research hypothesis 1).
- Exercise, self-monitoring of blood glucose, and foot care were significant predictors of the probability of a patient achieving the target (H1bAc level of 7.0% or less), of which self-monitoring of blood glucose was the most important predictor.
- Diabetes self-management has a moderate negative effect on utilization of health services (research hypothesis 2). Health services were used significantly less by patients who frequently complied with diabetes self-management activities.
- Diabetes self-management has a small negative effect on quality of life, while research hypothesis 3 demonstrates a positive effect.
- Patients beliefs, has a large positive effect on diabetes self-management (research hypothesis 4).
- Self efficacy has a large positive effect on diabetes self-management (research hypothesis 5).
- Misconception of fatalism has a negative effect on diabetes self-management.

  This relationship is mediated by self efficacy (research hypothesis 6).
- The effect of diabetes knowledge on diabetes self-management is mediated by the positive effect of diabetes knowledge on self efficacy and patients beliefs (research hypothesis 7).
- Social support has a positive effect on diabetes self-management. This relationship is mediated by self-efficacy (research hypothesis 8).

 Patient-provider communication has a positive effect on diabetes selfmanagement. This relationship is mediated by self-efficacy and patients beliefs, while research hypothesis 9 shows a mediating effect of knowledge.

- Age has a substantial effect on diabetes self-management. DSM is significantly higher in younger age-groups, while research hypothesis 10 shows a positive effect.
- Gender has no significant effect on diabetes self-management.
- Income has no significant effect on diabetes self-management, while research hypothesis 11 shows a positive effect.
- Geographic region has only a small effect on diabetes self-management. Those from the middle region were better in compliance with self-management activities.
- Co morbidity and clinical complications have no significant effect on diabetes self-management, while research hypothesis 12 shows a negative effect for comorbidity and research hypothesis 13 shows a positive effect for complications.
- Education level has a positive effects on diabetes knowledge (research hypothesis 14), whereas duration of diabetes has no significant effect on knowledge, while research hypothesis 15 shows a positive effect.
- Diabetes knowledge declines significantly with respect to age. Gender and geographic region has no effect on diabetes knowledge. Patients who attended diabetes education course had better knowledge where knowledge is highest in those patients who received group education (research hypothesis 16).

# **Chapter 6: Discussions & Conclusions**

This chapter discusses the research limitations and applications. It also discusses the research results presented in chapter 5, starting with detailed discussions of the outcomes as presented in the research model. This is followed by a discussion of each of the influential factors and a comparison of these results with other studies in the literature. Conclusions, recommendations and suggestions for future research are also presented in this chapter.

### 6.1 Introduction

The findings of this research suggest that the model is a valid tool to evaluate self-management programmes. The model shows the outcomes of self-management in terms of its effect on clinical outcome, on quality of life, and on utilization of health services. Clinical, economic, and psychosocial aspects are the most important outcomes for any health intervention. Self-management has a positive effect on clinical outcomes indicated by the negative effect on HbA1c. It also has a negative effect on utilization of health services indicating that self-management reduces the cost of health services by reducing unnecessary use of these services. Quality of life was also an outcome of importance as it reflects the level of coping with the condition. The findings of this research however suggest that self-management has a negative effect on quality of life.

Although measuring these outcomes is crucial for evaluating self-management programmes, it is not sufficient to provide a meaningful evaluation mainly because it does not show how self-management affects the outcomes of care. Therefore it was essential to investigate the factors that influence self-management to understand the underlying context within which self-management operates. Investigating these factors may lead to improvement in patients' behaviour for optimum adherence to self-management activities. The findings of this research suggest that self-efficacy is the most important factor to explain health behaviour, followed by patients' beliefs, indicating that the theoretical assumptions underpinning this research support the core assumptions of self-management.

The model also shows the factors that influence diabetes knowledge, providing suggestions for evaluating and improving diabetes self-management education programmes. The results show that the most important predictor of diabetes knowledge was the education level of participants, followed by the number of

education sessions attended. It also shows that group education was more effective in improving knowledge than individual education.

### 6.2 Research Limitations

This study was subject to certain methodological limitations related to the research design, measurements, and research setting. Although a cross-sectional design has many advantages, it does not support inferences about causality. Causality can be determined by experimental manipulation of variables and comparisons between cause present and cause absent conditions which was not feasible in this study. Therefore the interpretation of results was limited to whether or not a specific variable has an effect on another and the nature of that effect (positive or negative). Another limitation is the sampling technique used to select diabetes centres due to lack of relevant information regarding the numbers of diabetes centres in the country.

There are also limitations related to measurements of study variables. Most variables were measured based on information provided by participants (self-reported). This information was subject to bias of recall and inaccuracy specifically for measuring diabetes self-management activities. In addition these activities were measured for the last seven days where in some cases might not reflect the overall compliance of a participant. Therefore we suggest that patients engaged in self management programmes should keep a daily record for their activities that can be used for appropriate management and evaluation of their conditions and for future research.

Measurement of faith related issues is problematic. Measuring fatalism in this study was not an exception. Fatalism is a complex phenomenon that is difficult to capture using quantitative methods. I believe that people tend to be more fatalistic when the required action is too difficult for them to perform. However reaching this conclusion was not possible for this study using a questionnaire, mainly because belief is a construct that could not be changed in response to different questions. In addition the research setting is not ideal for measuring fatalism, because some people with extreme fatalistic belief rarely visit hospitals. Therefore I suggest further investigation for the effect of fatalism on self-management using a different methodological approach and a different research setting.

## 6.3 Research Implications

This model can be used to evaluate self-management programmes for any chronic condition. Thus the practical implications for the model extend beyond diabetes

management to other chronic conditions. Decision makers in top level management could use the model to compare several interventions in terms of outcomes, and success in improving patient behaviour. For example, self-management has a negative effect on utilization of health services, showing that it may be used as a cost containment strategy. Decision makers could use these results to build an argument toward further investment in self-management programmes. This comparison could also consider the clinical outcomes of different programmes in terms of improvement and achieving the required target to be the bases for rewarding or redirecting programmes.

The model can also be used to make important decisions related to improving patient behaviour. Investigating areas where patients need to improve is the first step for suggesting solutions for improvement. For example, in this study, compliance with exercise was very poor. Therefore clinicians could focus on this issue by helping patients to set reasonable targets and encouraging them to achieve their individual targets by continuous follow up and emotional support.

Considering the role of social support for improving self-management, decision makers could consider allowing family members or friends to participate in self-management education programmes. The results of this study indicate the importance of social support to improve self-efficacy, which in turn is one of the most important predictors of good self-management. Another example for practical implications of the model is related to the role of appropriate communication between patients and health providers. The results of this study show that the role of this communication was not only to improve knowledge, but also to meet the need of patients for encouragement and emotional support. This in turn should shift the focus of this communication not only to provide information but also to consider the emotional needs for patients.

The results of the factors that influence diabetes knowledge show the importance of educational level as a predictor of knowledge. It also shows that knowledge declines with respect to age. This information could lead to a considerable change in education programmes to count for education level and age of patients when preparing materials and education sessions.

