QATAR UNIVERSITY

COLLEGE OF PHARMACY

RELATIONSHIP BETWEEN THE STAGES OF CHANGE AND MEDICATION ADHERENCE IN PATIENTS WITH TYPE 2 DIABETES MELLITUS IN A PRIMARY HEALTH CARE SETTING IN QATAR

By

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Abstract

Background: Non-adherence to medications is a major concern among patients with type 2 diabetes mellitus (T2DM). Failure to achieve positive health-related outcomes could be associated with non-adherence. Medication non-adherence is considered a socio-behavioral problem, thus using a behavioral model such as the transtheoretical model (TTM) could improve it.

Objective: The primary objectives of this study were: (1) to determine the TTM's Stages of Change (SOC) and medication adherence scores of patients with T2DM in a primary health care setting in Qatar; (2) to determine the relationship between these two variables; and (3) to determine whether SOC could predict medication adherence whilst controlling for confounding factors. The secondary objectives were to assess the relationship: (1) between SOC and glycated hemoglobin (HbA1c); and (2) between medication adherence and HbA1c in the same population.

Method: The study was conducted in the non-communicable disease clinic. Non-Qatari patients were recruited from Mesaimeer Health Care Center, whereas Qatari patients were recruited from Westbay Health Care Center. Medication adherence was measured using the eight-item Morisky Medication Adherence Scale (MMAS-8), and SOC was determined using a two-item SOC questionnaire. HbA1c values were obtained from the electronic medical records at the clinic. Spearman rank correlation was conducted at α level of 0.05 to determine the relationship between variables of interest, and hierarchical regression was performed to determine if SOC could predict medication adherence, while controlling for confounding factors.

Results: A total of 387 patients were included in the analysis. The majority of the participants were non-Qatari (84.8% non-Qatari vs. 15.2% Qatari). The highest percentage of participants was in the maintenance stage (76.7%). The rate of low, medium, and high adherence to antidiabetic medications was 26.4%, 23.3%, and 50.3%, respectively. There was a significant positive correlation between SOC and adherence score ($r = 0.728$, $p < 0.001$), and SOC was able to significantly explain 58 % - 59 % of the variance when predicting medication adherence % ($p < 0.001$) while controlling for confounding factors.

Conclusion: There was a strong association between SOC and medication adherence, suggesting that the two-item SOC questionnaire could potentially be used as a simple tool to identify patients at risk of low adherence.

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Abbreviations

AASI	Ambulatory Arterial Stiffness Index
ART	Anti-retroviral Therapy
CHW	Community Health Workers
DM	Diabetes Mellitus
DSME	Diabetes Self-Management Education
HbA1c	Glycosylated Hemoglobin
HAART	Highly Active Anti-retroviral Therapy
HR-QOL	Heath related –Quality of Life
IBD	Inflammatory Bowel Disease
IDF	International Diabetes Federation
MMAS-8	Morisky Medication Adherence Scale-8
NCD	Non-Communicable Diseases
PHCC	Primary Health Care Corporation
SOC	Stages of Change
SBP	Systolic Blood Pressure
TTM	Transtheoretical Model
T2DM	Type 2 Diabetes Mellitus
WHO	World Health Organization

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Chapter 1: Introduction

1.1 Diabetes epidemiology worldwide and in Qatar

Many health organizations worldwide consistently highlight the importance of health promotion and disease prevention due to the high incidence and prevalence of several chronic diseases which continues to rise with time. In the last 20 years, the prevalence of diabetes mellitus (DM) has greatly increased in several parts of the world and it is currently considered a global public health problem (1). In 2012, DM was the cause of 1.5 million deaths which meant that every seven seconds a person died due to DM. More than 80% of these reported deaths were in low and middle income countries (2). In 2014, the global prevalence of DM in adults was estimated to be 8.5 % (3). There are currently around 387 million people living with type 2 diabetes mellitus (T2DM) worldwide, and the prevalence of the disease is projected to escalate to 592 million people by 2035. The number of people with T2DM is currently increasing in every country. In the Middle East and North Africa (MENA) region, 37 million people have T2DM, a figure estimated to rise to 68 million by 2035 (4). T2DM caused 368000 deaths in 2013 in the MENA region alone, and 50% of these deaths were in individuals under the age of 60 (4).

Qatar is a country which is currently experiencing an alarming increase in prevalence of T2DM. Qatar is a Middle Eastern country and it is part of the Gulf Cooperation Council. It has been a part of the International Diabetes Federation (IDF) since 1997. In 2015, Qatar had 239,100 cases of T2DM (13.5% of the adult population between the ages of 20 and 79 years old) (5). Figure (1) illustrates the prevalence of Diabetes in Qatar compared to the MENA region and the rest of the world in 2014.

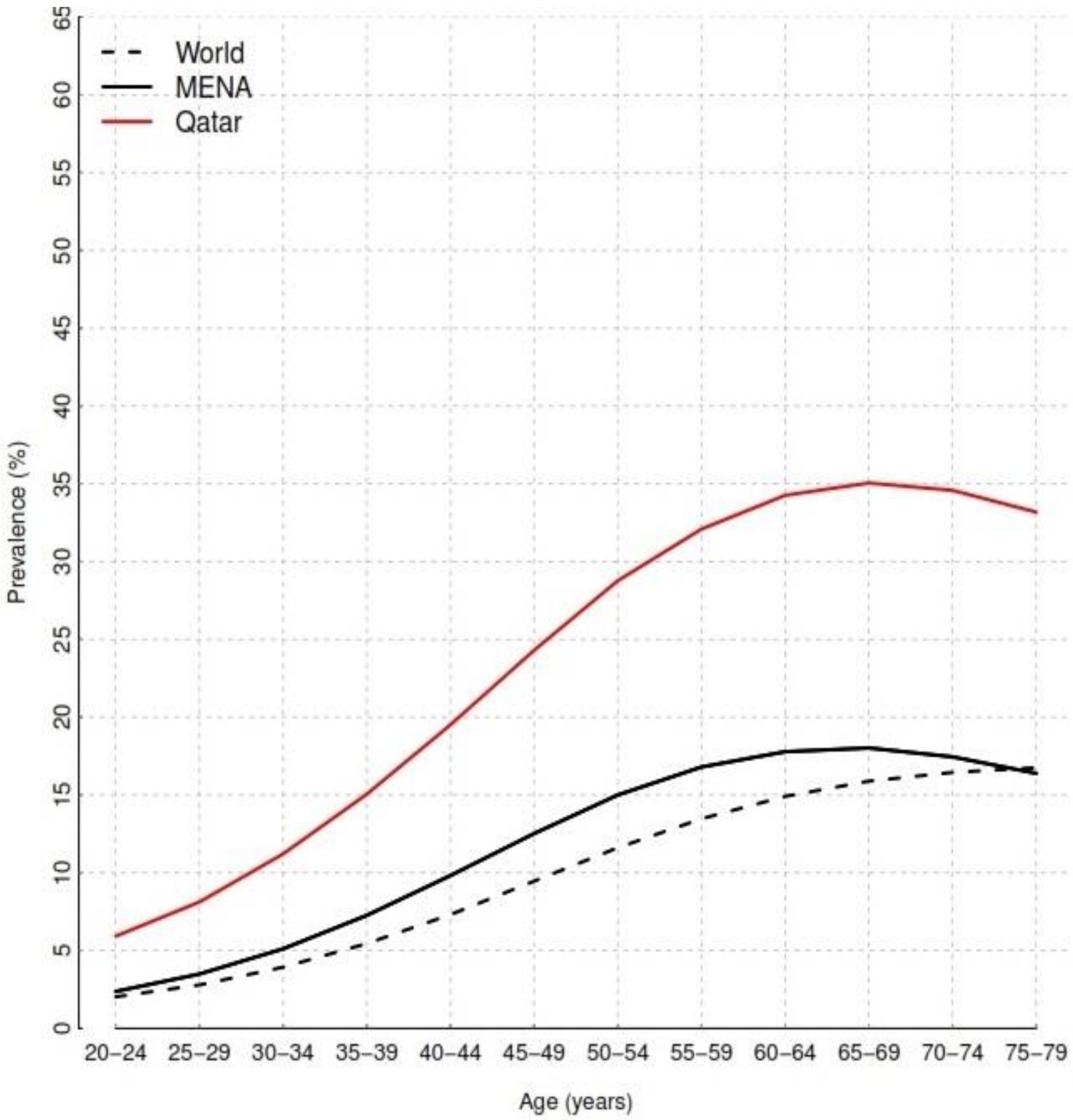

Figure 1: Diabetes prevalence in adults based on age groups in Qatar, MENA, and the world (6)

1.2 Economic burden of diabetes

In 2014, DM was responsible for at least USD 612 billion dollars in global health expenditure (4). Focusing particularly on the MENA region, USD 17 billion dollars (3% of the total worldwide expenditure) was spent on treating DM (4). The annual cost per person with diabetes in Qatar is estimated to be USD 2,868 dollars. There are approximately 16.5 million people with T2DM in the U.S, and their annual national cost is about USD 159.5 billion (7). In addition, there are 6.3 million adults with undiagnosed DM in the United States of America (USA) who are unaware that they have the disease. These individuals are left untreated and their associated cost was estimated to be USD 18 billion in 2007 (8). Nearly 57 million adults have pre-diabetes: a state of elevated blood glucose which is a precursor to diabetes. Pre-diabetes is associated with USD 25 billion annually in higher medical costs (9). The vast DM-related spending currently imposes a substantial burden on the global economy in the form of increased medical and indirect costs from absenteeism from work, reduction in productivity and labor force due to chronic disability, and premature mortality (10, 11). T2DM is specifically costly when patients begin to develop other associated chronic complications. In 1997, there were some data on complications associated with T2DM in the USA, but the results could not be extrapolated globally (11). However, several studies conducted later found that the cost of managing patients with uncontrolled T2DM or patients with diabetes complications was at least two to eight times more than that of managing patients with controlled or non-advanced diabetes (12, 13). T2DM increases the risk of developing several serious neurological, peripheral vascular, cardiovascular, renal, metabolic, and ophthalmic complications (11). While, the direct medical costs attributed to treat T2DM was USD 27 billion diabetes, the cost of treating chronic complications attributed to it was about USD 58 billion (11).

1.3 Diabetes treatment and self-management

Diabetes is a metabolic chronic disease which if left untreated, can affect the entire body systems and lead to a worse health-related quality of life (HR-QOL). It occurs when a person has a high concentration of glucose in the blood either because the pancreas does not produce enough insulin, or because the body cannot use insulin properly (14). According to the World Health Organization (WHO), a person is diagnosed with diabetes if the plasma glucose concentration is higher than 11.0 mmol/l after 2 hours of ingesting 75 grams oral glucose load, or/and if after fasting overnight, the plasma glucose concentration is ≥ 7.0

mmol/l, or/and if A1C is ≥ 6.5% (15, 16). There are three types of diabetes; gestational diabetes which is temporary and occurs during pregnancy, type 1 diabetes which occurs when the immune system of a person destroys the beta cells in the pancreas, and type 2 diabetes which occurs when the cells in the body are resistant to insulin or if the body is unable to produce sufficient insulin to control metabolic activities (17). T2DM is the most common type, and its' risk factors are obesity and lack of exercise especially in people who are genetically predisposed (18). Once developed, T2DM cannot be cured, but non-pharmacological strategies along with medications are necessary to manage the disease and delay its progression (19). Usually patients with T2DM do not need insulin as a treatment and instead they rely on oral antidiabetic medications including: metformin, sulphonylureas, glitazones, gliptine, repaglinide, or a combination of these (20). If patients with T2DM are unable to self-manage their disease, they will be at a higher risk of developing diabetes associated complications including cardiovascular diseases, retinopathy, nephropathy, neuropathy, and in some cases amputation of the lower limbs (21). In the USA alone, 28.5% of patients with T2DM have retinopathy, and 44% of all nephropathy cases were due to T2DM. Additionally, 65% of patients with T2DM aged 18 years or older suffered from dyslipidemia (22). Therefore, the ability to self-manage the disease is of paramount importance in improving HR-QOL in patients with T2DM.

Even though self-management of diabetes is the most crucial factor that contributes to the therapy's success and subsequently leading to a better HR-QOL, many patients still have a problem in being able to self-manage their disease. The main objectives of Diabetes Self-Management Education (DSME) are to encourage and aid patients in informed decision-making, self-care behaviors to improve clinical outcomes, and quality of life (23). Self-management of diabetes requires numerous activities that the patient needs to perform regularly. It requires patients to follow a healthy diet with no smoking or alcohol consumption, exercise regularly, and adhere to their medications as prescribed in order to achieve optimum glycemic control. It is also very important for patients with T2DM to monitor their blood glucose levels regularly. Due to the complexity of T2DM, and the need to make daily self-care decisions, focusing on adherence alone is not sufficient (24). Since there was a relationship between knowledge, attitude and practice (KAP) and DM, many DSME now include providing patients with the knowledge, abilities, and skills needed for self-care. In addition, for any educational intervention to be successful, it must incorporate the needs, goals, and life experiences of the patients with T2DM to engage and encourage them to self-manage their disease.

The World Health Organization guideline for a national program for diabetes emphasized the importance of educating patients with T2DM to help them attain a healthy quality of life and delay the disease progression as well as development of further complications (25). Many studies conducted in developed countries proved that lifestyle changes in patients resulted in a reduction in the prevalence of diabetes (26). However, there still seems to be a gap between the expected care and that provided by diabetes care teams, and the only way to close this gap is to conduct multidisciplinary interventions to achieve better HR-QOL (27).

The treatment of diabetes has advanced tremendously in the past several years, but many patients are still unable to achieve the desired clinical outcomes, and as a result suffer from a worse quality of life. Poor clinical outcomes are mainly because health care professionals depend solely on the biomedical model, which treats patients as passive recipients of doctors' instructions to treat chronic conditions (28, 29). This model provides a mechanistic view of any illness and it requires health care professionals to carry out mechanical solutions such as prescribing the correct medicine with the correct dose for the patient. Its main emphasis is on diagnosing and treating patients to return them to their preillness stage. Clinicians who apply this model believe that the problems of non-adherence to medications are due to certain characteristics in patients (30). However, the WHO, defines health as “a state of complete physical, mental, and social wellbeing, and not merely the absence of a disease or infirmity” (31). Since the biomedical model mainly focuses on improving physical wellbeing and not the remaining aspects of health, interventions began incorporating socio-behavioral models along with the biomedical to holistically improve personal health according to the WHO’s definition.

Over the years, several socio-behavioral models were developed to describe the mental and social well-being of patients. Social models of health focus on policies, education, and health promotion in order to address the broader influences on health such as environmental, cultural, or economic influences. Since the inability to self-manage diabetes is a complex socio-behavioral problem, adding a behavioral context might help patients control their diabetes leading to better clinical outcomes. Many social and behavioral models were used to promote self-management, but none were effective in diabetes care (32). However, one of the behavioral models known as the Transtheoretical Model (TTM) seems promising in supporting patients with T2DM.

1.4 The transtheoretical model

In the 1980’s, James O. Prochaska and Carlo C. DiClemente developed the TTM in an attempt to understand how people intentionally modify a certain behavior (33). The TTM, also known as the Stages of Change (SOC) model, is a socio-behavioral model that is commonly used in research and clinical practice. It is an integrative model of intentional change which explains how people acquire a positive behavior or change their unhealthy behavior by focusing on the decision making process of the individual. The TTM was originally used to focus on smoking behavior, but due to its popularity, it has been tested with several other behaviors such as weight loss (34), cancer screening behavior (35), and encouraging stroke victims to exercise (36). According to the TTM, changing an undesirable behavior is a long time dependent cognitive process. The TTM consists of 4 components: stages of change, processes of change, decisional balance, and self-efficacy.

1.4.1 Stages of change

Stages of change (SOC) can be conceptualized to either change or stop a specific undesirable behavior. The SOC are classified into: precontemplation, contemplation, preparation, action, and maintenance. The progression through SOC is not necessarily linear, and people move through these stages similarly to a cyclical pattern. Thus, individuals may regress to previous stages before moving forward. The following points describe each SOC of the TTM according to Prochaska et al. (1994) (37):

(i) Precontemplation stage: Individuals do not have the desire to change their behavior in the next 6 months. People at this stage are uninformed about changing certain behavior. Usually those at this stage will only consider changing their behavior if a significant person encourages them, or they are threatened in their life due to that behavior (e.g. might lose a job or a partner). If an individual says no to changing his/her behavior then he/she are considered to be in the precontemplation phase, but in order for those individuals to move forward in the cycle they must recognize and acknowledge their unhealthy behavior.

(ii) Contemplation stage: Individuals are aware that they have a problem with their behavior and they start thinking about the possibility of changing, but they have not yet made a commitment to change. Individuals at this stage start to search for ideas and facts in order to contemplate the idea of changing, and they weigh out the rewards and losses that will occur as a result of their behavior change. People at this stage know what they want to change already, but they are still not ready to do so. They plan to change within the next six months.

