Interventions to promote psychiatric patients’ compliance to mental health treatment: a systematic review

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DECLARATION OF LANGUAGE EDITING

I, Christina Maria Etrecia Terblanche, id nr 771105 0031 082, hereby declare that I have edited the dissertation of MB Serobatse entitled INTERVENTIONS TO PROMOTE PSYCHIATRIC PATIENTS’ COMPLIANCE TO MENTAL HEALTH TREATMENT: A SYSTEMATIC REVIEW, without viewing the final product.

Regards,

CME Terblanche
DECLARATION

I, Mosidi Belinda Serobatse, declare herewith that the mini-dissertation entitled Intervention to improve psychiatric patients' compliance to mental health treatment: a systematic review, is my own work and that all the sources that I have used or quoted have been indicated and acknowledged by means of complete reference, and this work has not been submitted previously for any other degree at any institution.

..........................................................................................  ..............................................

M. B. Serobatse       Date
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ABSTRACT

Non-compliance to treatment remains one of the greatest challenges in mental health care services, and knowledge about how to improve this is still a problem. The aim of this study is to critically synthesize the best available evidence regarding interventions to promote psychiatric patients’ compliance to mental health treatment. This study aims to provide the clinical practitioner with accessible information on interventions to promote psychiatric patients’ compliance to mental health treatment. Systematic review was chosen as a design method to identify primary studies that answer the following research question: What is the current evidence on interventions to promote psychiatric patients’ compliance to mental health treatment?

Selected electronic databases that were accessible were thoroughly searched: SA-Nexus (NRF), ProQuest, EBSCOhost Platform, ScienceDirect, Web of Knowledge, Cochrane Library, Sabinet and Google Advanced Scholar were searched for primary studies that were published from 2001 to 2011. Primary studies in any language with an abstract in English were included in the search results. The following key words were used in the search: intervention, mental health treatment, psychiatric treatment, compliance, adherence, psychiatric patients, mental health care user and combinations thereof. Pre-determined inclusion and exclusion criteria were applied during the selection of studies. Sixteen studies (n = 16) were included for critical appraisal of methodology and quality using standard instruments from the Critical Appraisal Skills Program (CASP), the (JHNEBP) John Hopkins Nursing Evidence-Based Practice Research Evidence Appraisal Tool and the American Dietetic Association’s (ADA) Evidence Analysis manual. Finally only fourteen studies (n = 14) were identified as evidence that answers the literature review question appropriately.

Evidence extraction, analysis and synthesis were conducted by means of the evidence class rating and grading of strength prescribed in ADA’s manual (ADA, 2008:62). The research was evaluated, a conclusion was given, limitations were identified and recommendations were formulated for nursing practice, education and research. Study findings indicated several interventions that can improve patients' compliance in mental health treatment. Adherence therapy and motivational interviewing techniques during in-hospital stay improved the compliance of psychiatric patients. The use of Meds-help Pharmacy-based Intervention and Treatment Adherence Therapy Program for all Healthcare Professionals improved compliance to treatment for severely mentally ill. A Treatment Initiation and Participation Program and the use of Management Flow Sheet Interventions for Depressed Patients in Out-Patient Settings improved overall compliance of depressed patients in out-patient settings. Community mental health nurses trained in Medication Management improved psychiatric patients’ compliance to treatment at the community health care centres. Antipsychotic medication combined with
therapeutic antipsychotic psycho-social interventions improved compliance of treatment for early-staged schizophrenia patients in out-patient settings. The use of Risperidone injections during the provision of home care and the long-acting injectable antipsychotic and atypical antipsychotic treatment used for schizophrenic patients served to improve compliance of mental health treatment in out-patient settings for schizophrenic patients. It is thus recommended that nurses should be exposed to clinical training regarding treatment compliance interventions of mental health care users during formal nursing education to enhance the mental health care practice and stimulate more innovative research on treatment compliance on the clinical field.

**Key words:** intervention, mental health treatment, psychiatric treatment, compliance, adherence, psychiatric patients and mental health care user.
OPSOMMING

Geen-samewerking met behandeling bly steeds een van die grootste uitdagings in geestesgesondheidsorgdienste, en kennis oor hoe om dit te verbeter is steeds ‘n probleem. Die doel van hierdie studie is om die beskikbare bewyse aangaande intervensies ter bevordering van psigatriese pasiënte se samewerking met geestesgesondheidsbehandeling krities te sintetiseer. Die studie poog om aan die kliniese praktisyn inligting beskikbaar te stel oor intervensies ter bevordering van psigatriese pasiënte se samewerking met geestesgesondheidsbehandeling. ’n Sistematiese literatuuroorsig is gekies as metode om primêre studies te identifiseer wat die volgende navorsingsvraag beantwoord: Wat is die huidige getuienis ten opsigte van intervensies wat psigatriese pasiente se samewerking met geestesgesondheidsbehandeling promoveer?

Geselekteerde beskikbare databasisse is deeglik deursoek; SA-Nexus (NRF), ProQuest, EBSCOhost Platform ScienceDirect, Web of Knowledge, Cochrane Library, Sabinet en Google Advanced Scholar is deursoek vir primêre studies wat gepubliseer is vanaf 2001 tot 2011. Primêre studies in enige taal met ‘n opsomming in Engels is ingesluit in die soekresultate. Die volgende sleutelwoorde is gebruik in die soektog: intervention, mental health treatment, psychiatric treatment, compliance, adherence, psychiatric patients, mental health care user en kombinasies daarvan. Vooraf bepaalde insluitings- en uitsluitingskriteria is toegepas gedurende die seleksie van geïdentifiseerde studies. Sestien studies (n = 16) is ingesluit vir kritiese gehalte beoordeling ten opsigte van metodologie en kwaliteit deur die gebruik van gestandaardiseerde instrumente van die Critical Appraisal Skills Program (CASP), die (JHNEBP) John Hopkins Nursing Evidence-Based Practice research evidence appraisal tool en die American Dietetic Association’s (ADA) Evidence Analysis Manual. Sleks tien studies (n = 10) is uiteindelik geïdentifiseer as bronne van bewyse wat die literatuuroorsigvraag toepaslik beantwoord.

Bewysonttrekking, -analise en -sintese is gedoen deur middel van die beoordeling van bewyseklas en -gradering van bewyssterkte soos voorgeskryf in die ADA se handleiding (ADA, 2008:62). Die navorsing is geëvalueer, ‘n samevatting is gegee, beperkings is geïdentifiseer en aanbevelings is geformuleer vir verpleegpraktyk, -onderwys en -navorsing. Studiebevindinge het gewys daar is heelparty intervensies wat psigatriese pasiënte se samewerking met behandeling kan verbeter. Samewerkingsterapie en motiveringsonderhoudstechnieke gedurende hospitaalverblyf verbeter die samewerking van psigatriese pasiënte. Die gebruik van Meds-help Aptekers-gebaseerde intervensies en die Behandeling en Samewerkingsterapie-program vir alle Gesondheidswerkers het samewerking met behandeling verbeter vir erge siek geestesgesondheid pasiente. Die Behandeling Iniëriëring en Deelname-program, en die gebruik van Bestuursvloeikaart Intervensies vir depressiewe pasiënte in die Buite-pasiënte-afdelings het
oorhoofs die samewerking van depressiewe pasiënte in die Buite-pasiënte afdeling verbeter. Die verbinding van antipsigotiese medikasie met terapeutiese psigososiale intervensie het samewerking verbeter van vroeë fase skisofreniese pasiënte in die Buite-pasiënte-afdelings. Gemeenskap-geestesgesondheidsverpleegsters opgelei in Medikasie-bestuur het psigiatriese pasiënte se samewerking in die gemeenskapsgesondheidsentruums verbeter. Die verbinding van antipsigotiese medikasie met terapeutiese psigososiale intervensie, die gebruik van Risperidone inspuitings gedurende die voorsiening van tuisversorging en langwerkende inspuitings van antipsigotiese en atipiese behandeling vir skisofreniese pasiënte het samewerking met behandeling verbeter in die Buitepasiënte Afdelings vir Skisofreniese pasiënte. Dit word dus aanbeveel dat verpleegkundiges blootgestel word aan kliniese opleiding aangaande behandeling-samewerking-intervensies van geestesgesondheidsorg verbruikers gedurende formele verpleergonderwys om geestesgesondheidsorg behandeling intervencias te verhoog in praktyk en meer innoverende navorsing te stimuleer in die kliniese veld.

**Sleutelwoorde:** Intervensie; geestesgesondheidsbehandeling; psigiatriese behandeling, samewerking; psigiatriese pasiënte en geestesgesondheidsverbruiker.
### Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>ADA</td>
<td>American Dietetic Association</td>
</tr>
<tr>
<td>AT</td>
<td>Adherence Therapy</td>
</tr>
<tr>
<td>CNA</td>
<td>Canadian Nurses Association</td>
</tr>
<tr>
<td>CASP</td>
<td>Critical Appraisal Skills Program</td>
</tr>
<tr>
<td>CEBS</td>
<td>Centre for Evidence-Cased Conservation Mental Health Centres</td>
</tr>
<tr>
<td>CMHC</td>
<td>Community Mental Health Centres</td>
</tr>
<tr>
<td>CRD</td>
<td>Centre for Reviews and Dissemination</td>
</tr>
<tr>
<td>DSM-IV-TR</td>
<td>Diagnostic and Statistical Manual of Mental Disorders, fourth edition (text revision)</td>
</tr>
<tr>
<td>EBP</td>
<td>Evidence-Based Practice</td>
</tr>
<tr>
<td>ITT</td>
<td>Intention-to-treat</td>
</tr>
<tr>
<td>JHNEBP</td>
<td>John Hopkins Nursing Evidence-Based Practice</td>
</tr>
<tr>
<td>LAI</td>
<td>Long-Acting Injectable</td>
</tr>
<tr>
<td>PICOT</td>
<td>Population, Interventions, Comparative interventions, Outcomes and Time frame.</td>
</tr>
<tr>
<td>RCD</td>
<td>Randomised Control Trials</td>
</tr>
<tr>
<td>RLAI</td>
<td>Risperidone Long-Acting Injection</td>
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<tr>
<td>TAP</td>
<td>Treatment Adherence Therapy</td>
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CHAPTER 1: OVERVIEW OF THE RESEARCH

1.1 INTRODUCTION

Non-compliance to treatment remains one of the greatest challenges in mental health care services (Nose et al., 2003:197). The aim of this study is to critically synthesize the best available evidence regarding interventions to promote psychiatric patients’ compliance to mental health treatment. This synthesis will be made available for health professionals to use in clinical practice.

This chapter aims to provide a clear overview of this research regarding interventions to promote psychiatric patients’ compliance to mental health treatment. It will systematically explain the background and rationale for the study, the problem statement, research questions, the purpose of the study and the paradigmatic perspective. It also includes a brief outline of the research design and methods, rigour and ethical considerations used in the study.

1.2 BACKGROUND AND RATIONALE OF THE STUDY

Compliance with treatment, or adherence, is a very important health care issue (Balon, 2002:1). Both health care provider and patients share responsibility for adherence which is rarely an all-or-none phenomenon (Patel & David, 2007:357). These researchers further explained that adherence includes the concepts of patient choice: both health care provider and patient share the responsibility for adherence. According to Balon (2002:1), in prescribing medication, compliance usually means “the extent to which the patient takes the treatment as prescribed”. The term compliance is used in this study, is intended to be nonjudgmental, and be used as a statement of fact to ensure that both psychiatric patients and health care provider take the responsibility to promote psychiatric patients’ compliance to mental health treatment. For patients’ long-term benefit, the ultimate goal is adherence, but when involuntary patients are psychotic and very disabled by illness, the immediate objective is compliance (Vuckovich, 2011:78). Compliance to treatment is a major problem, especially for patients repeatedly hospitalised for psychiatric disorders. It has been estimated that 20 - 50% of the patient population is at least partially non-compliant, and that in patients diagnosed with schizophrenia and related psychiatric disorders, non-compliance rates can run as high as 70 - 80% (Nose et al., 2003:197). Although psychiatric medication is effective in reducing relapse and re-hospitalisation, 30 to 40% of psychiatric patients relapse within one year after discharge, despite receiving maintenance medication (Kneisl & Trigoboff, 2009:377).
According to literature, there are many factors that contribute to non-compliance to treatment, namely:

- lack of insight, lack of social support, poor quality in patient-doctor relationship, limited effectiveness and severity of side effects of psychiatric medication (Montes et al., 2010:274);
- substance abuse, male gender, and cultural attitudes towards mental illness and its treatment (Malla et al., 2009:2);
- forgetting and losing or running out of medication; thinking that it was not needed; not wanting to take the drug; poor awareness of illness and embarrassment at having to take daily medication (Razali, 2010:69);
- lack of clear markers of efficacy, the complexity of treatment regimen (Brondolo & Mas, 2001:137); and
- psychiatric patients’ easy access to alcohol and other chemicals (Ruthbard & Kuno, 2000:19; Lamb & Bachrach, 2001:1039).

Poor compliance to treatment can create a multitude of problems, such as a high rate in re-hospitalisation, a longer hospital stay, elevated costs, increased risk of attempted and completed suicide, and poor outcome related to impaired patient functioning (Montes et al., 2010:274; Malla et al., 2009:2). Poor compliance to anti-psychotic medication increases the risk of relapse and re-admission, and relapse leads to an increased potential for assault and dangerous behaviour by psychiatric patients, especially during periods of psychosis (Zygmunt et al., 2002:1653). An increase in symptoms and in the potential for assault and dangerous behaviour, and a decrease in quality of life, have all been attributed to failure to comply to prescribe treatment (Vuckovich, 2011:79).

Different interventions have been used to promote psychiatric patients’ compliance to mental health treatment, including interventions aimed at patients and their family. Furthermore, Zygmunt et al. (2002:1653) compared different strategies for improving treatment compliance in psychiatric patients with schizophrenia namely: behavioural management compared to intensive case management; psycho-education plus family therapy compared to psycho-education plus relative groups. Their findings were: psycho-education and family therapy alone did not have a positive effect on compliance to mental health treatment, whereas behavioural interventions and programs that used cognitive techniques were often effective in improving compliance to mental health treatment. These interventions all effectively lowered relapse rates, reduced negative attitudes and improved the outcome of these patients (Zygmunt et al., 2002:1661).
However, the greatest improvement in compliance was seen when interventions employed a combination of educational, behavioural and cognitive strategies (Razali, 2010:7). Zygmunt et al. (2002:159) highlight the need for long term reinforcement and support to deal with poor medication compliance so that recurrent relapses could be avoided.