The model could also be used as a stratification tool. Patients could be grouped into different categories based on their social support level to facilitate engagement of community social programmes to target patients with desperate need for their services. This stratification is also applicable to patients' knowledge, where patients can be grouped into different categories based on their level of knowledge (for

example beginners, intermediate, advanced) and education sessions could be tailored for each level. This is also applicable to self-efficacy which is the most important predictor of self-management. Patients with low self-efficacy require special attention and should be targeted in order to enhance their confidence in their ability to perform self-management ability.

## 6.4 Discussion of Research Results

This section aims to discuss the research results in relation to the context of the literature review. This section begins with a discussion of self-management and outcomes, followed by discussions of the factors that influence diabetes self-management, and finally discussions of factors influencing diabetes knowledge.

#### 6.4.1 Self-management and Outcomes

Self-management is the core concept of this research. It was measured in terms of compliance with various activities required to manage diabetes. These activities include diet, exercise, taking medications, self-monitoring of blood glucose, and foot care. The results for assessing the level of compliance showed that compliance with these activities was generally below optimal level. Although compliance with taking medication was good with an average of 6.55 days, compliance with exercise self-monitoring of blood glucose and foot care was poor with an average of 2.59, 2.88, and 3.04 days respectively. However compliance with diet regimen showed a modest level of 4.34 days.

These results are consistent with several studies conducted in Saudi Arabia. Self-care and self reliance was found to be modest in a study conducted in the middle region for a sample of 975 diabetic patients (Elzubair et al, 1996). It was also found that compliance with attending appointments and taking medications was better than compliance with following diet regimen (khattab et al, 1999). Results also concur with other studies in the west where it was found that compliance with medical aspects such as taking medications was better than compliance with lifestyle aspects such as diet and exercise (Orme et al, 1989; Irvine, 1989). It has been also found that adherence to taking medication for people with different chronic condition including diabetes mellitus (96% of diabetic patients) was better than adherence to diet (75%) and doing regular physical exercise (19%), showing poor adherence to life style aspects of the treatment regimen (Kravitz et al., 1993).

Glycosylated haemoglobin (HbA1c) as a clinical indicator for diabetes control was assessed as an outcome for diabetes self-management. The average level of HbA1c in this study was 8.43% above the recommended target for diabetic patients (7% or less) where only 20.3% of participants achieved that target. This result reflects poor glycaemic control supporting one of the research problems of this study that diabetes control in Saudi Arabia is below optimal. When compared to other studies conducted in Saudi Arabia, it shows a high level of similarities for example, Eledrisi et al (2007) investigated 1107 diabetic patients from 20 diabetes clinics. It was found that the median HbA1c was 8.2% where 24% achieved the recommended target. Also only 27% achieved the target level of HbA1c (Akbar, 2001), and 77 % of diabetic people with poor control (Al-Ghamdi, 2004). Whereas European and United States data shows that about 33 % of people with type 2 diabetes achieved the recommended target between 6.5 and 7.5% (Massi-Benedetti, 2006).

The results of this study show a negative effect of self-management on HbA1c (Pearson's r = -.567 p < .001) indicating a positive effect of self-management on clinical outcomes (research hypothesis 1). Thus as the level of adherence to various self-management activities increase, clinical outcomes improve. This result is consistent with most related studies in the literature (Tankova et al., 2001; Berg & Wadhwa, 2002; Keers et al., 2005; Siminerio et al., 2005; Steed et al., 2005; Balamurugan et al., 2006; Siminerio et al., 2006; Brown et al., 2007; Farmer, 2007; Liebman et al., 2007; Thompson et al., 2007; Williams et al., 2007; Utz, 2008; Wangberg, 2008; Samuel-Hodge et al., 2009; Scain et al., 2009; Steinhardt et al., 2009).

On the other hand the findings of this research demonstrate that self-management has a negative effect on utilization of health services (research hypothesis 2), showing that patients with better scores in self-management were less likely to visit the emergency room and to be admitted for diabetes or diabetes related complications than those with lower scores. These findings suggest that self-management could be viewed as an effective cost containment strategy where several studies in the literature support this assumption (Balamurugan et al., 2006; Berg & Wadhwa, 2002; Keers et al., 2005; Urbanski et al., 2008; Richardson et al., 2008).

Although most studies in the literature suggest that diabetes self-management improves quality of life for patients, unexpectedly the results of this research show that this relationship is negative (Pearson's r = -.235 p < .001). It shows that the better the self-management, the worse the quality of life indicating that patients who performed better in self-management were less happy and less satisfied than those

with lower scores. This result contradicts with most studies in the literature ((Kirk et al., 2001; Tankova et al., 2001; Steed et al., 2005; Fisher et al., 2007; Kennedy et al.; 2007; Samuel-Hodge et al., 2009) who all suggest a positive effect of diabetes self-management on quality of life. However this result concurs with the finding of one study conducted by Claiborne and Massaro (2000) who found that patients engaged in a multidisciplinary diabetes education programme showed significant diminishment in overall emotional functioning negatively impacting quality of life.

Apparently, patients' commitment to self-management activities negatively influences their happiness and enjoyment of a normal life. It also reflects lack of coping skills where diabetic patients usually need psychological consultations to improve their coping skills and to reduce depression. However the author contacted a group of specialists to explain what could have led to this trend. One of the responses from Dr. Khalid Al-Rubeaan; Director of diabetes Centre at King Abdul-Aziz University Hospital in Riyadh

With regards to your e-mail below, it is expected that people who performed better in self-management are committed for their health care and for that reason they will have lower satisfaction score for their quality of life. I don't see any problem here. And the reason in my mind about this is that they compare their quality of life with normal people for that reason they will score low but if your questionnaire is assessing satisfaction of achieving target goal then the quality will be higher and the score will be better (Al-Rubeaan, 2010, pers. Comm. May 2010).

However, Dr Ali Al-zahrani; Consultant, Endocrinology, Deputy Chairman, Department of Medicine, King Faisal Specialist Hospital and Research Centre in Riyadh has a different point of view

I do not know the details of your study. Therefore, it is hard to speculate on the reasons for the low QoL in pts doing their diabetes self-management but I assume this is a questionnaire-based study. If that is the case, one possible reason for this result is the high expectations on the part of the patients. Patients who do self-management are usually more motivated and their expectations are high. Therefore, when asked about QoL, they may tend to give negative answers. In other words, those patients are perfectionists which may be suggested by them doing self-management and therefore the ceiling of satisfaction is high. Of course, other reasons would

have to do with the intrinsic validity of the study, the sample size, the design, the questionnaire ...etc. (Al-zahrani, 2010, pers.comm. Apr 2010).

However, in my opinion both reasons mentioned above in addition to lack of psychological support may have led to this trend. This result also opens the field for further investigations.