(iii) Preparation stage: Individuals at this stage will change in the near future (usually in the next month).This stage combines both intention and behavior strategies.

(iv) Action stage: Individuals have actively changed their unhealthy behavior. A person is considered at this stage when he/she has successfully changed their old habit and adopted a new healthy one instead for around one to six months. This stage requires a behavioral modification and a commitment of energy and time to change the problem behavior. Individuals at the action stage must adopt effective strategies to sustain the behavior.

(v) Maintenance stage: Individuals at this stage changed their behavior and have been practicing the new one for more than six months. Individuals at this stage must focus on developing reinforcement strategies to sustain the new behavior and prevent relapse.

1.4.2 Processes of change

Processes of change are defined as activities that people need to follow in order to alter their experiences or surrounding environments to modify their behavior (37). There are ten processes of change which are divided into cognitive and experiential and behavioral. In the cognitive and experiential processes, information is created based on people's own experiences or actions, whereas in the behavioral processes, behavioral strategies are used to change the undesirable behavior. The cognitive and experiential processes are consciousness raising, dramatic relief, self-reevaluation, environmental reevaluation, and social liberation. The behavioral processes of change are self-liberation, counterconditioning, reinforcement management, helping relationships, and stimulus control. The following points describe the processes of change used in the TTM according to Prochaska et al. (1994) (37):

(i) Consciousness raising: This process is used to move individuals from precontemplation to contemplation. It requires people to gather new information about a certain behavior in order to have a better understanding of it. Interventions which could increase the awareness or knowledge of the individuals include feedback and interpretations to support the healthy behavior change.

(ii) Dramatic relief: It is used to move patients from contemplation to action. It involves emotional experiences which are related to the changes in behavior. Interventions implementing dramatic relief can provide fear that becomes associated with the old behavior, or success stories about other people who already changed their behavior in order to be inspired by them.

(iii) Environmental reevaluation: It is used to move patients from contemplation to preparation. The individuals start to notice how their behavior affects their social environment. People at this stage begin to recognize that they can serve as either a positive or negative role model for others.

(iv) Self-reevaluation: This process moves people from contemplation to preparation. The individual starts to consider the cognitive and emotional values related to their behavior so they could assess their self-image with or without the specific unwanted habit.

(v) Social liberation: It is used to change patient from precontemplation to action. Individuals begin to realize that changing behavior is possible and is acceptable in the society. It helps people realize that social norms are supporting their healthy behavior.

(vi) Self-liberation: It is used to move people from preparation to maintenance. The individuals start to develop a new mindset that encourages them to change and commit to their new healthy behavior.

(vii) Counter conditioning: it is used to change individuals from action to maintenance. It requires people to learn new behaviors as substitutes for their undesirable behavior.

(viii) Helping relationships: It is used to change individuals from action to maintenance stages. Individuals rely on others to support them during their attempts to change their behaviors. Encouraging calls and rapport building are some of the activities which could be used as sources of social support.

(ix) Reinforcement management: It is used to change patient from action to maintenance. It provides rewards to people when they change their undesirable behavior and punishments if they practice it. People usually have very high expectations about people encouraging them, so it is important that they encourage themselves by saying self-statements such as "good job… you were able to resist the temptations".

(x) Stimulus control: It is used to change individuals from action to maintenance. It removes any cues or reminders related to old behavior, instead uses cues that remind people to engage in their new behavior.

1.4.3 Self-efficacy

The self-efficacy component in the TTM is based on Bandura's theory which states that "successful change is based on the increased level of confidence an individual demonstrates in coping with different tempting situations without relapsing" (38). Self-efficacy involves self-confidence of an individual in order to resist the temptations and be able to maintain their new behavior. As individuals move forward through the stages of change, self-efficacy should increase and the temptations decrease.

1.4.4 Decisional balance

Decisional balance assesses the advantages and disadvantages of adopting the new desirable behavior. Usually, individuals who are at the early SOC believe that the cons of changing their behavior are more than the pros of changing, but as individuals move forward across the SOC, the pros begin to outweigh the cons. There is usually a crossover between the pros and cons at the contemplation, preparation and action stages (39), and the strategies that help people move along the continuum from precontemplation to contemplation to preparation should work primarily on decreasing the cons.

1.5 Medication adherence

Medication adherence is a term that describes the extent to which patients take their medications as recommended by their health care professionals. Although, the terms medication adherence and compliance are considered the same for majority of people, they have different meanings in actual practice. Previously, the term medication compliance was described as the act of taking medications on schedule and as prescribed, whereas medication adherence was the act of filling new prescriptions or refilling prescriptions online (40). Many researchers felt that the term compliance gave an impression that doctors and other health care professionals order patients to take their medications in a specific way, and hence the term adherence is now commonly used in its place (41). The following are the most common techniques currently used separately or together to measure medication adherence (42):

1) Objective measurements which are obtained by assessing the pharmacy refill records, counting pills, or by using electronic medication event monitoring systems.
2) Subjective measurements which are obtained by asking questions related to the patient's medication use patterns to the patient, family members, or the health care professionals.

3) Biochemical measurements which are obtained by incorporating a nontoxic marker to the medication taken and detecting its presence in blood or urine or measurement of serum drug levels.

The most common indirect method of measuring medication adherence used in clinical settings is patient self-reported measures. There are questionnaires which have a high degree of agreement with electronic medication monitoring devices (43), and they are a way to measure medication adherence both simply and effectively (44, 45). Medication adherence scales are usually validated and compared to an objective measure of medication adherence before they are given to different patient populations with different disease conditions. A good medication adherence scale should be able to identify the beliefs, barriers or behavior of the patients regarding taking their medications, and it needs to be very accurate and precise (46). The problem with these self-reported questionnaires is that patients could misinterpret the information in it and distortion of some results could occur by patient themselves (47).

There are many medication adherence self-reported measures used in clinical settings including Beliefs about Medication Questionnaires (BMQ) (48), Adherence Self-Report Questionnaire (ASRQ) (49), Medication Adherence Rating Scale (MARS) (50), and the most commonly used Morisky Medication Adherence Scale (MMAS) which was developed in 1986 (51). The original MMAS scale has four items with dichotomous responses of either Yes or No. The reason the four items were chosen was because "the drug errors of omission could occur in any or all of several ways: forgetfulness, carelessness, stopping the drug when feeling better or starting the drug when feeling worse" (51). It was first validated in an outpatient setting to measure adherence to antihypertensive medications (51). The problem with the four items original scale was that it did not show good psychometric properties. It had specificity and sensitivity of 44% and 81% respectively, and a Cronbach's alpha reliability of 0.61, which is considered below the acceptable value of 0.7. However, the original scale was still used in a lot of studies that identified medication adherence scores for multiple medications until a modified scale was developed in 2008. The new scale was an eight-item Morisky Medication Adherence Scale (MMAS-8) (52). The first seven items require dichotomous responses of either Yes or No, and the last item is a five point likert response. The added four items in the modified scale identify the situations related to medication taking behavior, and it was found to have better psychometric properties compared to the original scale: sensitivity and specificity of 93% and 53%, respectively, and a Cronbach's alpha value of 0.83 which is above the acceptable value (52). According to Muntner et al. (2011), a change of two or more in the MMAS-8 score in a person before and after an intervention is considered a significant change of medication adherence behaviors (53). The original Morisky Scale and the modified one both have advantages compared to the other questionnaires used to measure medication adherence such as it could be used in different countries, on different populations and various diseases since it was translated and validated in several foreign countries. Furthermore, they have a high degree of concordance with electronic monitoring devices and pharmacy fill data. They also have fewer items compared to other self-report measures which results in less burden on the patients. However, they both have a few drawbacks such as they do not allow a comprehensive evaluation of the medication adherence behavior, so it would be difficult to develop a well-designed intervention that aims to enhance medication adherence (54).

Uncontrolled T2DM can lead to severe complications such as retinopathy, nephropathy, neuropathy, hypertension, and dyslipidemia, and a worsened HR-QOL. Preventing those complications will not only be beneficial to patients, but it will also reduce the overall health care expenditure (55). One of the most common reasons for uncontrolled DM is non-adherence to medications. Good health-related outcomes cannot occur if patient does not take their medications consistently (56). Another common reason for uncontrolled T2DM is that health care professionals in most institutions still use the biomedical model to treat patients even though it has failed to improve clinical outcomes and HR-QOL. Since the biomedical model has failed, and non-adherence to medications is considered a behavioral problem, health care professionals have started using socio-behavioral models such as TTM to improve medication adherence.

1.6 Study rationale

There is currently an alarming increase in the prevalence of T2DM among the adult population in Qatar, and this trend is expected to continue for the next few years unless appropriate strategies are put in place. Since most patients with T2DM in Qatar primary health care setting are uncontrolled, there will most likely be a high prevalence of diabetes-associated complications (57). As a result, there is more spending on diabetes, more economic burden, and an increase in morbidity and mortality rates. The primary reason for uncontrolled diabetes is non-adherence of the patients to their prescribed medications which is often associated with higher costs to treat T2DM (58). In fact, non-adherent patients can have annual inpatient costs of 41% higher than adherent patients suggesting that significant costs could be avoided if patients were adhering to their prescribed medications (59). The present study was conducted because there is currently no available data describing the medication adherence patterns in patients with T2DM in a primary health care setting in Qatar. Since non-adherence to medications is considered a socio-behavioral problem, using a behavioral model such as the TTM could address this issue. Before developing and implementing any TTM intervention to encourage patients with T2DM to adhere to their medications, it is important to determine the SOC and medication adherence scores of the patients and to determine if there is an association between these variables. If medication adherence could be improved in patients using TTM interventions, then more patients would likely have controlled diabetes resulting in a reduction in glycated hemoglobin (HbA1c), better HR-QOL, and a significant reduction of costs spent to treat diabetes. Previous studies suggested that the efficacy of medication adherence interventions might be improved by applying the SOC theory of behavior change (60-62). Thus, the association between the SOC and medication adherence using MMAS-8 was determined in patients with T2DM attending primary health care clinics in Qatar.

1.7 Study objectives

The overall goal of the study is to assess whether the TTM stages of change is applicable to medication adherence in adult patients with T2DM in Qatar primary health care setting. Whether or not TTM SOC fits the target population will help us better understand the use of the model in a developing country, as well as yield possible intervention strategies to help enhance adherence in those who are not adhering to their medications. Once the SOC of an individual patient is correctly identified, then stage specific intervention strategies will be applied to help the individual progress through the SOC toward adopting a positive behaviour. The above goal would be achieved through the following specific objectives:

i. To determine the SOC of adult patients with T2DM in a primary health care setting.
ii. To measure the medication adherence scores of patients with T2DM.
iii. To evaluate the relationship between the SOC and medication adherence while controlling for confounding factors.
iv. To evaluate the relationship between SOC and glycemic control while controlling for confounding factors.
v. To evaluate the relationship between medication adherence and glycemic control while controlling for confounding factors.

1.8 Significance of the study findings

To our knowledge, this will be the first study evaluating the association between TTM's SOC and medication adherence in patients with T2DM in the MENA region. The findings will provide evidence on whether TTM's SOC is a strong predictor of medication adherence, and HbA1c, and determine if there is an association between medication adherence and HbA1c in patients with T2DM. The findings of this study are of significance since they will help us understand the medication adherence patterns and SOC of patients with T2DM in a primary health care setting in Qatar. Once the targeted relationships are established, the TTM intervention which incorporates the ten processes of change would be applied to those with low adherence and earlier SOC. The potential intervention will be of major significance to patients as it will help them enhance their medication adherence which would in return lead to better clinical outcomes including reduction in HbA1c, and a better HR-QOL. It will also help patients achieve a controlled diabetes status which would minimize the risks of developing diabetes-related complications, and reduce the risk of hospitalization. In addition, it would also provide benefits to the healthcare system, especially at primary health care level. If the TTM is proven to be significantly effective, it will tremendously reduce healthcare expenditure for managing diabetes and its related complications, since the setting would have less emergency department (ED) visits and future admissions related to the disease. Finally, if TTM was able to accomplish these outcomes, then it could be part of primary health care clinics' policy and practice to help patients with T2DM manage their disease and achieve a better control of diabetes.

Chapter 2: Review of Literature

2.1 What is already known?

For many years, health care professionals have relied on the biomedical model in managing patients with T2DM to encourage them to adhere to their antidiabetic medications. However, since this model focused on only one aspect of health according to the WHO definition of health, diabetes burden began to significantly increase over the years, and a more promising strategy to address the issue of non-adherence was highly needed. Since non-adherence to medications is a behavioral problem, socio-behavioral models such as TTM started to evolve in an effort to address the problem. It is important that patients with T2DM adhere to their prescribed medications to be able to achieve a better control of their disease. The government of Qatar would also have less health care expenditure on the disease if it is controlled, and if there is a low incidence of its associated complications. Although the use of TTM to predict medication adherence was not previously tested in a population with T2DM, it seems promising as TTM's ability to predict medication adherence was previously evaluated in other chronic conditions. For example, it was able to predict medication adherence in patients with HIV (63). Moreover, identifying the SOC of patients with T2DM regarding following a healthier diet, and exercising more regularly, was determined in previous studies. The investigators reported that TTM was able to help patients with T2DM follow a healthier diet, and exercise more. However, the study did not investigate the relationship between SOC and medication adherence or the effect of TTM on the adherence. This chapter explains in details how TTM was used in previous studies among patients with T2DM.

2.1.1 Self-management of diabetes

Several self-management interventions emerged for patients with T2DM to be able to manage their condition, and daily life activities. Many approaches were identified during the development of educational interventions to strengthen the beliefs to self-manage their diabetes, and to control the disease (64). Lifestyle guidelines and increasing patients' knowledge about diabetes are both important to self-manage diabetes, but they are not adequate to achieve appropriate behavioral changes (65). Several research studies conducted globally focused on health promotion, and disease prevention due to increasing prevalence of chronic diseases which have multifactorial etiologies including a social component (66, 67).

Systematic reviews and meta-analyses conducted previously provided evidence that implementing a self-management intervention which incorporates educational or behavioral strategies could enhance the ability of patients with T2DM to self-manage their condition and increase target behavior actions such as following a healthier diet, blood glucose monitoring, following medical appointments and increasing physical activity (68, 69). Moreover, various studies were conducted to determine the most appropriate method to encourage patients with T2DM to adhere to a prolonged regime of self-management. These studies which utilized behavioral or educational strategies reported significant improvements in glycemic control (67, 70-74), but the improvements decreased gradually overtime in two studies (72, 74). Two studies reported that the baseline values of HbA1c had an effect on the reduction of glycated hemoglobin post the self-management intervention, in which there was a greater reduction when the baseline values of HbA1c were higher (67, 75). There is no evidence that self-management interventions are able to reduce mortality or morbidity among patients with T2DM, hence there is a need to study the impact of those interventions on long-term and definitive outcomes (73). One study which evaluated patient education found that behavioral outcomes rather than physiological outcomes should be rewarded in order to maintain self-management activities (76). Moreover, a previous study by Moser et al. (2008) evaluated interventions which were conducted to enhance self-management activities of patients with T2DM. The study reported that all the interventions evaluated consisted of dynamic and very complex set of processes which all need to be implemented in each patient's unique life situation (75). Multiple lifestyle modifications are needed in order to self-manage diabetes (77). Other factors such as patient involvement (78), family involvement (79), cultural adaptation (80), and individualization (81) were also found to be important in the development of self-management interventions.

2.1.2 Previous use of TTM

TTM could be used to enhance several self-management activities since it is a socio-behavioral model. Although it was first introduced to help smokers quit (82), TTM interventions were later applied on several other populations to enhance their behavior. According to a study by Gong et al. (2015), a TTM intervention reduced blood pressure, stroke and heart attack incidents in patients with hypertension (83). Similarly, some studies were conducted to determine the effect of TTM interventions on patients with myocardial infarction. The results indicated that TTM approach had a significant positive effect on exercise (84), reduced fat intake in Dutch patients who were at high risk of cardiovascular events (85), and it helped patients quit smoking (86). Additionally, interventions using the model helped breast cancer survivors follow a healthier diet, and exercise more (87), and motivated women to enhance Pap smear uptake (88). In a study by Fahs et al. (2013) TTM improved the diet, and lowered the blood pressure of women living in rural areas (89).

