

**ASSESSMENT OF PHARMACIST
INTERVENTION ON DEPRESSION PATIENTS'
ADHERENCE AND CLINICAL OUTCOMES IN A
TERTIARY CARE CENTRE AT RIYADH, SAUDI
ARABIA**

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TERTIARY CARE CENTRE AT RIYADH, SAUDI ARABIA**

by

KHALAF ALI AL-JUMAH

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For the Degree of
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DEDICATION

I would like to acknowledge and dedicate this thesis to my parents for their support throughout my education and to my wife and kids, who tolerated much for my own benefit and success. I would like to thank you for all of your support and encouragement throughout my thesis work. God bless you all and I thank God for all of my achievements. I pray to God to accept my modest achievements and consider them as good deeds.

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LIST OF ABBREVIATIONS

BMQ	Beliefs About Medicine Questionnaire
CG	Control Group
CSS	Cross Sectional Study
DA	Decision Aids
IG	Intervention group
MADRAS	Montgomery–Åsberg Depression Rating Scale
MAQ	Medication Adherence Questionnaire
MDD	Major Depressive Disorder
MMAS	Morisky Medication Adherence Scale
MOH	Ministry of Health
MRC	Medical Research Council
NIH	National Institutes of Health
NPC	National Prescribing Centre
OPTION	Observing Patient Involvement in decision
PDA	Patent Ductus Arteriosus
PIS	Participant Information Sheet
QOL	Quality of life
RCT	Randomized Controlled Trial
SDM	Shared Decision Making
TSQM	Treatment Satisfaction Questionnaire for Medication
WHO	World Health Organization

**PENILAIAN INTERVENSI AHLI FARMASI KE ATAS KEPATUHAN
MEMAKAN UBAT DAN KESAN KLINIKAL PESAKIT MURUNG DI
SEBUAH PUSAT PENJAGAAN TERTIER DI RIYADH, ARAB SAUDI**

ABSTRAK

Kemurungan atau depresi merupakan penyakit mental kronik yang mempunyai kesan yang boleh menimbulkan ketidakupayaan yang signifikan terhadap kualiti hidup pesakit. Prevalens kemurungan mencecah 15% di seluruh dunia dan 18% di Arab Saudi. Secara am, ubat antikemurungan menjadi kurang berkesan kerana ketidakpatuhan pesakit dalam pengambilan ubat. Hal ini boleh menyebabkan akibat yang serius seperti kegagalan rawatan, komplikasi, penggunaan penjagaan perubatan yang tinggi, dan kerosakan tubuh sehingga tidak berupaya melakukan sesuatu kerja. Peranan ahli farmasi dalam sistem penjagaan kesihatan kini menjadi lebih luas sehingga meliputi kerja-kerja ujian klinik, ekonomi kesihatan, pendidikan pesakit, dan penjagaan pesakit secara langsung. Intervensi ahli farmasi terbukti dapat memberi manfaat dalam usaha meningkatkan hasil rawatan dalam pelbagai keadaan penjagaan kesihatan. Justeru, projek penyelidikan ini bertujuan untuk menilai impak intervensi ahli farmasi yang berdasarkan perkongsian pembuatan keputusan bagi memperbaiki tahap kepatuhan mengambil ubat antimurung dan hal-hal yang berkaitan dengan kesan pada pesakit. Satu kajian keratan rentas analisis deskriptif telah dijalankan untuk memerihalkan populasi Saudi yang mengalami kemurungan berhubung dengan kepatuhan pengambilan ubat antimurung dan untuk menentukan faktor-faktor risiko dan hubungan antara kepatuhan dengan kesan-kesan berkaitan pesakit yang lain. Selepas itu, satu kajian rawak terkawal prospektif, dengan kajian susulan 6 bulan, telah dijalankan untuk menilai impak intervensi ahli farmasi. Satu kajian rentas telah dijalankan ke atas 403

orang pesakit. Keputusannya menunjukkan bahawa 52.9% pesakit tersebut telah melaporkan kepatuhan rendah dalam pengambilan ubat antimurung dan purata skor skala kepatuhan ubat Morisky (5.23 daripada 8) dengan perbezaan signifikan secara statistik dalam tahap kepatuhan memihak kepada pesakit lelaki, pesakit yang berumur lebih tua, pesakit yang mengalami tempoh sakit yang lebih pendek, dan mereka yang membuat lawatan susulan lebih daripada tiga kali setahun di klinik psikiatri. Tentang peramal kepatuhan pengambilan ubat antimurung, keputusannya menunjukkan bahawa kepercayaan bimbang ($R = 0.40$; $P < .001$; $R^2 = 0.162$) merupakan peramal terpenting bagi kepatuhan pengambilan ubat antimurung. Dalam kajian rawak terkawal yang dijalankan, 239 pesakit yang memenuhi kriteria sampel telah ditetapkan ke dalam kumpulan intervensi ($n = 119$) dan kumpulan kawalan ($n = 120$). Bagaimanapun, 19 orang pesakit telah menarik diri daripada kajian ketika dalam fasa susulan. Selepas 6 bulan, pesakit dalam kumpulan intervensi telah menunjukkan perbezaan yang signifikan secara statistik dalam kepatuhan pengambilan ubat, berpuas hati dengan rawatan, percaya bahawa secara amnya mereka lebih memakan ubat, kepercayaan bimbang khusus dan secara am lebih percaya tentang ubat berbanding dengan mereka yang di dalam kumpulan kawalan. Bagaimanapun, perbezaan signifikan secara statistik tidak dikesan antara kedua-dua kumpulan dari segi teruknya kemurungan dan kesihatan yang berkait dengan kualiti hidup. Sebagai kesimpulan, intervensi ahli farmasi yang berdasarkan perkongsian membuat keputusan dengan pesakit yang menghadapi kemurungan menunjukkan penambahbaikan yang signifikan dari segi kepatuhan makan ubat, kepuasan terhadap rawatan, dan kepercayaan pesakit terhadap ubat antimurung apabila dibandingkan dengan penjagaan biasa. Oleh itu, dapatan ini menyarankan bahawa peranan ahli farmasi boleh dikembangkan bagi menyediakan penjagaan pesakit secara langsung