#### 6.4.2 Factors influencing diabetes self-management

The findings of this research revealed that the theoretical assumptions underpin selfmanagement specifically the health beliefs model, self-efficacy theory, and locus of control theory were of significant importance to understand and to predict patients' behaviour. Self-efficacy was the most significant factor influencing diabetes selfmanagement in this study. The largest  $\beta$  weight in the model was 0.565 for self efficacy, followed by (-.144) for age and by (.101) for patients beliefs implying that self efficacy was the most important predictor of diabetes self-management. For every standardised unit increase in self efficacy the self-management score increased by .565 standardised units. These three variables explain more than 43% of the variations in self-management. The effects of self-efficacy and patients beliefs on self-management reflect the relevance of these theories in explaining patients' behaviour. These findings support these theories and concur with many similar findings in the literature that investigated the effect of self-efficacy on diabetes self-management (Hurley and Shea, 1992; Rubin et al., 1993; Anderson et al., 1995; Corbett, 1999; Bernal et al., 2000; Senecal et al., 2000; Johnston-Brooks et al., 2002; Gastal et al., 2007; Trief et al., 2009; King et al., 2010). It also concurs with studies that investigated the effect of both patients' beliefs of the severity of diabetes and beliefs of the effectiveness of treatment regimen on self-management (Cerkoney & Hart, 1980; Harris & Linn, 1985; Brownlee-Dtiffeck et al., 1987; Bond et al., 1992). Using theoretical approaches to enhance patients' confidence in their ability to perform self-management activities and their beliefs about the effectiveness of the treatment regimen is of significant importance.

Similarly, the findings of this study suggest that misconception of fatalism as an external locus of control has a negative effect on self-management where patients with higher level of misconception of the fatalistic belief from the Islamic point of view score lower in self-management scale (Pearson's r= -.228, p<.05). When controlling the effect of self-efficacy, the partial correlation coefficient dropped to (-.006) implying that there was a strong mediating effect of self-efficacy to explain the relationship between misconception of fatalism and self-management. Misconception of fatalism

negatively influence patients adherence to treatment regimen through its negative effect on their confidence in their ability to perform self-management activities. This result supports the findings of Waller and Bates (1992) who concluded that internals have high self-efficacy and externals have low self-efficacy.

Social support was one of the factors that positively influence diabetes self-management. The results of the relationship between social support and diabetes self-management indicate a positive effect (Pearson's r=.302, p<.05) implying that patients with better social support had better adherence to self-management activities. Self-efficacy was also a strong mediator between social support and diabetes self-management since the partial correlation coefficient dropped to (.016) after controlling for the effect of self-efficacy indicating that social support improve the confidence of patients in their ability to perform self-management activities. This result concurs with the findings of William and Bond (2002) who found that when the effect of self-efficacy was controlled, social support was no longer a significant independent predictor of self-care.

Diabetes knowledge was also an important factor to influence diabetes self-management. The findings of this research suggest a positive effect of diabetes knowledge on diabetes self-management (Pearson's r= .292, p < .05). However when controlling for self-efficacy, the partial correlation coefficient dropped to (.170), and when controlling for patients beliefs, the partial correlation coefficient dropped to (.193) showing that the mediating effect of self-efficacy and patients beliefs were weak. These results imply that diabetes knowledge is a significant independent predictor of diabetes self-management supporting many studies that reached a similar conclusion (Garay-Sevilla et al., 1995; Oren et al, 1996; Tillotson & Smith, 1996; Robison, 1993; Toljamo & Hentinen, 2001).

Appropriate communication between patients and health providers has been shown to play an important role in patients' engagement in self-management activities. The results of this study suggest a positive effect of this communication on diabetes self-management (Pearson's r=. 248, p < .05). Many studies suggest that the importance of patients-provider communication is that it improves the knowledge of patients necessary for performing self-management activities. Therefore it was suggested that knowledge mediate the relationship between patients-provider communication and self-management (Golin et al. 1996; Heisler et al., 2002). However the results of this research show when controlling for the effect of knowledge, the partial correlation coefficient dropped from .248 to .240 indicating a very weak mediating effect of knowledge to explain the relationship between patient-provider communication and

diabetes self-management. These results imply that the importance of appropriate communication is not only to provide knowledge but more importantly is to provide emotional support and encouragement.

#### 6.4.3 Factors influencing diabetes knowledge

There are several factors contribute in determining the level of knowledge of patients. The results of this research suggest that the educational level of patients, diabetes education, and age were included in the model as significant predictors, whereas diabetes duration was excluded because it was not significantly correlated to diabetes knowledge. In this model the three predictors; educational level of patients, diabetes education, and age, explain 10.5% of the variations in diabetes knowledge. Similar to the findings of Rothman et al. (2005b), the most significant predictor of diabetes knowledge in this model, was the educational level of patients (β weight= 0.199). These results imply that diabetes education session needed to improve patients knowledge should consider the variations in educational level. Apparently patients with low education level require tailored sessions that count for their level of education and a specific scale to measure their knowledge similar to the low-literacy scale developed by Rothman et al. (2005).

In Saudi Arabia as in many other developing countries age is negatively correlated with education level. In fact the first university in Saudi Arabia was established in 1957. Therefore, it is quite understandable that older people have lower education level in Saudi Arabia. Apparently this negative relationship between age and education level explains the negative effect of age on diabetes knowledge (Pearson's r = -.215, p < .05). On the other hand, the findings of the research suggest that patients who received group education scored better in the diabetes knowledge test than those who attended individual sessions or both. These results concur with the findings of Rickheim et al., (2002) and Deakin et al. (2005) who found that group education produce better results for patients, and contradicts with the findings of Campbell et al. (1994) and Brug et al. (1999) who found that individual education was more effective. Interestingly patient who received both group and individual sessions scored the lowest among those who attended education sessions. Apparently this group has a problem in their adherence or in their knowledge that health providers try different ways to assist them solving these problems. Group education is probably more effective because it assists patients to socialise with others to share ideas and solve common problems. It also creates a competitive atmosphere that may assist patients to participate in discussions and improve their knowledge.

#### 6.4.4 Barriers to diabetes self-management

Barriers that prevent or reduce a patient's ability to adhere to diabetes self-management activities were assessed using an open-ended question. The qualitative analysis of this question revealed that more than 50% of the reported barriers were related to adherence to lifestyle change especially to following the recommended diet. This is also consistent with the findings of Orme et al. (1989) and Irvine (1989) who found that compliance with medical aspects such as taking medications was better than compliance with lifestyle aspects such as diet and exercise. It also concurs with finding of Glasgow et al. (1997) who found that the most reported barriers were related to diet and exercise.

The traditional daily food in Saudi Arabia is dates, lamb and rice, which are all not recommended for diabetic patients. Therefore, people who got used to this type of food for years, usually find it difficult to change to more healthy options. In addition, Saudi people practice different types of social activities on regular basis. In many areas, women exchange visits on a daily basis. Also there are countless occasions that require inviting people to banquets. As a symbol of generosity, traditionally the host usually provides Arabic coffee with dates in reception, a number of whole lambs with rice as the main course, and traditional Arabic desserts that are full of sugars and fats. Accepting these invitations is a symbol of respect, and usually people find it difficult not to respond. The problem however, is that this type of traditional food is the only option provided in these occasions which explains why most people with diabetes find it difficult to adhere to diet when dining out.

#### 6.5 Conclusion

Self-management is an essential component of care for people with chronic conditions. The nature of managing chronic conditions requires patients to move from a powerless role to a proactive position where they can be involved in identifying problems, setting goals, taking responsibilities and effectively participating in decision-making. To play this role, patients with chronic conditions need to have the necessary knowledge and skills that allow them to engage and efficiently perform the required activities which are different from one condition to another.