2.1.3 Previous use of MMAS-8

Several studies were conducted in various populations to assess the psychometric properties of MMAS-8. One study in Italy tested its predictive value for increased ambulatory arterial stiffness index (AASI) in a population with hypertension, and it reported that MMAS-8 is a strong predictor of AASI (90). The MMAS-8 questionnaire was also validated in patients with irritable bowel diseases (IBDs) in which prescription claim data was correlated with MMAS-8, and the results suggest that 85% of the subjects who were identified as patients with low adherence by MMAS-8 had non persistent fill rates compared with 11% of medium and high adherers (91). MMAS-8 was also validated in a population with T2DM. The validation in that population indicated that MMAS-8 had three dimensions which are forgetting to take medications, stopping medications when feeling better or worse, and the complexity of the drug regimen, and it suggested that MMAS-8 could be used to assess medication adherence in diabetes (92). Another study was conducted to determine the correlation of MMAS-8 with pharmacy prescription refill data in community dwelling seniors with hypertension, and findings suggested that MMAS-8 had a significant association with antihypertensive drug pharmacy refill adherence (93). MMAS-8 was used to identify medication adherence in some interventions which were conducted to enhance adherence. One study was done to evaluate the effectiveness of a trained community health workers' (CHW) intervention among Hispanic people who were newly diagnosed with T2DM and the intervention was able to enhance medication adherence (94). Another study assessed the effectiveness of a lifestyle intervention on systolic blood pressure (SBP), and medication adherence which was measured using MMAS-8 in minority elderly people with hypertension. The intervention was successfully able to reduce SBP, and enhance medication adherence (95).

2.1.4 TTM and medication adherence

Over the past years, studies were conducted to determine the ability of TTM to enhance medication adherence. TTM has been used to measure the SOC regarding medication adherence in patients receiving antihypertensive medications (96). In another study conducted among patients with hypertension, individuals who received the TTM intervention had higher medication adherence to their antihypertensive medications at 12 and 18 months of the intervention as compared to their counterparts who received usual care (73.1% of participants in the intervention group were at the action or maintenance stages after

12 months, as compared to 57.6% in the control group, and 69.1% in the intervention group versus 59.2% in the control group at 18 months) (97). TTM-based interventions have also been shown to improve medication adherence, diet, and exercise in individuals taking lipid lowering drugs (98). Participants in the treatment group who were at pre-action stages (precontemplation, contemplation, preparation) before the intervention, moved to action and maintenance stages regarding their medication adherence post the TTM intervention, and there was significant improvement in exercise, and dietary fat reduction compared to the control group (56% versus 37.8% for medication adherence, 43.3% versus 24.7% for exercise, and 24.7% versus 12.5% for diet). Furthermore, two studies were conducted to evaluate the effectiveness of TTM on medication adherence in patients with HIV who were actively taking antiretroviral therapy (ART) (63, 99). A study by Genberg et al. (2013) reported an association between TTM and medication adherence which was determined using electronic monitoring devices. The study also stated that those at the earlier SOC had significantly lower adherence compared to those at the later SOC (action or maintenance stages) (63). Another study suggested that incorporation of the social, behavioral, and cognitive aspects of TTM is necessary for an intervention to enhance medication adherence in patients taking highly active antiretroviral therapy (HAART) (99).

Another study used TTM to predict interferon beta-1a-Biogen (known as Avenox®) treatment discontinuation in people with multiple sclerosis. Pros and cons of Avenox® treatment, highest educational qualification obtained, and the extent of disability were the major factors which led 82% of the participants to discontinue Avenox® (100). The study supported the use of TTM to determine patients with multiple sclerosis who were not adherent to their medications and help them improve it. Moreover, TTM was recommended to be used as a screening tool to identify patients with HIV (63), and multiple sclerosis (100) who are not adhering consistently to their prescribed medications.

Corelli et al. (1999) highlighted the importance of pharmacists to use TTM to help patients with T2DM manage their disease. The study stated that if pharmacists could determine each patient's SOC regarding all behaviors associated with diabetes, they would be able to help patients self-manage their diabetes and achieve better clinical outcomes (101). So far, TTM was used in interventions on patients with T2DM to assess its ability to motivate patients to exercise regularly and to follow a healthier diet with less salt and fat consumption. It was never studied to determine if there is an association between SOC and medication adherence in patients with T2DM. TTM interventions helped patients with T2DM move forward through the SOC regarding exercise as compared to patients in the control group receiving usual care (102-104). TTM also helped patients with T2DM follow a healthier diet (103, 105), which involved using herbs instead of salt, cooking with canola or olive oil, using artificial sweeteners in baking (106). There was also a significant reduction in fat intake in patients with T2DM after the TTM intervention was implemented (107). Other studies tested the ability of TTM interventions to reduce HbA1c in patients with T2DM, and results suggest that due to the different processes of change applied, TTM was able to cause a significant reduction in HbA1c (102, 103, 105, 108).

2.1.5 Reasons for non-adherence to medications

Non-adherence to medications could have a negative impact on clinical outcomes in patients with T2DM, and could lead to an increase in mortality rates. The WHO suggests that if medication adherence could be increased for chronic conditions such as diabetes, the health outcomes would improve significantly, and the health economic burden would decrease (109). The WHO classified the factors which cause a decrease in medication adherence into five different categories: socioeconomic factors, patient-related factors, factors associated with the health care team and health care system, disease-related factors, and therapy-related factors (109). The following section describes these factors in more details:

(i) Socio-economic factors: These usually include time commitment, cost of therapy, income and social support. Time commitment means that patients sometimes might not be able to take some time off their work for treatment or clinic visits and as a result their adherence could be influenced (110-112). To address this issue, a study suggested that a shorter traveling time for patients between their homes and their health care providers could enhance medication adherence (113). In addition, cost of therapy is a major issue that influences medication adherence especially for chronic diseases since the treatment is prescribed for a much longer time (112, 114). Health care costs are not considered a big burden if the patient has a high income. In fact, studies have found that patients with low income were more likely to be non-adherent to their medications compared to those with high income (115-117). Finally, social support from family members, friends, and health care providers helps patients adhere to their treatment mainly because their support reduces the negative attitudes to treatment, and provides constant motivation and reminders to take their medications (118-121)

(ii) Patient-related factors: These include lack of involvement in the decision making process which determines the patient's medication regimen (122), and lack of understanding the disease condition (123). Another factor that contributes to medication non-adherence is health literacy (124). About 90 million adults in the USA have inadequate health literacy (125), which results in more incidences of hospitalization, and poor clinical outcomes (126, 127). Other patient-related factors, which influence medication adherence behavior, are the patient's health attitudes and beliefs regarding the prescribed medications, previous treatments patients received, and the extent of motivation to adhere to their pharmacological therapies (47, 128, 129).

(iii) Health care team and health care system-related factors: The absence of an effective communication between a physician and a patient can affect the patient's understanding of the disease and its associated complications. The absence of communication between health care professionals and patients would lead to undermining the importance of adhering to medications from the patient's perspective (130). In primary health care clinics and hospitals, the direct effective communication is present in less than 20% of the cases, and the discharge summaries are available at less than 34% of first discharge visits (131). Thus, a poor health care system, which lacks effective communications between physicians and patients could limit patients' access to care, and create several barriers to medication adherence (132). Moreover, unaffordable drug costs and co-payments result in a poor medication adherence (133, 134). If a health care system is overtaxed and receives a large number of patients without having the resources or time to treat them, this could result in poorer medication adherence due to the lack of time to discuss its importance and the possible methods to improve it.

(iv) Disease-related factors: Good health outcomes would never be achieved if patients are not consistently taking their medications as prescribed (56). Non-adherence to medications could be intentional or unintentional (135), and adherence is usually better if the regimen is simpler (136). Approximately 50% of patients with chronic diseases do not take their medications as prescribed (109, 137). Focusing particularly on patients with T2DM, their reported adherence to medications ranges from 36% to 93% worldwide (138). Adherence is usually determined on the basis of the patient's clinical outcomes (139). Therefore, strict glycemic control would be a surrogate indicator of good medication adherence (140).

(v) Therapy-related factors: The route of administration could tremendously affect medication adherence. For example, patients with asthma have better compliance to oral medications as compared to inhalers (141, 142). Treatment complexity is also an important factor because the higher the frequency of daily dosing for all prescribed medications, the lower the medication adherence (143-145). Side effects also threaten adherence to prescribed medications (146-148). A study conducted in Germany indicated that the second most common reason to non-adherence to antihypertensive medications was the side effects associated with the medications (149). Treatment duration is another factor that influences adherence to medications as patients with longer disease duration could have better adherence to medications (150, 151).

2.1.6 SOC and HbA1c

Several studies were conducted to test the relationship between SOC and HbA1c. For example, a study reported that for patients with T2DM attending primary care, advancement in SOC for diet, led to better glucose control and higher levels of continuity of care with the primary care providers (152). Another study compared HbA1c values in a TTM intervention group with those of patients in a control group receiving usual care. After the TTM intervention, the study indicated a significant reduction in HbA1c in the intervention group as compared to the control group (105). Three other studies proved the effectiveness of the TTM intervention in encouraging patients with T2DM to follow a healthier diet, and exercise more regularly which subsequently led to a significant reduction in HbA1c (102, 103, 108).

2.1.7 Medication adherence and HbA1c

Many studies found that there is a direct relationship between medication adherence and HbA1c, where higher adherence is associated with a reduction in HbA1c. One study suggested that for each 10% increment in drug adherence, HbA1c decreases by 0.16% even after controlling for demographic characteristics and disease duration (153). The study also highlighted that African Americans had poorer medication adherence and higher HbA1c as compared to Caucasians. Better medication adherence was also associated with lower HbA1c even after controlling for age, gender, race, BMI, disease duration, and diabetes therapy (154). In addition, a review of the literature reported that most studies involving patients with T2DM showed an association between medication adherence and HbA1c regardless of the tool used to measure adherence, but interestingly the association was not always apparent at low income populations (155).

2.2 What does the research add to existing knowledge?

The SOC and medication adherence patterns in patients with T2DM in a primary health care setting in Qatar were not previously investigated. Therefore, this is the first study of its kind to determine these variables in Qatar primary care setting. Earlier studies suggested that there was an association between TTM and medication adherence for chronic conditions such as HIV (63), and that TTM could be used to enhance medication adherence in patients with hypertension (97). Even though TTM seems to be associated with medication adherence in some chronic populations, that relationship was not studied in patients with T2DM worldwide. So far, TTM was only used in studies involving patients with T2DM to help them follow a healthy diet, and exercise regularly. The present study will therefore identify medication adherence scores of patients with T2DM in a primary health care setting in Qatar to determine the prevalence of non-adherence to medications in this target population. It will also determine the SOC of patients with T2DM regarding their anti-diabetic medications, and assess the relationship between the SOC and HbA1c. If a positive relationship between the SOC and medication adherence in patients with T2DM is proven, then that would conclude that SOC is associated with self-management activities of T2DM. If SOC can also predict medication adherence in our target population, then the two-item SOC questionnaire could be used as a screening tool instead of the longer MMAS-8 to identify patients with T2DM who are not adhering to their medications, and encourage them to receive a TTM intervention to enhance their adherence.

2.3 Research conceptual framework

Figure (2) shown below is a conceptual framework describing the associations to be determined between several variables of interest in the study. The main objective as stated previously is to determine the relationship between SOC and medication adherence, SOC and HbA1c, and medication adherence and HbA1c. Additionally, the study will also determine if demographic characteristics, disease duration, and total prescribed medications are associated with SOC, medication adherence, or HbA1c.

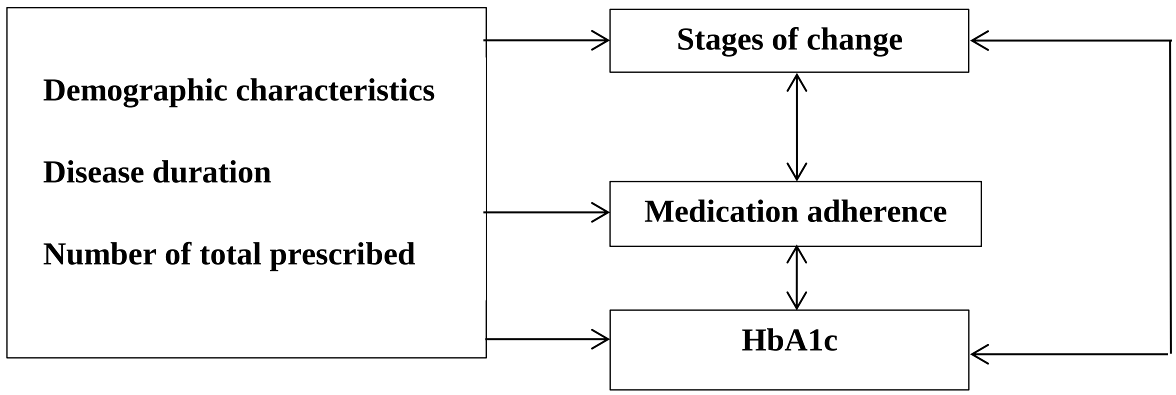

Figure 2: Conceptual framework describing the associations to be explored between the variables in the study

2.4 Primary hypotheses

The following hypotheses will be tested in this study:

1) We hypothesize that SOC will be positively associated with medication adherence, while controlling for confounding factors. We expect that patients at pre-action stages (precontemplation, contemplation, and preparation) will have low or medium

adherence and those at late SOC (action and maintenance) will have high medication adherence. This is expected because patients who claim are adherent to medications, should have more advanced SOC regarding consistently taking their prescribed medications.

2) We also hypothesize that earlier SOC will be negatively associated with HbA1c, while controlling for confounding factors. Participants at the early SOC (precontemplation, contemplation, and preparation) would have higher HbA1c levels, whereas those at advanced SOC (action and maintenance) would have lower HbA1c levels. This is anticipated because patients who are at the late SOC might have been compliant to their medications for a long time and therefore should have lower HbA1c levels.

3) Lower medication adherence will also be negatively associated with HbA1c, while controlling for confounding factors, since patients with T2DM who are taking their prescribed medications regularly should ideally have lower HbA1c. This implies that patients with low adherence scores would have high HbA1c levels, while those with high adherence score would have low HbA1c levels.

Chapter 3: Methodology

3.1 Study design

This was a cross-sectional observational study involving adult patients with T2DM in a primary health care setting in Qatar. A questionnaire to identify SOC regarding medication adherence, and a tool to measure medication adherence were both administrated to every participant recruited as part of the study sample. HbA1c was the main clinical outcome recorded for all patients recruited.

3.2 Ethics approval

The research study was approved by the Primary Health Care Corporation (PHCC) with a reference number "PHCC/RC/15/05/008" (see Appendix A) and Qatar University's Institutional Review Board with a reference number "QU-IRB 593-A/16" (see Appendix B). All recruited participants were given a participant information and informed consent sheet (see Appendix C) to help them understand the nature and procedure of the study, and they were asked to sign the consent upon agreeing to participate. Participants were allowed to withdraw from the study at any time they desire.

3.3 Study setting and timeline

The PHCC was the chosen setting to conduct this study since it is known to receive the largest number of patients with T2DM in Qatar. The PHCC was established as an independent corporation in 2012, and it currently consists of 21 primary health care centers which are located in central, northern, and western parts of Qatar. Since the PHCC regularly receives a high number of visitors (5.2 million visits in 2014), more primary health care center are expected to open soon. In order to keep up with the increasing number of patients and to serve that large population, 12 new health care centers are expected to open by 2019 (156). The PHCC offers a wide range of services including pharmacy services, mental health, laboratory services, and health education. All the services provided by the PHCC aim to shift the balance of care from a curative model towards a preventive and community based model. Two PHCC centers were selected as study sites. Mesaimeer Primary Health Center was chosen because it has a high percentage of patients with T2DM attending the non-communicable diseases (NCD) clinic and Westbay Primary Health Center was chosen since it has a high number of Qatari patients attending the NCD clinic regularly. The recruitment of participants began on 7 February 2016 and ended on 28 April 2016.

3.4 Study population and sampling

The target population from which the study participants were selected was adult patients with T2DM in Qatar. In 2015, there were approximately 239,100 adults with T2DM in Qatar (157), and 43,466 of those were Qataris, hence representing 18% of the target population (158). This indicates that there were 195,634 (82%) non-Qatari patients diagnosed with T2DM in Qatar. The sample size was calculated proportionately to be representative of the target population. The formula used to calculate the required minimum sample size for the study was: $n = Z_{1-\alpha/2}^{2}\, p\, (1-p)/\, d^{2}$ (159). $Z_{1-\alpha/2}$ is the standard normal variate which is considered 1.96, since the type I error was set at 5%, p is the expected proportion of adult patients with T2DM in Qatar which is 13.5%, and d is the absolute error or precision which was set at 5% . Substituting the variables in the formula, $n = 1.96^{2} \times 0.135 \times (1-0.135)/\, 0.0025 = 180$. Therefore, the minimum sample size required was 180 patients with T2DM. A total of 387 patients with T2DM were recruited from both centers with the number of Qataris and non-Qataris in the sample proportionate to the target population. The method of sampling was convenience sampling. However, in order to obtain a random sample the researchers randomly selected 10-15 patients every day at the NCD clinic out of a total of around 40 patients attending the clinics daily. Those selected were approached for their consent to participate in the study. Out of the non-Qataris attending the NCD clinic in Mesaimeer

Primary Health Center, 328 patients with T2DM participated in the study, whereas 59 Qatari patients from Westbay Primary Health Center participated in the study. These numbers were representative of the target population. All participants were recruited during their regular scheduled visits, and none were requested for any further follow-up related to the research. The inclusion criteria for the study were: (i) adults with confirmed T2DM diagnosis (HbA1c $\geq$ 6.5%, FPG $\geq$ 126 mg/dl, and/or 2h plasma glucose $\geq$ 200 mg/dl); and (ii) prescribed oral antidiabetics, and/or insulin. The exclusion criteria were: (i) age < 18 years old; (ii) pregnant women, because diabetes could be gestational; (iii) mentally incompetent patients, as mental defects might affect the ability to correctly understand the questionnaires administrated; and (iv) receiving only on non-pharmacologic therapy (i.e. lifestyle modifications). Figure (3) describes the sampling procedure for the patients recruited from each clinic for the study.