dalam amalan psikiatri dan dalam amalan farmasi biasa untuk menambah baik kepatuhan pesakit memakan ubat dan mengatasi kesan pesakit yang lain yang pernah dilaporkan.

**ASSESSMENT OF PHARMACIST INTERVENTION ON DEPRESSION
PATIENTS' ADHERENCE AND CLINICAL OUTCOMES IN A TERTIARY
CARE CENTRE AT RIYADH SAUDI ARABIA**

ABSTRACT

Depression is a chronic mental illness with a significant disabling effect on the patient's quality of life. Depression lifetime prevalence reach up to 15% worldwide and up to 18% in Saudi Arabia. In general the effectiveness of antidepressants is reduced due to patients' non-adherence. This may result in serious consequences such as treatment failure, complications, high medical care utilization, and impairment in work functioning. The role of pharmacists in the healthcare system has expanded to include involvement in clinical trials, health economics, patient education, and direct patient care. Pharmacist interventions have proved to be beneficial in improving treatment outcomes in a variety of healthcare settings. Therefore, this research aims to evaluate the impact of a pharmacist intervention based on shared decision making to improve adherence to antidepressant medication and related patient outcomes. A cross-sectional descriptive analysis study was carried to describe depressed Saudi population with respect to adherence to antidepressant and to determine the risk factors and the association between adherence and other patient-related outcomes. Then, a prospective randomized controlled study, with six-month follow-up, was conducted to evaluate the impact of pharmacist intervention. A cross-sectional study was conducted on 403 patients. The result showed that 52.9% of the patients reported low adherence to antidepressant medication and average Morisky medication adherence scale score (5.23 out of 8) with statistically significant differences in adherence level in favour of males, older patients, patients with a shorter duration of illness, and those having more than three follow-up visits

with a psychiatric clinic per year. Regarding the predictors of adherence to antidepressant, the result showed that the concerns beliefs ($R = 0.40$; $P < .001$ $R^2 = 0.162$) was the most important predictor associated with adherence to antidepressants. In the randomized controlled study, 239 patients met the inclusion criteria and were assigned to the intervention group ($n = 119$) and the control group ($n = 120$). However, 19 patients dropped out of the study during the follow-up phase. After 6 months, patients in the intervention group showed statistically significant differences in adherence to medication, treatment satisfaction, general overuse beliefs, specific concerns beliefs and the total general beliefs about medicines compared with those in the control group. However, no statistically significant difference was observed between the two groups in terms of severity of depression and health-related quality of life. In conclusion, pharmacist intervention based on shared decision making with depressed patients showed a significant improvement in adherence, treatment satisfaction and patients' belief of antidepressants compared with patients having the usual care. Thus, this finding suggests that the pharmacist role can be enhanced to provide direct patient care in psychiatric and in regular pharmacy practice to improve adherence to medication and other patients reported outcomes

CHAPTER ONE

General introduction

1.1 The health care system in Saudi Arabia

The healthcare system in Saudi Arabia has improved significantly in the last four decades (Almalki et al., 2011, Walston et al., 2007). In 2005, the World Health Organization (WHO) had ranked the Saudi healthcare system at 26th compared to 190 other health systems worldwide (WHO, 2005). The Saudi population reached 29.1 million in 2013, with a high annual population growth rate and fertility rate (3.19 % and 2.87 % annually, respectively). Approximately half of the population (50.2%) are males and 49.8% are females; 33 % of the population is younger than 15 years of age, 2.7% of the population is over 65 years old, and the life expectancy is 73.8 years (Almalki et al., 2011, Amir, 2012, MOH, 2013).

Article number 31 of the Saudi constitution states that “the government provides all citizens and expatriates working within the public sector with full and free access to all public health care services”. Additionally, Article number 27 states that “The government is responsible for caring for the citizen and his family in case of emergency, illness, disabilities and during old age” (Almalki et al., 2011, Jannadi et al., 2008).