Acquiring these skills necessitates that health providers introduce self-management education programmes. The main goal of these programmes is to enhance patient

engagement in performing self-management activities to improve the quality of care, to improve clinical outcomes, to improve quality of life and to reduce the cost of healthcare services. The required knowledge and skills for diabetes self-management involves providing information and training skills necessary to the management of diabetes. The most important activities for patients with diabetes are healthy diet, physical exercise, taking medications as prescribed, self-monitoring of blood glucose, and foot care.

Evaluation of self-management programmes is very important to maintain and improve these programmes. It also facilitates adopting new interventions. Without appropriate measurements of the inputs and the outputs of these programmes, it becomes difficult to judge their effectiveness and relevance. Adequate measurement of relevant components of self-management programmes demonstrate the strength and weaknesses of these programmes allowing for further improvements or modifications to certain aspects.

Several steps have been followed to develop this evaluation model. As in any health intervention, the outcomes or the outputs of the intervention should be clearly determined in the initial plan. Without clear identification of the outcome, it becomes irrelevant to evaluate the success or the failure of the intervention. Therefore it was essential to consider the outcomes of diabetes self-management programmes as the first step to start with. In most diabetes intervention, researchers measure different clinical outcomes such as fasting blood glucose or HbA1c to assess the effect of a specific intervention. For the purpose of this research choosing HbA1c as a clinical indicator was relevant because assessing behavioural changes require a measure that gives an indication for a long period of time.

Because of the limited resource for all health organizations, it became very essential to investigate the cost effectiveness of health interventions. Therefore the second step for developing the model was to find the effect of diabetes self-management programmes on cost of diabetes care using an indirect approach through utilization of health services. In addition, health professional should also consider the effect of any intervention on the quality of life for patients to make sure that patients do not suffer as a result of being involved in such interventions. Therefore the effect of self-management on the quality of life was also considered as an outcome in the proposed model.

The final step for developing the model was to investigate the factors that influence patients' ability and willingness to adhere to the treatment regimen. For better

understanding of these factors, it was necessary to refer to health behaviour research and theories to find the most relevant theories to explain and predict patients' behaviour. The health beliefs model, self-efficacy, and locus of control were the most relevant theories to explain patients' engagement in self-management activities. These theories have been summarised to be used as measurable variables in the model. It was also important to include in the model any possible factor that may influence patients' ability to engage in self-management activities.

The proposed model in this research appears to be a valid tool for evaluating diabetes self-management programmes. It could also be used to evaluate other chronic conditions where the role of patients is significant. It measures the level of adherence to various activities required to self-manage the disease. Adherence to taking medications in this research was much better than adherence to diet and physical exercise. Apparently patients with diabetes find it difficult to adhere to lifestyle changes. Understanding these difficulties by health providers is crucial to suggest possible answers and to suggest different methods to assist patients to overcome these difficulties.

In addition, the model measures different outcomes relevant to patients' adherence to self-management activities. These outcomes include clinical outcomes to investigate the level of improvement in clinical outcomes associated with improving self-management where the results show that better adherence was associated with better clinical outcomes. It also measure socioeconomic outcomes by measuring the effect of self-management on utilisation of health services where the results show that patients with better adherence to self-management were less likely to visit the emergency room and less likely to be admitted to hospitals. The model also measures psychosocial outcomes by assessing the effect of self-management on the quality of life where the results of this research implies the importance of incorporating psychosocial consultations to improve coping skills and reduce depression associated with diabetes.

Moreover, the model measures different factors that may influence patients' adherence to the required treatment regimen based on theoretical assumptions underpin self-management and accumulative knowledge in diabetes and health behaviour research. Investigating theories that explain and predict patients' behaviour enables health providers and health researchers to understand different phenomena that enhance or prevent patients from effective engagement in self-management activities. The results of this research support the theoretical assumptions of health behaviour where self-efficacy was found to be the most significant determinant of self-management. It was also found that patient's beliefs and misconception of fatalism as an external locus of

control also play significant roles in determining patients' adherence to treatment regimen. In addition to these important theories, the model does not overlook the importance of other factors such as diabetes knowledge, social support, appropriates communications and other relevant demographic and disease related factors which influence diabetes self-management.

The model also measures different factors relevant to diabetes knowledge. It is of a significant importance to investigate these factors to understand the appropriate way that self-management education programmes could adopt to provide patients with the necessary knowledge and skills. The results of this research provide evidence that group education is better than individual education, and also the age of patients and diabetes education determine their knowledge indicating that these factors should be understood by health providers to modify their education programmes to meet the needs of their patients. The model also measures barriers to self-management. Investigating these barriers on a regular bases helps in identifying problems that prevent or diminish adherence to the required activities. Understanding these barriers could be the base for appropriate actions.

The model is a valid decision-making supporting tool that could assist decision-makers to make important decisions. Outcomes for different programmes could be compared against predetermined criteria. This comparison could be the base for rewarding and motivating staff or making other decisions to correct deviations. It could also assist in making different changes based on the analysis of factors influencing patients' adherence. It could also be used as a stratification tool where patients could be grouped into different categories based on their level of knowledge, level of social support level, and/or self-efficacy. This stratification may assist in targeting patients with desperate need for help and/or extra services.

#### 6.6 Recommendations

Based on the findings of this research, and based on the strong evidence of the literature, I recommend that the government of Saudi Arabia represented by the Ministry of Health, Ministry of Defence, and all other providers of health services, invest further in developing new self-management programmes for chronic conditions including diabetes mellitus. I also recommend adopting this model as an evaluation tool for these programmes. Adopting this model will contribute in reducing the burden of chronic conditions especially diabetes mellitus as a significant health problem in the country.

Diabetes self-management education programmes should be based on theoretical approaches for better understanding of patients' behaviour to enhance their confidence and to improve their ability to make informed decisions related to different circumstances. Using the learning cognitive theory approaches to enhance self-efficacy by setting reasonable and achievable targets to improve the mastery skills and also by introducing successful models and using effective education materials. It is also recommended to incorporate psychological consultations through these programmes to enhance the coping skills and reduce depressive symptoms associated with diabetes.

A collaborative effort is needed from other government agencies to increase people's awareness about diabetes. The media could play an important role in increasing the awareness level. Also Islamic scholars could utilise people gathering in mosques or provide lectures in diabetes centres to provide clear explanation about the reality of the fatalistic belief to eliminate any misconception of this important pillar of faith.

For future research, I recommend repeating this study using a control group of patients who are not engaged in self-management programmes to investigate the outcomes of diabetes self-management programmes. Using an experimental design will enhance making inferences about the cause and effect relationships illustrated in the model. This model was based on patients-related aspects. However there are other important system-related factors such as qualifications and training of staff, availability of routine preventive measures, and access to the services which were beyond the scope of this research and could be investigated in future research. Fatalism is a complex phenomenon that could be investigated in depth using qualitative methods to capture different dimensions of such a complex concept. Time management appears to be an important factor influencing patients' ability to engage in self-management activities. Therefore I recommend extending the model to include time management as a predicting factor to be tested in future research.