In addition, the following interventions were suggested by Malla et al. (2009:2):

- Good therapeutic alliance at the start of treatment. A strong therapeutic alliance established between patients, caregivers and the treating doctor will promote treatment compliance.
- Use of long-acting injectables (LAI) in the first episode of psychosis.
- Using an approach that focuses on the patient’s current treatment capacity and risk of non-adherence. The risk consequences of relapse and the ethical principles of autonomy, beneficence, and non-maleficence are used to direct which specific interventions to apply.

Another example to promote psychiatric patients’ compliance to mental health treatment is discussed by Gutierrez-Casares et al. (2010:327) whose study based in Spain compared oral medication and injectable medication with follow-up by a psychiatrist as interventions to improve compliance to treatment by schizophrenic patients. Their results found that patients treated with injectable drugs were more frequently found in the “good compliant” group compared to patients taking oral medication. Another strategy to improve compliance to antipsychotic treatment by psychiatric patients was a telephonic-based nursing strategy in Spain (Montes et al., 2010:274). These researchers found that a simple intervention consisting of a monthly telephone call provided by a mental health nurse was more effective than only routine clinical care in the promotion of compliance to antipsychotic treatment.

Non-compliance to treatment among psychiatric patients is also considered a problem in South Africa. In South Africa, as part of the deinstitutionalisation movement, patients with mental illness were discharged from hospitals as soon as possible/acute episode is resolved and went for follow-up treatment at their nearest community mental health clinics (Kazadi et al., 2008:52). Treatment at these clinics focus mainly on pharmacotherapy, with little psychosocial support services owing to a lack of human and material resources, as well as the difficulties of integrating various treatment modalities (Kazadi et al., 2008:52). Different studies, as discussed above, had indicated a variety of outcomes of interventions used to promote psychiatric patients’ compliance to mental health treatment. There are interventions that did not improve compliance to treatment and those with positive results, improving compliance to treatment. Therefore, there is a need for more current interventions that can promote psychiatric patients’
compliance to mental health treatment.

1.3 PROBLEM STATEMENT

There is a widespread problem with psychiatric patients that do not remain compliant to their mental health treatment (Malla et al., 2009:2). In the researcher’s experience, psychiatric patients tend to default before their first follow-up appointment because of mental health treatment non-compliance. Complete compliance is difficult to achieve in most psychiatric patients, and non-compliance is compounded by the need to take medication over extended periods of time. This, in turn, leads to psychiatric patients who frequently re-enter the system within a short period and who are unable to function because of persistent symptoms and poor compliance to treatment. This phenomenon is commonly referred to as the “revolving door syndrome” (Fortinash & Holoday-Worrent, 2000:23). These patients have a poor quality of life and a deteriorated functional capacity. Their families and the societies in which they live also suffer greatly, due to social stigma and a significant socio-economic burden (Gutierrez-Casares et al., 2010:328).

Although interventions have been developed to reduce poor compliance to treatment, problems with compliance recur, and no single intervention has yielded impressive results (Zygmunt et al., 2002:1663). Therefore, a review of available current evidence regarding the promotion of psychiatric patients’ compliance to mental health treatment could be helpful. The current available interventions will be critically synthesized and made available for health care professionals and for clinical practice. When this information becomes accessible for health care professionals, it could be used in the contribution to reduce non-adherence by discharged psychiatric patients. A systematic review is a method that can be used to collect and critically combine available evidence. A preliminary search indicated that no systematic review had been done on interventions to promote psychiatric patients’ compliance to mental health treatment.

1.4 RESEARCH QUESTION

What is the current evidence on interventions to promote psychiatric patients’ compliance to mental health treatment?

1.5 RESEARCH OBJECTIVE

The objective of the research is to critically synthesize the best available evidence on interventions to promote psychiatric patients’ compliance to mental health treatment.
1.6 PARADIGMATIC PERSPECTIVE

The paradigmatic perspective of this study comprises meta-theoretical, theoretical and methodological assumptions that will be discussed below.

1.6.1 Meta-theoretical assumptions

The researcher bases her meta-theoretical assumptions on the nursing theory developed by Martha E. Rogers of unitary human beings (Kozier et al., 2000:40). Assumptions regarding person, nursing, environment and health are consequently discussed.

1.6.1.1 Person

Rogers views the person as a unitary human being who is an irreducible and four-dimensional energy (Kozier et al., 2000:40). The person is viewed as a unified whole with his or her own distinctive characteristics that cannot be perceived by looking at, describing, or summarising the parts. Human beings are dynamic energy fields in continuous exchange with environmental fields, both of which are infinite. These energy fields can become unbalanced in response to stress in any of the three domains of body, mind, and spirit. The qualities of field vary from person to person and are affected by pain and illness. The person has the capacity to participate knowingly and probabilistically in the process of change.

The researcher thus views psychiatric patients as holistic and unique creations with their own rights and responsibilities. In this study the researcher considered the psychiatric patient’s clinical status, his or her preferences, and the environment. The researcher believes that during decision-making psychiatric patients must be treated as unique. They should participate in the discussion, which means that they are treated as a whole. The researcher also considered the psychiatric patient’s family, culture and community as important aspects of interventions to promote his or her compliance to mental health treatment.

1.6.1.2 Nursing

The researcher views nursing as a science and an art. The uniqueness of nursing, like that of other sciences, lies in the phenomenon central to its focus, which is to promote the health and well-being of all people. The nurses are more concerned with people and their environment. The nurse facilitates the promotion of compliance to treatment of psychiatric patients by engaging in the nursing process, a methodology through which nursing care is provided (Kozier et al., 2000:235). It includes assessment, nursing diagnoses, planning, implementation and evaluation as continuous and integrated activities. Therefore it is the responsibility of the nurse
to find the best interventions to help psychiatric patients organise and execute compliance to treatment.

### 1.6.1.3 Environment

Rogers views the environment as an irreducible, indivisible, pan-dimensional energy field identified by pattern and integral to the human field. The environment and the person are both energy fields and they are in constant interaction (Koizer et al., 2000:40).

In this research, the researcher views health professionals, families and peers as important sources of interpersonal influence that can increase or decrease commitment by psychiatric patients to engage in promoting compliance to mental health treatment. Situational influences in the environment can thus increase or decrease commitment by psychiatric patients to comply with treatment. Therefore the nurse must consider how the psychiatric patient interacts with and relates to the external environment and others in order to make decisions on the best available evidence on interventions that can promote their compliance to mental health treatment.

### 1.6.1.4 Health

The researcher views health as the state of feeling whole with regard to body, soul and spirit. Health is an expression of the life process. The life process entails mutual, simultaneous interaction of the human and the environment. These interactions with the person’s environment reflect the relative health status of the patient. Human life is one aspect of nature that must be in harmony with the rest of nature.

The researcher sees the psychiatric patient as a person who has a limited drive towards health as they often have limited insight into their illness and are not always able to initiate behaviours like good compliance to treatment. It is therefore important that the researcher finds the best available evidence of interventions to promote the psychiatric patient’s compliance to treatment.

### 1.6.2 Theoretical assumptions

Theoretical assumptions are theoretical statements that serve as framework in the study and include theories, models, and concepts (Klopper, 2008:67). The theoretical assumptions of this study include the central theoretical statement, as well as the theoretical framework and clarification of terminology.

#### 1.6.2.1 Central theoretical statement

The systematic review will provide a critical synthesis of the best available evidence concerning
interventions to promote psychiatric patients’ compliance to mental health treatment. The outcomes of the systematic review will be published and can therefore be helpful when it becomes accessible to health care professionals. It can be used in the clinical practice and decision making process related to the promotion of compliance to mental health treatment in psychiatric patients.

1.6.2.2 Theoretical Framework

In this research the model for Evidence-Based Clinical Decisions developed by Haynes et al, (2002:1350) was used. The Canadian Nurses Association (CNA) (2002:01) defines evidence-based decision-making as, “a continuous interactive process involving the explicit, conscientious and judicious consideration of best available evidence to provide care”. It is essential to optimize outcomes for (psychiatric) patients, improve clinical practice, achieve cost-effective nursing care and ensure accountability and transparency in decision-making. Evidence-based practice (EBP) thus designates a process of clinical decision-making that integrates research evidence, clinical expertise, and patient preferences and characteristics (Spring, 2007:611). The ultimate goal of EBP is to optimise patient outcomes while minimizing inappropriate use of health care service (Alexander et al., 2003:01). In this research, the model of Evidence-Based Clinical Decisions will be used as a guideline in the execution of the systematic review. Figure 1.1 shows the Model for Evidence Based Clinical Decisions as updated by (Haynes et al., 2002:1350).

![Figure 1.1: The Model for Evidence Based Clinical Decisions (Haynes et al., 2002:1350)](image-url)
There are four aspects of clinical decision making, as is indicated in the model. These are discussed as far as they are applicable in this study.

First, the patient’s clinical and physical circumstances have to be considered in order to establish a diagnosis and to consider what treatment options are available. Patients’ clinical state, the clinical setting and the clinical circumstances they find themselves in when they seek medical attention are key and often dominant factors in clinical decisions (Haynes et al., 2002:1350). For example, when an evidence-based decision should be made concerning the best available intervention for promoting psychiatric patients’ compliance to mental health treatment, both patients’ clinical status and circumstances should be taken into consideration. The psychiatric patients’ functional status, readiness to change and level of social support will determine the type of intervention that patients can receive.

Secondly, the latter needs to be moderated by researched evidence concerning the current interventions that can be used to promote psychiatric patients’ compliance to mental health treatment. Evidence is information acquired through research (CNA, 2002:01). The Canadian Nurses Association further explains sources to facilitate the use of evidence. These include: systematic reviews, research studies and abstract journals that summarises valid and clinically useful published studies. Research evidence should be showed in such a way that practitioners can see the meaning of findings and can decide whether to apply this evidence in daily practice or not (Oermann et al., 2009:35). In addition a reliable source to provide information needed for practice is evidence-based guidelines. Rather than ignoring individual differences, guidelines help to focus consideration of individual circumstances on choosing between treatment plans that have the highest probability of producing the best result (Alexander et al., 2002:04). Therefore, this study will attempt to develop research findings useful to health care professionals. Such professionals can then consider the relevance of evidence and can decide to apply the evidence given to find the best interventions to promote psychiatric patients’ compliance to mental health treatment.

Thirdly, given the likely consequences associated with each option, the patient’s preferences and actions must be considered (in terms of what interventions she or he is ready and able to accept). The rationale for shared decision making is to engage patients more fully into self-management of their own illness and health care. There are two preconditions for shared decision-making to become a reality (Spring, 2007:614). One is departing from a paternalistic care model in which the provider makes decisions on the patient’s behalf. The other is the progress towards a more culturally informed model of care. Treatment of patients with psychotic illness should be approached more holistically, including the patient’s subjective experience with treatment and its side effects and involvement of family members. Factors such as desired
effects, side-effects, cultural acceptance of treatment, and pharmacological versus non-pharmacological interventions all have to be considered (Nielsen & Nielsen, 2009:1053). For many psychiatric conditions the patient needs to determine whether to be treated pharmacologically, behaviourally or both (Spring, 2007:614). In this study the patient’s preferences will be considered by the health care professionals during decision making. There has been a shift towards greater patient involvement in treatment decisions, hopefully resulting in a better attitude towards and greater adherence to medication (Nielsen & Nielsen, 2009:1053).

Finally, clinical expertise is needed to bring these considerations together and to recommend the intervention that the patient is ready to agree to. The clinical expertise includes the general skills of clinical practise as well as the experience of the individual practitioner (Haynes et al., 2002:1350). The health care professionals in this study should have knowledge and an understanding of the process with regard to carrying out the research, and critiquing it (O’Mathuna et al., 2008:102). They have to understand the patient value and circumstances and determine the relevance of external evidence to the psychiatric patient at hand and must be committed to blending the best evidence available with their expertise and judgement with psychiatric patient preferences and values when making a clinical decision (Bradt, 2009:300). Combining these undertakings will contribute to bringing about the best possible health care outcomes.

In conclusion, health care professionals will be able to use the Model for Evidence Clinical Decisions when treating individual psychiatric patients and implementing the interventions to promote psychiatric patients’ compliance to mental health treatment.

1.6.2.3 Clarification of terminology

The clarifications of terminology used in this study are displayed in Table 1.1 for more clarity and to guide the process of the systematic review.
Table 1.1: The clarification of terminology

| Intervention | 
| --- | --- |
| To become involved in order to promote health and well-being or reduce incidence of illness (Stuart & Laraia, 2001:865). In this research the researcher searched for best evidence of interventions to promote psychiatric patients’ compliance to mental health treatment. |

| Psychiatric patients | The Mental Health Care Act No 17 of 2002 refers to psychiatric patients as mental health care users receiving care, treatment, and rehabilitation services, or using a health service at a mental health care institution aimed at enhancing their mental health (Uys & Middleton, 2010:106). In this research psychiatric patients refer to those patients who use health care institutions and who are non-compliant to mental health treatment. |

| Mental health treatment | In this research treatment refers to mental health treatment such as antipsychotic treatment and psychosocial treatment, including is psycho-education, motivational interviewing, cognitive and behavioural approaches and assertive community models, psychotherapy, prompts, specific service policies and family therapies (Montes et al., 2010:274; Nose et al., 2003:197). |

| Compliance Or Adherence | The extent to which a person’s behaviour (in terms of taking medication, following a specific diet, modifying habits, or attending a clinic) coincides with medical health advice (McDonald et al., 2002:2868). In this study it refers to psychiatric patients who have received their treatment and who follow the instructions as given by health care professionals. When patients fail to comply it is referred to as non-compliance or non-adherence to treatment. This means failure to enter a treatment programme, premature termination of therapy and incomplete implementation of instructions (including prescriptions) (Nose et al., 2003:197). In this study it refers to psychiatric patients who fail to comply with mental health treatment and who relapse or are re-hospitalised. |

| Best evidence | Evidence is information acquired through research and the scientific evaluation practice. Best evidence include empirical evidence from randomised control trials, evidence from scientific methods such as descriptive and qualitative research, as well as use of information from case report, scientific principles and expert opinion (CNA, 2002:1). In this study it refers to the best available evidence of interventions to promote psychiatric patients’ compliance to mental health treatment found from primary studies |

1.6.3 Methodological assumptions

The research model of Botes (1995:34) was applied in this systematic review. The model provides a holistic perspective and makes provision for different methodologies from both quantitative and qualitative approaches to be used. It is functional and it introduces nursing activities in three orders; nursing practice, nursing science and paradigmatic perspectives. The first order entails the practice of nursing. This order forms part of the empirical world (reality). Nursing research problems are derived from this empirical world / nursing practice, providing the focus on health care. In this research the aim of the first order is to improve nursing practice for the benefit of psychiatric patients who need the best available interventions to promote compliance to treatment. The second order of the Botes model represents nursing science and
research methodology. The researcher, who functions at the second order, is continually in interaction with the practice situation. It can be said that nursing practice influences the nature of the research to a large extent, just as research provides guidelines for practice. The interdependence of research and practice is emphasised in this way. The researcher is co-responsible for nursing practice. The practitioner, in turn, is responsible for applying the knowledge that is generated by research and theory formulation to practice, in order to confirm its usefulness. The third order represents the paradigmatic perspective of nursing. A paradigm implies a commitment to a collection of convictions that are meta-theoretical, theoretical and methodological in nature. The researcher selects assumptions for his/her research from the paradigm.