The Saudi government increases the budget of the Ministry of Health (MOH) annually. Allocations to the MOH from the government general budget have steadily increased over the years from 800,000,000 \$ (representing 2.8% of the total government budget) in 1970 to 20,400,000,000 \$ (representing 6.8%) in 2013, which represents 680 \$ per citizen per year (MOH, 2013).

The MOH provides health services at three levels: primary, secondary and tertiary (Almalki et al., 2011, MOH, 2013). Primary care services are provided through primary health care centres (PHCCs) that are distributed throughout the country to provide preventive services, vaccinations, curative services, maternity care, paediatric care and chronic disease follow-up. Moreover, via the referral system, the primary care system refers the cases that require more advanced care and intervention to the general hospitals (secondary level) or specialized hospitals (tertiary level) (Almalki et al., 2011, MOH, 2013).

The MOH is the major provider of healthcare services, with a total of 259 hospitals (35,828 beds) and 2,250 PHCCs (Almalki et al., 2011, Amir, 2012, MOH, 2013). The MOH provides health care services at a rate of 24.4 physicians per 10,000 citizens, 47.8 nurses per 10,000 citizens and 5.3 pharmacists per 10,000 citizens (MOH, 2013). Furthermore, the private sector also provides health care services, with a total of 137 hospitals (14,165 beds) and 2,366 dispensaries and clinics (MOH, 2013).

The healthcare system in Saudi Arabia is facing several challenges, ranging from the development of health care service to the population growth, particularly in the elderly and as a result of the high fertility rates amongst the Saudi population; this also increases the demand for social services including health care (Almalki et al., 2011, Al Yousuf et al., 2002, MOH, 2013). Another challenge facing the healthcare system in Saudi Arabia is the rapid increase in the costs of healthcare services because of changes in public expectations and demands for high quality services (Almalki et al., 2011, Al Yousuf et al., 2002, MOH, 2013). In general, increasing services leads to increased demands for health manpower, which includes

pharmacists; however, the medical staff is experiencing a shortage in Saudi Arabia (MOH, 2013). Another challenge facing the healthcare system in Saudi Arabia is the increase in the prevalence of chronic diseases (hypertension, diabetes, chronic heart disease, mental health and cancer) as a result of modernization and changes in lifestyle (MOH, 2013). There is also a shortage of hospital beds and an overwhelming demand for inpatient services for mental health patients (Koenig et al., 2014). Finally, the lack of information and prevalence studies about mental health in the general population in Saudi Arabia represents an important challenge facing all healthcare providers working in psychiatric hospitals (Koenig et al., 2014).

1.2 Mental health services

As part of the progress in the healthcare system in Saudi Arabia, the identification and treatment of mental health disorders over the last three decades has improved significantly (Qureshi et al., 2013). Currently, mental health care services are provided through 25 specialized hospitals compared to only one such mental hospital 30 years ago (Shehar mental hospital) that served the entire population of Saudi Arabia (Dubovsky, 1983, Koenig et al., 2014). The mental health expenditure is reported as 640,000,000 \$ (Qureshi et al., 2013).

The MOH provides free mental health services to the public in Saudi Arabia through twenty-five mental hospitals, corresponding to 12 beds per 100,000 citizens (MOH, 2013). The admission rate in psychiatric hospitals is 1.92 per 100,000 citizens per year. The predominant diagnoses of patients admitted to psychiatric hospitals are schizophrenia (50%), substance-abuse disorders (20%), and mood disorders (20%). The average length of hospitalization is 45 days (Qureshi et al., 2013).

The MOH also provides mental health services through 94 public outpatient clinics. Of these, 20 clinics are specialized in child psychiatry and are located in non-psychiatric hospitals. The outpatient clinics treat approximately 1,846 patients per 100,000 citizens per year. Six percent of individuals seen in outpatient clinics are children and adolescents. Patients treated in outpatient facilities are most frequently diagnosed with mood disorders (35%), neurotic, stress-related, or somatoform disorders (36%), schizophrenia (13%), substance abuse (9%), personality disorders (2%), and others (5%) (MOH, 2013, Qureshi et al., 2013). Patients with an identified psychiatric problem in Saudi Arabia have an average of 3 outpatient visits per year (Qureshi et al., 2013).

In 2013, the Saudi government passed a Mental Health Act (MHA) that aimed to achieve the following purposes: "(1) improving access to mental healthcare generally, (2) ensuring the least restrictive level of care, (3) preserving the rights of patients, family members, and other caregivers, (4) streamlining competence, capacity, and guardianship issues, including voluntary and involuntary treatment, (5) ensuring the accreditation of professionals and facilities, (6) enforcing mental health laws and other legal issues, and (7) establishing mechanisms to implement these provisions" (Qureshi et al., 2013, Koenig et al., 2014).