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# **Appendices**

# **Appendix A Ethical Approvals**

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Research and Ethics Committee

ARMED FORCES HOSPITAL

Southern Region P.O. Box 101 Khamis Mushayt Kingdom of Saudi Arabia Tel No: 2230

.

#### MEMORANDUM

To:

Major Abdullah Shahri

MSD

From:

Dr Zaka Ullah Khan

Chairman, Research and Ethics Committee

Date:

26.10.2008

Subject:

Questionnaire Study on Patient Medication of Diabetes Mellitus,

as Ph'D at Southampton University, U.K.

Ref/C/memo/zaka/Mj-Shahri

Dear Major Shahri

The Committee has received your proposal and approved it for you to carry out your research.

Please do not hesitate to ask for any assistance at any time should you need it.

Dr Z U Khan, MRBS, FRCS, FRCS (Tr & Oct ) Chairman of Research & Ethics Company of Street Company of S

KING FAHD ARMED FORCES HOSPITAL P.O. BOX: 9862 JEDDAH 21159 KINGDOM OF SAUDI ARABIA



مستشفى الملك فهد للقوات المسلحة ص. ب: ٩٨٦٢ جـــدة ٢١١٥٩

March 30, 2009 / 1430H-04-3

To

Lt. Col. Abdullah Al-Shehri PhD Student, Southampton University

Lt.Col./Dr. Fawaz M. Al-Hamaid From:

Chairman of Research Ethics Committee

Research Questionnaire: Evaluating Diabetes Self-Management Re

At our recent Research Ethics Committee meeting held yesterday Sunday, 29th March 2009. The committee has approved the research questionnaire which is prepared in Arabic Text and carried-out in the hospital.

We are forwarding this letter along with the filled questionnaires.

Regards,

Lt. Col. / Dr. Fawaz M. Al-Hamaid Chairman of Research Ethics Committee

All Committee Members

Maj./Engr. Saleh Al-Ghamdi

Encl: 49 Research Questionnaires



Mr Abdullah Alshehri 22 Fitzroy Close Southampton S016 7LW

RGO Ref: 6514

03 June 2009

Dear Mr Alshehri

Project Title A model to evaluate quality, effectiveness and influencing factors of diabetes self-management in Saudi Arabia

This is to confirm the University of Southampton is prepared to act as Research Sponsor for this study, and the work detailed in the protocol/study outline will be covered by the University of Southampton insurance programme.

As the sponsor's representative for the University this office is tasked with:

- 1. Ensuring the researcher has obtained the necessary approvals for the study
- Monitoring the conduct of the study
- Registering and resolving any complaints arising from the study

As the researcher you are responsible for the conduct of the study and you are expected to:

- 1. Ensure the study is conducted as described in the protocol/study outline approved by this
- Advise this office of any change to the protocol, methodology, study documents, research team, participant numbers or start/end date of the study
- Report to this office as soon as possible any concern, complaint or adverse event arising from the study

Failure to do any of the above may invalidate the insurance agreement and/or affect sponsorship of your study i.e. suspension or even withdrawal.

On receipt of this letter you may commence your research but please be aware other approvals may be required by the host organisation if your research takes place outside the University. It is your responsibility to check with the host organisation and obtain the appropriate approvals before recruitment is underway in that location.

May I take this opportunity to wish you every success for your research.

Yours sincerely

Dr Lindy Dalen

Research Governance Manager

Tel: 023 8059 5058

email: rgoinfo@soton.ac.uk

Corporate Services, Enlistesity of Southampton, Highfield Compus, Southampton SCF9 1KJ United Engylem Tel: -44 (e) as 8659 4654 Fax: +44 (e) as 8659 5781 www.southampton.sc.uk

## Appendix B Research Questionnaire

HbA1c =	
	١

Dear Participant

Diabetes mellitus is one of the most common chronic diseases in Saudi Arabia. Diabetic patients play a very crucial role to control this disease and to reduce its complications by following a specific diet, exercise, taking medications or insulin injections as prescribed, continuous examination of blood glucose and foot care. This study is provided to the University of Southampton for a PhD in health management. It aims to assess the patients' role in controlling the disease and to evaluate the clinical and economical effects of this role. In addition it aims to understand the factors that influence patients' compliance with treatment plan. The results and recommendations of this study will contribute in providing better services for you and better understanding of the barriers that prevent you from adhering to your treatment plan.

I would like to thank you very much for participating in this study taking into consideration that your HbA1c, will be recorded by a specialist nurse. I would like to confirm that all collected information will be used for research purposes only and will be dealt with in complete confidentiality.

This questionnaire consists of 10 sections; please take your time to fill every question in each section. However if you do not wish to answer a particular question you can leave a dash (-) in the blank, and if you think it is not applicable in your case you may leave a slash (/) in the blank,

If you have any questions about this questionnaire, do not hesitate to ask the receptionist in your centre or you can call the researcher at 0503337416. However if you have any concerns regarding the research you may contact Dr Zaka the head of research ethics committee at 05042079773.

PLEASE READ CARFULLY THE CONSENT FORM NEXT PAGE AND SIGN IT BEFORE ANSWRING ANY OUESTION.

Best regards Yours (researcher) Abdullah Alshehri

Consent Form
Iagree to participate in a research project entitled (name of participant)
A model to evaluate quality, effectiveness and influencing factors of diabetes self- management in Saudi Arabia, conducted by Abdullah Alshehri, a PhD research student in the University of Southampton

The researcher or one of his assistants has discussed this research with me. I have had the opportunity to ask questions about this research and I have received answers that are satisfactory to me. I have read and kept a copy of the Information Sheet and understand the general purposes, risks and methods of this research.

I agree to take part because:

- 1. I know what I am expected to do and what this involves.
- 2. The risks, inconvenience and discomfort of participating in the study have been explained to me.
- 3. All my questions have been answered to my satisfaction.
- 4. I understand that the project may not be of direct benefit to me.
- 5. I can withdraw from the study at any time.
- 6. I am satisfied with the explanation given in relation to the project as it affects me and my consent is freely given.
- 7. I can obtain a summary of the results of the study when it is completed.
- 8. I understand that my personal information will be kept private.
- 9. I agree to the publication of results from this study provided details that might identify me are removed.
- 10. I authorize the researcher or one of his assistants to record the readings of the level of my <u>Glycosylated</u> <u>Haemoglobin</u>

Signed by the participant:	_ Date:
Signed by an independent witness:	Date:
(Print name in full - independent witness)	
Address of independent witness (Professional or Home):	
Signed by the researcher:	Date:

Should you have any queries concerning this research please contact Dr Zaka Khan, Director of research committee, Armed Forces Hospital Southern Region, Level 1, Administrative building. <u>Tel:00966(7)2500001</u>, EX: 2901, Mobile 00966542079773