The Botes model of nursing research (Botes, 1995:39) describes research methodology as research decisions taken within the framework of the determinants of research. These determinants include the methodological assumptions of the researcher that guided her decisions on the research aim and design. Furthermore, the researcher is committed to conduct research that provides high-quality evidence. The research evidence used is those selected by the researcher and the selected reviewer. All selected studies were critically appraised. This evidence should serve practice by being translated into clinical decisions. The systematic review will be available for practice to provide valuable recommendations for research, education, policy and practice.

1.7 RESEARCH DESIGN AND METHOD

The design in this study was explorative and descriptive in nature and is aimed at critically synthesizing the best available evidence regarding interventions to promote psychiatric patients’ compliance to mental health treatment. (CRD, 2009:48). Systematic reviews are research reviews that combine the evidence of multiple studies regarding a clinical problem to inform clinical practice (Whittemore & Knafl, 2005:547). These reviews use an explicit methodology to research, critically appraise, and synthesize international literature systematically (Akobeng, 2005:845). In this research different primary studies were used and a narrative synthesis was undertaken (CRD, 2009:48).

The main advantages of carrying out systematic reviews is that they allow the researcher to take into account the whole range of relevant findings on a particular topic, and not just the result of one or two studies (Akobeng, 2005:845). As a result, systematic reviews lead to less bias and more generally applicable answers. They can be used to establish whether the scientific findings are consistent and generalisable across populations, settings, and treatment variations, or whether findings vary significantly.
Systematic reviews of randomised controlled trials (RCT) are considered to be evidence of the highest level of research designs evaluating the effectiveness of interventions. A limited number of RCT’s in this field were available, therefore in this research all relevant studies that comply with the inclusion criteria were selected to prevent bias and to ensure that current evidence on intervention to promote compliance to treatment are identified.

The purpose of this systematic review was to obtain the best available evidence regarding interventions to promote psychiatric patients’ compliance to mental health treatment. The methods used in systematic review limit bias and, hopefully, will improve reliability and accuracy in the conclusions on interventions to promote psychiatric patients’ compliance to treatment. Relevant studies were critically appraised, summarised and synthesised. The steps followed in this systematic review (adopted from the American Dietetic Association (ADA), 2008:16) are outlined in Table 1.2

**Table 1.2: Steps followed in this systematic review (adopted from ADA, 2008:16)**

<table>
<thead>
<tr>
<th>Step 1</th>
<th>Formulation of a focused review question</th>
</tr>
</thead>
<tbody>
<tr>
<td>Step 2</td>
<td>Gathering and classifying the evidence, search strategy and selection of studies to be included.</td>
</tr>
<tr>
<td>Step 3</td>
<td>Performing critical appraisal</td>
</tr>
<tr>
<td>Step 4</td>
<td>Summarising the evidence (which includes data extraction and data analysis/synthesis)</td>
</tr>
<tr>
<td>Step 5</td>
<td>Drafting conclusion statements (including conclusions, limitations and recommendation)</td>
</tr>
</tbody>
</table>

A more detailed overview of the methodology and realisation of the study in accordance with the steps of the study is provided in chapter 2 and 3 respectively.

1.8 **RIGOUR**

Rigour in this research involves the concepts validity (both internal and external validity) and reliability. Internal validity of the study refers to the degree to which its results are likely to be free from bias (Khan et al., 2003:37). Bias has been defined as any process at any stage of inference tending to produce results that differ systematically from the true results (Egger et al., 2001:89). There are several types of biases that impact on internal validity of a study, namely: selection bias (an important requirement for valid results in primary studies is that the comparison groups should be similar at the beginning); performance bias (the care plans should be standardised and the researcher and the participants kept blind to the group allocation), since blinding is important for preventing both performance and measurement bias; intention-to-
treat (ITT) analysis is needed, and it requires the data of all patients; attrition bias, which means that participants’ outcomes are analysed according to their initial groups, regardless of whether they fully complied with the intervention or changed their intervention group after initial allocation or left the study.

Furthermore, publication bias is a threat to internal validity (Akobeng, 2005:847). Publication bias occurs when studies that report significant results favouring the test intervention compared to studies with non-significant results are more likely to be published, more likely to be published quickly, (time lag bias) more likely to be published in English (language bias) and more likely to be cited by others (cited bias) (O'Mathuna et al., 2008:105). In an effort to reduce language bias, researchers must cover all literature, including non-English sources (Henymay & Brereton, 2009:04). To avoid publication bias, ideally a comprehensive search strategy should be attempted that includes not only published results, but also those reported in abstracts, personal communication and other studies (Skapinakis et al., 2001:196). ‘Grey literature’ is also searched using specialised search engines, data base and websites in order to reduce publication bias (Henymay & Brereton, 2009:04).

External validity is concerned with the extent to which study findings can be generalised beyond the sample used in the individual studies (Burns & Grove, 2005:218). The external validity is a matter of judgement that will depend on the characteristics of the patients included in the trial, the setting, the treatment regimens tested, and the outcomes assessed. Inconsistency was prevented by ensuring that the reviewer had to critically asses and interpret the studies in order to increase validity (CRD, 2009:34). The problem and purpose should be clearly stated in a systematic review in order to increase rigour (Badr, 2007:80). The steps to enhance rigour in this study are explained in Table 1.3.
### Table 1.3: Steps to enhance rigour

<table>
<thead>
<tr>
<th>Steps</th>
<th>Rigour concepts</th>
<th>Study application</th>
</tr>
</thead>
<tbody>
<tr>
<td>Problem statement</td>
<td>The systematic review should set a clear question that will provide meaningful information that can be used to guide decision making (CRD, 2009:19). A systematic review question must be answerable to the problem statement and searchable, and therefore should include the following variables: population of interest (P), interventions (I), comparative interventions (C) and the outcomes (O) to measure the effect and time frame (T); known as the PICOT format (ADA, 2008:16).</td>
<td>A review question was formulated in PICOT format. The paradigmatic perspective and the theoretical perspective were described.</td>
</tr>
<tr>
<td>Literature search</td>
<td>All relevant literature should be included in the review. The literature research process should be clearly documented in the method section, including the key terms, data bases, and search strategy. Inclusion and exclusion criteria should be determined by the research problem and objectives to enhance rigor. The search strategy should be comprehensive and sensitive to improve the credibility of the review and to reduce bias and increase the repeatability (CRD, 2009:19).</td>
<td>The researcher used a comprehensive research strategy that was well-stated and defined in the method section. A multi-sampling process was used. A database was purposefully selected for accessibility and appropriateness. Inclusion criteria and exclusion criteria were set and well documented. A comprehensive audit tool was used to audit and present the literature set.</td>
</tr>
<tr>
<td>Critical appraisal</td>
<td>Different instruments for critical appraisal can be used. It is important to use appropriate instruments that fit the research design to appraise a research study, as this will strengthen its internal validity (Akobeng, 2005:848). The disadvantage of critical appraisal tools is that there is not one single tool that can be fully applied in all reviews (CRD, 2009:44).The purpose of critical appraisal in a systematic review is to determine the studies’ validity, to interpret their results and to evaluate its applicability in clinical practise and/or in conducting future studies (Abalos et al., 2001:2).</td>
<td>The researcher used the appraisal strategy according to the steps of systematic review. Using standardised CASP instruments and JHNEBP to enhanced reliability and validity during appraisal. Using a second independent reviewer to enhance reliability and validity during appraisal, and having personal meetings to discuss results when conflicting results arose in order to reach consensus.</td>
</tr>
<tr>
<td>Data Extraction</td>
<td>According to CRD (2009:82), data extraction is the process through which the researcher obtains the necessary information about the study characteristics and the findings of the included studies. This means that the data collection for the systematic review is done by the extraction of the relevant research studies from the sample studies. Standardised data extraction forms can provide consistency, while reducing bias and improving validity and reliability. The primary sources included in systematic review can be classified around the type of the design. The nature of the data extracted will depend on the question being addressed and the type of the study</td>
<td>The researcher proposes a data extraction strategy according to steps of systematic review. This includes the following: Data reduction Data display The extracted data of all the relevant selected studies were coded on a spreadsheet.</td>
</tr>
</tbody>
</table>
available. The tools commonly used in data extraction are general word processing packaging, spreadsheets and data bases. Data extraction needs to be as unbiased as possible. Clear instruction and decision about coding data should be used. Data extraction must be done by two researchers.

| Data Synthesis | Data synthesis involves bringing the results of individual studies together and summarising their findings. It can be done quantitatively, using formal statistical techniques such as meta-analysis, or if formal pooling of results is inappropriate, through narrative approach. The results are drawn together and the strength of evidence is considered. Synthesis should also explore whether observed intervention effects are consistent across the studies and investigate possible reason for any inconsistency. This enables the researcher to draw a reliable conclusion (CRD, 2009:76). | Critical synthesis of the individual findings of primary studies towards a conclusion consists of data comparison, conclusion drafting and verification. Data comparison is a repetitive process of examining the data displayed to identify patterns and themes of and the relationship between the variable. |
| Presentation | The conclusion of systematic review can be presented in a structured format represented by the acronym EPICOT (Evidence, Population(s), Intervention(s), Comparison(s), Outcome(s), and Time Stamp). Timeliness (duration of intervention follow-up), disease burdens a suggested study design are considered and research recommendation (CRD, 2009:82). | The researcher presented the findings in a structured format. The characteristics of included studies and a summary of the findings and limitations and recommendation were well explained. |
1.9 ETHICAL CONSIDERATIONS

The researcher submitted the research proposal to the Post Graduate and Research Ethics Committee of the School of Nursing Science of North-West University for approval and consent before the research was conducted. The chairperson of the Ethics committee was consulted and she indicated that ethical approval was not required before performing a systematic review due to the fact that no participants were used as sample, as primary studies were the unit of analysis.

Although ethical permission is not required before performing a systematic review, there are ethical factors that should be taken into consideration. It is the researcher's responsibility to do research of high quality. Therefore, high standards were maintained concerning planning, implementing and reporting on the research. Planning, implementation and reporting were conducted as carefully as possible in consultation with the School of Nursing Science’s research committee, supervisor and co-supervisor.

The conduct of nursing research requires honesty and integrity (Burns and Grove, 2005:176). The researcher accepts total responsibility for conducting and reporting on this research by: being honest, accurate and competent in reporting the studies reviewed and keeping a detailed record of review and appraisal for audit purpose (Brink, 2006:40). Plagiarism was avoided by giving credit where due in the text and including bibliographic details in the list of references. The researcher ensured that the data drawn from the internet was reliable and valid by critically appraising the studies identified. The research process is discussed in detail in order to ensure auditability. All relevant evidence included both side of the issue.

1.10 SUMMARY

Chapter 1 provided an overview of the research. The background and rationale for the study, the problem statement, research questions, the purpose of the study and the paradigmatic perspective were explained. A brief outline of the research design and methods, rigour and ethical considerations used in the study were also included. The research method will be discussed in chapter 2.
CHAPTER 2: RESEARCH DESIGN AND METHOD

2.1 INTRODUCTION

The research method selected for this research was a systematic review of the interventions to promote psychiatric patients’ compliance to mental health treatment. Systematic reviews are research reviews that combine the evidence of multiple studies regarding a clinical problem to inform clinical practice (Whittemore & Knafl, 2005:547). This chapter discusses the five steps of the systematic review.

2.2 RESEARCH DESIGN

Research designs are the plans and procedures for research that span the decisions from broad assumptions to detailed methods of data collection and analysis (Creswell, 2009:3). The design in this study is explorative and descriptive in nature, and is aimed at exploring and describing the identified best available scientific evidence regarding interventions to promote psychiatric patients’ compliance to mental health treatment (CRD, 2009:48). The selection of a research design is based on the nature of the research problem or issues being addressed, the researcher’s experiences, and the audiences for the study (Creswell, 2009:3). In this study a systematic review was used as method.

2.3 RESEARCH METHOD: SYSTEMATIC REVIEW

A systematic review was chosen as method for this research, as it provides a balanced summary of published and unpublished literature in specific issues with the benefit of presenting evidence emanating from a large body of knowledge (Badr, 2007:79).

According to Higgis and Green (2008:06) the characteristics of systematic reviews are:

- A clearly stated set of objectives with pre-defined eligibility criteria for studies;
- An explicit, reproducible methodology;
- A systematic search that attempts to identify studies that meet the eligible criteria;
- An assessment of the validity of the findings of the included studies, for example through the assessment of bias; and
- A systematic presentation, and synthesis, of the characteristics and findings of included studies.
Health care professionals conduct systematic reviews for:

- supporting evidence-based practice;
- personal professional development;
- informing clinical policy;
- publishing in a peer-reviewed journal;
- writing an introduction to research or a thesis;
- preparing a presentation at a conference;
- technical report; and
- for an invented commentary (Khan et al., 2003:4).