Mental health research has increased slowly over the past decades in Saudi Arabia; there were no published studies before 1975 whereas a limited number of studies have been published during the last decade (Dubovsky, 1983, Jaalouk et al., 2012). Moreover, although the annual publication rate increased in Saudi Arabia from 0 - 1 between 1966 and 1985 to 18 between 1996 and 2006, there remains a huge gap between the research situation in Saudi Arabia and that in Western countries (Jaalouk

et al., 2012, Koenig et al., 2014). Until now, no studies have investigated the prevalence of mental disorders in the general Saudi population despite the fact that this information is essential to improve mental health services in Saudi Arabia (Koenig et al., 2014).

1.3 Role of pharmacists in the mental health care system

Recently, experts and organizations such as the WHO have supported the increased role of pharmacists in the care of mentally ill patients (Al-Aqeel et al., 2012, Everard, 2005). In Saudi Arabia, out of 2,293 pharmacists and 6,619 pharmacy technicians working in the MOH, only 89 pharmacists and 197 pharmacy technicians work in mental health services (representing 3.8% of pharmacists and 2.9% of pharmacy technicians working in the MOH) (MOH, 2013).

Al-Aqeel et al., 2012 investigated the experience and future expectations of psychiatrists with pharmacists in mental health services in Saudi Arabia. Overall, the study reported a positive experience and positive expectations. In total, 66% of the psychiatrists agreed that pharmacists are reliable sources of clinical drug information, 65% thought that pharmacists should inform doctors if patients are experiencing some problems with their medications, and 62% of the psychiatrists agreed that pharmacists are willing to take personal responsibility for resolving drug related problems they have discovered. Moreover, 43% agreed that pharmacists routinely counsel patients about drugs, and 48% stated that pharmacists inform doctors about the most cost-effective alternative. Furthermore, 66% of the psychiatrists agreed that pharmacists should routinely adjust the drug therapy for patients under an approved protocol (Al-Aqeel et al., 2012).

1.4 Future plan for the mental healthcare system

The health authorities in Saudi Arabia have developed a comprehensive plan to improve the quality of services and to implement the best practices in this field. This is performed by seeking accreditation by the local accreditation body in Saudi Arabia and the international accreditation bodies. Simultaneously, efforts are increased to implement new policies, expand mental healthcare services in primary healthcare and update the therapeutic drugs policy and guidelines (Al-Habeeb and Qureshi, 2010). However, based on an extensive literature review, the effect of these actions and plans on patient outcomes and adherence is has yet to be studied because there are no published studies investigating the effect of healthcare system related factors on patient adherence to psychotropic medications in Saudi Arabia.

1.5 Depression

Depression is a major chronic illness that affects approximately 15% of the population worldwide (Hunot et al., 2007, Vergouwen et al., 2003, Kessler and Bromet, 2013). Depression is defined as "a mental illness that features low mood, a sense of guilt and worthless. Patients report feeling sad, having low energy, and low self-esteem; patients also report feeling hopeless and beginning to think of death if this feeling continues for a long time. Some patients suffer from losing interest in things that they usually enjoyed before" (Al-Qadhi et al., 2014).

Depression is classified as mild, moderate, or severe according to the severity of symptoms. It can also be classified as unipolar depression or bipolar mood disorder according to a history of manic episodes (Burcusa and Iacono, 2007, WHO, 2012). All types of depression can be chronic if the depressive symptoms are present for

more than 12 months with relapse of disease. Relapses and recurrences are common with depression, particularly amongst non-adherent patients or patients with comorbidities. Moreover, the onset of the first episode and the number of depressive episodes can affect the outcome and increase the risk of relapse (Burcusa and Iacono, 2007).

The WHO reported that approximately 350 million people worldwide suffered from depression in 2012 (WHO, 2012). Moreover, major depression is estimated to be the second most disabling disease by 2020 (WHO, 2012). In Saudi Arabia, the prevalence of depression has been estimated in several studies to range from 12 to 20%. The estimated prevalence differed in those studies because of differences in the study settings, populations included, age groups selected, times, and geographic locations (Abdelwahid and Al-Shahrani, 2011, Al-Khathami and Ogbeide, 2002, Becker et al., 2002, El - Rufaie et al., 1988).

The population in Saudi Arabia has several risk factors for depression, including an already high prevalence of depression, a growing population, and increased comorbidities due to chronic diseases and the stress of modernization (Hidaka, 2012). Based on a literature review, little is known about the disease, treatment outcomes and the cost of treatment. The effect of disease symptoms and the loss of productivity or a pharmacoeconomic evaluation of therapy available in Saudi Arabia have yet to be reported (Al-Qadhi et al., 2014).

1.6 Treatment of depression

There are two main treatment approaches for depression: psychotherapy and pharmacological treatments. Electroconvulsive therapy is a third option that can be

used only if the main options of therapy are contraindicated or if the patient is unable to tolerate them (Amsterdam and Hornig-Rohan, 1996, Trivedi et al., 2010). According to the severity of disease, the healthcare team will select one of the two options. In severe cases, the combination of both options can be used. Additionally, for moderate-to-severe depression, the healthcare team will recommend a combination of antidepressant medication and psychotherapy (Al-Harbi, 2012, Marques et al., 2012, WHO, 2012). The therapeutic response rate to antidepressant therapy has reached 70%. This high response rate is difficult to achieve with other therapeutic approaches except for electroconvulsive therapy. Non-responders may show treatment-resistant symptoms combined with other social disorder symptoms (Al-Harbi, 2012, Marques et al., 2012).