# Section 1

1 -	Gender: male □ female □
2-	Age : less than 30 $\square$ 30 – 39 $\square$ 40 - 49 $\square$ 5059 $\square$ 60 or above $\square$
3-	Region: Middle Western Eastern Northern Southern
4-	Social Status single   Married   Divorced   Widow
5-	Educational level: illiterate $\square$ Primary $\square$ intermediate $\square$ Secondary $\square$ Bachelor $\square$ Post graduate $\square$
6-	Monthly income: less than 4000□ 40008000□ 9000 13000 □ 14000 18000 □ 19000 or above□
7-	How long since you have been diagnosed with type 2 diabetes mellitus? Please specify the number of yearsyears.
8-	In addition to diabetes, do to you suffer any of the following conditions? High blood pressure $\square$ High level of cholesterol $\square$ both $\square$ None $\square$
9-	Do you suffer any of the following complications of diabetes? (Choose all that apply) Retinopathy (eye problems)   Neuropathy (nerve problems)   Heart disease   Foot problems
10-	Have you been involved in any diabetes education sessions in the last 12 months?  Yes No If yes, please answer the following 2 questions:
	10.1- were these sessions group□ Individual□ or both□?
	10.2 How long were these sessions? (Example 40 minutes for 10 days)
	Minutes for days.
11-	In the last 12 months, have you ever visited the emergency room in any hospital for diabetes or diabetes related problems? Yes $\square$ No $\square$
	If yes, please answer the following question:
	11.1 How many times did you visit the emergency room? Times.
12-	In the last 12 months, have you been admitted to any hospital for diabetes or diabetes related problems? Yes □ No□
	If yes, please answer the next 2 questions:
	12.1 How many times have you been admitted? times.
	12.2 How many days did you spend in the hospital(s) for all these admissions?
	days.

# Section 2- Diabetes self-management Scale

		0	1	2	3	4	5	6	7
1-	On how many of the last seven days have you followed your diabetes diet as it was recommended?								
2-	On how many of the last seven days have you taken your medications as they were prescribed by your physician?								
3-	On how many of the last seven days have you participated in at least 30 minutes of physical exercise?								
4-	On how many of the last seven days have you tested your blood sugar by yourself?								
5-	On how many of the last seven days did you check and take care of your feet?								

## Section 3: Patient's Beliefs Scale

		Strongly disagree	Disagree	Not sure	Agree	Strongly agree
1-	Following diabetes diet is important to control the level of blood glucose					
2-	Following diabetes diet is important to prevent diabetes complications					
3-	Doing physical exercise is important to control the level of blood glucose					
4-	Doing physical exercise is important to prevent diabetes complications					
5-	Self-monitoring of blood glucose is important to control its level in the blood					
6-	Self-monitoring of blood glucose is important to prevent diabetes complications					
7-	Taking medications as prescribed is important to control the level of blood glucose					
8-	Taking medications as prescribed is important to prevent diabetes complications					
9-	Checking and taking care of your foot is important to prevent diabetes complications					

## **Section 4- Diabetes Self-efficacy Scale**

		Yes	Probably	May be	Probably	Definitel
	Do you think you are able to	Definitely	yes	yes	no	y not
				may be		
				no		
1-	Check your blood glucose by yourself?					
2-	Follow your recommended diet most of the time?					

3-	Follow your recommended diet while			
	dinning outside in occasions?			
4-	Examine and take care of your feet?			
5-	Do physical exercise on regular			
	bases?			

#### Section 5- Fatalism scale

		Strongly	Agree	Do not	Disagre	Strongly
		agree		know	e	disagree
1-	All believers should accept whatever Allah has meant for them					
2-	Whatever illness I will have, Allah has already planned it					
3-	Whatever future complications result from my disease is definitely happening					
4-	I do not need to try to improve my health because I know it is up to Allah to improve it					
5-	When I am sick I give my burdens to Allah without doctors having to do anything					
6-	If Allah wants me to have a good health in the future that will happen without having to take care of myself					

## Section 6- Patients-Providers Communications Scale

Hov	v often did	Never	Rarely	somet	Often	Alway
				imes		S
1-	Your doctor talk to you using medical terms that you do not understand?					
2-	Your doctor listen carefully to what you had to say about your medical problems?					
3-	Your doctor answer your questions and concerns about diabetes?					
4-	Your doctor explains why a test was being done and what were the results?					
5-	Your doctor explain to you how to take your medications?					

# Section 7- Social Support Scale

To what extent have your family and/or friends	Not at all	Α	A moderate	A lot	Α
		little	amount		great
					deal
1 - Listened carefully for what you had to say about your illness?					
2- Encouraged you to commit to your treatment plan?					
3- Bought and cooked food that suits your diet?					

4-	Praised you for your commitment to your treatment plan?			
5-	Reminded you to take your medications on time?			

#### Section 8- Diabetes Quality of Life Scale

If I	do not have diabetes	A great	Better	The	Worse	A great
		deal		same		deal
		better				worse
1-	My employment/ career opportunities would be					
2-	My social relationships would be					
3-	My sex life would be					
4-	My sporting holiday/ leisure opportunities would be					
5-	My future hopes and expectations would be					

#### Section 9- Diabetes Knowledge Scale

This section aims to assess your general knowledge about diabetes, please select only one answer by drawing a circle around the corresponding number for each of the following 10 questions

Q1-Which of the following is high in carbohydrates:

- 1) Baked chicken
- 2) Swiss cheese
- 3) Baked potato
- 4) I don't know

Q2-Eating food lowers in fat decreases your risk for:

- 1) Nerve disease
- 2) Kidney disease
- 3) Heart disease
- 4) I don't know

Q3- Which is the best method for testing blood glucose?

- 1) Urine testing
- 2) Blood testing
- 3) Both are equally good
- 4) I don't know

#### Q4- Self-monitoring of blood glucose is:

- 1) The key to determining the right amount of medication
- 2) Important to see the effect of diabetes control such as diet and exercise
- 3) Both a and b
- 4) I don't know

#### Q5- The action of diabetes pills:

- 1) Lower blood sugar
- 2) Increase insulin secretion
- 3) Increase insulin sensitivity
- 4) All above
- 5) I don't know

#### Q6- Low blood glucose may be caused by

- 1) Too much insulin
- 2) Too little insulin
- 3) Too much food
- 4) I don't know

#### Q7- For a person in good control, what effect does exercise has on blood glucose?

- 1) Lowers it
- 2) Raises it
- 3) Has no effect
- 4) I don't know

#### Q8- In general, fit patients with diabetes should exercise for

- 1) 1 hour once a week
- 2) 20 to 30 minutes 3 to 5 times a week
- 3) 1 hour every day
- 4) I don't know

#### Q9- Which of the following is usually not associated with diabetes?

- 1) Vision problems
- 2) Nerve problems
- 3) Lung problems
- 4) I don't know

#### Q10 - The best way to take care of your feet is to:

- 1) Look at and wash them every day
- 2) Massage them with alcohol every day
- 3) Buy shoes a size larger than usual
- 4) I don't know

## **Section 10-Barriers**

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Please mention in the space below(or in the back of this page if you need more space) any barriers that prevent you or reduce your ability to follow your treatment plan
including diet, exercise, taking medications, checking blood glucose, and/or taking
care of your feet
Thank you for your cooperation

# Appendix C Research Questionnaire (Arabic Version)

₩		~ ~	
البخير البخير	لِجْحَرِ	انتكا	ڔٮؿٚؠٚٙ

عزيزي المشارك : عزيزي المشارك :

إن أهم العوامل للسيطرة على مرض السكري والحد من مضاعفاته هو ما يقوم به المريض بنفسه تجاه السيطرة على مستوى السكر في الدم، وذلك بإتباع الحمية الغذائية وممارسة الرياضة واستخدام العلاج طبقاً للإرشادات الطبية ،وكذلك الفحص المستمر لمستوى السكر في الدم والعناية بالقدمين ، ويتم تقديم هذه الدراسة بغرض الحصول على درجة الدكتوراه في الإدارة الصحية من جامعة ساوث همبتون بالملكة المتحدة والتي تهدف إلى تقييم دور المريض في العناية بنفسه والنتائج المترتبة على قيامه بهذا الدور ، و تهدف أيضاً إلى معرفة العوامل المؤثرة أو المساعدة لقيام المريض بدوره بالشكل الأمثل.