In this case systematic review was conducted for the purpose of Masters Research and for informing clinical practice on current intervention available for improving psychiatric patients’ compliance to mental health treatment.

2.4 STEPS OF THE SYSTEMATIC REVIEW

An important way to avoid bias in systematic reviews is to develop a protocol in order to indicate prospective planning regarding the methodology of the study. The protocol should explain the specific steps within systematic reviews as outlined in Chapter 1 (Table 1.2). These steps are consequently discussed in more detail.

2.4.1 Step 1: Formulation of a focused review question

The research question should be a clear identification of the purpose of the research to determine variables of interest and the sample frame. The review question for this study was formulated according to the PICOT format (see Table 2.1), namely:

- population;
- interventions;
- comparison;
- outcome; and
- time frame (adopted from ADA, 2008:6).
Table 2.1: Application of PICOT format

<table>
<thead>
<tr>
<th>Population</th>
<th>Intervention</th>
<th>Comparison</th>
<th>Outcome</th>
<th>Time frame</th>
</tr>
</thead>
<tbody>
<tr>
<td>Psychiatric patients according to the full text revision of the fourth edition of Diagnostic and Statistical Manual of Mental Disorder (DSM-IV-TR)</td>
<td>Different interventions or combination of interventions to promote compliance to mental health treatment</td>
<td>Not applicable</td>
<td>• Improved compliance to mental health treatment; • prevented relapse; and • reduced re-hospitalisation</td>
<td>Within a year after discharge.</td>
</tr>
</tbody>
</table>

The review question for this study is thus:

- What is the current evidence on interventions to improve psychiatric patients’ compliance to mental health treatment?

2.4.2 Step 2: Gathering and classifying the evidence

The next step in conducting a systematic review is to gather all the relevant literature using a structured search strategy. The search process should be as transparent as possible and documented in a way that enables it to be evaluated and reproduced (CRD, 2009:16).

2.4.2.1 Search strategy

The search strategy aims to identify all the best available evidence relevant to the research question. The use of only electronic databases that mainly include references to published journal articles could result in public bias. A comprehensive search was conducted as it is important to ensure that many studies are identified and to minimise selection bias (Akobeng, 2005:847). The search strategy was not limited to the English language, as doing so will introduce language bias (CRD, 2009:17). Studies in any language with an abstract in English were included in the research. In order to retrieve a set of studies on a topic, several different sources were searched to identify relevant studies pertaining to interventions on promoting psychiatric patients’ compliance to mental health treatment (published and unpublished). The multiple sources that were used in this study were electronic databases, grey literature and manual searches.

The following key words were used in electronic data-bases to search for information:
intervention, mental health treatment, psychiatric treatment, compliance, adherence, psychiatric patients and mental health care user. Scanning reference lists of papers that have been identified by the database searches followed to identify further studies of interest. Furthermore, the search strategy was conducted under the supervision of experienced researchers who are familiar with conducting systematic reviews. The researcher included all studies published from June 2001 up to June 2011 to obtain evidence on current interventions used to improve psychiatric patients’ compliance to mental health treatment.

2.4.2.2 Selecting studies to be included

Studies were selected by using inclusion and exclusion criteria. Burns and Grove (2005:343) explain inclusion and exclusion criteria as follows:

- Inclusion criteria are those characteristics that an element must possess to be part of the target population; and
- exclusion criteria are those characteristics that can cause an element to be excluded from the target population.

Studies chosen for this research included those studies that focus on interventions used to promote psychiatric patients’ compliance mental health treatment, both male and female, but excluding patients with medical conditions. The studies included are studies were psychiatric patients were recruited from health care institutions, out-patient departments, and community health settings.

Study design as criteria included systematic reviews, Randomised Control Trials (RCT’s), non-randomised intervention studies, quasi-experimental studies, cross sectional studies and case studies. Publication type included conference abstracts/grey literature, and international and local theses and dissertations.

Studies in English were included, as well as studies written in other languages with an English abstract to avoid language bias.

Time Frame for this research was all studies from 2001 to 2011 to include most current interventions to promote psychiatric patients compliance to mental health treatment. A record of all research is kept for audit purposes. The inclusion and exclusion criteria for this study are explained in more detail in chapter 3, Table 3.2.

2.4.3 Step 3: Performing the critical appraisal

Critical appraisal is the process of carefully and systematically examining research to judge its
trustworthiness and its value and relevance in a particular context (Burls, 2009:01). The purpose of the critical appraisal is to determine the study’s validity, to interpret the results and to evaluate the applicability of the research in clinical practice and/or in conducting future research (Abalos et al., 2001:15). It is an essential skill in evidence-based medicine because it allows clinicians to find and use research evidence reliably and efficiently.

According to CASP (2006:41) the main issues to consider when appraising a study are:

- The validity of the study;
- The interpretation of the results; and
- The applicability of the results to your patient or population.

The first step for the critical appraisal of a study is to establish its methodological quality to determine the validity of the result. If the review has not been conducted with methodological rigour, it is unlikely that the results will reflect the truth. Such studies should therefore not be taken into account, or the deficiencies should be considered. Once the methodological quality of the study had been evaluated and conclusion of the findings identified, the results are interpreted. After having interpreted the results of the study the next step is to evaluate whether they can be applied to a specific clinical setting.

In this study, all relevant studies were appraised for methodology and quality using the standard checklists from the Critical Appraisal Skills Program (CASP, 2006:41). A record of all the appraised studies, tools used for appraisal outcomes and motivation for decisions on inclusion and exclusion was kept for auditing. A second reviewer independently appraised the selected studies for methodological quality and inclusion or exclusion from the systematic review to enhance reliability and validity of the study.

Lists of studies excluded from the review during the critical appraisal process were recorded together with the reasons for exclusion as discussed in chapter 3 (Table 3.3). The studies that were included after critical appraisal served as the final sample for the next step as outlined in chapter 3 (Table 3.4).

### 2.4.4 Step 4: Summarising the evidence

Summarising the evidence from the selected studies involves a process of data extraction and data analysis/synthesis. Data extraction is the process through which researchers obtain the necessary information about study characteristics and findings from the included studies (CRD, 2009:28). This means that the data collection for the systematic review is done by extracting the findings relevant to the review question from the included studies (O’Mathuna et al., 2008:103).
Determining the level of evidence allows the researcher to determine which data will be most important in answering the review question. For instance, studies with high quality (high score) will carry more weight in the evidence summary than “medium-quality” studies (ADA, 2008:51–52).

The first stage of data extraction is to plan the type of analyses and list the literature that will be included in the report. This helps to identify which data should be extracted. In this study the characteristics and findings of the selected studies were extracted and presented in carefully designed spreadsheets (Centre for Evidence based Conservation (CEBC), 2009:12). The report on the data extraction serves as information for reviewers and is helpful in compiling the conclusion. How and which data was extracted are determined according to the research question and the types of studies that are assessable. Data of each particular study can be extracted and documented in different ways. It is recommended that before data is categorised, extraction of the data must be done as thoroughly as possible to ensure that all data will be saved during the data extraction (CRD, 2009:28–29).

Data analysis/synthesis involves bringing the results of individual studies together and summarising their findings (CRD, 2009:76). The findings from the selected studies were aggregated to produce a “bottom line” on the clinical effectiveness, feasibility, appropriateness and meaningfulness of the intervention. This procedure is known as evidence synthesis. In this study the aims of data synthesis are the combination of outcomes, contemplation of the strength of outcomes, investigation into the consistency of effects of interventions within the studies and identification of studies with inconsistent findings. These aims provide reliable conclusions from the studies included (CRD, 2009:45).

After analysing the data, it is recommended that a summary of the evidence be written, which serves as a basis for the next step of drafting the conclusion statements, limitations and recommendations. This summary is available in Chapter 4.

2.4.5 Step 5: Drafting the conclusion statements, limitations and recommendations

2.4.5.1 Conclusions

The final step in the systematic review is the writing of the concluding statements. Conclusions are clear and based on the findings of reviewed studies (O'Mathuna et al., 2008:104). The conclusions of this study summarise the evidence and draw out the implications for health care. Conclusions are related to the research question(s) and serve as a reflection on the systematic review per se. Conclusions were formulated and are presented in Chapter 5.
2.4.5.2 Limitations

Limitations are restrictions or problems in a study that may decrease the generalisability of the findings (Burns & Grove, 2005:39). Burns and Grove (2005:39) indicate that there are two types of limitations namely theoretical and methodological.

*Theoretical limitations* involve the weakness in a study framework and conceptual and operational definition of variables that restrict the abstract generalisation of the findings.

*Methodological limitations* are weakness in the study design that can limit the credibility of the finding of the population to which the findings can be generalised (Burns & Grove, 2005:40).

In this study the limitations were recorded and considered after conclusions were drawn (see Chapter 5).

2.4.5.3 Recommendations

Recommendation for practice is usually only made in guidelines, and is formulated from a variety of sources of information in addition to the review findings (CRD, 2009:82). A clear statement of the implications or recommendations for future research should be made. Implications for practice or policy and recommendations for future research should be specific and based on evidence contained in the review. Merely stating that “more research is needed” is not appropriate. Finally, in general, recommendations must be arranged in hierarchical order of importance.

In this study, recommendations were made based on the quality of the findings of the studies included to guide decision making during clinical practice (See Chapter 5).

2.5 SUMMARY

This chapter provided an overview of the systematic review methodology. The systematic review was defined and an explanation of the method chosen for this review was provided. Steps followed in the systematic review were discussed as outlined in Table 1.2. Chapter 3 will provide a detailed account of the realisation and findings of the systematic review.
CHAPTER 3: REALISATION AND FINDINGS OF THE SYSTEMATIC REVIEW

3.1 INTRODUCTION

The chapter provides an overview of the realisation of the systematic review conducted according to the first three of the five steps of systematic review namely:

- Step 1: formulation of the focused review question;
- Step 2: gathering and classifying the evidence; and
- Step 3: performing critical appraisal.

Step 4 will be discussed in chapter 4 and Step 5 in chapter 5.

3.2 STEP 1: FORMULATION OF FOCUSED REVIEW QUESTION

The review question guided the systematic review. The review question for this study was formulated according to the PICOT format, namely:

- Population;
- Interventions;
- Comparison;
- Outcome; and
- Time frame (adopted from ADA, 2008:6) as outlined in Table 2.1.

The review question for this study is stated as follows:

- What is the current evidence available on interventions to promote psychiatric patients’ compliance to mental health treatment?

The steps following the formulation of the focused review question is the realization of the search strategy.

3.3 STEP 2: GATHERING AND CLASSIFYING THE EVIDENCE

This step in conducting the systematic review comprised gathering all the relevant literature using a structured search strategy. The aim of the search was to include all studies relevant to the review question.
3.3.1 Sources

Several different sources were searched to identify relevant studies relating to interventions on promoting psychiatric patients’ compliance to mental health treatment (published and unpublished). Relevant studies were located by using electronic databases, as outlined in Table 3.1.

Table 3.1: Databases used in search strategy

<table>
<thead>
<tr>
<th>Database/Platform</th>
<th>Subdivision</th>
</tr>
</thead>
<tbody>
<tr>
<td>SA-Nexus (NRF)</td>
<td>Completed and current research in South Africa.</td>
</tr>
<tr>
<td>ProQuest</td>
<td>International theses and dissertations.</td>
</tr>
<tr>
<td>EBSCOhost Platform:</td>
<td></td>
</tr>
<tr>
<td>Academic Search Premier</td>
<td>International journals on health science - primary studies.</td>
</tr>
<tr>
<td>CINAHL</td>
<td></td>
</tr>
<tr>
<td>CINAHL with full text</td>
<td></td>
</tr>
<tr>
<td>Health source</td>
<td></td>
</tr>
<tr>
<td>Nursing/Academic Edition</td>
<td></td>
</tr>
<tr>
<td>MEDLINE (nursing and</td>
<td></td>
</tr>
<tr>
<td>allied professions)</td>
<td></td>
</tr>
<tr>
<td>Psych INFO</td>
<td></td>
</tr>
<tr>
<td>African-Wide NIPAD</td>
<td></td>
</tr>
<tr>
<td>ScienceDirect</td>
<td>International journals on health science - primary studies.</td>
</tr>
<tr>
<td>Web of Knowledge</td>
<td>International journals on health science - primary studies.</td>
</tr>
<tr>
<td>Cochrane Library</td>
<td>International systematic reviews and clinical trials in health science.</td>
</tr>
<tr>
<td>Sabinet: ISAP</td>
<td>South African journals and Publications - primary studies.</td>
</tr>
<tr>
<td>Google</td>
<td>Grey literature such as conference proceedings, discussion papers, report booklets and unpublished research theses.</td>
</tr>
<tr>
<td>Hand search</td>
<td>Hand search of pertinent journal that are not electronically available</td>
</tr>
</tbody>
</table>

3.3.2 Key words

The following key words were used in the search were, intervention, mental health treatment, psychiatric treatment, compliance, adherence, psychiatric patients and mental health care user and combinations thereof. The key words were searched in the categories of All or Title,
Abstract or Author-Supplied Abstract or Key words in order to ensure that no relevant data were missed.

3.3.3 Inclusion and exclusion criteria of this study

Inclusion and exclusion criteria were determined to make certain that the boundaries of the review question are clearly defined. The aim of the search was to include all the studies relevant to the research question. These inclusion and exclusion criteria are summarised in Table 3.2.