1.7 Adherence to antidepressants

Depression is usually misdiagnosed by physicians, resulting in 50 % of patients with depression left untreated worldwide; therefore, it is expected that the use of antidepressants and other treatment options will increase worldwide (Dijkstra et al., 2008, WHO, 2003). Antidepressants improve depressive symptoms by up to 70% within one month compared to a 30% improvement in the placebo group. The only other type of therapy to reach this improvement rate is electroconvulsive therapy (Marques et al., 2012). Although antidepressants have been shown to be effective, many patients do not receive an adequate dosage for an adequate duration (Katon et al., 1992, Marques et al., 2012). Their effectiveness is further reduced because of non-adherence to the medication by the patients. A total of 28% of patients discontinue medication after one month, and between 44 and 52% of patients discontinue medication after three months (Hunot et al., 2007). This is consistent

with a study conducted by Viguera et al. (1998) that showed that it is not uncommon in clinical practice for depressed patients to discontinue taking their medication. A study conducted with 4,312 subjects showed that adherence rates dropped to 51% after 4 months of treatment and decreased further to 21% after 8 months (Sawada et al., 2009). Similar results were found in Finland in the Vantaa depression study, which reported that only half of patients adhere to medication for one year (Sawada et al., 2009). Likewise, Peveler et al. found a non-adherence rate of 34–58% (Peveler et al., 1999). This is supported by a study by Cantrell et al. in which non-adherence to antidepressant treatment reached 57% in patients (Cantrell et al., 2006).

Chronic diseases, mental disorders, human immunodeficiency virus/acquired immunodeficiency syndrome and tuberculosis together represented 54% of the burden of all diseases worldwide in 2001 and will exceed 65% worldwide by 2020 (WHO, 2003). The evidence has shown poor adherence to antidepressant medications amongst patients diagnosed with a major depressive disorder (Sabatâe, 2003). Data from different sources support the view that adherence to antidepressant medication is a dynamic behaviour that can vary from early to late treatment stages (Remien et al., 2003). Insufficiently treated depression may lead to serious complications such as relapse, drug resistance, increased treatment costs, and impairments in daily functioning (Hunot et al., 2007). These, in turn, may lead to increased rates of morbidity and mortality (Demyttenaere and Haddad, 2000, Julius et al., 2009).

Several methods have been used to improve adherence to antidepressants in patients with mental illnesses, and these methods have been well-studied in the literature (DiMatteo, 2004, Loh et al., 2007). They include educational interventions directed

towards the patients and their families, cognitive-support, reinforcement techniques and drug monitoring or a combination of these methods. However, few studies have been conducted to evaluate the interventions aimed to improve the quality of the patient-healthcare provider communication process regarding treatment options to improve adherence to antidepressant medication (Loh et al., 2007). Patient involvement in the decision-making process is an important predictor of patient adherence to antidepressants (Dwight-Johnson et al., 2001, Loh et al., 2007). The involvement of patients in the treatment process is considered to be the cornerstone in enhancing adherence in depressive patients (Vergouwen et al., 2009).

Shared decision-making (SDM) supports the hypothesis that a patient's participation in the treatment decision-making will result in improved adherence, satisfaction and improved clinical outcomes. This study will focus on pharmacists' interventions to improve the adherence of depressed patients to antidepressant medications based on the shared decision-making approach. The role of pharmacists in the health system has expanded beyond the dispensing function to include clinical trials, health economics, patient education, and other roles related to patient care (Rubio-Valera et al., 2009). Moreover, pharmacist interventions have been shown to be beneficial for improving treatment outcomes in a variety of healthcare settings (Al-Jumah and Qureshi, 2011, Hanlon and Artz, 2001). Additionally, because of their excellent position of having direct patient contact, accessibility and availability, pharmacists can help patients to address barriers to adherence (for example: concerns about adverse effects, increased duration of therapy, frequency of drug administration and pill burden) and incorporate interventions into the care of their patients through

several strategies such as patient education, drug monitoring and management of adverse reactions (Al-Jumah and Qureshi, 2011, Marques et al., 2012).

In Saudi Arabia, the concept of SDM is still in the beginning stages. It was first introduced by AlFaleh (AlFaleh et al., 2011), who developed and applied SDM to select either indomethacin prophylaxis or symptomatic treatment of Patent Ductus Arteriosus (PDA) for extremely low birth weight infants. The study revealed an improvement in both knowledge and decisional conflict scales (AlFaleh et al., 2011). Additional research in Saudi Arabia is necessary to evaluate interventions based on the improvement of patient involvement in the treatment decision-making process.