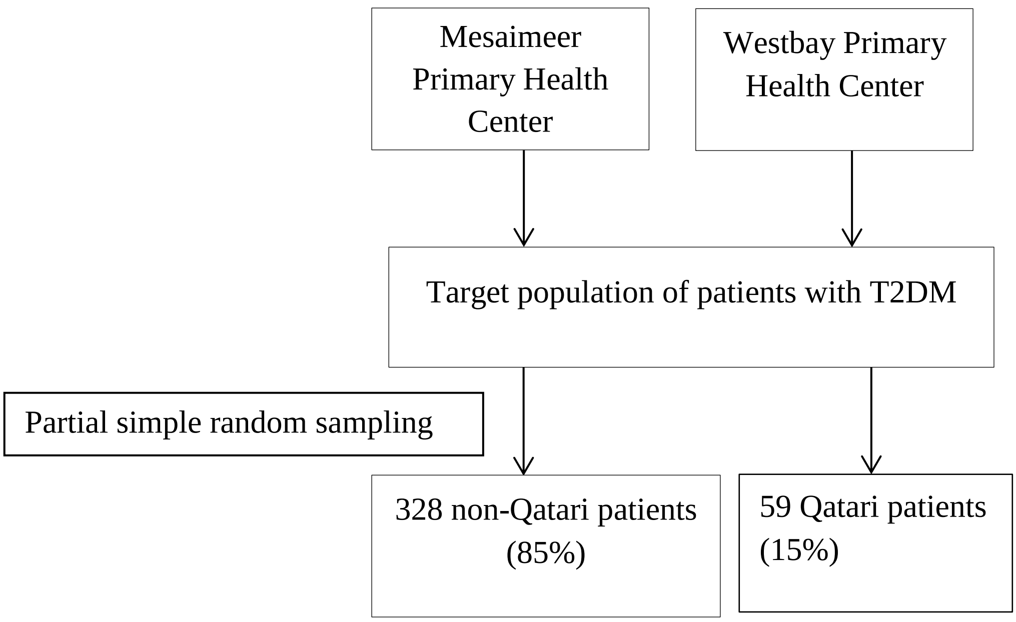

Figure 3: Flowchart for sampling patients with T2DM from the target population for the study.

3.5 Study confounding factors

Other variables which could be confounding factors were determined and placed in the data collection tool in order to control for those which significantly impacted SOC, medication adherence or HbA1c. Based on a thorough literature search, the potential confounding factors recorded were disease duration, total number of prescribed medications, and demographic characteristics including age, gender, marital status, nationality, ethnicity, highest educational attainment, and occupation (26).

3.6 Development and validation of SOC questionnaire

The SOC questionnaire was used to determine patient's SOC regarding their adherence to anti-diabetic medications. The tool was available and validated in English, and translated to Arabic for the participants who preferred to use the Arabic version. The English version consisted of two previously validated survey items (160) (see Appendix D). The questionnaire was validated in patients with HIV, and patients with hypertension, but the results suggested that it could be used to determine the SOC about medication adherence for patients with any other chronic conditions (160). Upon validating the questionnaire, construct validity was demonstrated by associations between the SOC and previously validated measures of adherence ($P<0.001$), and the predictive validity was supported by significant associations between the SOC for medication adherence and medication adherence score ($P<0.03$) (160). Since the SOC questionnaire was not available or validated in Arabic, the English version was translated using forward translation, followed by backward translation, pre-testing, and cognitive interviewing in order to obtain the final version of the Arabic questionnaire (see Appendix E).

3.7 Development and validation of MMAS-8

MMAS-8 was the tool used to assess medication adherence of the recruited participants from both centers. The English version (see Appendix F) was developed in 2008 from the original four-item Morisky scale (52). The first seven items are dichotomous response categories of either Yes or No. The seven items include questions about: (i) forgetting to take medicine; (ii) how many days did a patient forget to take the medications over the past 2 weeks; (iii) if the patient stopped taking their medications; (iv) whether the patient forgets to take the medicine when they leave home or travel; (v) whether they took their medicine yesterday; (vi) if the patient forgets to take their medications if he/she feels like their symptoms are under control; and (vii) if the patient feels hassled about following their treatment plan. The last item on the scale has a five-point Likert response in which patients describe how often they have difficulty remembering to take medications (i.e. never/rarely, once in a while, sometimes, usually, or all the time). The English version of MMAS-8 was validated in other chronic diseases such as hypertension (52), where it showed strong reliability ($\alpha = 0.83$), sensitivity and specificity of 93% and 53%, respectively. The Urdu version of the scale was also validated in 2012 (see Appendix G) (161). It had a Cronbach's alpha of 0.701 which is considered within the acceptable range (162), and its specificity and sensitivity were 46.15% and 60%, respectively. The Arabic version of MMAS-8 was also used in this study (see Appendix H). It was validated in 2015, and it demonstrated a Cronbach's alpha of 0.7. All the corrected item total correlations were optimal (0.34 - 0.51), except for the fifth item which had the lowest corrected item total correlation ($r = 0.25$), but removing it did not significantly improve the alpha value (0.71). The Arabic version of MMAS-8 had a sensitivity and specificity of 63.9%, and 82.3%, respectively (163).

3.8 Development and validation of the data collection tool

The data collection form was designed to obtain all relevant patient information for this study. It consisted of the following nine sections respectively: (i) demographic profile which included PHCC identification number, date of birth, age, gender, marital status, nationality, ethnicity, educational attainment, and occupation; (ii) date of diabetes diagnosis; (iii) date of first visit with DM diagnosis at NCD; (iv) comorbidities; (v) number of medications for other chronic conditions; (vi) stage of change; (vii) medication adherence; (viii) clinical outcomes; and (ix) medication regimen for T2DM (see Appendix I).

3.9 Outcomes measured and tools used

The main outcomes of interests were participants' SOC, medication adherence scores, and HbA1c. The SOC about adherence to anti-diabetic medications was measured using the two-item SOC questionnaire. The first item placed participants in precontemplation, contemplation, preparation, or action and maintenance stages. The second item differentiated between individuals at action and maintenance (160). Medication adherence of patients with T2DM was measured using MMAS-8, which provides scores ranging from 0 to 8. Scores were classified as follows: (i) low adherence if the score from 0 to 5.75; (ii) medium adherence if the score was between 6 and 7; and (iii) high adherence if the score was 8. MMAS-8 is a self-reported measure, and the weakness of such measures is that there is often some social desirability bias upon using them.

In order to ensure that social desirability bias while using MMAS-8 was not a prominent limitation, an objective method was used to calculate medication adherence for participants who had sufficient data. This was done to check if the other measure will give similar adherence results as those obtained from MMAS-8. Two of the commonly used objective measures of adherence are medication possession ratio (MPR) and proportion of days covered (PDC) (164). MPR formula is (the sum of the days' supply for all fills of a given drug in a particular time period / the number of days in the time period) × 100. However, PDC which is a newer and more conservative objective measure of adherence is (number of days in the period covered / the number of days in the time period) × 100. The major issue with MPR is that it sometimes overestimates adherence because some patients refill their medications early, hence they will have an inflated MPR. PDC considers this, and makes an adjustment if a patient refills his/her medications prior to running out of it since it incorporates in the formula the days covered, not supplied. In addition, PDC is recommended for medication regimens such as multiple medications for diabetes and it considers the days within a particular period only when a patient is covered for all medications in a regimen. Although MPR is more commonly used, PDC is becoming the preferred adherence measurement because of its advantages as outlined above. Therefore, PDC was the objective measure chosen in this study to compare its adherence scores with those obtained from MMAS-8, where a percentage of 80% or higher obtained from PDC is considered high adherence.

HbA1c was extracted from each patient's electronic health record available at the electronic database. Based on the American Diabetes Association (ADA), the HbA1c values were later categorized into 2 groups: controlled diabetes status if a patient had HbA1c of ≤ 7 %, or uncontrolled diabetes status is if the HbA1c was > 7 % (165).

3.10 Data collection procedure

Patients attending the Non-Communicable Diseases Clinic (NCD) at Mesaimeer and Westbay Primary Health Centers were requested to answer the SOC, and MMAS-8 questionnaires. The items in the questionnaires were read along with all possible answers to the patients in English, Arabic, or Urdu based on their preference. Moreover, HbA1c and FPG were obtained from each patient's health record available at the electronic database. Information about each patient's medication's start date, dose, and frequency, number of total prescribed medications along with the date of their first visit in the NCD clinic was extracted from each patient's paper-based medical record. Some demographic characteristics; age, gender, ethnicity, nationality were obtained from each patient's health record from the electronic database available at both clinics. Ethnicity was categorized into: Arab, Asian, or Others, whereas the nationality was divided into either: Qatari or Non-Qatari. The remaining demographic characteristics; marital status, latest educational attainment, and occupation were not available in the paper-based medical record or in the electronic database. Therefore, the patients were asked directly about them and the answers were recorded in the data collection form. Participants were also asked about the date of diabetes diagnosis since it was not available in the medical records. All the data were entered in the data collection form by the researcher.

In some cases, the medications prescribed in the paper-based medical records to a patient were not consistent with the prescribed medications shown in the same patient's health record available in the electronic database. In such circumstances, patients were asked about the medications they were currently taking to ensure accuracy in reporting the medications. In most cases, the patient's electronic health records were the most reliable sources of correct medications prescribed.

3.11 Data analysis and management

Data were coded and entered into SPSS version 22 for analysis (IBM Corp. Released 2013. IBM SPSS Statistics for Windows, Version 22.0. Armonk, NY: IBM Corp.) Every participant was given a unique identifier that was used on all the study instruments and data collection forms. Backup of files was regularly conducted, and backup copies were stored in separate secure locations. Before conducting the data analysis, descriptive statistics were performed to ensure that the percentages of Qataris and Non-Qataris were similar to that of our target population. Descriptive analyses were conducted to determine the SOC, medication adherence scores, and diabetes status of the participants. Normality distribution was determined for all the variables to decide on the choice of statistical analyses. The variables tested for their normality distribution were: SOC, medication adherence, HbA1c, disease duration, and total number of prescribed medications. Shapiro-Wilks test and histograms were used to assess the normality of the variables. For Shapiro-Wilks, if the p-value for any of the variables was less than the alpha (α) level of 0.05, then the variable was considered not normally distributed, and if the p-value was more than the α level of 0.05, the variable would be considered normally distribution (166). Histograms were examined for each of the variable mentioned above to determine if it was normally distributed. If the histogram had a bell-shaped curve, the variable was considered normally distributed, otherwise not normally distributed (166). The following statistical tests were conducted:

(i) Chi-square test of association to examine the relation between different baseline characteristics.

(ii) An interrater reliability analysis using the Kappa statistic was performed to determine consistency between MMAS-8 and PDC when measuring medication adherence.

(iii) Spearman rho correlation to determine the relationship between SOC and medication adherence, SOC and HbA1c, medication adherence and HbA1c. For all the correlations, the α level was set at 0.05 for significance.

(iv) Spearman rho correlation was conducted to determine the relationship between all demographic characteristics with SOC, medication adherence, and HbA1c with an α level set at 0.05 for significance.

(v) Spearman rho correlation was also used to determine the association of disease duration with SOC, medication adherence, and HbA1c, and to determine whether or not the number of total prescribed medications is associated with SOC, medication adherence, or HbA1c. The α was set as 0.05 for significance for all the analyses

(vi) Hierarchical regression was performed to assess if SOC could predict medication adherence; if SOC could predict HbA1c; and if medication adherence could predict HbA1c, in all cases while controlling for demographic and clinical characteristics which have a significant correlation with the variables.

3.12 Pilot study

A sample of 8 patients was selected from the NCD clinic and used for pilot testing to evaluate the feasibility of recruitment and to identify and resolve any issues which might arise while conducting the larger study. Both questionnaires were read to the patients. Out of the 8 participants, 3 were females, and 5 were males; 7 were at the maintenance stage of change and 1 was at the action stage of change. Moreover, 4 had low adherence to their antidiabetic medications, 3 had medium adherence, and 1 had high adherence. The mean HbA1c of the patients in the pilot study was 7.93 % which is considered an uncontrolled diabetes status. According to the results of the pilot study, there was non-significant positive correlation between SOC and medication adherence, a non-significant negative correlation between SOC and HbA1c, and a non-significant negative correlation between medication adherence and HbA1c. Based on the pilot study, no changes were required in the study tools before proceeding to the main study.

Chapter 4: Results

4.1 Demographic characteristics of the study participants

Three hundred eighty-seven patients with T2DM were included in the analysis. The mean age (± sd) of the participants was 54.3 ± 10.2 years, and 153 (39.5%) of them were in the age group of 55-65 years old. There were more male participants than females (63% vs. 37%), and more non-Qataris compared to Qataris (84.8% vs. 15.2%). Additionally, there were more Arab participants than Asians or other races (51.9%, 44.2%, and 3.9%, respectively). Most of the participants were married (94.6%), and almost half (49.9%) of the participants recruited had a bachelor's degree. Moreover, approximately 36.7% of the participants were working as assistants or helpers, while 25.8% were unemployed. Table 1 describes the demographic characteristics of the recruited participants.

Table 1: Demographic characteristics of the study participants (n=387)

Characteristic	Frequency (%)	Mean ± SD
Age (years), mean ± SD		54.29 ± 10.20
Age group		
Less than 45 years old	69 (17.8)	
45-54 years old	117 (30.3)	
55-65 years old	153 (39.5)	
Above 65 years old	48 (12.4)	
Sex		
Male	244 (63.0)	
Female	143 (37.0)	
Nationality		
Qatari	59 (15.2)	
Non-Qatari	328 (84.8)	
Race		
Arab	201 (51.9)	
Asian	171 (44.2)	
Others	15 (3.9)	
Marital status		
Single	13 (3.4)	
Married	366 (94.6)	

Divorced	1 (0.3)
Widowed	7 (1.7)
Educational attainment	
Postgraduate	15 (3.8)
Bachelor	193 (49.9)
Lower than Bachelor	179 (46.3)
Occupation	
Professional	88 (22.7)
Managerial	32 (8.3)
Assistants and helpers	142 (36.7)
Unemployed	100 (25.8)
Retired	25 (6.5)

4.2 Clinical characteristics of the study participants

Of all the 387 participants recruited in the study, 137 (35.4%) had controlled diabetes, and 250 (64.6%) participants had uncontrolled diabetes based on the cut off value of 7% of HbA1c. The median (IQR) HbA1c of the participants was 7.5% (2.2). In addition, 118 (30.5%) of the participants were diagnosed with diabetes for less than 5 years, and 117 (30.2%) for 5-9 years. The most common antidiabetic medication regimen was two oral antidiabetics (29.2 %) followed by one antidiabetic (27.1%). Most of the participants had other chronic conditions: 77.3% of the participants had dyslipidemia, 66.4% had hypertension, and 5.7% did not have any chronic conditions other than diabetes. One hundred and seventy nine (46.3%) participants were taking less than 5 medications, whereas 208 (53.7%) were on polypharmacy (defined as taking 5 or more medications). Table 2 describes the relevant clinical characteristics of the participants.