Table 3.2: Inclusion and exclusion criteria for this study are as follows:

<table>
<thead>
<tr>
<th>Inclusion criteria</th>
<th>Exclusion criteria</th>
<th>Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Population:</strong></td>
<td>Primary Studies of patients diagnosed only with a</td>
<td>To direct review and focus to the review question</td>
</tr>
<tr>
<td>Studies related to psychiatric patients</td>
<td>medical condition, and not with psychiatric condition</td>
<td></td>
</tr>
<tr>
<td>and compliance to mental health treatment</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Setting:</strong></td>
<td>Private settings</td>
<td>To include all possible settings where psychiatric patients might receive mental health treatment</td>
</tr>
<tr>
<td>Health care institutions, outpatient</td>
<td></td>
<td></td>
</tr>
<tr>
<td>departments and community health care</td>
<td></td>
<td></td>
</tr>
<tr>
<td>centres, public settings</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Condition of the patients:</strong></td>
<td>Patients with medical conditions</td>
<td>To direct the review question and focus to the study</td>
</tr>
<tr>
<td>Psychiatric conditions</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Outcome:</strong></td>
<td></td>
<td>To direct the review question and focus to the study</td>
</tr>
<tr>
<td>Compliance to mental health treatment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>as evidenced by Improved compliance to</td>
<td></td>
<td></td>
</tr>
<tr>
<td>mental health treatment; prevented</td>
<td></td>
<td></td>
</tr>
<tr>
<td>relapse; and reduced re-hospitalisation</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Study design:</strong></td>
<td>Studies that do not address research questions. Studies</td>
<td>To identify the most appropriate recent research to answer the review question</td>
</tr>
<tr>
<td>Primary studies, including RCTs, non-</td>
<td>where the exploration of interventions did not focus on</td>
<td></td>
</tr>
<tr>
<td>randomised intervention studies, cross-</td>
<td>compliance to mental health treatment</td>
<td></td>
</tr>
<tr>
<td>sectional and case reports and Systematic reviews</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Publications included:</strong></td>
<td>Non-research papers e.g. discussion editorials</td>
<td></td>
</tr>
<tr>
<td>Conference abstracts /Grey literature -</td>
<td></td>
<td></td>
</tr>
<tr>
<td>international and local theses,</td>
<td></td>
<td></td>
</tr>
<tr>
<td>dissertations and discussion editorials</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Time Frame:</strong></td>
<td>Studies published before 2001</td>
<td>To identify most current published studies</td>
</tr>
<tr>
<td>Studies published from January 2001 to</td>
<td></td>
<td></td>
</tr>
<tr>
<td>December 2011</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
3.3.4 Documentation of the search

The articles were retrieved through the databases, using the key words. Google and library loan were used to obtain all possibly relevant articles. An experienced librarian at the North-West University assisted in a specific search strategy in Nexus (a national electronically database).

The study selection was first conducted by screening titles and abstracts against the inclusion criteria to identify potentially relevant papers and for availability of evidence. In this study, all articles selected for critical appraisal were critically evaluated to find out whether they answer the review question and meet the inclusion criteria. The studies that appeared to meet the inclusion criteria were selected after reading the abstract. This was followed by a screening of the full papers identified as possibly relevant in the initial screen as described by CRD (2009:13). The study review and selection was first done by the author, and then by the second person who has experience with systematic review. Accurate record keeping was maintained throughout the process for audit purposes to enhance rigour.

Studies identified, excluded and included are tabulated in Flow chart 3.1.
Flow Chart: 3.1: Realisation of search strategy

Initial search
EBSCOhost: n = 240
ScienceDirect: n = 86
Web of knowledge: n = 194
Sabinet: n = 9
ProQuest: n = 69
SA Nexus: n = 28
Cochrane: n = 104

Manual
Reference list: n = 13
Google: n = 635

Total: n = 1365

All titles and abstracts screened for relevance to interventions to promote psychiatric patients’ compliance to mental health treatment.
Excluded: n = 1254
Remaining: n = 111

Remaining identified studies: n = 111
All titles and abstracts screened for relevance to the interventions to promote psychiatric patients’ compliance to mental health treatment.
Excluded studies not answering the review question:
n = 55
Remaining = 56

Remaining identified studies = 56
Further excluded article were those studies that does not meet the inclusion criteria.
Excluded: n = 27
Remaining: n = 29

Remaining identified studies: n = 29
Excluded duplicate: n = 3
Excluded unobtainable full text: n = 9
Remaining: n = 16

Eligible studies for inclusion in critical appraisal: n = 16
Table 3.3 indicates the articles excluded after reading the abstract and titles according to databases used. The articles that could not be obtained are displayed in Table 3.4. All the remaining possibly relevant articles were obtained directly via the databases.
Table 3.3: Excluded articles according to the databases with reasons for exclusion from 56: n = 27

<table>
<thead>
<tr>
<th>No</th>
<th>Authors and journal details</th>
<th>Title</th>
<th>Design</th>
<th>Rationale for exclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Bucci, K.K. <em>et al</em>., 2003. <em>Am J Health-Syst Pharm</em>, 60:2601-2605</td>
<td>Strategies to improve medication adherence in patients with depression</td>
<td>Systematic review</td>
<td>Literature review The outcome not compliant to mental health treatment</td>
</tr>
<tr>
<td>6</td>
<td>Forsner, T. <em>et al</em>., 2008. <em>BMS Psychiatry</em>, 8:64</td>
<td>An approach to measure compliance to clinical guidelines in psychiatric care</td>
<td>Quantitative design</td>
<td>Not addressing review question</td>
</tr>
<tr>
<td>9</td>
<td>Brodwin, P. 2010. <em>Anthropology &amp;</em></td>
<td>The assemblage of compliance in psychiatry case</td>
<td>Case report</td>
<td>Not addressing review question</td>
</tr>
<tr>
<td></td>
<td>Medicine, 17(2):129-143</td>
<td>management</td>
<td></td>
<td></td>
</tr>
<tr>
<td>---</td>
<td>------------------------</td>
<td>------------</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>12</td>
<td>Ren, X.S. et al., 2011. <em>Journal of clinical pharmacy and therapeutics</em>, 36:383-389</td>
<td>Evaluation of health services use following the initiation of Risperidone long-acting therapy among schizophrenia patients in the veterans health administration</td>
<td>Quantitative design</td>
<td>Not addressing review question</td>
</tr>
<tr>
<td>15</td>
<td>Robbins, C.P. et al., 2006. <em>Administration and policy in mental health and mental health services research</em>, 33:226-236</td>
<td>The use of housing as leverage to increase adherence to psychiatric treatment in the community</td>
<td>Quantitative design</td>
<td>Not addressing review question</td>
</tr>
<tr>
<td>16</td>
<td>Kikkert M.J. et al., 2006:786-794) <em>Schizophrenic bulletin</em>, 32(4), August</td>
<td>Medication adherence in schizophrenia: exploring patients’, carers’ and professionals’ views</td>
<td>Qualitative design</td>
<td>Not addressing review question</td>
</tr>
<tr>
<td>No.</td>
<td>Author(s)</td>
<td>Year</td>
<td>Title</td>
<td>Methodology</td>
</tr>
<tr>
<td>-----</td>
<td>-----------</td>
<td>------</td>
<td>-------</td>
<td>-------------</td>
</tr>
<tr>
<td>19</td>
<td>Wetherill et al.</td>
<td>1987</td>
<td>The role of the community psychiatry nurse in improving treatment compliance in alcoholics</td>
<td>Qualitative design</td>
</tr>
<tr>
<td>20</td>
<td>Dodds et al.</td>
<td>2000</td>
<td>A systematic review of randomized controlled trials that attempt to identify interventions that improve patient compliance with medication</td>
<td>Systematic review</td>
</tr>
<tr>
<td>21</td>
<td>Doyle, L. &amp; Keogh, B.</td>
<td>2008</td>
<td>Reduction relapse in psychosis through medications management</td>
<td>Qualitative research</td>
</tr>
<tr>
<td>23</td>
<td>Merinder, L.B.</td>
<td>2000</td>
<td>Patient education in schizophrenia: a review</td>
<td>Systematic review</td>
</tr>
<tr>
<td>25</td>
<td>Bentley, K.E. et al.</td>
<td>1990</td>
<td>Promoting medication compliance: Strategies for working with families of mentally ill people</td>
<td>Literature review</td>
</tr>
<tr>
<td>26</td>
<td>Trauer, T. &amp; Sacks, T.</td>
<td>1998</td>
<td>Medication compliance: a comparison of the views of severely mentally ill clients in the community, their doctors and their case managers</td>
<td>Qualitative design</td>
</tr>
<tr>
<td></td>
<td>Duplicate studies n =3</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>---</td>
<td>---------------------------------------------------------------------------------------</td>
<td>------------------------------------------------------------------</td>
<td>------------------------------------------------------------------</td>
<td>------------------------------------------------------------------</td>
</tr>
<tr>
<td>2</td>
<td>Gervasoni, N. et al., <em>Psychiatry</em>, 64(4):65-67</td>
<td>Early telephone intervention for psychiatry out-patients starting antidepressant treatment</td>
<td>Quantitative design</td>
<td>Duplicate</td>
</tr>
<tr>
<td>3</td>
<td>Townsend. 2009. <em>Journal of Human Behaviour in the Social Environment</em>, 19:512-530</td>
<td>How effective are interventions to enhance adherence to psychiatric medications? Practice implications for social workers working with adults diagnosed with severe mental illness</td>
<td>Systematic review</td>
<td>Duplicate</td>
</tr>
</tbody>
</table>

A further ten articles were excluded from the 56 studies because they were not obtainable through library loan, see table 3.4
<table>
<thead>
<tr>
<th>No</th>
<th>Authors and journal details</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>Morken, G. et al., 2007. J Clin Psychiatry. 68:566-571</td>
<td>Effects of integrated treatment on antipsychotic medication adherence in a randomized trial in recent-onset schizophrenia. Links Export Central Citation. Source-Cochrane</td>
</tr>
<tr>
<td>7</td>
<td>Gervasoni, N. et al., Psychiatry, 64(4):65-67</td>
<td>Early telephone intervention for psychiatry out-patients starting antidepressant treatment</td>
</tr>
</tbody>
</table>
3.4 STEP 3: PERFORMING THE CRITICAL APPRAISAL

Critical appraisal is the process of carefully and systematically examining research to judge its trustworthiness and its value and relevance in a particular context (Burls, 2009:01). The purpose of the critical appraisal is to determine the validity of the research, to interpret the results and to evaluate the applicability of the research in clinical practise, in public health and in future research (Abalos et al., 2001:15).

The evidence of primary studies selected for this review were analysed in accordance with the evidence class rating recommended by ADA to enhance rigour of the study (ADA, 2008:20). First, studies are classified according to the categories of primary studies and systematic reviews. Secondly, studies are classified according to the study design. Randomised control trials (RCT) are considered to be evidence of the highest level in the hierarchy of research designs that evaluate the effectiveness of interventions (Akobeng, 2005:845) and are classified as Class A. The class of evidence have been adapted to comply with the current review study, and are displayed in table 3.5.

Table 3.5: Classes of evidence (as adapted from ADA, 2008:30)

<table>
<thead>
<tr>
<th>Primary reports of new data collection</th>
<th>Reports that synthesise or reflect on collections of primary reports</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>RCT</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>B</td>
<td>Cohort</td>
</tr>
<tr>
<td>C</td>
<td>Non-randomised trial with concurrent or historical controls</td>
</tr>
<tr>
<td></td>
<td>Case control study</td>
</tr>
<tr>
<td></td>
<td>Study of sensitivity and specificity of a diagnostic test. Population based descriptive study</td>
</tr>
<tr>
<td></td>
<td>Time series</td>
</tr>
<tr>
<td>D</td>
<td>Cross-sectional</td>
</tr>
<tr>
<td></td>
<td>Case series</td>
</tr>
<tr>
<td></td>
<td>Case report</td>
</tr>
<tr>
<td></td>
<td>Before and after study</td>
</tr>
</tbody>
</table>
3.4.1 Quality assessment

The first step for the critical appraisal of a review is to establish its methodological quality to determine the validity of the result. If the review was not conducted with methodological rigour, it is unlikely that the results will reflect the truth and therefore they should not be taken into account, or they should be considered, bearing in mind that the intrinsic errors may distort the results.

Once the methodological quality of the review has been evaluated, the conclusions of the results were interpreted. After having interpreted the results of the studies the next step was to evaluate whether they can be applied to the patients that this review is aimed at. All selected studies were critically appraised using piloted tools to ensure quality.

In this study, primary studies selected for critical appraisal were evaluated for methodology and quality using standard checklists from the Critical Appraisal Skills Program (CASP) and the (JHNEBP) John Hopkins Nursing Evidence-Based Practice research evidence appraisal tool (Newhouse et al., 2007:206). The CASP tool was used for all studies of RCTs and JHNEBP for non-experimental and quasi-experimental studies. The scoring was adapted by the researcher for inclusion and exclusion purposes after the appraisal for both the CASP and JHNEBP instruments.

Individual studies were identified with symbols used for quality rating as shown in the quality criteria checklist of primary studies. The study was either rated (+) positive, indicating that the report clearly addresses issues of inclusion/exclusion, bias, generalisability, and data collection and analysis; (ø) neutral, indicating that the report is neither exceptionally strong nor exceptionally weak; or (-) negative: indicating that these issues are not adequately addressed.

The included studies were appraised for reliability, validity and credibility by the appropriate criteria of the Critical Appraisal Skills Program (CASP) to determine whether the findings can be considered as good, medium or low evidence (CASP, 2006:17). The studies included in this review were from medium to high quality and obtained a quality rating between at least 5/10 and ≥ 8/10. The researcher appraised the material for a second time in order to promote consistency of quality ratings of studies to be included for evidence analysis, and to compare quality ratings.

The studies were appraised on the basis of the criteria as recommended by the American Dietetic Association Evidence analysis manual (ADA, 2008:42) by using a quality checklist for primary studies. A second reviewer independently appraised the selected studies for methodological quality and for inclusion in or exclusion from the systematic review. The checklists were completed and filed for audit purposes.
The comparison of the quality rating system of ADA (2008:43); the CASP score and JHNEBP (2007:206) scores are displayed in Table 3.6.