1.8 Shared Decision-Making

Over the past two decades in the literature, significant efforts have been made to encourage the active participation of patients in the treatment process and in decisions about their medications. These efforts have led to progressive concepts such as shared decision making (SDM) and patient-centeredness to create a way in which the patients can be involved in the entire treatment process (Osterberg and Blaschke, 2005). Since the 1990s, there has been increasing interest in the decision-making authority of the patient. Moreover, several terms have been used to explain patient participation in treatment choices including ‘informed decision-making’, ‘concordance’ and ‘evidence-based patient choice’. SDM sits in the middle between the two extremes of a traditional paternalistic model and an informed choice model (Godolphin, 2009). The most accurate definition of shared decision making is "that it is a two-way exchange of information, consultation and decision-making, where deliberation and decisions are made by both the healthcare professional and the

"patient" (Elwyn et al., 2000, Godolphin, 2009). Patients will be more motivated to follow agreed prescriptions and therapeutic plans, and the healthcare professional will deal with the patient as a partner to make collaborative decisions about the treatment (Dwight-Johnson et al., 2001, Godolphin, 2009). Without this partnership, there is concern that there will be an increase in non-adherence to treatment (Brody et al., 1989, Godolphin, 2009, Wilson et al., 2010).

A close and significant association between the patient's active participation in medical treatment and improvements in clinical outcomes was reported by Lewin and et al (Brody et al., 1989, Lewin et al., 2002). Similar results were found by Wilson and et al regarding asthma treatment and clinical outcomes (Wilson et al., 2010).

A systematic review has shown that there is a positive relationship between patient participation in the decision-making process and outcome, satisfaction, and improved self-esteem for patients (Joosten et al., 2008). Generally, the evidence supports the benefits of patient-centred care (Murray et al., 2005) and decision aids to improve deliberative treatment decisions (Orlando and Meredith, 2002). Moreover, when patients have the chance to share their decisions about treatment, there is a decrease in the discontinuation rate (Drake et al., 2009).

Research on SDM in psychiatry is at an early stage. However, several randomized controlled trials have supported its positive effects on patient reported outcomes. Drake et al reported positive outcomes regarding patient satisfaction compared to a control group two years after applying multiple shared decision-making sessions on patients diagnosed with schizophrenia (Drake et al., 2009). Similarly, Von Korff et

al. reported an improvement in adherence and depressive symptoms in depressed patients after applying multiple sessions of shared decision making at 3, 6, 9, and 12 months (Von Korff et al., 2003).

Positive associations have also been found between shared decision making and depressed patient satisfaction. In fact, patients became more satisfied with their care and treatment after participating in their care decisions (Swanson et al., 2007).

In a recent analysis of SDM models, three systematic reviews showed that the predominant models were based on the physician–patient relationship without the participation of other healthcare providers who have roles in the decision-making process. This finding indicates the need for a new approach to provide opportunities for other healthcare professionals to be involved in the SDM processes (Towle and Godolphin, 1999, Légaré et al., 2011).

In patients with depression, factors that are associated with non-adherence to treatment have been identified, but few investigations have been conducted to evaluate interventions that enhance patient participation in the selection of treatment regimes. This is an important consideration for further investigation into improving the management of the depressed patient

1.9 Characteristics of shared decision-making

Specific characteristics have been defined to categorize the interaction between patient and healthcare professionals; these characteristics are continuous rather than dichotomous variables (Stacey et al., 2010).

- Two parties are involved in shared decision-making.

- Both parties take steps to participate in the process of treatment decision-making.
- Sharing of information occurs by both parties in the process of shared decision-making.
- Both parties agree to whatever treatment decision is made.

1.10 Steps for shared decision-making

A competency framework is a collection of those competencies that are important to perform effectively. Competencies are developed and adopted to improve performance. Steps and skills (competences) were qualitatively studied and evaluated, and those that are required for practitioners to involve patients in the treatment process have been described by (Elwyn et al., 2000, Clyne et al., 2007, Stacey et al., 2010) and are identified in eight steps, as shown in Table 1.1

Table 1.1 Competency framework for shared decision-making (Simmons et al., 2010)

	Competencies
1	Develop a partnership with the patient
2	Establish or review the patient's preference for information (e.g., amount and format of information)
3	Establish or review the patient's preferences for their roles in decision-making
4	Ascertain and respond to the patient's ideas, concerns, and expectations
5	Identify the choices and evaluate the research evidence in relation to the individual patient
6	Present (or direct to) evidence, taking into account the above steps, and help the patient reflect upon and assess the effect of alternative decisions with regard to their values and lifestyles
7	Make or negotiate a decision in partnership and manage conflict
8	Agree upon an action plan and complete arrangements for follow-up

1.11 Patient participation in shared decision making

Despite all of the efforts to involve patients in SDM, the main factor in adopting shared decision-making into practice still resides in the willingness of the patient to participate. However, encouragingly, approximately 40 % of patients are willing to participate in the process of SDM regarding medications and treatment. These patients are usually more educated and from a younger age group (Deber, 1994, Marques et al., 2012). Moreover, it has been found that patients suffering from depressive disorders are more willing to participate compared to patients with

hypertension, cardiac patients and diabetic patients (Arora and McHorney, 2000, Marques et al., 2012).