Table 2: Clinical characteristics of the study participants (n=387)

Characteristic	Frequency (%)	Median (IQR)
Diabetes status		
Controlled	137 (35.4)	
Uncontrolled	250 (64.6)	
HbA1c (%)		7.5 (2.2)
Diabetes duration		
Less than 5 years	118 (30.5)	
5-9 years	117 (30.2)	
10-14 years	74 (19.1)	
15-19 years	50 (12.9)	
20 years and above	28 (7.3)	
Diabetes medication regimen		
1 oral antidiabetic	105 (27.1)	
2 oral antidiabetics	113 (29.2)	
3 oral antidiabetics	57 (14.7)	
4 oral antidiabetics	7 (1.8)	
Insulin only	17 (4.4)	
Insulin and 1 oral antidiabetic	39 (10.1)	
Insulin and 2 oral antidiabetics	36 (9.3)	
Insulin and 3 oral antidiabetics	12 (3.1)	
Insulin and 4 oral antidiabetics	1 (0.3)	
Comorbidities		
Dyslipidemia	299 (77.3)	
Hypertension	257 (66.4)	
Thyroid abnormalities	58 (15)	
Neuropathy	25 (6.5)	
Nephropathy	13 (3.4)	
Others	9 (2.3)	
Number of other medications for comorbidities		
0	22 (5.7)	
1	71 (18.3)	
2	76 (19.6)	
3	94 (24.3)	
4	54 (14)	
≥5	70 (18.1)	
Total number of medications received		5 (3)
Total number of prescribed medications		
Less than 5	179 (46.3)	
5 or more	208 (53.7)	

4.3 SOC and medication adherence scores of study participants

More than 75% of the participants reported that they were in the maintenance stage, whereas 14.7% were in the preparation stage. On the other hand, the mean adherence score obtained from MMAS-8 was 6.88 ± 1.62, which is classified as medium medication adherence. In addition, more than half of the participants self-reported high adherence to their antidiabetic medication regimen. Table 3 describes in details the SOC and Morisky medication adherence scores of the participants.

Table 3: Stages of change and Morisky medication adherence scores of the study participants (n=387)

Variable	Frequency (%)	Mean ± SD
Stages of change		
Precontemplation	5 (1.3)	
Contemplation	13 (3.4)	
Preparation	57 (14.7)	
Action	15 (3.9)	
Maintenance	297 (76.7)	
Morisky medication adherence score		
Low adherence (0 to 5.75)	94 (24.3)	
Medium adherence (6 to7)	69 (17.9)	
High adherence (8)	224 (57.8)	
Mean adherence score ± SD		6.88 ± 1.62

4.4 MMAS-8 and PDC

Kappa statistic was conducted to evaluate the degree of agreement between MMAS-8 and PDC in measuring medication adherence. PDC was calculated for 117 participants who had sufficient data, and the results indicated a significant moderate agreement between MMAS-8 and PDC's assessment of medication adherence [$\kappa = 0.436$; ($p < 0.001$), 95% CI (0.504, 0.848)].

4.5 Demographic characteristics of the study participants based on stages of change

Since precontemplation, contemplation, and preparation stages represent participants who were not adhering to their antidiabetic medications, the three SOC were grouped together when describing the baseline characteristics of the participants. Similarly, action and maintenance stages were grouped together when describing the baseline characteristics of the participants as both stages indicate that participants were adhering to their medications. There were 153 participants in the age group of 55-65 years old; and 127 (83%) of them were in the action and maintenance stages. Based on chi-square test, there was a significant association between the SOC and age groups of participants ($p < 0.05$). Most of the Qataris were in the action and maintenance stages, and only four (6.8%) of all Qataris were in the pre-action stages. In addition, there were more participants in the action and maintenance stages as compared to pre-action stages in all ethnicities. There were more Arabs than Asians or other ethnicities in the action and maintenance stages (81.1%, 80.7%, and 73.3%, respectively). Out of all married participants, 68 (18.6%) were in the pre-action stages, while 298 (81.4%) were in the action and maintenance stages. Based on chi-square test of association, there was a significant association between the marital status of participants and their SOC ($p < 0.05$). Table 4 provides a full description of the demographic characteristics of all participants according to their SOC.

Table 4: Description of demographic characteristics of the study participants according to their stages of change (n=387)

Characteristic	Pre-action	Action and Maintenance	Total	p-value
Age (years), mean ± SD[a]	53.82 ± 5.73	54.76 ± 10.0		
Age group				
< 45 years old	24 (34.8)	45 (65.2)	69 (100)	
45-54 years old	24 (20.5)	93 (79.5)	117 (100)	
55-65 years old	26 (17.0)	127 (83.0)	153 (100)	0.88
Above 65	1 (2.0)	47 (98.0)	48 (100)	
Gender				
Male	51 (20.9)	193 (79.1)	244 (100)	
Female	24 (16.8)	119 (83.2)	143 (100)	0.66
Nationality				
Qatari	4 (6.8)	55 (93.2)	59 (100)	
Non-Qatari	71 (21.6)	257 (78.4)	328 (100)	0.08
Ethnicity				
Arab	38 (18.9)	163 (81.1)	201 (100)	
Asian	33 (19.3)	138 (80.7)	171 (100)	0.06
Others	4 (26.7)	11 (73.3)	15 (100)	
Marital status				
Single	6 (46.2)	7 (53.8)	13 (100)	
Married	68 (18.6)	298 (81.4)	366 (100)	0.04*
Divorced	0 (0.0)	1 (100)	1 (100)	
Widowed	1 (14.3)	6 (85.7)	7 (100)	
Educational attainment				
Postgraduate	5 (33.4)	10 (66.6)	15 (100)	
Bachelor	40 (20.7)	153 (79.3)	193 (100)	0.28
Lower than Bachelor	30 (16.8)	149 (83.2)	179 (100)	
Occupation				
Professional	23 (26.1)	65 (73.9)	88 (100)	
Managerial	9 (28.1)	23 (71.9)	32 (100)	
Assistants and helpers	27 (19.0)	115 (81.0)	142 (100)	
Unemployed	15 (15.0)	85 (85.0)	100 (100)	0.203
Retired	1 (4.0)	24 (96.0)	25 (100)	
Total	75 (19.4)	312 (80.6)	387 (100)	

** $p < 0.01$
a independent samples t-test

4.6 Clinical characteristics of the study participants based on stages of change

Clinical characteristics of the participants were also classified according to their SOC. Of all the participants with uncontrolled diabetes, 50 participants (20%) were in the pre-action stages, whereas 200 (80%) were in the action and maintenance stages. Furthermore, there were 118 participants diagnosed with diabetes for less than five years; out of which 29 (24.6%) were in the pre-action stages, and 89 (75.4%) were in the action and maintenance stages. There was a significant association between the diabetes duration and the participants' SOC ($p < 0.05$). Of the patients who had hypertension, 39 (15.2%) were in the pre-action stages and 218 (84.8%) were in the action and maintenance stages regarding their adherence to medications. There was a significant association between hypertension and the SOC of participants ($p < 0.05$). There was a significant association between dyslipidemia and the SOC of participants ($p < 0.001$). Twenty-two participants were not receiving any medications for other comorbidities; 10 (45.5%) of those were in the pre-action stages, and 12 (54.5%) of them in the action or maintenance stages. A significant association between the number of the medications taken for comorbidities and the SOC was shown ($p < 0.05$). Finally out of the 208 participants on polypharmacy (i.e. receiving five or more medications), 33 (15.8%) were in the pre-action stages, whereas 175 (84.2%) were in the action and maintenance stages. There was a significant association between the total prescribed medications and the SOC of participants ($p < 0.05$). Table 5 presents the clinical characteristics of participants based on their SOC.

Table 5: Description of the clinical characteristics of the study participants according to their stages of change (n=387)

Characteristic	Pre-action	Action and Maintenance	Total	p-value
Diabetes status				
Controlled (≤ 7%)	25 (18.2)	112 (81.8)	137 (100)	0.89
Uncontrolled (> 7%)	50 (20.0)	200 (80.0)	250 (100)	
Diabetes duration				
Less than 5 years	29 (24.6)	89 (75.4)	118 (100)	
5-9 years	25 (21.4)	92 (78.6)	117 (100)	
10-14 years	8 (10.8)	66 (89.2)	74 (100)	
15-19 years	11 (22.0)	39 (78.0)	50 (100)	0.04 *
20 years and above	2 (7.1)	26 (92.9)	28 (100)	
Medication regimen				
1 oral antidiabetic	24 (22.9)	81 (77.1)	105 (100)	
2 oral antidiabetics	22 (19.5)	91 (80.5)	113 (100)	
3 oral antidiabetics	9 (15.8)	48 (84.2)	57 (100)	
4 oral antidiabetics	0 (0.0)	7 (100)	7 (100)	
Insulin only	2 (11.8)	15 (88.2)	17 (100)	
Insulin and 1 oral antidiabetic	8 (20.5)	31 (79.5)	39 (100)	0.84
Insulin and 2 oral antidiabetics	6 (16.7)	30 (83.3)	36 (100)	
Insulin and 3 oral antidiabetics	4 (33.3)	8 (66.7)	12 (100)	
Insulin and 4 oral antidiabetics	0 (0.0)	1 (100)	1 (100)	
Comorbidities				
Dyslipidemia	52 (17.4)	247 (82.6)	299 (100)	0.00 **
Hypertension	39 (15.2)	218 (84.8)	257 (100)	0.04 *
Neuropathy	4 (16.0)	21 (84.0)	25 (100)	0.79
Nephropathy	2 (15.4)	11 (84.6)	13 (100)	0.87
Thyroid abnormalities	6 (10.9)	49 (89.1)	55 (100)	0.63
Others	3 (25.0)	9 (75.0)	12 (100)	0.18
Number of medications for comorbidities				
0	10 (45.5)	12 (54.5)	22 (100)	
1	15 (21.1)	56 (78.9)	71 (100)	
2	20 (26.3)	56 (73.7)	76 (100)	
3	16 (17.0)	78 (83.0)	94 (100)	0.04 *
4	7 (87.0)	47 (13.0)	54 (100)	
≥5	7 (10.0)	63 (90.0)	70 (100)	
Total prescribed medications				
<5	42 (23.5)	137 (76.5)	179 (100)	
≥5	33 (15.8)	175 (84.2)	208 (100)	0.04 *
Total	75 (19.4)	312 (80.6)	387 (100)	

* $p < 0.05$
** $p < 0.01$

4.7 Demographic characteristics of the study participants based on medication adherence

Demographic characteristics were classified based on medication adherence levels. Out of the 153 participants in the 55-65 years old age group, the proportion of participants with low, medium, and high adherence were 36 (23.5%), 26 (17%), and 91 (59.5%), respectively. Of the 244 males enrolled in the study, 60 (24.6%) had low adherence, 52 (21.3%) had medium adherence, and 132 (54.1%) had high adherence to their antidiabetic medications. Furthermore, 113 (56.1%) of Arabs, 103 (60.35) of Asians, and 8 (53.3%) of other ethnicities who participated in the study had high adherence to their antidiabetic medications. There were 366 married participants; 86 (23.5%) had low adherence, 66 (18%) had medium adherence, and 214 (58.5%) had high adherence. Chi-square test suggests that there was a significant association between the marital status of participants and their medication adherence level ($p < 0.05$). Similarly, there was a significant association between the latest educational attainment and the medication adherence levels of participants ($p < 0.001$). Table 6 describes the demographic characteristics of the study sample based on medication adherence levels.

Table 6: Description of the demographic characteristics of the study participants according to medication adherence scores (n=387)

Characteristic	Low adherence	Medium adherence	High adherence	Total	p-value
Age (years), mean ± SD[a]	52.65 ± 4.58	54.68 ± 5.67	58.23 ± 6.25		
Age group					
<45 years old	24 (34.8)	13 (18.8)	32 (46.4)	69 (100)	
45-54 years old	31 (26.5)	22 (18.8)	64 (54.7)	117 (100)	0.74
55-65 years old	36 (23.5)	26 (17.0)	91 (59.5)	153 (100)	
>65 years old	3 (6.3)	8 (16.7)	37 (77.0)	48 (100)	
Gender					
Male	60 (24.6)	52 (21.3)	132 (54.1)	244 (100)	0.43
Female	34 (23.8)	17 (11.8)	92 (64.4)	143 (100)	
Nationality					
Qatari	9 (15.3)	7 (11.9)	43 (72.8)	59 (100)	0.45
Non-Qatari	85 (25.9)	62 (18.9)	181 (55.2)	328 (100)	
Ethnicity					
Arab	52 (25.9)	36 (18.0)	113 (56.1)	201 (100)	
Asian	38 (22.2)	30 (17.5)	103 (60.3)	171 (100)	
Others	4 (26.6)	3 (20.1)	8 (53.3)	15 (100)	
Marital status					
Single	6 (46.2)	3 (23.1)	4 (30.7)	13 (100)	
Married	86 (23.5)	66 (18.0)	214 (58.5)	366 (100)	0.04 *
Divorced	0 (0.0)	0 (0.0)	1 (100)	1 (100)	
Widowed	2 (28.6)	0 (0.0)	5 (71.4)	7 (100)	
Educational attainment					
Postgraduate	6 (40.0)	3 (20.0)	6 (40.0)	15 (100)	
Bachelor	54 (28.0)	44 (22.8)	95 (49.2)	193 (100)	
Lower than a bachelor	34 (19.0)	22 (12.3)	123 (68.7)	179 (100)	0.00 **
Occupation					
Professional	31 (35.2)	20 (22.7)	37 (42.1)	88 (100)	
Managerial	9 (28.1)	2 (6.3)	21 (65.6)	32 (100)	
Assistants and helpers	42 (29.6)	22 (15.5)	78 (54.9)	142 (100)	0.41
Unemployed	19 (19.0)	11 (11.0)	70 (70.0)	100 (100)	
Retired	3 (12.0)	4 (16.0)	18 (72.0)	25 (100)	
Total	94 (24.3)	69 (17.9)	224 (57.8)	387 (100)	

* p < 0.05
** p < 0.01
a independent samples t-test

4.8 Clinical characteristics of study participants based on medication adherence

Clinical characteristics were also classified based on medication adherence levels. Out of 137 participants who had controlled diabetes, 81 (59.1%) had high medication adherence, whereas 143 (57.2%) from those with an uncontrolled diabetes status had high medication adherence. There were 118 participants who were diagnosed with T2DM for less than 5 years; 36 (30.6%) of these had low medication adherence, 22 (18.6%) had medium medication adherence, and 60 (50.8%) had high medication adherence. In addition, 162 (63.1%) of the participants with hypertension had high adherence to their DM medication regimens, and there was a significant association between having diagnosis of hypertension and adherence to antidiabetic medications ($p < 0.05$). Of the 299 participants with dyslipidemia, 178 (59.6%) had high adherence to their DM regimen and there was also a significant association between the presence of dyslipidemia and the participants' adherence to their DM medications ($p < 0.05$). Surprisingly, 97 (54.2%) of the participants taking less than 5 prescribed medications had high medication adherence compared to 127 (61.1%) of those participants taking 5 or more medications. Table 7 displays the relevant clinical characteristics of all participants recruited based on medication adherence levels.

Table 7: Description of the clinical characteristics of the study participants based on medication adherence scores (n=387)

Characteristic	Low adherence	Medium adherence	High adherence	Total	p-value
Diabetes status					
Controlled	32 (23.4)	24 (17.5)	81 (59.1)	137 (100)	0.20
Uncontrolled	63 (25.2)	44 (17.6)	143 (57.2)	250 (100)	
Disease duration					
<5 years	36 (30.6)	22 (18.6)	60 (50.8)	118 (100)	
5-9 years	33 (28.2)	22 (18.8)	62 (53.0)	117 (100)	
10-14 years	11 (14.9)	17 (23.0)	46 (62.1)	74 (100)	
15-19 years	11 (22.0)	7 (14.0)	32 (64.0)	50 (100)	0.95
≥20 years	3 (10.7)	1 (3.6)	24 (85.7)	28 (100)	
Medication regimen					
1 oral antidiabetic	29 (27.6)	24 (22.9)	52 (49.5)	105 (100)	
2 oral antidiabetics	32 (28.3)	18 (15.9)	63 (55.8)	113 (100)	
3 oral antidiabetics	11 (19.3)	11 (19.3)	35 (61.4)	57 (100)	
4 oral antidiabetics	0 (0.0)	2 (28.6)	5 (71.4)	7 (100)	
Insulin only	1 (5.9)	1 (5.9)	15 (88.2)	17 (100)	

Insulin and 1 oral antidiabetic	10 (25.6)	7 (17.9)	22 (56.5)	39 (100)	1.0
Insulin and 2 oral antidiabetics	6 (16.7)	5 (13.9)	25 (69.4)	36 (100)	
Insulin and 3 oral antidiabetics	5 (41.7)	1 (8.3)	6 (50.0)	12 (100)	
Insulin and 4 oral antidiabetics	0 (0.0)	0 (0.0)	1 (100)	1 (100)	
Comorbidities					
Dyslipidemia	65 (21.7)	56 (18.7)	178 (59.6)	299 (100)	0.02 *
Hypertension	51 (19.8)	44 (17.1)	162 (63.1)	257 (100)	0.03 *
Neuropathy	5 (20.0)	3 (12.0)	17 (68.0)	25 (100)	0.99
Nephropathy	2 (15.4)	4 (30.8)	7 (53.8)	13 (100)	0.89
Thyroid abnormalities	9 (16.4)	11 (20.0)	35 (63.6)	55 (100)	0.82
Others	9 (13.4)	32 (47.8)	26 (38.8)	67 (100)	0.72
Number of medications for comorbidities					
0	10 (45.5)	2 (9.0)	10 (45.5)	22 (100)	
1	22 (31.0)	12 (16.9)	37 (52.1)	71 (100)	
2	20 (26.3)	17 (22.4)	39 (51.3)	76 (100)	
3	20 (21.3)	16 (17.0)	58 (61.7)	94 (100)	0.25
4	11 (20.1)	9 (16.7)	34 (63.2)	54 (100)	
≥5	11 (15.7)	13 (18.6)	46 (65.7)	70 (100)	
Total prescribed medications					
<5	51 (28.5)	31 (17.3)	97 (54.2)	179 (100)	0.622
≥5	43 (20.6)	38 (18.3)	127 (61.1)	208 (100)	
Total	94 (24.3)	69 (17.9)	224 (57.8)	387 (100)	

* $p < 0.05$

4.9 Demographic characteristics of the study participants based on diabetes control

Demographic characteristics were described based on the diabetes control of the participants (i.e. controlled vs. uncontrolled DM). The mean age of the participants with controlled diabetes status was 52.28 ± 10.6 years vs. 56.30 ± 9.8 years for those with uncontrolled diabetes status. Among the 69 participants who were less than 45 years old, 21 (30.4%) had a controlled diabetes, whereas 48 (69.6%) had uncontrolled diabetes. Furthermore, 81 (33.2%) of male participants had controlled diabetes compared to 56 (39.2%) of female participants. In addition, 119 (59.2%) of Arab participants, 123 (71.9%) of Asian participants, and 8 (53.3%) of participants of other ethnicities had uncontrolled DM. There was a significant association between the latest educational attainment of participants and their diabetes status ($p < 0.05$), whereby 76 (39.4%) of all participants who had a bachelor's degree had controlled DM. Finally, 33 (37.5%) of the participants who had professional occupations had controlled DM when compared with 35 (24.6%) of the participants working as assistant or helpers. Consequently, there was a significant association between the patients' occupation and their diabetes control status ($p < 0.001$). Table 8 presents all the demographic characteristics of the sample based on diabetes status.