**Table 3.6: Adapted quality ratings for methodological quality of studies (adapted from ADA, 2008:43; CASP, 2006 & JHNEBP, 2007)**

<table>
<thead>
<tr>
<th>Description in words</th>
<th>ADA quality rating</th>
<th>CASP score quality rating</th>
<th>JHNEBP</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIGH</td>
<td>(+)</td>
<td>≥8/10</td>
<td>≥5/6</td>
</tr>
<tr>
<td>MEDIUM/ NEUTRAL</td>
<td>(ø)</td>
<td>≥5/10 to &lt;8/10</td>
<td>3/6 to 4/6</td>
</tr>
<tr>
<td>LOW</td>
<td>(-)</td>
<td>≥1/10 to &lt;5/10</td>
<td>1/6 to 2/6</td>
</tr>
</tbody>
</table>

The studies that were included after critical appraisal served as the final sample for the next step: extracting data and drafting a summary of all relevant studies. Table 3.7 indicates 16 studies that were critically appraised.
Table 3.7: Critical appraisal (n = 16)

<table>
<thead>
<tr>
<th>Reference</th>
<th>Settings &amp; Sample size</th>
<th>Intervention</th>
<th>Adherence Measure</th>
<th>Data analysis</th>
<th>Rigour</th>
</tr>
</thead>
<tbody>
<tr>
<td>Valenstein et al. (2011:727-736) 1</td>
<td>Using A pharmacy-based intervention to improve antipsychotic adherence among patients with serious mental illness. Setting: In-patients with severe mental illness (SMI). Sample: 118 patients with schizophrenia, schizoaffective or bipolar disorder.</td>
<td>Intervention group: Pharmacy-based intervention (Meds-Help) including unit-of-use packing the medication, a medication and packing education session, refill reminders mailed two weeks before refill dates, notification of clinicians when patients failed to fill antipsychotic prescription within 7-10 days. Control group: Usual care (UC).</td>
<td>Medication possession ratio (MPR); Positive and Negative Symptoms Scale (PANSS); Quality of Well-being Scale (QWB) and Client satisfaction Questionnaire (CSQ-8).</td>
<td>Intent-to-treat analysis Multivariate analyses</td>
<td>Instrument used: CASP. RCT. A clearly focused question was stated. An appropriated design was applied, and the sample was allocated in control and study group. The data collection was clearly stated. The results were precisely and clearly presented. Follow-up was done and all participants who entered were accounted for in conclusion. Blinding not done. Overall the study was well planned, executed and reported High quality rating: ADA = (+) positive Class A CASP = 8/10 Relevance: + Decision: Included</td>
</tr>
<tr>
<td>Guo et al. (2010:895-904) 2</td>
<td>Effect of antipsychotic medication alone vs. combined with psychosocial intervention outcomes of early-stage schizophrenia Setting: Out-patient psychiatric clinics. Sample: 1268 patients with schizophrenia.</td>
<td>Intervention group: Antipsychotic medication plus psychosocial intervention consisting of psycho-education, family interventions, skills training, and cognitive behaviour therapy. Control group: Antipsychotic medication treatment.</td>
<td>Appointment adherence records</td>
<td>Intention-to-treat-principle Fisher exact test</td>
<td>Instrument used: CASP. A clearly focused question was stated. An appropriate design was applied. All participants were accounted for in the conclusion. Single Blinding used. The data collection was done and the results were precise and clearly presented. All outcomes were considered. Follow-up was done and adverse events reported. Class A ADA High quality rating: (+) positive Score CASP 9/10 Decision: Included</td>
</tr>
<tr>
<td>3</td>
<td>Sirey et al. (2010:554-562)</td>
<td>Improved antide-pressant adherence and depression outcomes in Primary care: The treatment Initiation and Participation</td>
<td>Setting: Two primary care clinics in New York</td>
<td>Intervention group: Treatment Initiation and Participation (TIP) 30 minutes meeting of pharmacotherapy, telephone calls and counselling sessions.</td>
<td>Self report measure: the medication and non-medication treatment compliance data form.</td>
</tr>
<tr>
<td>4</td>
<td>Maneesakorn et al. (2006:1302 - 131)</td>
<td>An RCT of adherence therapy for people with schizophrenia in Chiang Mai, Thailand</td>
<td>Setting: Psychiatric hospital, Chiang Ai Thailand</td>
<td>Intervention group: Adherence therapy (AT) and motivational interviewing techniques</td>
<td>Positive and negative syndrome scale (PANSS)</td>
</tr>
<tr>
<td></td>
<td>Gray et al. (2006:508-514)</td>
<td>Setting: General adult mental health community services in four European countries. <strong>Sample size:</strong> 409 patients with schizophrenia</td>
<td><strong>Intervention group:</strong> Compare the effectiveness of adherence therapy; and <strong>Control group:</strong> Health education <strong>Follow-up time:</strong> 52 weeks</td>
<td><strong>Medication adherence questionnaire (MAQ)</strong></td>
<td><strong>Intention-to-treat basis</strong></td>
</tr>
<tr>
<td>---</td>
<td>---</td>
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<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>5</td>
<td>Brook et al. (2005:487-489) A pharmacy-based coaching program to improve adherence to antidepressant treatment among primary care patients</td>
<td>Setting: Out-patient psychiatric clinic. 10 clinical sites in China <strong>Sample:</strong> 19 community pharmacist in various regions in The Netherlands 135 patients with major depression</td>
<td><strong>Intervention group:</strong> Electronic pill container called eDEM with three coaching contact and 25-minutes take-home video emphasizing the importance of adherence. <strong>Control group:</strong> Usual care using an electronic pill container without coaching. <strong>Follow-up time:</strong> 6 months</td>
<td><strong>Electronic pill container (eDEM) Computerised patients medication records</strong></td>
<td><strong>Intention-to-treat analysis Per control analyses</strong></td>
</tr>
</tbody>
</table>
| 7 | **Gray et al.** (2004:157-162)  
Effects of a medication management training package for nurses on clinical outcomes for patients with schizophrenia | **Setting:**  
Out-patient clinic and Community. London, UK  
**Sample size:**  
72 patients with schizophrenia  
60 Community mental health nurses | **Intervention group:**  
Medication management training package for community mental health nurses (CMHNs)  
**Control group:**  
Treatment-as-usual, 80 hours training delivered on a day release basis over 10 weeks.  
**Follow-up time:**  
26 weeks | **Self report and research-worker-rated report**  
The Clinician rating of compliance scale; | **Statistical Package for the Social Sciences (SPSS) Version 11 for windows**  
Instrument used: CASP RCT  
A clearly focused question was stated. An appropriated design was applied, and sample were allocated in control and study group. The data collection was clearly stated. The results were precisely and clearly presented. Follow-up was done and all participants who entered were accounted for in conclusion. Single-blind controlled study. Overall the study was well planned, executed and reported. ADA Results neutral quality rating = (ø) neutral  
Class A, CASP = 7/10  
Relevance: +  
Decision: Included |
| 8 | **O’Donnel et al.** (2003:834-840)  
Compliance therapy: a randomised controlled trial in schizophrenia | **Setting:**  
Hospital. Dublin  
**Sample size:**  
56 patients schizophrenia | **Intervention group:**  
compliance therapy  
**Control group:**  
Non-specific counselling therapy consisting of 5 sessions each lasting for 30 to 60 minutes  
**Follow-up time:**  
12 months | **Self report**  
Intent-to-treat using SPSS Version 12. Analysis of Co-variance | **Instrument used:** CASP RCT  
A clearly focused question was stated. An appropriated design was applied, and samples were allocated in control and study group. The data collection was clearly stated. Single blinding was done. The results were precisely and clearly presented. Follow-up was done and all participants who entered were accounted for in conclusion. Evaluators were blinded to intervention. Overall the study was well planned, executed and reported. ADA Results high quality: (+) positive. Class A and CASP = 8/10.  
Relevance: +  
Decision: Included |
<table>
<thead>
<tr>
<th>No.</th>
<th>Reference</th>
<th>Study Title</th>
<th>Setting</th>
<th>Sample</th>
<th>Intervention</th>
<th>Review of Medical Charts</th>
<th>Medication Adherence Rating Scale (MARS); Brief evaluation of Medication Influence and Belief (BEMiB)</th>
<th>Instrument used</th>
<th>JHNEBP Score</th>
<th>Evidence Level</th>
<th>ADA Rating</th>
<th>Decision</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Lizer et al. (2011:122-127)</td>
<td>The impact of a pharmacist assisted clinical trial on medication adherence and quality of life in mental health patients</td>
<td>Out-patient psychiatric clinic. USA</td>
<td>Size 27</td>
<td>Health education on medication and disease states by Pharmacists; Use of medication schedules and pill boxes to improve adherence. All had to come to the pharmacist for three visits (baseline, 3 and 6 months)</td>
<td>PASWv18, t-test, Wilcoxon Sign Rank test or McNemar’s test.</td>
<td></td>
<td>Instrument used: Instrument used: JHNEBP</td>
<td>3/6</td>
<td>Level III Class D</td>
<td>(ø)</td>
<td>Excluded. Poor rigour</td>
</tr>
<tr>
<td>2</td>
<td>Chang et al. (2010:16-19)</td>
<td>Treatment effectiveness and adherence in patients with schizophrenia treated with Risperidone long-acting injection.</td>
<td>Hospital for acute care; a day-care institution, a psychiatric rehabilitation institution, a community rehabilitation center, home visits, a specialised hospital, and 10 local clinics. Taiwan.</td>
<td>137 patients with schizophrenia</td>
<td>Risperidone long-acting injection with provision of home care service. Versus Risperidone long-acting injection with illicit drugs.</td>
<td>SPSS version 15.0 for Windows to perform descriptive analysis, Cox regression analysis' independent sample t-tests. Bayesian analysis using AMOS 7.0 statistical software package.</td>
<td></td>
<td>Instrument used: Instrument used: JHNEBP</td>
<td>5/6</td>
<td>Class B</td>
<td>(+) positive</td>
<td>Included</td>
</tr>
<tr>
<td>Setting:</td>
<td>Intervention:</td>
<td>Medication Event monitoring System (MEMS) Medication Adherence Rating Scale (MARS)</td>
<td>Non-parametric Kruskal-Wallis test Chi square test</td>
<td>Instrument used:</td>
<td>JHNEBP</td>
<td>A clearly focused question was stated. An appropriate design was used. Data collection was clearly stated. The results were precise and clearly presented. Ethical issues taken into consideration. Follow-up done. Data analysis done. Overall, the study was well planned, executed and reported.  Rigor JHNEBP score= 5/6  Class:  B  ADA Results high quality rating:  (+) positive  Evidence level:  Level III  Decision:  Included</td>
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<td>Out-patient. Spain Mental Health care center  Sample: 1.848 Out-patients with schizophrenia or schizo-affective disorder</td>
<td>Oral antipsychotic medication  <strong>Versus</strong> Long-acting injectable antipsychotic.  <strong>Follow-up time:</strong> 3 months</td>
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<td>Rouff (2006:846-851)  A method that dramatically improves patients’ adherence to depression treatment.</td>
<td>Flow sheet to record pertinent data including co-morbidities coupled with patient education and telephone follow-up.  <strong>Versus</strong> Results compared with the adherence rates documented in other studies.  <strong>Follow-up time:</strong> 9 months</td>
<td>Review of medical charts  Patients’ charts were audited and results compared with existing data to demonstrate that the procedures significantly improve adherence to prescribed regimen</td>
<td></td>
<td></td>
<td>JHNEBP</td>
<td>Clearly focused question was stated. An appropriate designed was used. No control group, although the results were compared with existing literature. The results were clearly represented. Conclusion was based on clearly presented results and limitation stated. Overall the study was well planned, executed and presented.  Rigor JHNEBP score= 5/6  Evidence Level: III  Class D  ADA high quality rating  = (+) positive Relevant to this study  Decision:  Included</td>
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<td></td>
<td>Kemppainen et al. (2003:39-49)</td>
<td>Setting: VA psychiatric nurses representing six health care facilities within a region that includes northern California, Nevada and Hawaii</td>
<td>Interventions: Patient Education. Direct observation during medication administration. Tailored individual intervention. Engage patients in treatment.</td>
<td>Direct observation of behaviour and evaluation of mental status. Electronic record review. Written and verbal reports. Direct observation during medication administration. Communication with family or care giver.</td>
<td>Descriptive statistics Coding categories were developed</td>
<td>Instrument used: Instrument used: JHNEBP A clearly focused question was stated. An appropriate design was used. Data collection was clearly stated. The results were precise and clearly presented. Ethical issues taken into consideration. Data analysis done. Overall, the study was well planned, executed and reported. Rigor good JHNEBP score = 5/6 Class of evidence: D Strength of evidence: Level III ADA high quality rating: (+) positive Decision: Exclude due to study’s generalizibility being restricted to VA health care settings only, therefore, not relevant.</td>
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<td></td>
<td>Gevasoni et al. (2010:265-267) Early telephone intervention for psychiatric outpatients starting antidepressant treatment.</td>
<td>Setting: Out-patients at the Department of Psychiatry, Geneva University Hospital.</td>
<td>Intervention: Telephone interventions by psychiatric nurse. Each contact included brief structured assessment of current depressive symptoms, current use of antidepressant medication and antidepressant side-effects, in addition to motivational support for study adherence. <strong>Versus</strong> Usual Care Follow-up time: 8 weeks</td>
<td>Plasma level. Montgomery-Asberg Depression Rating Scale (MADRS)</td>
<td>Fisher exact test Mann-Whitney U-test. Statistical analysis was done with the SPSS package.</td>
<td>Instrument used: JHNEBP A clearly focused question was stated. An appropriate design was used and sample was allocated into control and study group. Data collection was clearly stated. Results was precise and clearly stated. Overall study was well planned, executed and reported. Level II Class: C JHNEBP score = 5/6 ADA high quality rating = (+) positive Decision: Included</td>
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<tr>
<td>Study</td>
<td>Authors</td>
<td>Year</td>
<td>Title</td>
<td>Setting</td>
<td>Intervention</td>
<td>Medication</td>
<td>Tools</td>
<td>Rigour</td>
<td>Evidence Level</td>
<td>Conclusion</td>
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<td>2</td>
<td>Patel et al. (2010:269-274)</td>
<td>An attempt to improve antipsychotic medication adherence by feedback of medication possession ratio scores to prescribers</td>
<td>Community mental health centres (CMHC’s), State of Missouri</td>
<td>Treatment Adherence Program (TAP) with early alert system to notify caregivers when patients failed to refill essential prescriptions in a timely manner.</td>
<td>Medication Position Ratio (MPR)</td>
<td>SAS inversion 9.1' t-test and chi-square test</td>
<td>Instrument used: JHNEBP</td>
<td>A clearly focused question was stated. An appropriate design was applied. Data collection was clearly stated. The results were precise and clearly presented. Overall, the study was well planned, executed and reported. Level II. Class B</td>
<td>Evidence Level: Level II</td>
<td>Relevant to my study</td>
<td></td>
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<tr>
<td>3</td>
<td>Dolder et al. (2002:103-108)</td>
<td>Antipsychotic medication adherence: Is there a difference between typical and atypical Agents?</td>
<td>Out-patients settings Department of Veterans Affairs (VA), California America</td>
<td>Atypical antipsychotic medication</td>
<td>Pharmacy refill records</td>
<td>Independent test Scheffe’s post hoc test Chi-square analysis</td>
<td>Instrument used: JHNEBP</td>
<td>A clearly focused question was stated. An appropriate design was applied. Data collection was clearly stated. The results were precise and clearly presented. Overall, the study was well planned, executed and reported. Level II</td>
<td>Evidence Level: Level II</td>
<td>Relevant to this study</td>
<td></td>
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</tr>
</tbody>
</table>
The studies obtained and included for critical appraisal totalled 16. The total number of articles excluded was 2 and included articles for data extraction after critical appraisal numbered 14 articles.