1.12 Decision aids

Patient decision aids have been developed to facilitate and support shared decision-making between the healthcare professional and the patient. Moreover, psychiatric patients must utilize decision aids more than patients with chronic diseases because psychiatric patients may face stigma associated with the treatment, delayed onset of action, have higher risks of side effects, and have choices between two or more alternatives to address their health problem (O'connor et al., 2004, O'Connor et al., 2007, Stacey et al., 2011).

These decision aids can be in the form of software, web applications, leaflets and structured counselling. A review of 55 randomized controlled studies found that decision aids improved participation in SDM more than standard counselling (O'Connor et al., 2009). Moreover, there is no evidence that decision aids increase the demand for expensive treatments (O'Connor et al., 2007). The best method is to provide both the healthcare provider and the patient with the same information and provide each with additional information if required, which is tailored according to their individual needs. The provision of information is crucial to be involved in the decision making process and may be required to reassure a patient's decisions. It can support all types of involvement in the decision-making process: active, collaborative and passive (O'Connor et al., 2007, Sheridan et al., 2006, Simmons et al., 2010). Most decision aids share the following characteristics (O'Connor et al., 2007):

- Provide facts about the medical condition, treatment options and outcomes.

- Clarify the treatment outcomes that are most important to the patient.
- Guide and educate the patient so that a treatment selection can be made.

1.13 Factors influencing shared decision-making

There have been some factors that influence and accelerate the process of SDM, such as (Towle and Godolphin, 1999, Young et al., 2008):

- Applying real partnerships between healthcare professionals and patients.
- Type of healthcare system policies.
- Patients' ability to access more information related to treatment options.
- Use of decision aids to facilitate SDM.
- Accessibility of health services to patients.

1.14 Barriers in the implementation of shared decision-making

There are some barriers to the successful implementation of SDM in clinical practice. These barriers include negative attitudes of healthcare professionals, time pressure, lack of skills, inability to apply the concept because of the patient's characteristics, and the clinical setting. The motivation of health professionals and their perception that shared decision-making will improve the outcome of the treatment is crucial in the removal of barriers to implement SDM (Gravel et al., 2006, Légaré et al., 2008).

1.15 Intervention design according to shared decision-making

There are three types of approaches to improve a patient's participation in SDM (Simon et al., 2007):

- The education and training of health professionals so that they can interact and communicate with the patients effectively and improve their participation.
- The use of decision aids to achieve better adherence to medication, patients' satisfaction with treatment, less conflict with health professionals, and realistic expectations for the treatment.
- Education of the patients and encouraging them to ask more questions during consultations and play an active role in shared decision making. This will make the patients realize that they are playing an important role in decision-making and will improve adherence and the success rate of treatment.

1.16 Theoretical explanation for medication adherence

Adherence to medication is a contentious decision making process, and a positive association has been reported between patients' beliefs and adherence to medication (Clifford et al., 2008). A review of the literature found several hypotheses about the relationship between patients' beliefs and decision-making. The authors of these studies attempted to explain the change in patient behaviour and how this can be applied in clinical practice to change patient behaviour related to health decision making. The most important and commonly used theories in explaining the relationship between patients' beliefs and behaviours, particularly in terms of adherence decision making, are as follows (Munro et al., 2007):

Rosenstock (1966b) proposed the health belief model (HBM) to explain and predict health-related behaviour from patterns of belief related to "the recommended health behaviour" and "the health problems" (Rosenstock, 1966a). Ajzen and Fishbein have

proposed the theory of planned behaviour (TPB) (Fishbein and Ajzen, 1975, Prochaska, 2013), which is an extension of the theory of reasoned behaviour (TRA) that includes perceptions of behavioural control as predictors of behavioural intentions and behaviour (Fishbein and Ajzen, 1975). Such models are often used to examine the determinants of behavioural decision making and to predict a variety of behaviours. Focusing on the intention to perform the behaviour, TRA suggests that attitude and behaviour mainly reflects voluntary behaviour, whereas TPB is used to predict human behaviour that can be deliberated and planned (Munro et al., 2007). In addition, Prochaska and DiClemente (1983) have proposed the theory of trans-theoretical model (TTM) (Prochaska, 2013) to explain and predict the five stages of change (the phases people go through) that individuals use to change their troubled behaviour: pre-contemplation, contemplation, preparation, action, and maintenance. This model advocates that an appropriate and successful intervention can only be implemented when the stage an individual is at has been determined.

Several models of health belief do in fact exist. Moreover, several attempt have been made to devise interventions based on these models. For example the Fuzzy Trace Theory (FTT) has been applied to health and medical decision making in conditions such as HIV prevention, surgical risk assessment, cancer prevention and smoking cessation (Reyna, 2008). The FTT assumes that intuitive processing is more sophisticated and more capable of making decisions that are in context and that intuitive processing will lead to increased experience and cognitive development, which is associated with increasing reliance on gist processing (as one of memory classification by fuzzy trace theory verbatim and gist) (Reyna and Brainerd, 1995, Reyna, 2008). In addition, Rob Horne proposed a theoretical model to predict

patients' beliefs and attitudes to explain patient behaviour. This model identified a balance between a patients' perceived need for treatment (necessity) and their concerns regarding the harmful effects of the medication; this model suggested a four-fold classification of patients according to their attitudes towards antidepressants (Horne et al., 1999, Tibaldi et al., 2009). There are, however, some criticisms regarding these models and their application in the real world to enhance adherence (Munro et al., 2007). Nonetheless, these models help describe medication taking behaviours and play roles in designing new interventions to enhance medication taking behaviours. Further investigation and research is necessary to determine which models are suitable to enhance medication taking behaviours in chronic diseases.