Table 8: Description of demographic characteristics of study participants based on diabetes status (n=387)

Characteristic	Controlled	Uncontrolled	Total	p-value
Age (years), mean ± SD[a]	52.28 ± 10.6	56.3 ± 9.8		
Age group				
<45 years old	21 (30.4)	48 (69.6)	69 (100)	0.66
45-54 years old	42 (35.9)	75 (64.1)	117 (100)	
55-65 years old	54 (35.3)	99 (64.7)	153 (100)	
>65 years old	20 (41.7)	28 (58.3)	48 (100)	
Gender				
Male	81 (33.2)	163 (66.8)	244 (100)	0.24
Female	56 (39.2)	87 (60.8)	143 (100)	
Nationality				
Qatari	21 (35.6)	38 (64.4)	59 (100)	0.97
Non-Qatari	116 (35.4)	212 (64.6)	328 (100)	
Ethnicity				
Arab	82 (40.8)	119 (59.2)	201 (100)	
Asian	48 (28.1)	123 (71.9)	171 (100)	0.03 *
Others	7 (46.7)	8 (53.3)	15 (100)	
Marital status				
Single	4 (30.8)	9 (69.2)	13 (100)	
Married	131 (35.8)	235 (64.2)	366 (100)	0.84
Divorced	0 (0.0)	1(100)	1 (100)	
Widowed	2 (28.6)	5 (71.4)	7 (100)	
Educational attainment				
Postgraduate	8 (53.3)	7 (46.7)	15 (100)	
Bachelor	76 (39.4)	117 (60.6)	193 (100)	0.04 *
Lower than Bachelor	53 (29.6)	126 (70.4)	179 (100)	
Occupation				
Professional	33 (37.5)	55 (62.5)	88 (100)	
Managerial	16 (50.0)	16 (50.0)	32 (100)	
Assistants and helpers	35 (24.6)	107 (75.4)	142 (100)	0.00 **
Unemployed	40 (40.0)	60 (60.0)	100 (100)	
Retired	13 (52.0)	12 (48.0)	25 (100)	
Total	137 (35.4)	250 (64.6)	387 (100)	

* $p < 0.05$
** $p < 0.01$
a independent samples t-test

4.10 Clinical characteristics of the study participants based on diabetes status

Clinical characteristics were also classified based on the diabetes status of the patients. Fifty seven (48.3%) of the participants who were diagnosed with T2DM for less than five years had controlled diabetes, while 46(39.3%) of participants who were diagnosed with T2DM for 5-9 years had controlled diabetes. There was a significant association between diabetes duration and diabetes status ($p < 0.001$). Furthermore, of all the participants taking one oral antidiabetic medication, 64 (61%) had controlled diabetes, compared to 46 (40.7%) of all the participants taking 2 oral antidiabetic medications. The findings revealed that there was a significant association between the medication regimen for T2DM and the diabetes status of the participants ($p < 0.001$). Finally, 107 (59.8%) of the patients taking less than five medications had uncontrolled DM vs. 143 (68.7%) of the patients taking five or more medications. Table 9 provides more details regarding the clinical characteristics of the study sample based on the diabetes control status.

Table 9: Description of the clinical characteristics of the study participants based on diabetes status (n=387)

Characteristic	Controlled	Uncontrolled	Total	p-value
Disease duration				
<5 years	57 (48.3)	61 (51.7)	118 (100)	
5-9 years	46 (39.3)	71 (60.7)	117 (100)	
10-14 years	17 (23.0)	57 (77.0)	74 (100)	0.00 **
15-19 years	10 (20.0)	40 (80.0)	50 (100)	
≥20 years	7 (25.0)	21 (75.0)	28 (100)	
Medication regimen				
1 oral antidiabetic	64 (61.0)	41 (39.0)	105 (100)	
2 oral antidiabetics	46 (40.7)	67 (59.3)	113 (100)	
3 oral antidiabetics	13 (22.8)	44 (77.2)	57 (100)	
4 oral antidiabetics	1 (14.3)	6 (85.7)	7 (100)	
Insulin only	3 (17.6)	14 (82.4)	17 (100)	
Insulin and 1 oral antidiabetic	3 (7.7)	36 (92.3)	39 (100)	0.00 *
Insulin and 2 oral antidiabetics	3 (8.3)	33 (91.7)	36 (100)	
Insulin and 3 oral antidiabetics	4 (33.3)	8 (66.7)	12 (100)	
Insulin and 4 oral antidiabetics	0 (0.0)	1 (100)	1 (100)	
Comorbidities				
Dyslipidemia	111 (37.1)	188 (62.9)	299 (100)	0.19
Hypertension	95 (37.0)	162 (63.0)	257 (100)	0.37
Neuropathy	5 (20.0)	20 (80.0)	25 (100)	0.09
Nephropathy	3 (23.1)	10 (76.9)	13 (100)	0.35
Thyroid abnormalities	21 (38.9)	33 (61.1)	54 (100)	0.92
Others	4 (30.8)	9 (69.2)	13 (100)	0.85

Number of medications for comorbidities				
0	6 (27.3)	16 (72.7)	22 (100)	
1	25 (35.2)	46 (64.8)	71 (100)	
2	28 (36.8)	48 (63.2)	76 (100)	0.97
3	34 (36.2)	60 (63.8)	94 (100)	
4	18 (33.3)	36 (66.7)	54 (100)	
≥ 5	26 (37.1)	44 (62.9)	70 (100)	
Total prescribed medications				
< 5	72 (40.2)	107 (59.8)	179 (100)	0.06
≥ 5	65 (31.3)	143 (68.7)	208 (100)	
Total	137 (35.4)	250 (64.6)	387 (100)	

* $p < 0.05$
** $p < 0.01$

4.11 Association between outcome measures

Correlation analyses were conducted to investigate the relationship between the following pairs of outcome measures: SOC and medication adherence, SOC and HbA1c, and medication adherence and HbA1c. The SOC is a categorical variable, while the medication adherence and HbA1c scores were both not normally distributed continuous variables. Hence, Spearman rho correlation was used to perform the correlation analyses. There was a significant positive relationship between SOC and medication adherence ($r = 0.728$, $p < 0.001$). Conversely, there was no significant correlation between SOC and HbA1c ($r = -0.012$, $p > 0.05$), or between medication adherence and HbA1c ($r = -0.002$, $p > 0.05$).

4.12 Association of confounding factors with outcome measures

The correlation of demographic characteristic with outcome measures was determined. Table 10 presents the correlations between demographic characteristics with: SOC, medication adherence, and HbA1c. There was a significant positive relationship between age and SOC ($r = 0.276$, $p < 0.001$), and between age and medication adherence ($r = 0.218$, $p < 0.001$). In addition, there was a significant negative relationship between the nationality of participants and their SOC ($r = -0.13$, $p < 0.05$), and between their nationality and medication adherence ($r = -0.126$, $p < 0.05$). There was also a significant positive, but weak relationship between medication adherence and marital status ($r = 0.107$, $p < 0.05$).

Similarly, there was a significant negative weak relationship between the latest educational attainment and medication adherence ($r = -0.202$, $p < 0.001$). Finally, there was a significant negative correlation between the occupation of participants and their SOC ($r = -0.159$, $p < 0.05$), and between occupation and medication adherence ($r = -0.194$, $p < 0.001$).

Spearman rho correlation was performed to determine the relationship between disease duration and the outcome measures. Disease duration had a positive significant weak correlation with the SOC of participants ($r = 0.167$, $p \leq 0.001$), their medication adherence ($r = 0.152$, $p < 0.05$), and their HbA1c scores ($r = 0.196$, $p < 0.001$). Table 11 presents the results of the correlation analyses between disease duration and SOC, medication adherence, and HbA1c. Spearman rho correlation was also performed to determine the relationship between total number of prescribed medications and the outcome measures. Total number of prescribed medications had a significant positive weak correlation with SOC ($r = 0.214$, $p < 0.001$), medication adherence of participants ($r = 0.17$, $p < 0.001$), and their HbA1c scores ($r = 0.171$, $p < 0.001$). Table 12 shows the results of the correlation analyses between total number of prescribed medications and SOC, medication adherence, and HbA1c.

Table 10: Spearman rho correlation of demographic characteristics and stages of change, medication adherence, and glycated hemoglobin

Characteristic	Age	Gender	Nationality	Ethnicity	Marital status	Education	Occupation
SOC	r = 0.28 Sig. = 0.00 **	r = 0.06 Sig.= 0.21	r = - 0.13 Sig. = 0.01 **	r = 0.03 Sig.= 0.48	r = 0.09 Sig.= 0.07	r = - 0.09 Sig. = 0.06	r = - 0.16 Sig. = 0.002 **
Medication adherence	r = 0.22 Sig.= 0.00 **	r = 0.09 Sig.= 0.09	r = -0.13 Sig. = 0.01 **	r = 0.03 Sig.= 0.58	r = 0.10 Sig.= 0.04*	r = - 0.20 Sig. = 0.00**	r = - 0.19 Sig. = 0.00**
HbA1c	r = -0.08 Sig.= 0.12	r = -0.05 Sig. = 0.30	r = -0.05 * Sig. = 0.36	r = 0.06 Sig.= 0.20	r = -0.03 Sig.= 0.59	r = - 0.09 Sig. = 0.06	r = - 0.01 Sig. = 0.83

* p < 0.05
** p < 0.01

Table 11: Spearman rho correlation of disease duration with stages of change, medication adherence and glycated hemoglobin

Characteristic	SOC	Medication adherence	HbA1c
Disease duration (years)	r = 0.167 Sig.= 0.001 **	r = 0.152 Sig. = 0.003 **	r = 0.196 Sig. = 0.00 **

** $p < 0.01$

Table 12: Spearman rho correlation of total number of medications prescribed with stages of change, medication adherence and glycated hemoglobin

	SOC	Medication adherence	HbA1c
Number of Medications prescribed	r = 0.214 Sig.= 0.00 **	r = 0.17 Sig. = 0.001 **	r = 0.171 Sig. = 0.001 **

** $p < 0.01$

4.13 Hierarchical regression between SOC and medication adherence

After proving a significant positive correlation between SOC and medication adherence, hierarchical regression was conducted to investigate if SOC could predict medication adherence, while controlling for the following confounding factors which had significant correlations with SOC or medication adherence: age, marital status, occupation, education, nationality, total prescribed medications, and disease duration. Multicollinearity is a violated assumption of hierarchical regression between some confounding factors; hence not all were placed in the same model. Multicollinearity existed between: age and total prescribed medications (r = 0.39), occupation and education (r = 0.49), and total prescribed medications and diabetes duration (r = 0.372). As a result, two independent hierarchical regressions were performed to determine whether SOC could predict medication adherence. The first hierarchical regression was done whilst controlling for age, disease duration, and occupation of participants, whereas the second one controlled for the total number of prescribed medications, education, and nationality of the participants. All the other assumptions were met for both hierarchical regressions: the dependent variable which was medication adherence was continuous; there were 2 or more independent variables in both regressions, there was an independence of observations, a linear relationship between the dependent variable and each independent variable, homoscedasticity, no significant outliers, or any high leverage or influential points, no multicollinearity, and finally the residuals were normally distributed. To test the hypotheses that medication adherence can be predicted by four variables (age, disease duration, occupation, marital status and SOC), a hierarchical regression was performed. Tests for multicollinearity indicated that there was very minimal multicollinearity present (VIF= 1.187 for age, 1.152 for disease duration, 1.097 for occupation, 1.022 for marital status, and 1.082 for SOC). Results of the regression provided partial confirmation for the research hypotheses which states that age is considered a covariate when the association between SOC and medication adherence needs to be determined **(** β= 0.17, t= 3.20, $p < 0.001$). In addition, SOC significantly predicted medication adherence while controlling for age, disease duration, and occupation (β= 0.79, t= 25.132, $p < 0.001$). The first model significantly predicted medication adherence, explaining 8 % of its variance [R= 0.27, R^2 **=** 0.08, F (4,382) = 7.74, $p < 0.001$]. In the second model, SOC alone predicted 58% of the variance in medication adherence, and including all the variables in the second model significantly improved the model, predicting 65 % of the variance in medication adherence [R= 0.81, R^2= 0.65, F (5,381)= 142.73, $p<0.001$].

A second hierarchical regression was performed to determine whether the hypotheses stating that medication adherence can be predicted by total prescribed medications, education, nationality, and SOC are true or not. There was also a very low level of multicollinearity (VIF= 1.106 for total prescribed medications, 1.022 for education, 1.104 for nationality, and 1.053 for SOC). As shown in the first model, total prescribed medications and education were able to significantly predict medication adherence [(β = 0.14, t = 2.61, p < 0.05) and (β = - 0.17, t = -3.44, p ≤ 0.001) respectively]. The first model as a whole significantly predicted medication adherence, explaining 6.0% of its variance [R= 0.25, R^2 = 0.06, F (3,383) = 8.23, p < 0.001]. In the second model, SOC predicted 59 % of the variance in medication adherence, whereas the second model collectively significantly predicted medication adherence by 65% [R= 0.81, R^2 = 0.65, F (4,382) = 184.75, p < 0.001]. Table 13 present the results of the two hierarchical regressions.

Table 13: Hierarchical regression analysis of prediction of medication adherence by stages of change, controlling for confounding factors

	Model 1			Model 2		
Variables	**B**	**T**	**Sig.**	**B**	**T**	**Sig.**
			First hierarchical regression			
Age	0.17	3.20	0.001 **	-0.01	-0.09	0.93
Disease duration	0.08	1.54	0.12	0.05	1.39	0.17
Occupation	-0.12	-2.25	0.02 *	-0.05	-1.627	0.10
Marital status	0.02	0.35	0.73	0.02	0.51	0.61
SOC				0.79	25.13	0.00 **
R		0.27			0.81	
R^2		0.08			0.65	
R^2 for change		0.08			0.58	
F		7.74			142.73	
Sig. F change		0.00**			0.00**	
			Second hierarchical regression			
Total prescribed medications	0.14	2.61	0.009**	-0.01	-0.19	0.84
Education	-0.17	-3.44	0.001**	-0.12	-3.83	0.00 **
Nationality	-0.04	-0.79	0.43	0.01	0.13	0.89
SOC				0.79	25.9	0.00 **
R		0.25			0.81	
R^2		0.06			0.65	
R^2 for change		0.06			0.59	
F		8.23			184.75	
Sig. F change		0.00**			0.00**	

* p < 0.05
** p < 0.01

Chapter 5: Discussion

Based on a thorough review of the literature, this is a novel study that explored the association between SOC and medication adherence in a T2DM population. To our knowledge, it is also the first study utilizing TTM on diabetic patients in a developing country. Other objectives of the study were to determine if SOC or adherence to medication could be used to predict HbA1c, and whether disease duration and the total number of currently prescribed medications could predict individuals' adherence to their medication. The instruments used in the study had previously been validated and used in other studies. The SOC questionnaire was validated using two populations: 161 patients with HIV, and 731 patients with hypertension (160). In both populations, construct validity ($p < 0.001$) and predictive validity ($p < 0.03$) were demonstrated. In addition, the English version of MMAS-8 had high sensitivity and specificity of 93%, and 53% respectively, whereas the Arabic version of MMAS-8 demonstrated sensitivity and specificity of 63.9%, and 82.3%, respectively.