إن نتائج هذه الدراسة وتوصياتها سوف تسهم بمشيئة الله في تحسين الخدمات المقدمة إليك وتذييل الصعاب التي يعاني منها المرضى في التعامل مع هذا المرض.

ولذا أتوجه إليك — عزيزي المشارك — بخالص شكري وتقديري على استقطاعك لهذا الجزء من وقتك لتعبئة هذه الإستبانة ، علماً بأن المعلومات المتعلقة بمستوى السكر في الدم والموجودة في الجزء الأعلى الأيسر من هذه الصفحة سيتم تسجيلها من قبل المرضة المختصة وسوف تستخدم جميع هذه المعلومات فقط لأغراض البحث العلمي ويتم التعامل معها بسرية مطلقة ، ولن يتم الاستدلال بأي حال من الأحوال على صاحب الإستبانة.

كما أود أن ألفت انتباهك — عزيزي المشارك — إلى ضرورة تعبئة كامل الاستمارة إلا أنه في حالة عدم رغبتك الإجابة على أي من فقرات الإستبانة أو في حالة عدم مطابقتها لوضعك فأرجو ترك هذه الفقرة فارغة. كما الرجو عدم البدء بالاجابة قبل قراءة الاقرار المرفق والتوقيع بالموافقة على المشاركة في البحث وتقبلوا مني خالص الشكر والتقدير لكريم تعاونكم ،،، ،،، ،،،

عبد الله بن رافع الشهري

هاتف: 🗆 🗆 🗎 🗎

	الجنس:		نکر		أنثى		
.2	العمسر:		أقل من 30 عاماً 59-50 عاماً		39-30 عاماً 60 عاماً فأكثر		49-40 عاماً
.3	المنطقة:		الوسطى الغربية		الشرقية الجنوبية		الشمالية
.4	الحالة الاجتماعية:		اعـــزب أرمـــل		متـــزوج		مطلق
.5	المستوى التعليمي:		أم <i>َّى</i> الثانوية		ابتدائية جامعي		المتوسطة دراسات عليا
.6	الدخل الشهري:		أقل من 4000 ريال 18000- 14000		8000-4000 19000 فأكثر		13000-9000
.7	منذ کم عام تم تشخیصك بأ	أنك مصا □	ب بداء السكري؟ أقل من خمس سنوات		5-9 سنة		10 - 14 سنة
			15 – 19 سنة		20 – فأكثر		
.8	إضافة إلى داء السكري هل	) تعان <i>ي</i> د  -  -	ن أي من الأمراض التالية ارتفاع ضغط الدم لا أعاني من أي منهما		ارتفاع نسبة الدهون		كلاهما
.9	هل تعاني من أي من مضاد		مكري التالية: (اختر جميع أمراض العيون أمراض القلب	ينطبق عليا    -  -	ک) أ مراض الكلى مشاكل القدمين		أمراض الأعصاب
.10	حصلت خلال ألاثني عشر ش		اضیة علی دورات (جلسات نعم	أو محاضراه		سکري؟	
	إذا كانت إجابتك بنعم أرجو	إجابة ال	سؤالين التاليين:				
10.1	هل كانت هذه الجلسات:		جماعية		فردية		كلاهما
10.2	كم كانت مدة هذه الجلسات	······	دقيقة لمدة				
.11	هل راجعت قسم الطوارئ بـ	بأي مست	,	ِ أ <i>ي من م</i> ظ □	ساعفاته خلال ألاثني عش لا	نىر شىھرا الە	ضية؟
	إذا كانت إجابتك بنعم أرجو	إجابة ال	سؤال التالى:				
11.1	كم مرة راجعت قسم الطوار	رئ ؟			مرة		
.12	هل سبق وان أدخلت للتنوير		، مستشفى بسبب مرض الد نعم	ري أو أحد ا □	مضاعفاته خلال ألاثني . لا	عشر شهرا	ماضية؟
	إذا كانت إجابتك بنعم أرجو	إجابة ال	سؤالين التاليين:				
12.1			مرة ك	رة تم تنويه	ণ ব		
12.2	كم كان إجمالي عدد أيام الت	تنويم في	هذه المرات ؟		يومأ		

# انياً: يهدف هذا الجزء الى معرفة مدى التزامك بالخطة العلاجية

7 أيـام	6 أيـام	5 أيام	4 أيام	3 أيـام	يومان	يوم	ولا يوم		م
						واحد			
								في كم يوم خلال السبعة الأيام الماضية التزمت بالأكل الصحي	1
								المناسب لمرضك	
								في كم يوم خلال السبعة الأيام الماضية التزمت بتناول العلاج أو	2
								الأنسولين حسب ما هو موصوف لك	
								في كم يوم خلال السبعة الأيام الماضية مارست الرياضة لمدة	3
								نصف ساعة على الأقل	
								في كم يوم خلال السبعة الأيام الماضية قمت بفحص مستوى السكر	4
								في الدم بنفسك	
								في كم يوم خلال السبعة الأيام الماضية قمت بفحص أقدامك	5
								والعناية بها	

# ثالثاً: إلى أي مدى تعتقد بأهمية كل من العناصر التالية في السيطرة على مستوى السكر في الدم وفي الحد من مضاعفات مرض السكري

بالغ الأهمية	مهم جدأ	مهم إلى حد ما	ليس مهمأ	ليس له أهمية		م
				تذكر		
					أهمية الحمية الغذائية في السيطرة على مستوى السكر في الدم	1
					أهمية الحمية الغذائية في الحد من مضاعفات السكري	2
					أهمية التمارين الرياضية في السيطرة على مستوى السكر في الدم	3
					أهمية التمارين الرياضية في الحد من مضاعفات السكري	4
					أهمية قياس مستوى السكر في الدم في السيطرة على هذا المستوى	5
					أهمية قياس مستوى السكر في الدم في الحد من مضاعفات السكري	6
					أهمية تناول الأدوية أو جرعات الأنسولين في السيطرة على مستوى	7
					السكر في الدم	
					أهمية تناول الأدوية أو جرعات الأنسولين في الحد من مضاعفات	8
					السكري	
					أهمية فحص القدمين والعناية بهما في الحد من مضاعفات السكري	9