1.17 Patient beliefs about antidepressants and adherence

Patients' beliefs and concerns about medicine play an important role in adherence to medication (Horne et al., 1999). Patients who believe that taking their medications is necessary for good health adhere to their medication strictly whereas patients who have concerns about taking medication display non-adherence to their medication (Horne et al., 1999). Studies of patients with renal disease, asthma, diabetes, cancer, coronary heart disease, hypertension, HIV/AIDS, haemophilia, and depression have reported an association between low adherence to medication and patient beliefs towards the need for medication and concerns about potential adverse effects (Horne, 2006).

Patients have their own set of beliefs and views about medication regarding the necessity of taking medicine, the method of taking medicine, and the timing or

quantity of dosage. These beliefs and views are based on their past experience, knowledge, word of mouth from friends and family, their own personal judgement about the nature of symptoms or what is suitable for their lifestyle (Tibaldi et al., 2009).

Low adherence to medication in patients with bipolar disorder was related to the patients' beliefs about the need for treatment and strong concerns about potential side effects (Clatworthy et al., 2009). Similarly, it has been shown that patient's adherence to antidepressants depended on their perceived need for treatment (necessity) and concerns about harmful effects of the medication (Clifford et al., 2008). Knowledge of and attitudes towards depression and its treatment may have a significant effect on adherence to antidepressants (Gabriel and Violato, 2010). For antidepressant medication, "necessity-minus-concerns" is strongly related to the adherence rate: patients reported high adherence when necessity exceeded concerns and low adherence when concerns exceeded necessity.

1.18 Research problems

Non-adherence to antidepressants is a common challenge in clinical practice because of the nature and severity of symptoms of the disease and the characteristics of some pharmacological treatments used (e.g., medications that require up to one month until the patients feel their condition/symptoms resolved, serious adverse effects, etc.). Moreover, the recurrence of disease, relapse and serious complications can result from non-adherence to medication. Until now, few published papers regarding shared decision making and medication adherence amongst depressed patients have been reported in the Saudi Arabia context.

1.19 Justification of the study

The literature has reported different pharmacist interventions targeting adherence to antidepressants using several strategies. However, there is a lack of published studies that evaluate the effects of pharmacist interventions using shared decision-making. Although research on shared decision-making has displayed promising results regarding outcomes in depressed patients, few studies have examined patient participation in depression treatment decisions, in contrast to other diseases that have been extensively studied (Perestelo-Perez et al., 2011).

Although it is useful to learn from studies in the literature that were conducted in other countries regarding this topic, their findings cannot be extrapolated to the Saudi healthcare system because there are differences between the healthcare systems in terms of socioeconomic status, culture, lifestyle habits, and spiritual belief towards psychiatric diseases (Alsolami et al., 2012, Griffiths et al., 2005, Koenig et al., 2012).

Although pharmacists have been shown to be beneficial for improving treatment outcomes in a variety of healthcare settings, the evaluation of new pharmacist approaches to enhance adherence to antidepressants will provide new data that will be valuable for health authorities and policy makers. The role of a pharmacist in this study is defined as a drug expert amongst the healthcare team who is responsible for applying shared decision making interventions regarding the use of medication as a part of direct patient care, which is the responsibility of the pharmacist in psychiatric hospitals (Santschi et al., 2011).

1.20 Importance of the study

Evidence has shown poor adherence to antidepressant medication amongst patients diagnosed with major depressive disorder. Moreover, there is a paucity of data in Saudi Arabia regarding adherence to medication (Al-Omran et al., 2000). In particular, after conducting an extensive literature search, we identified no studies that were conducted to address adherence to antidepressants in Saudi Arabia. Therefore, it is important to conduct this research project to provide healthcare providers with useful information about patient medication behaviour amongst depressed patients in Saudi Arabia.

Insufficiently treated depression may lead to serious complications such as relapse and drug resistance; additionally, there may be pharmaco-economic consequences and impairment in daily functioning (Hunot et al., 2007), which may lead to increased rates of morbidity and mortality (Demyttenaere and Haddad, 2000, Jannadi et al., 2008, Julius et al., 2009).

However, the adherence of patients with chronic disease to their medications results in lower disease-related medical costs and lower hospitalization rates (Sokol et al., 2005). In the same context, patients' adherence to antidepressants results in lower total healthcare costs. Adherence to antidepressant therapy has been shown to improve economic outcomes (White et al., 2003). Moreover, the literature suggests that when depressed patients adhere to their antidepressant medication, their adherence to other medications used to treat other medical conditions also improves (Katon et al., 2005).