5.1 SOC and medication adherence

Since there was no significant correlation between SOC and HbA1c, or between adherence to medication and HbA1c at the bivariate level, we did not proceed with multivariate analysis to test the extent that SOC and adherence could predict HbA1c. Other objectives were to determine if demographic characteristics, the duration of disease, and the total number of currently prescribed medications had an association with SOC, medication adherence, or HbA1c. As presented in earlier tables, only the demographic characteristics which had a significant correlation with SOC or adherence had to be controlled for while determining if SOC was a significant predictor of adherence. The study's results are similar to previous ones. For example, a significant relationship between age and adherence has been found in several populations, suggesting that as age increases, adherence to medication increases (112, 167-169). The published literature also suggests that ethnicity had an effect on adherence, with Caucasians generally having better adherence than African-Americans, Hispanics, and other minorities (120, 170, 171). However, although these papers suggest that nationality could influence adherence, most of the studies were conducted in countries with mixes of nationalities and ethnicities that differed from that investigated in our study. It is therefore difficult to compare our results with other findings.

Additionally, marital status seems to have a strong effect on adherence to medication, with several studies suggesting that marriage has a positive impact on adherence as patients who are married often receive support and constant reminders from their spouses to take their prescribed medications on time (172-174). Surprisingly, we found that patients with lower educational attainment had higher adherence than those with a bachelor's or postgraduate degree. This finding contradicts the results of other studies (175-177) and the expectation that patients with higher education have better knowledge of both their disease state and the medications they are prescribed. However, there are two previous studies that support our findings, showing patients with lower educational levels having better compliance to their medication (168, 178). Our finding may result from the patients with limited education having more faith in the advice given to them by their health care professionals. Occupation also showed a negative effect on medication adherence, with people in occupations classified as having higher social status having lower adherence to medications. This contrasts with the results of a previous study, which stated that unemployed patients have poorer adherence (179). However there seems to be little consistency in this, with the results of studies depending on the health care systems in, and the medical practices of, particular countries (26). Moreover, disease duration and the total number of currently prescribed medications both had significant correlations with SOC and medication adherence. These were therefore chosen as confounding factors to be controlled in the hierarchical regression to maintain the internal validity of the study. A few studies agree with our finding, that disease duration is associated with medication adherence and patients who have been diagnosed with T2DM for a longer period of time, have better adherence to medications (150, 151, 180). As the total number of currently prescribed medications increased, adherence to these medications also increased. A study by Richard et al. (2003) found patients with T2DM to have high medication adherence rates regardless of the total number of medications they were prescribed (181). This suggests that physicians must not be restricted in prescribing a limited number of medications to patients.

In addition, our study demonstrates that some demographic characteristics have an impact on the SOC about medication adherence in chronic populations, and this contradicts the findings of a study, which indicated that not all demographic characteristics influence stages of change or medication adherence in a HIV population (63). In the first model in the initial hierarchical regression, age, disease duration, occupation, and marital status together explained 8 % of the variation in adherence to medication. A second model, containing only SOC explained 58 % of the variation. This increased to 65 % when all the other variables were also included. In the first model in the second hierarchical regression total prescribed medications, educational attainment, and ethnicity were able to explain 6 % of the variation in adherence; adding SOC to the second model increased the proportion of variation explained to 65 %. The remaining 35 % of unexplained variance in these models is likely to be due to other confounding factors that were not included in the model, such as health literacy, patient knowledge, and patient-prescriber relationship. Health literacy means the ability to read, understand, and remember instructions associated with medications, and to be able to act on health information (182). Patients with lower health literacy are usually less adherent to their therapy (141), whereas patients with higher health literacy, who can read and understand drug labels, tend to be found to be more adherent to their medications (183, 184). Patient knowledge is thought to also influence adherence to medication. Often patients do not have an adequate level of knowledge about their disease or prescribed treatment, or they do not comprehend the importance of the therapies prescribed for their treatment, and therefore do not adhere to their medications consistently (114). Other patients lack the understanding of the importance and the value of regular clinic visits. Observations in both clinics showed several patients with T2DM failing to attend their scheduled appointments in the NCD clinics. That might influence adherence to medication because they would seem not to understand the importance of these visits. Finally, the patient-prescriber relationship could be one of the factors to explain the 34.8% unexplained variance. Several studies concluded that patient-prescriber relationship is an important factor, which affects patients' medication adherence (177, 185, 186). Studies have found that good compliance occurs when doctors are emotionally supportive, giving reassurance or respect, and treating patients as an equal partner (110, 185). Moreover, roughly one out of ten patients who had medium or low adherence admitted that it is unintentional non-adherence, where they forgot to take their medications only when they are busy at work or with the family but other than that they took them regularly. Another reason for medium or low adherence for patients receiving metformin was that the physicians told the patients to take the drug with meals, so when they skipped meals, they did not take the medication. This indicates that they were not informed that they should not skip doses, and they did not understand that the right thing to do was to take a small meal instead of skipping a meal, so that they could take metformin.

Owing to the policies of institutions in Qatar, research related to practitioners and health care providers meets more resistance than research related to patient care. It was therefore difficult to measure these confounding factors; however it is important to pay attention to these factors as they could potentially have confounding effects on adherence to medications.

The results of our study found that SOC explains 58 % - 59 % of the variation in adherence when controlling for demographic or clinical characteristics, though these had relatively small impacts on adherence to medication. A thorough review of the literature found only one study in T2DM that investigated whether the SOC model could enhance adherence to medication; this also encouraged patients to exercise regularly and follow a healthier diet (102). The results of the study showed that SOC was able to encourage patients to exercise more, and stick to a healthier diet which consequently led to a reduction in HbA1c. However, there was little or no change in adherence to medication, except for a decrease in the numbers of patients in the precontemplation stage. As this is the only study published assessing whether SOC could enhance adherence to medication, or looking for an association between these variables in patients with T2DM, the results of this study will be compared with other studies that determined the association between SOC and medication adherence in other populations with chronic diseases. A study conducted on patients with HIV to determine the relationship between SOC and medication adherence had similar results to our study (63). That study identified a positive relationship between SOC and adherence to ART, with patients with HIV who were identified to be in precontemplation, contemplation, or preparation having medication adherence scores roughly 10% lower than the scores obtained from patients at the action or maintenance stages. However, in contrast with to our results, the study concluded that demographic characteristics were poor predictors of adherence. Moreover, the study also suggested using the same two-item SOC questionnaire as a screening tool to identify patients who were at earlier SOC because they were not adhering to their medication. In addition, another study was done to understand several factors associated with non-adherence to antidepressant medications in a setting similar to our study (primary care setting) (187). It was found that patients who had lower adherence to medications had lower SOC. In fact, the SOC of patients was a significant predictor of adherence to antidepressants ($p=0.047$), and it was the strongest predictor of medication adherence in all other variables tested in the study such as patients satisfaction with their physicians, and the type of depression.

5.2 SOC and HbA1c

In the study sample, no statistically significant relationship was found between SOC and HbA1c ($p > 0.5$). This result contradicts other studies that have investigated the relationship between SOC and HbA1c; they all reported significant negative relationships between SOC and HbA1c (102, 103, 105, 108). For example, in a study on patients with T2DM, comparing a control group with a group receiving a TTM intervention, the SOC was found to be significantly better in helping patients lower their HbA1c and led to better diabetes control (105). Three other studies on patients with T2DM have also reported that TTM led to a significant reduction in HbA1c (102, 103, 108). All these studies determined the SOC of patients with T2DM who were following a healthy diet plan or exercising regularly, which led to reductions in HbA1c. This means that, when the TTM model was used to identify the SOC of these patients, regarding their diet or exercise, a relationship was identified between the SOC and HbA1c. However, in our study the SOC was related to the patients' adherence to the prescribed medications and showed no statistically significant relationship with HbA1c. This might be because, even though SOC could predict adherence, adherence to treatment for T2DM in our population was unconnected to HbA1c. Another possible explanation for our having found no association between SOC and HbA1c is a lack of continuity of care in patients with T2DM. A previous study has found that continuity of care with a primary care provider who identified patients SOC about diet and exercise led to an improved SOC for self-management behaviors, and that continuity of primary health care was associated with better glucose control in a diabetic population (152).

5.3 Medication adherence and HbA1c

Contrary to previous studies, this study found no significant association between medication adherence and HbA1c ($p > 0.5$). Most published literature reports significant negative correlations between medication adherence and HbA1c. One study stated that for every 10% increment in drug adherence, HbA1c decreased by 0.16% ($p < 0.001$) in a poor indigent population (153). In that study African-American patients had higher HbA1c than white patients, which led the authors to conclude that minority and indigent groups have less controlled HbA1c. The results of our current study suggest that Arabs have more controlled HbA1c than Asians (21.2% vs 12.4%) ($p < 0.05$). Another potential explanation of the lack of association between medication adherence and HbA1c is patients failing to attend appointments. A previous study found an association between medication adherence and HbA1c, and provided evidence that, for patients with T2DM, every appointment they attended was associated with a 0.12% decrease in HbA1c (154). Moreover, a published systematic review concluded that there is an association between antidiabetic medications and HbA1c, regardless of the method used to determine medication adherence. However, this association was not always found in low income populations (155). This could be interpreted as supporting the results of our study because almost half of the sample reported their highest educational attainment to be below a bachelor's degree and 36.7% were assistants and helpers who might be expected to have low incomes. However, if patients with T2DM who have low incomes and high adherence to medications have no reduction in HbA1c, other factors which affect HbA1c need to be considered. It is possible that these patients are taking their antidiabetic medications regularly and consistently, but consuming a diet high in sugar and other carbohydrates and not exercising regularly. That could be expected to result in a mean HbA1c higher than that observed in other populations who both follow a healthier diet and stick to an exercise regime.

5.4 Limitations

Several issues must be considered when interpreting the data presented in the current study. First, the SOC model can be criticized for failing to represent the complexities of behavioral change (189). For instance, adhering to a particular medication regimen requires many different behaviors other than just swallowing a pill: it requires attending appointments with the prescribing professional, filling prescriptions, and consistently taking doses (189). It is unclear which of these many behaviors the stages of change are intended to target. Instead the SOC model is related to the overall medication adherence and based on the answers to the questions in MMAS-8. Despite this limitation, our study was able to identify patients at higher risk of non-adherence. Another limitation while using TTM is that progress through the SOC is not linear. People can often move from the action or maintenance stages to the pre-action stages. Therefore, it is impossible to ensure that participants who were at the maintenance stage will always remain to be in this stage.

The study may also be subject to social desirability bias resulting in the misreporting of SOC and medication adherence scores. That would lead to the underestimation of the proportions of individuals in the early stages of change and with low medication adherence. Self-reported measures do generally tend to yield inflated adherence estimates or advanced SOC, so the actual adherence to prescribed medication was probably somewhat lower than we observed and there may well have been fewer patients actually at the action and maintenance stages. To ensure that the results obtained are not due to social desirability, PDC, which is an objective measure, was used to calculate adherence. The scores obtained from PDC were similar to those obtained from MMAS-8, suggesting social desirability biases were unlikely to have been important.

Another limitation is that convenience sampling was the method of sampling used to recruit participants in the study. The drawback of using convenience sampling is that the sample might not be representative of the population being studied. This undermines the ability to make generalisations from the sample recruited to the target population. Convenience sampling was the chosen method of sampling due to the limited time of the study. Nevertheless, to ensure that the sample is to some extent representative of the target population, 10-15 patients were randomly selected every day at the NCD clinic out of a total of around 40 patients attending the clinics daily

Moreover, the SOC determined were only regarding taking the antidiabetic medications as prescribed by the patients' physicians. The SOC related to following a healthy diet or exercising was not determined, even though both of these are factors that contribute to self-management of T2DM.

5.5 Future directions and recommendations

This cross-sectional study gives a good starting point for using the TTM on patients with T2DM regarding their medication adherence, but further investigations are required. The effectiveness of TTM, as a tool for improving adherence to prescribed medication in our target population, has not been fully investigated. Further interventions applying TTM, while using the processes of change relevant to the SOC, are needed to determine TTM's ability, usefulness, and impact on medication adherence in a T2DM population. Without conducting further research, no clear recommendations can be provided regarding the effectiveness of TTM in improving the drug use process.

Based on observations in both clinics, we suggest applying an educational and behavioral self-management intervention in order to increase the patients' knowledge regarding the nature of T2DM, the treatments taken, importance of adherence to medications, and to encourage them to regularly attend their appointments in the clinics. This intervention will need to incorporate the goals and life experiences of each patient with T2DM to engage and aid them in self-managing their condition. Additionally, there is still no evidence suggesting that self-management interventions can significantly reduce mortality and morbidity rates in patients with T2DM, therefore it is important to study the effect of self-management interventions on long term outcomes such as the HR-QOL.

We also suggest improving the knowledge of patients with T2DM because it can influence adherence to medications. It is crucial that each patient understands the pathology of diabetes, how their prescribed medications work, and both the diet they need to maintain and the foods they need to avoid. Many patients were not aware that carbohydrates break down into sugar, so they were only cautious about eating sugar but paid no attention to the amounts of carbohydrates they consumed. If patients were educated by health care providers' their adherence to medications would be higher, and they would have better clinical outcomes and a better quality of life.

In addition, determining the medication adherence scores using a tool other than MMAS-8 could potentially be important. MMAS-8 has advantages when compared to other self-reported measures that determine medication adherence scores, however its' main drawback is that it does not provide a complete evaluation of adherence behaviors. Without understanding different behaviors which lead patients to be non-adherent to their medications it would be difficult to develop a well-designed intervention that aims to improve adherence.

Moreover, PHCC should always ensure that patients are capable of using insulin pens. It is not unusual for a nurse to repeatedly explain to a patient how to administer insulin, but the patient, who only heard the verbal instructions, to remain incapable of doing it themselves. In fact, some patients in our study sample who were prescribed oral antidiabetic medications and insulin were adhering to their oral medications but not insulin only because they did not know how to administer it themselves. These patients would only take the insulin when there was someone available in their homes to give them the pen. We therefore suggest that nurses should not only explain use of the pen to new users of insulin, but also watch the patients administer it themselves to ensure that they are comfortable doing so. We also recommend that the health care team in Mesaimeer health care center devotes more time to understanding the importance of encouraging patients with T2DM to always follow up with an ophthalmologist because retinopathy is a common major complication in patients with diabetes. At the NCD clinic in Mesaimeer the physicians and nurses often overlooked the health of the eye of the patient, instead they only asked whether the patients also visiting an ophthalmologist and did not assess the results of any follow up visits that occurred. Many patients said that they did not visit an ophthalmologist because in Mesaimeer they are only available at the morning shift, when many patients are busy at work. It would be worthwhile to have an ophthalmologist available during both morning and evening shifts because Mesaimeer has the second highest number of patients with T2DM in a primary health care center.

5.6 Conclusion

The SOC explained 58 % - 59 % of the variance in medication adherence in patients with T2DM in a primary health care setting in Qatar; however there was no significant relationship found between SOC and HbA1c, nor between medication adherence and HbA1c. More than half of the sample was classified as highly adherent to their antidiabetic medication, and more than 75% of the sample was at the maintenance stage. Out of all the demographic characteristics included in the study, age, nationality, marital status, education, and occupation had a significant correlation with either SOC or adherence. Total number of currently prescribed medications and disease duration were the only two clinical characteristics with statistically significant correlations with both SOC and adherence to medication. These results suggest that the two-item SOC could potentially be used to identify patients at risk of low adherence to conduct a TTM intervention to shift those patients to the action or maintenance stages, and to enhance their medication adherence, consequently leading to better clinical outcomes such as a reduction in HbA1c, and ultimately a better health related quality of life.