# رابعاً: هذا الجزء من الاستبيان يهدف إلى معرفة مدى استطاعتك القيام ببعض الأعمال

			ممكن نعم		
	نعم بالتأكيد	احتمال نعم	وممكن لا	احتمال لا	بالتأكيد لا
ل السكر في الدم بنفسك					
لغذائية في معظم الوقت					
لغذائية أثناء العزائم والمناسبات					
والعناية بهما					
ضة بشكل منتظم					
أو جرعات الأنسولين حسب ما					

# خامساً: يهدف هذا الجزء من الاستبيان إلى قياس بعض المفاهيم والمعتقدات لديك،

لا أوافق بشدة	لا أوافق	لست متأكداً	أوافق	أوافق بشدة		م
					يجب على كل مؤمن أن يتقبل ما قدره الله له	1
					إن جميع ما يصاب به المرء من أمراض هو مقدر من الله سلفاً	2
					إن جميع ما يترتب على مرضي من مضاعفات مستقبلية أمر واقع لا	3
					محالة	
					لا يجب على الإنسان بذل أي جهد لتحسين صحته لأنها خاضعة	4
					لمشيئة الله تعالى وحده	
					عندما يشتد بي المرض فاني ألجأ إلى الله بالدعاء فقط دون الحاجة	5
					للذهاب إلى الطبيب	
					إذا أراد الله أن يمتعني بالصحة في المستقبل فإن ذلك سيحدث وليس	6
					علي الاعتناء بصحتي في الوقت الحاضر	

# سادساً: يهدف هذا الجزء إلى معرفة مدى قدرتك على التواصل مع الطبيب المعالج

دائماً	غالباً	أحيانا	نادرا	لا يحدث		م
				أبدأ		
					إلى أي مدى يتحدث الطبيب باستخدام مصطلحات طبية لا تستطيع	1
					فهمها	
					إلى أي مدى يستمع الطبيب إلى ما تود قوله عن مرضك	2
					إلى أي مدى يجيب الطبيب على أسئلتك واستفسار اتك عن حالتك	3
					إلى أي مدى يشرح لك الطبيب عن أسباب إجراء التحاليل الطبية	4
					ونتائجها	
					إلى أي مدى يشرح لك الطبيب كيفية تناول الأدوية أو جرعات	5
					الأنسولين	

# سابعاً: يهدف هذا الجزء إلى معرفة مدى تعاون عائلتك أو محيطك الاجتماعي في التعامل مع هذا المرض

دائماً	غالبأ	أحيانا	نادرا	لا يحدث		م
				أبدأ		
					إلى أي مدى تستمع عائلتك باهتمام عندما تحدثهم عن مرضك	1
					إلى أي مدى تشجعك عائلتك على ممارسة الرياضة والحمية الغذائية	2
					وفحص الدم والقدمين	
					إلى أي مدى تقوم عائلتك بشراء وطبخ المأكولات التي تتناسب مع حميتك	3
					الغذائية	
					إلى أي مدى تكافئك عائلتك على التزامك بالحمية الغذائية وممارسة	4
					الرياضة	
					إلى أي مدى تساعدك عائلتك على تذكر تناول الأدوية أو جرعات	5
					الأنسولين في الوقت المناسب	

# ثامناً: يهدف هذا الجزء إلى التعرف على مدى تأثير مرض السكري على حياتك بشكل عام .. فكيف تقيم الأمور التالية لو لم تكن مصاباً بمرض السكري

أسوأ بكثير	أسوا	لا أتوقع أي	أفضل	أفضل بكثير	لو لم تكن مصاباً بمرض السكري <b>لكانت</b>	م
		فرق				
					حياتك الوظيفية أو المهنية	1
					علاقاتك الاجتماعية	2
					علاقاتك الزوجية	3
					استمتاعك بالإجازات والعطلات	4
					أمالك وطموحاتك المستقبلية	5

تاسعاً: يهدف هذا الجزء إلى التعرف على معلوماتك عن مرض السكري لذا أرجو اختيار إجابة واحدة فقط بوضع دائرة حول الفقرة التي تمثل الإجابة الصحيحة في كل من الأسئلة العشرة التالية

أي من الأطعمة التالية غنى بالكربو هيدرات:	و هیدر ات	غنى بالكر ب	التالية	من الأطعمة	ـ أي
---	-----------	-------------	---------	------------	------

- أ) الدجاج
- ب) الأجبان
- ج) البطاطا
- د) لا أعلم

## 2- تناول الأطعمة قليلة الدسم يقلل خطر الإصابة:

- أ) بأمراض الأعصاب
  - ب) بأمراض الكلى
  - ج) بأمراض القلب
    - د) لا أعلم

# 3- أي الطرق التالية أفضل لقياس مستوى السكر:

- أ) قياس مستوى السكر في البول
- ب) قياس مستوى السكر في الدم
- ج) كلاهما يقيس مستوى السكر بنفس الدقة
  - د) لا أعلم

## 4 - فحص ومراقبة مستوى السكر:

أ) يفيد في تحديد الجرعة المناسبة للأدوية أو الأنسولين

- ب) مهم لمعرفة تأثير الحمية الغذائية والتمارين الرياضية في السيطرة على مستوى السكر في الدم
  - ج) كلا الإجابتين السابقتين صحيحة
    - د) لا أعلم
    - 5 مفعول أدوية السكر:
    - أ) يقلل مستوى السكر في الدم
      - ب) يزيد من إفراز الأنسولين
  - ج) يزيد من فعالية الجسم لامتصاص الأنسولين
    - د) جميع الإجابات السابقة صحيحة
      - هـ) لا أعلم
  - 6 انخفاض مستوى السكر في الدم قد يكون نتيجة لـ:
    - أ) جرعة زائدة من الأنسولين
    - ب) جرعة قليلة من الأنسولين
    - ج) تناول كميات كبيرة من الطعام
      - د) لا أعلم
  - 7 ما هو تأثير التمارين الرياضية على مستوى السكر لدى الشخص المسيطر على مرض السكر:
    - أ) تقلل مستوى السكر
    - ب) ترفع مستوى السكر
      - ج) ليس لها تأثير
        - د) لا أعلم
    - 8 بالنسبة للأشخاص الذين يتمتعون بصحة جيدة ، يجب ممارسة الرياضة بمعدل:
      - أ) مرة واحدة في الأسبوع لمدة ساعة
      - ب) من 20 30 دقيقة ، ثلاث إلى خمس مرات أسبوعياً
        - ج) ساعة كاملة كل يوم
          - د) لا أعلم
        - 9 أي من المشكلات التالية ليس لها علاقة بمرض السكري:
          - أ) مشكلات النظر
          - ب) مشكلات الأعصاب
            - ج) مشكلات في الرئة

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د) لا أعلم

- أ) فحصها وغسلها جيداً كل يوم
- ب) تدليكها باستخدام الكحول كل يوم
  - ج) استخدام حذاء أكبر من مقاسك
    - د) لا أعلم

او العقدص المسلمر لما	ياضه أو تناول الأدوية	ئية او ممارسة الرب	، إتباع الحمية الغذا	المرض من حيث	
			العناية بالقدمين:	السكر في الدم أو	

شاكرين حسن تعاونكم ،،، ،،، ،،،