3.5 SUMMARY

Chapter 3 provided a detailed account of the realisation of this study according to step 1 to 3 of a systematic review. Extracting data and drafting of all relevant studies with data analysis/synthesis will be discussed in chapter 4.
CHAPTER 4: FINDINGS OF THE STUDY AND SUMMARISING EVIDENCE

4.1 INTRODUCTION

In this chapter the findings of the study are discussed and summarised in a clear and logical order. The characteristics of included studies are presented, data analysed and the summary of the extracted findings is displayed in a table format.

4.2 STEP 4: SUMMARISING THE EVIDENCE

Summary of the evidence presents the cumulative information, data and quality of evidence for the most important outcomes. The summary of the evidence contains discussions on Compliance Measurement Tools as well as the data extraction and summary, data analysis strategy, and summary of the findings.

4.2.1 Compliance Measurement Tools

The interventions to promote psychiatric patients compliance to mental health treatment from included studies indicated that they were effective by means of measurement tools used to measure compliance. There are various methods that can be used for measuring medication compliance in primary studies such as electronic methods and saliva, plasma and urine assay tests. Electronic devices have been developed that can be attached to the medication bottle. These devices record the time and date on every occasion that the bottle is opened. The saliva, plasma and urine assay tests are said to be the most objective measure of adherence, but tests do not exist for all psychiatric drugs. The tests are also expensive and more invasive (Patel & David, 2007:258). All the instruments used in the primary studies were described as validated for reliability and validity. The following compliance measuring tools were used in the primary studies included in this review:

Medication position rations (MPR) & Prescription (refill) monitoring. The primary outcome measure for this review was medication adherence. Different measures were used in the included studies. Patel et al. (2010:269-274) and Valenstein (2009:730) used medication possession ratio (MPR) to measure medication compliance for patients with severe mental illness in their studies. The MPR is the ratio of the number of out-patient day’s supply of medication that a patient has received during the designated time period divided by the number of days supply they needed to receive to take their prescribed dose of antipsychotic continuously during non-institutionalized days. The MPR was the primary outcome because it is
based on data (pharmacy fill) that can be collected unobtrusively, making it less likely to affect adherence behaviours; it can be calculated for a patient even if he or she stops participating in the study; and it is associated with important outcomes in observational studies. Because patients may fill a prescription but not ingest their antipsychotic medications, the more stringent composite compliance measure (CAM) is based on multiple data sources. Patients are considered adherent on the CAM only if: (1) their MPR during the study was > 0.8; (2) they reported that they “always” took their antipsychotic “a couple times” in response to questions from Schizophrenia Outcome Module, and (3) their blood test indicated the presence of some antipsychotic medication. Pharmacy refill records were also used by Dolder et al. (2002:103) to measure compliance of psychotic patients. According to Dolder et al. (2002:103) rates of adherence based on pharmacy refill records have been reported to correlate with other adherence behaviours such as appointment keeping, serum drug levels, and drug effects such as blood pressure control.

Medical charts review as a tool to measure compliance to treatment was used by Chang et al. (2010:16) for schizophrenic patients using Resiredone long acting injections and by Rouff (2006:846) for depression patients.

Self-report methods include interviews and questionnaires (e.g. Tablet routing questionnaire) that assess the daily routine medication and the proportion of medication an individual has missed in the previous week and previous month. It has been chosen for depression patients as it does not increase attention to adherence behaviours and might potentially serve as intervention in itself (Sirey et al., 2010:557).

The Hogan Drug Attitude Inventory (DAI-30) measuring tool and the Clinician Rating of Compliance Scale were used by Gray et al. (2004:158) to measure compliance in schizophrenic patients. The Hogan Drug Attitude Inventory (DAI-30) measuring tool is a 30-item self-report measure predictive of compliance in people with schizophrenia. Each item is rated by the patient as being true or not and produces a total score ranging from +30 to -30. A positive score is predictive of compliance and a negative score is predictive of non-compliance.

The Clinician Rating of Compliance Scale is an observer rating compliance on a seven-point scale ranging from 1 (complete refusal) to 7 (active participation in treatment). These methods have been criticised because they may introduce bias. However, they have been used because the direct methods such as electronic monitoring were empirical and costly and can also be subject to bias (Gray et al., 2004:161).

The Medication Event Monitoring System (MEMS) and Medication Adherence Rating Scale (MARS) were used by Gutierrez-Casares et al. (2010:327) to measure compliance of
Compliance with the pharmacological treatment was assessed by direct questions to both patients and/or their relatives using the Medication Adherence Rating (MARS), the Drug Attitude Inventory (DAI), and other scales, manual counting of oral and injectable medication, and via the Medication Event Monitoring System (MEMS).

The MEMS has been regarded as the “reference standard” method for assessing compliance. Compliance with the MEMS device was defined as the consistency between the number of openings (regardless of the hour) and the prescribed regimen on at least 75% of the days of the study period. Compliance with intramuscular treatment was evaluated as the percentage of correct administrations in keeping with indications and correct administration was considered as a dose administered within 3 days of the scheduled dose. Patients with compliance rates of \( \geq 80\% \) were considered as showing “good compliance with treatment”. The MEMS device was said to overestimate compliance and there may be a bias towards compliance because patients know that this behaviour is being monitored.

Medication Adherence Rating Scale (MARS), used by Gutierrez-Casares et al. (2010:327), is a 10 item yes/no self-report instrument. It was developed from two existing scales: the 30 item DAI and the 4 item Medication Adherence Questionnaire, with the aim of developing a more reliable and valid tool for assessing medication adherence behaviour in psychosis. Total scores range from 0 (low likelihood of medication adherence) to 10 (high likelihood). This reflects an understanding that compliance is a continuous variable. An individual can reach a decision anywhere between complete compliance and complete non-compliance, such as only taking medication when feeling unwell (Gutierrez-Casares et al., 2010:327).

Maneesakorn et al. (2007:1302-131) and Gou et al. (2010:898) used the Positive and Negative Syndrome Scale (PANSS) for schizophrenic patients. The PANSS has been assessed for its reliability and validity. Thirty items are evaluated on the absence, presence or severity of positive symptoms (seven items), negative symptoms (seven items) and general psychopathology (16 items). Each item is rated from a 1 (absent) to 7 (extreme) scale based on a 30-40 minutes structured clinical interview conducted by trained assessors. Maneesakorn et al. (2007:1306) suggested that, since there is no gold standard measure of compliance, psychotic symptoms together with attitude towards and satisfaction with medication could represent potential outcomes that patients may acquire after receiving the intervention.

4.2.2 Data extraction and summary

Data extraction followed immediately after the critical appraisal. Data extraction elements of each study involved the focus of the study, the main findings, and findings that were relevant to
this systematic review. All data extracted were graded on the strength of their evidence supporting the conclusions or recommendation according to American Dietetic Association Evidence analysis manual (ADA, 2008:62). The evidence was graded as follows:

- “Grade I refers to good/strong evidence derived from studies of strong design for answering the question addressed. The results are both clinically important and consistent with minor exceptions at most. The results are free of serious doubts about generalisability, bias, and flaws in research design. Studies with negative results have sufficiently large sample sizes to have adequate statistical power”.

- “Grade II refers to fair/medium evidence derived from studies of strong design answering the question addressed, but there is uncertainty attached to the conclusion because of inconsistencies among the results from different studies or because of doubts about generalisability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from weaker designs for the questions addressed, but the results have been confirmed in separate studies and are consistent with minor exceptions at most”.

- “Grade III is limited or poor evidence that means that the evidence consists of results from a limited number of studies of weak design for answering the questions addressed. Evidence from studies of strong design is either unavailable because no studies of strong design have been conducted, or because the studies that have been done are inconclusive due to lack of generalisability, bias, design, flaws, or inadequate sample sizes”.

- “Grade IV evidence refers to expert opinion only, which means that the support of the conclusion consists solely of the statement of informed medical commentators based on their clinical experience, unsubstantiated by the results of any research studies”.

- “Grade V evidence is not assignable, which means that there is no evidence available that directly supports or refutes the conclusion”.