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Appendix A

مؤسسة الرعاية الصحية الأولية
PRIMARY HEALTH CARE CORPORATION

Primary Health Care Corporation
Clinical Affairs
Research Section
researchsection@phcc.gov.qa

Form RS/AF1

Research/Project/Study
Approval Notice Form

Title of the Project:	Transtheoretical model of change on medication adherence among type 2 diabetes mellitus patient in a Primary Health Care setting in Qatar	
Reference No:	**PHCC/RC/15/05/008**	**Date:28/12/2015**
Principal Investigator:		
Name	Dr. Mohammed Izham	
Title	Professor of Social & Administrative Pharmacy	
Department/Organization	College of Pharmacy, Qatar University	
Contact details	Email: mohamedizham@qu.edu.qa , Tell: 4403 5580	

Required Information Checklist	**Ref. No**	**Yes**	**No**	**N/A**	**Date**
Research Proposal Submission Form signed and Completed		✓			
Research Proposal Supplementary Form Completed		✓			
HMC /WCMCQ IRB Approval Obtained, (or Previously HMC Research Committee Approval)			✓		
PHCC Research Committee Approval Obtained		✓			
Investigator agreement Form Signed		✓			
Other Ethics Committee Approval (Please specify) e.g. Qatar University		✓			
Informed Consent Form Copy Provided		✓			
Sponsors	QU				

Dear Dr. Izham,

Having considered the ethical and logistical (site specific) issues relating to the above project, the PHCC Research Committee confirms that there are no objections to carrying out this project. Therefore the departments of Clinical Affairs and Operations give **approval** for it to commence. Please see the accompanying letter which sets out the **specific terms and conditions** of this approval that must be adhered to in carrying out the research.
We wish you every success in this endeavor.

Kind Regards,

Hanan

Dr. Hanan Al Mujalli
Executive Director of Clinical Affairs

Dr. Mohamed Bekhiet
Executive Director Of Operations

For more information: Researchsection@phcc.gov.qa

مؤسسة الرعاية الصحية الأولية
PRIMARY HEALTH CARE CORPORATION

RS/RC/FL6/15/12

Our Ref: PHCC/RC/15/05/008

28th December 2015

Dear Dr. Izham,

Final Opinion: Transtheoretical model of change on medication adherence among type 2 diabetes mellitus patient in a Primary Health Care setting in Qatar

I write to confirm approval from the PHCC Research Committee at its last meeting on 16th November 2015 for you to carry out the above research study in PHCC **Health Centers**. This **Final Opinion** follows further review by the Research Committee following your response to the Committee's request for further information and clarification. Approval is valid for the period: 28th December 2015 until 28th December 2016 subject to the following conditions: that

- You adhere to the principles of good research practice and ensure patient safety, privacy, confidentiality and data protection throughout the study
- You ensure the necessary logistical support is in place at the **named** Health Centres prior to commencement of the study.
- You ensure that participants are fully briefed on the nature and purpose of the study and what is expected of them, as part of the consent process
- You do not undertake other procedures and / or use patient materials or data outside of the scope of this present study, or for future use beyond this study.
- You agree to provide a progress report within **6 months** of the start and a final report at the end of the study or in the event that the study terminated early, an appropriate report.

This final opinion requires no further review. However please note that this favourable opinion is applicable only in so far as you adhere to the terms of approval and the Committee reserves the right to revise its favourable opinion should this become necessary.

On behalf of the Research Committee, I wish you success in the conduct of this study and look forward to receiving your final report following its completion.

Yours Sincerely,

29-12-2015

Dr Nagah Selim

Chair, PHCC Research Committee
Department of Clinical Affairs.

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هاتف : ٤٤٤٧٨٧٤١ / ٤٤٤٧٨٩١١ (+٩٧٤)
فاكس : ٤٤٤٧٨٧٢٨ (+٩٧٤)
ص.ب : ٢٦٥٥٥ الدوحة - قطر

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Appendix B

جامعة قطر
QATAR UNIVERSITY

Qatar University Institutional Review Board
QU-IRB

April 27, 2016

Dr. Mohamed Izham
College of Pharmacy
Qatar University
Tel.: 4403-5580 / 55615789
Email: mohamedizham@qu.edu.qa

Dear Dr. Mohamed Izham,

Sub.: Research Ethics Review Approval
Ref.: Project titled, "Increasing medication adherence in type 2 diabetes patients in Qatar's primary care clinics using an interventional transtheoretical model"

We would like to inform you that your application along with the supporting documents provided for the above proposal, has been reviewed by the QU-IRB, and having met all the requirements, has been granted research ethics approval for one year effective from April 27, 2016 till April 26, 2017.

Documents Reviewed: Checklist, Application, Questionnaires (English & Arabic), Morisky Medication Adherence Scale 8, Consent (Arabic and English), PHCC Approval

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

Your Research Ethics Approval No. is: **QU-IRB 593-A/16**

Kindly refer to this number in all your future correspondence pertaining to this project.

Dr. Khalid Al-Ali
Chairperson, QU-IRB

جامعة قطر
Institutional Review Board
(IRB)
Office Of Academic Research

Qatar University-Institutional Review Board (QU-IRB), P.O. Box 2713 Doha, Qatar
Tel +974 4403-5307 (GMT +3hrs) email: QU-IRB@qu.edu.qa

Appendix C

Primary Health Care Corporation
Clinical Affairs
Research Section
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مؤسسة الرعاية الصحية الأولية
PRIMARY HEALTH CARE CORPORATION

PARTICIPANT INFORMATION SHEET

Transtheoretical Model of Change on Medication Adherence among Type 2 Diabetes Mellitus Patients in Qatar Primary Care Setting

Dear Participant,

We invite you to take part in this research project which we believe will help us to gather useful information about type 2 diabetes mellitus. You are being invited because you are a diabetic patient. We hope by taking part you will help us to gather the information we need. In this letter, we have provided answers to questions that you might wish to ask about the research.

What is this research and what is the purpose of this research?
The goal of this research is to establish an effective Health Promotion Clinic at the Primary Healthcare setting in Qatar to improve medication adherence. The effectiveness of the 4-month (baseline and 2 points follow-up) comprehensive transtheoretical model on medication adherence and medicine taking behavior will be evaluated.

Why have you been invited to participate as a research subject?
Patients are chosen randomly. Any individuals diagnosed with diabetes defined as HbA1C ≥6.5% or any with classic symptoms of hyperglycemia or hyperglycemic crisis

How does this research differ from your routine care? [Optional]:
In this study, the transtheoretical model will be applied on patients in order to enhance their medication adherence.

What procedures will be carried out and why?
The medication adherence (the extent to which patients take medications as prescribed by their health care providers) will be measured using a pills count technique which will determine the number of pills used by every patient, and the adherence level will be determined by a validated 8-item Morisky Medication adherence scale (MMAS-8).

Are there any risks and discomforts involved? What safety precautions are we taking in this research?
The intervention and method used are not invasive. The participants will not be exposed to any risks or harms because their lifestyle and drug patterns will not be changed.

What are the benefits of the study?
The study will allow patients to comply to their medications and always make sure they are taken in time, which will result in better control of their blood glucose.

In case of Injury or if you wish to make an enquiry during the research, who do you contact?

Name: Yara Arafat
Number: 55705561

Dec, 2014

Are there any financial or other compensation which might be provided to research participants?
The patients enrolled in the study will be willingly volunteering, and no money would be given to them.

How long will your participation in this research be?
Participants will only be required to arrive to the hospital 3 times during the entire study. Their data will be collected at baseline, then 1, and 3 months post the intervention to evaluate the significance of the study.

Will any of your information or samples collected be stored for future research or shared with others?
No. It will be anonymous and information gathered will be kept confidential. It will only be used by the 3 researchers named above.

Names of the sponsors of the research:
Qatar University (Grant ID: QUUG-CPH-CPH-14/15-5)

What assurance can we give you of your anonymity and confidentiality?
Patient's confidentiality will be taken into consideration where the names of participants will not be collected in the data forms (anonymous) and the data will be saved privately in a location accessible only to the 3 investigators.

Non-coercive disclaimer: *[A statement that there is no pressure on the prospective subject to participate in the study, that he/she is free to choose any of the treatment modalities offered and that there is no pressure on the participant to continue in the study even after enrollment]*

After agreeing to take part, if you change your mind or do not wish to take part in some aspects of the research, do you have an option to withdraw from the study without penalty?
Participants have the right to withdraw from the study at any time they choose, and their decision will not affect the medical care they receive.

Details of the instances in which there might be incomplete disclosure of information:
Patients will be able to determine whether the study was beneficial to them or not depending on whether it provided better medication adherence to them or not. Patients will be given more details about the results of the study after the 4 months when the entire study is complete.

Who do you contact if you need further information?

Name: Yara Arafat
E-mail: ya1404916@qu.edu.qa

We hope that you will accept to participate in our study. If you decided to participate, we will ask you to read and sign the consent form for the project.

Thank you.

Name:	______________________	Signature:	______________________
Role:	______________________	Date:	______________________

Dec, 2014

Appendix D

Questions to assess the stages of change for medication adherence in diabetic patients

1. People sometimes find it difficult to take their medication as directed by their physician. As directed means consistently taking the amount of medication prescribed by your physician at the times(s) prescribed by your physician. Please find the statement that best describes the way you feel right now about taking your diabetes medication as directed

   A. No, I do not take and right now I am not considering taking my diabetes medication as directed
   B. No, I do not take but right now I am considering taking my diabetes medication as directed
   C. No, I do not take but I am planning to start taking my diabetes medication as directed
   D. Yes, right now I consistently take my diabetes medication as directed

If the answer to question 1 is D, then ask:

2. How long have you been taking your diabetes medication as directed?
   A. ≤3 months
   B. > 3 months to 6 months
   C. >6 months to 12 months
   D. >12 months

Appendix E

أسئلة لتقييم مراحل التغير للالتزام الدوائي للنوع الثاني من مرضي السكري

١. الناس في بعض الأحيان تجد صعوبة في اتخاذ أدويتهم حسب توجيهات الطبيب .حسب توجيهات الطبيب تعني أخذ كمية الدواء الموصوفة من قبل الطبيب بثبات و في الأوقات المنصوص عليها من قبله. برجاء اختيار العبارة التي تصف الطريقة التي تشعر بها الان عن اتخاذ أدوية السكري وفقاً للتوجيهات.

أ. لا. أنا لا أخذ دواء السكري الأن ولا أفكر في أخذه وفقاً للتوجيهات
ب. لا. أنا لا أخذ دواء السكري الأن و لكنني أفكر في أخذه وفقاً للتوجيهات
ت. لا. أنا لا أخذ دواء السكري الأن و لكنني أخطط للبدء في اتخاذه وفقاً للتوجيهات
ث. نعم. أنا الأن أخذ الدواء السكري باستمرار وفقاً للتوجيهات

إذا كانت الإجابة علي السؤال الأول ث برجاء الإجابة علي السؤال الثاني

٢. منذ متي و أنت تأخذ أدوية السكري وفقاً للتوجيهات ؟

أ. ≤ ٣ أشهر
ب. > ٣ أشهر إلي ٦ أشهر
ت. > ٦ أشهر إلى ١٢ شهرا
ث. > ١٢ أشهر

Appendix F

Morisky Medication Adherence Scale-8

1) Do you sometimes forget to take your medicine?	No=1 , Yes=0
2) People sometimes miss taking their medications for reasons other than forgetting. Thinking over the past two weeks, were there any days when you did not take your medicine?	No=1 , Yes=0
3) Have you ever cut back or stopped taking your medicine without telling your doctor because you felt worse when you took it?	No=1 , Yes=0
4) When you travel or leave home, do you sometimes forget to bring along your medicine?	No=1 , Yes=0
5) Did you take all your medicine yesterday?	Yes=1 , No=0
6) When you feel like your symptoms are under control, do you sometimes stop taking your medicine?	No=1 , Yes=0
7) Taking medicine every day is a real inconvenience for some people. Do you ever feel hassled about sticking to your treatment plan?	No=1 , Yes=0
8) How often do you have difficulty remembering to take all your medicine? (A)= Never/rarely , (B) Once in a while (C) Sometimes , (D) Usually ,(E) All the time	(A)=4, (B)=3, (C)=2, (D)=1, (E)= 0 Divide score by 4

Appendix G

MMAS (Urdu Version)

نہیں	ہاں	برائے مہربانی صحیح جواب پر(✓) کا نشان لگائیں
		سوال نمبر ۱:کیا آپ کبھی کبھار دوائی کھانا بھول جاتے ہیں؟
		سوال نمبر ۲: پچھلے دو ہفتوں میں کبھی ایسا ہوا ہے کہ بھولنے کے علاوہ کسی وجہ سے آپ نے دوائی نہ کھائی ہو؟
		سوال نمبر ۳:کیا کبھی ایسا ہوا ہے کہ آپ کی طبیعت دوائی کھانے کی وجہ سے زیادہ خراب ہوئی ہو اور آپ نے ڈاکٹر کو بتائے بغیر دوائی کھائی کم کردی ہو یا بند کردی ہو؟
		سوال نمبر ۴: کیا آپ دوران سفر دوائی ساتھ رکھنا بھول جاتے ہیں؟
		سوال نمبر ۵: کیا کل آپ نے اپنی دوائی کھائی تھی؟
		سوال نمبر ۶: اگر آپ اپنی طبیعت بہتر محسوس کرتے ہیں تو کیا آپ اپنی دوائی بند کر دیتے ہیں؟
		سوال نمبر ۷: کیا آپ بلڈ پریشر کی دوائی ہدایت کے مطابق کھانے کو مصیبت سمجھتے ہیں؟ کیونکہ روزانہ دوائی کھانا کچھ لوگوں کیلئے مشکل عمل ہوتا ہے۔
		سوال نمبر۸:آپ کے لیے کتنی دفعہ ایسا ہوا ہے کہ دوائی کے وقت کو یاد رکھنا مشکل رہا ہو؟ صحیح جواب پر نشان لگائیں
		کبھی نہیں
		کبھی کبھی
		بعض اوقات
		عام طور پر
		اکثر اوقات
		ہمیشہ

Appendix H

مقياس موريسكي للالتزام الدوائي

١) هل تنسي في بعض الأحيان تناول دوائك؟	لا= ١, نعم= ٠
٢) أحياناً الناس لا يتناولون دوائهم لعدة أسباب غير النسيان. أعد التفكير علي مدي الأسبوعين الماضيين هل يوجد أي يوم لن تتناول فيه دوائك؟	لا= ١, نعم= ٠
٣) هل سبق و خفضت أو توقفت عن تناول الدواء دون إبلاغ طبيبك لأنك شعرت سوءاً عندما أخذته؟	لا= ١, نعم= ٠
٤) عندما تسافر أو تغادر المنزل هل تنسي أحياناً أن تأخذ معك دوائك؟	لا= ١, نعم= ٠
٥)هل أخذت كل أدويتك بالأمس؟	نعم= ١, لا= ٠
٦) عندما تشعر بأن أعراض المرض تحت السيطرة هلّ تتوقف في بعض الأحيان عن أخذ دوائك؟	لا= ١, نعم= ٠
٧) أخذ الدواء إزعاج حقيقي بالنسبة لبعض الناس. هل تشعر بإنزعاج بخصوص الإلتزام بخطة العلاج؟	لا= ١, نعم= ٠
٨) كم مرة يكون لديك صعوبة في تذكر أخذ كل أدويتك؟ أ: أبداً/نادرا ب: مرة كل فترة ت: أحياناً ث: عادةً ج: كل الوقت	(أ)=٤ , (ب)=٣, (ت)=٢, (ث)=١, (ج)=. تقسم النتيجة على ٤

Appendix I

patient code: **Date:**

Using the Transtheoretical Model to Enhance Medication Adherence in Type 2 Diabetic Patients in a Primary Healthcare Setting

Data Collection Form

I. Demographics:

I. HC I.D#:

II. Date of Birth: _____/___/_____

dd mm yyyy

III. Age: □ above 65 □ 55-65 □ 45-54 □ <45(Please specify ______)

IV. Gender: □ M □F

V. Marital status: □ Single □ Married □ Divorced □ Widowed

VI. Nationality: □ Qatari □ Non Qatari (Specify :_________________)

VII. Race/Ethnicity: □ Arab □ Asian □ Others (pl specify:_____________________)

VIII. Educational attainment: □Postgraduate □Bachelor's □Highschool □Elementary □None

IX. Occupation: --------------------------------

II. Date of first diabetes diagnosis: □ More than 30 □30-20 □ 19-11 □10-5 □ <5

III. Date of first visit with DM diagnosis at NCD: --------------------------------

IV. Other medical conditions:

□ Hypertension

□ Dyslipidemia

□ Retinopathy

□ Neuropathy

□ Nephropathy

□ Others (please specify):

V. Number of medications for other medical conditions: ___________________________

IX. Medications regimen

Anti-hyperglycemic medication	Baseline			2 months		4 months	
	Start date	Dose	Frequency	Dose	Frequency	Dose	Frequency
Insulin only							
Insulin + 1 oral antidiabetic							
1 oral antidiabetic							
2 oral antidiabetics							
3 oral antidiabetics							
4 oral antidiabetics							

VI. Stage of change

Stage of change	Date	Date	Date
	Baseline	2 months	4 months
Precontemplation	□	□	□
Contemplation	□	□	□
Preparation	□	□	□
Action	□	□	□
Maintenance	□	□	□

VII. Medication adherence outcomes

Test	Date	Date	Date
	Baseline	2 months	4 months
Pill count technique			
MMAS-8			

VIII. Clinical outcomes

Test	Date	Date	Date
	Baseline	2 months	4 months
HbA1C			
FPG			