Table 4.1 outlined the data extraction step.
<table>
<thead>
<tr>
<th>No</th>
<th>Reference</th>
<th>Focus of the study</th>
<th>Bottom-line finding</th>
<th>Findings relevant to this study and Evidence grading</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Valenstein et al. (2011:727-736) Using a pharmacy-based intervention to improve antipsychotic adherence among patients with serious mental illness</td>
<td><strong>Focus of the study:</strong> To conduct a randomised control trial to examine the effectiveness of a pharmacy based intervention, Meds-Help, in improving antipsychotic adherence among patients with severe mental illness (SMI).</td>
<td><strong>Bottom-line findings:</strong> <em>Effects of intervention on adherence</em> 34% of patients on pharmacy-based intervention (Meds Help) and 18% of patients on Usual Care (UC) met the criteria for adherence.</td>
<td>Findings from this study showed that a low-complexity pharmacy-based intervention improves antipsychotic compliance among patients with SMI, a poor patient population in which poor compliance is common. Evidence grading: Grade I</td>
</tr>
<tr>
<td>2</td>
<td>Sirey et al. (2010:554-562). Improving antidepressant adherence and depression outcomes in primary care: the treatment initiation and participation.</td>
<td><strong>Focus of the study:</strong> To test the impact of a novel psychosocial intervention to improve antidepressant adherence and depression outcomes among older adults prescribed pharmacotherapy by their primary care physician.</td>
<td><strong>Bottom-line findings.</strong> Treatment Initiation and Participative Program (TIP) is useful in improving early compliance to antidepressant therapy provided in primary care settings. The patients also showed a greater decrease in depressive symptoms.</td>
<td>Findings from this study show that Patients in TIP were significantly more compliant to treatment at all points. Evidence grading: Grade II</td>
</tr>
<tr>
<td>3</td>
<td>Guo et al. (2010:895-904) Effect of antipsychotic medication alone vs. combined with psychosocial intervention outcomes of early-stage schizophrenia</td>
<td><strong>Focus of the study:</strong> To evaluate the effectiveness of antipsychotic medication alone versus combined with psychosocial intervention on outcomes of early-stage of schizophrenia.</td>
<td><strong>Bottom-line findings:</strong> <em>Combined treatment:</em> The combined treatment improves medication adherence, risk of relapse, and hospital admission, insight, quality of life and social/occupational functioning. There is lower rate of medication discontinuation.</td>
<td>Findings from this study shows that antipsychotic medication combined with psychosocial interventions are able to improve psychotropic patients’ compliance to mental health treatment in the early stage of schizophrenia. Evidence grading: Grade I</td>
</tr>
<tr>
<td>4</td>
<td>Maneesakorn et al (2006:1302 -1312) An RCT of adherence therapy for people with psychotic symptoms</td>
<td><strong>Focus of the study:</strong> To evaluate the effectiveness of adherence therapy with a brief intervention based on therapy and</td>
<td><strong>Bottom-line findings:</strong> Patients who received adherence therapy significantly improved in overall psychotic symptoms, attitude towards</td>
<td>Findings from this study found that adherence therapy improved compliance to treatment in the hospital settings.</td>
</tr>
<tr>
<td>Study</td>
<td>Focus of the study</td>
<td>Bottom-line findings</td>
<td>Evidence grading</td>
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<td>5</td>
<td>Gray et al. (2004:157-162) Effects of a medication management training package for nurses on clinical outcomes for patients with schizophrenia</td>
<td><strong>To assess the effectiveness of a medication management training package for community mental health nurses (CMHNs) in improving compliance and clinical outcomes in patients with schizophrenia.</strong>&lt;br&gt;&lt;br&gt;<strong>Bottom-line findings:</strong>&lt;br&gt;This study demonstrated that medication management training for CMHN’s is effective in improving clinical outcomes in people with schizophrenia. The primary efficacy measure (PANSS total) showed statistically significant improvements compared to treatment as usual. Significant improvement was observed in patients’ attitudes toward treatment (DIA-30) and compliance compared to treatment as usual. Training equips CMHN’s with the skills that they need to be effective in delivering compliance therapy.</td>
<td>Findings from this study regarding compliance to treatment: Medication management training for community mental health nurses (CMHNs) was found to be a significant benefit to nurses and it improved psychiatric patients’ compliance to mental health treatment in the community. Evidence grading: Grade II</td>
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<td>6</td>
<td>Gray et al. (2006:508-514) Adherence therapy for people with schizophrenia</td>
<td><strong>To compare the effectiveness of adherence therapy with a health education control intervention (which allows the therapies time and relationship), in improving health-related quality of life for people with schizophrenia, compared with health education.</strong>&lt;br&gt;&lt;br&gt;<strong>Bottom-line findings</strong>&lt;br&gt;This study showed that the adherence therapy had no clear benefit in terms of treatment adherence, psychopathology or quality of life when compared with health education, for people with general chronic schizophrenia, in general adult mental health services.</td>
<td>Findings from this study regarding compliance to treatment showed that adherence therapy does not significantly improve compliance to treatment for people with schizophrenia in in-patient and community settings. Evidence grading: Grade I</td>
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<tr>
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<td>Brook et al. (2005:487-489)</td>
<td>Focus of the study</td>
<td>Bottom-line findings</td>
<td>Evidence grading: I</td>
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<td></td>
<td>A pharmacy-based coaching program to improve adherence to antidepressant treatment among primary care patients</td>
<td>A pharmacy-based coaching program to improve adherence to antidepressant treatment among primary care patients. To evaluate the effect of a pharmacy based coaching approach together with a take-home video tape in improving adherence therapy to antidepressant treatment among depressed primary care patients in Netherlands.</td>
<td>A brief contacts by pharmacists together with an information videotape improved neither adherence to antidepressants regimens nor depressive symptoms.</td>
<td>Findings of this study regarding compliance to treatment showed that a pharmacy-based coaching program does not significantly improve compliance to mental health treatment.</td>
</tr>
<tr>
<td></td>
<td>O’Donnel et al. (2003:834-840)</td>
<td><strong>Focus of the study</strong></td>
<td>Bottom-line findings</td>
<td>Evidence grading: Grade I</td>
</tr>
<tr>
<td></td>
<td>Compliance therapy: a randomised controlled trail in schizophrenia</td>
<td>To evaluate the efficacy of compliance therapy for improving compliance to prescribed drug treatment among patients with schizophrenia. Compliance therapy is explained as a cognitive behaviour intervention with techniques adapted from motivational interviewing as well as psycho-education.</td>
<td>Compliance therapy did not have any advantage over non-specific therapy in improving compliance at one year, or in any of the secondary outcome measures – symptomatology, attitude to treatment, insight, global assessment of functioning, and quality of life.</td>
<td>The findings of this study showed that compliance therapy did not significantly improve compliance to treatment for people with schizophrenia in in-patients settings</td>
</tr>
<tr>
<td></td>
<td>Chang et al. (2010:16-19)</td>
<td>Focus of the study:</td>
<td>Bottom-line findings:</td>
<td>Evidence grading: Grade II</td>
</tr>
<tr>
<td></td>
<td>Treatment effectiveness and adherence in patients with schizophrenia treated with Risperidone long-acting injection</td>
<td>To evaluate factors related to the effectiveness and adherence to treatment in patients with schizophrenia treated with Risperidone long-acting injection (RLAI).</td>
<td>The efficacy of RLAI was affected most by the provision of home care and history of illicit drugs. Patients who received home care services continued treatment on average 15.26 days longer than patients who did not. Patients who had a history of illicit drugs use continued treatment for 17.3 fewer days on average than patients with no such history.</td>
<td>The findings from this study showed that RLAI with the provision of home care improves compliance to psychiatric patients’ compliance to mental health treatment, especially when medication is changed and/or discontinued.</td>
</tr>
<tr>
<td></td>
<td>Gutierrez-Casarez et al. (2010:327-337)</td>
<td>Focus of the study:</td>
<td>Bottom-line findings:</td>
<td>Evidence grading: Grade I</td>
</tr>
<tr>
<td></td>
<td>Adherence to treatment and therapeutic strategies in schizophrenic patients: The</td>
<td>To assess the degree of compliance and adherence to treatment during the follow-up after a new therapeutic strategy had been identified.</td>
<td>After three months’ visits, 84% of patients had changed their treatment and in these, the compliance rate of those in injectable medication was 94% versus</td>
<td>The findings of this study indicated that injectable medication increases psychiatric patients’ compliance to mental health treatment more than oral</td>
</tr>
<tr>
<td>ADHERE study</td>
<td>87% of patients taking oral medication. medication in outpatients with schizophrenia. Evidence grading: Grade II</td>
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<td>---</td>
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<tr>
<td>3 Rouff (2005:846-851) A method that dramatically improves patient adherence to depression treatment</td>
<td><strong>Focus of the study:</strong> To increase patient adherence to prescribed regimen for depression or depressive symptoms.</td>
<td><strong>Bottom-line findings:</strong> 40 of the 61 patients (66%) adhered to prescribed daily drug therapy for depression for at least 9 months – double the 33% adherence rate described in clinical literature.</td>
<td>The findings showed that the use of a flow sheet, coupled with patient education and diligent follow-up improved compliance to mental health treatment. Evidence grading: Grade III</td>
<td></td>
</tr>
<tr>
<td>1 Patel et al. (2010:267-274) An attempt to improve antipsychotic medication adherence by feedback of medication possession ratio score to prescribers</td>
<td><strong>Focus of the study:</strong> To improve treatment adherence by implementing an early alert system to notify caregivers when patients fail to refill essential prescriptions in a timely manner, and educational resources for providers on best practices.</td>
<td><strong>Bottom-line findings:</strong> The intervention group had a significantly greater increase in MPR scores between pre-intervention and intervention. After the conclusion of Treatment Adherence Program (TAP) intervention, the medication possession ratio (MPR) score was decreased somewhat, but was still higher than during the pre-intervention period.</td>
<td>The findings of this study showed that TAP programs improved compliance to mental health treatment. Evidence grading: Grade II</td>
<td></td>
</tr>
<tr>
<td>2 Dolder et al. (2002:103-108) Antipsychotic medication adherence: is the difference between typical and atypical agents?</td>
<td><strong>Focus of the study:</strong> To examine adherence to medication regimens to typical versus atypical antipsychotics among Department of Veterans Affairs (VA) out-patients with psychotic disorder.</td>
<td><strong>Bottom-line findings:</strong> The patients with prescriptions for atypical antipsychotics had a significantly higher adherence rate at 6 months. At 12 month patients receiving atypical agents had a higher adherence rate.</td>
<td>In this study the out-patients with prescriptions for atypical antipsychotics had greater medication adherence compared to patients with prescriptions for typical agents. Evidence grading: Grade II</td>
<td></td>
</tr>
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</table>
| 3 | **Gevasoni et al.**  
(2010:265-267) | **Focus of the study** | **Bottom-line findings** | The findings from this study showed that a brief high-intensity structured telephone intervention does not significantly improve compliance to treatment for patients starting antidepressant medication treated in psychiatric outpatient clinics.  
Evidence grading: Grade II |
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<tr>
<td>Early telephone intervention for psychiatric out-patients starting antidepressant treatment</td>
<td>To examine the effectiveness of early telephone intervention for psychiatric outpatients starting antidepressant treatments in improving compliance to treatment</td>
<td>The intervention proved to have no significant effect on treatment compliance attrition rate, exclusion rate for adverse events or improvement of depression severity</td>
<td></td>
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</table>
4.2.3 Analysis strategy

In this review, primary studies of randomised control studies, non-experimental studies and quasi-experimental studies were included. A meta-analysis was not appropriate as it is a type of systematic review that uses statistical methods to combine and summarise the results of primary studies (Akobeng, 205:8) that would not be appropriate in this review. In a case where the primary studies uses difference in design, population studied, interventions and comparison used or outcome measured, it is more appropriate to report the findings descriptively according to themes (Grag et al., 2008:253). Therefore thematic analysis was used as an appropriate analysis strategy. The method of thematic analysis is used to identify major or recurrent themes in the findings, followed by a summary of findings under these thematic headings (Dixon-Woods et al., 2006:15). The findings regarding each theme were combined and summarised; thereafter the conclusion statements are made.

4.2.4 Summary of findings

A conclusion of the summary of the findings regarding the included studies according to the following review question is provided:

- What is the current evidence on interventions to promote psychiatric patients’ compliance to mental health treatment?

In order to answer this review question, a summary of the findings under thematic headings referring to psychiatric conditions (schizophrenic patients, psychiatric patients, depressed patients and seriously mentally ill patients) treated in specific settings both public and private (hospital, community, clinics or out-patients), are provided.

4.2.4.1 Finding 1: Adherence Therapy and motivational interviewing are effective to promote compliance to treatment to hospital settings for schizophrenic patients

Findings indicated that Adherence Therapy (AT) and motivational interviewing can improve schizophrenic patients’ compliance to treatment in hospital settings. Adherence Therapy is a brief cognitive behavioural approach that evolved from compliance therapy. It is a collaborative, flexible, structured way of working and draws on cognitive behavioural therapy and motivational interviewing techniques.

The AT manual describes a detailed phased approach to promoting treatment compliance in patients with schizophrenia. The key therapeutic techniques used are exchanging information, developing discrepancy and effectively dealing with resistance to discuss psychiatric medication
and treatment. The phases of AT are engagement, assessment, rating or readiness to take medication, intervention and evaluation. The therapist works through the stages in a flexible patient-centred way. AT strategies emphasize patient engagement and enable patients to make joint decisions about medication in cooperation with health professionals (Maneesakorn et al., 2006:1302). The findings of this study indicated that there was a statistical improvement overall, including psychotic symptoms, attitude towards medication, and satisfaction with medication with schizophrenic patients in the hospital setting. Therefore it is important that health care professionals receive training on Adherence Therapy and motivational interviewing and put it into practice in hospital settings to promote compliance to mental health treatment.

Contradictory findings were found two studies done by O’Donnel et al. (2003:834) & Gray (2006:511). According to the study done by O’Donnel et al (2003:834) compliance therapy could not improve psychiatric patients’ compliance to treatment for schizophrenic patients in both in-patients and out patient’s settings. Compliance therapy is cognitive behaviour intervention with techniques adapted from motivational interviewing and other cognitive therapy as well as psycho-education. This intervention consists of five sessions each lasting for 30 to 60 minutes, and covered a review of the patient illness history and understanding of illness and his or her ambivalence treatment, maintenance, medication and stigma. This study was supported by the study done by Gray (2006:511) on adherence therapy on patients with schizophrenia in in-patients setting that did not improve compliance to treatment.

4.2.4.2 Finding 2: Meds Help and Treatment Adherence Therapy are effective to promote compliance to treatment used in community settings for seriously mentally ill patients

Using pharmacy-based intervention (Meds Help): According to Valenstein et al. (2011:727-736), the findings from this study showed that a low-complexity pharmacy-based intervention (Meds Help) improves antipsychotic compliance among patients with serious mental illness (SMI) who live in the community and receives treatment at clinic. The Meds-Helps consisted of unit-of-use packaging that included all patients’ medications; a medication and packaging education session; refill reminders mailed two weeks before scheduled refill dates and notification of clinicians if patients failed to refill their treatment within 7-10 days. Meds-Help staff serve as contacts for patient questions regarding pharmacy services or doctors prescriptions. Pharmacy technicians, with oversight by pharmacists, completed many of these intervention components. The medication education was done by pharmacists, usually in person, but occasionally by telephone. During the session the pharmacist reviewed patients’ prescribed medications, including treatment indications. The pharmacist also explain the unit-of-use medication packaging (eg. Package usage and warning labels, lack of child proofing) and plans
for interim use of pill boxes when medication changes were made by clinicians before the next shipment of medication packages. Therefore, this intervention can be implemented for outpatients (Valenstein et al., 2011:727-736).

Treatment Adherence Therapy (TAP) program: A Treatment Adherence Therapy (TAP) program as an intervention improved compliance to treatment for patients with severe and persistent mental illness in out-patients at clinics. The programs consist of community health care professionals trained in monitoring patients receiving treatment at community mental health centres (CMHCs). The program uses alert systems at CMHCs 2-weekly when patients fail to refill their treatment. The Medication possession ratio (MPR) score were also monitored. MPR scores were calculated as the ratio of days of medication in a patient’s possession divided by the days of medication prescribed by the clinicians based on Medicaid data. This single point of contact will inform the prescribing clinicians and the case manager. The case managers/supervisors from the TAP program at CMHCs participated in 4 hour long patient’s adherence educational training seminar. Physicians and psychiatrist working at the centre are orientated regarding the TAP program. The findings of this study indicated that there was a statistically significant association between the TAP interventions and MPR score and an improvement in antipsychotic medication compliance. Therefore, Training on the TAP program for community mental health professionals should be encouraged. The above intervention can be implemented for out-patients in community health care centres as it has proven that it can promote psychiatric patients’ compliance to mental health treatment (Patel et al., 2010:267-274).

4.2.4.3 Finding 3: A Treatment Initiation and Participative Program and the use of a depression management flow sheet are effective in improving compliance to treatment used at clinics settings for depressed patients

Treatment Initiation and Participative Program: Findings indicated that the Treatment Initiation and Participative Program (TIP) is useful in improving early compliance to antidepressants therapy provided at the clinics and primary care settings. The patients also showed decrease in depressive symptoms. The TIP intervention format is three 30-minutes individual meetings with the patient during the first six weeks of pharmacotherapy, followed by two follow-up telephone calls at 8 and 10 weeks. The three sessions allow the TIP Counsellor and older adult participant to establish an alliance and work together on barriers to compliance (e.g. patient perceptions of stigma, illness severity, and concern about treatment). TIP intervention uses a number of techniques such as motivational interviewing, problem solving tasks and psycho-education. The TIP model offers a framework for exploring and improving adherence in different settings were depression in older adults is treated. The TIP intervention has been proven to be effective in
treated adult depressive patients, and can be implemented for adults receiving treatment at urban clinics (Sirey et al., 2010:554-562).

The use of a depression management flow sheet coupled with patient education, a checklist for co-morbid disorders; a medical reference guide; a major depression guide and diligent follow-up dramatically improved the rate of treatment compliance for depressed patients at clinic. Patients were asked to complete Patients Health Questionnaire (PHQ-9s) and medication side effects were assessed 2-weekly. They are also educated by the attending physician during their initial appointment, and is given information material to explain the disease and the necessity of compliance to the prescribed regimen for a period of nine months. A flow sheet, containing information relative to office calls, follow-up PHQ-9s, and other summaries of medication, co-morbidities, and treatment regimens was inserted in their respective charts. During their visits physicians stressed the need for continuing medication. Patient who did not return for a follow-up appointment after 6 months, as indicated by systematic chart review, was contacted by telephone by a registered nurse. The finding of this study has indicated that the above intervention has significantly improved compliance to mental health treatment by depressed patients. Therefore, it is important that the above intervention be conducted as it improves compliance to mental health treatment (Rouff, 2005:846-851).

The findings of the study done by Gevasoni et al. (2010:265) has proven that a brief high-intensity structured telephone intervention alone does not improve compliance to treatment in patients treated at clinics with antidepressent medication.

**4.2.4.4 Finding 4: Medication management training for Community Mental Health Nurses (CMHNs) and antipsychotic medication combined with psychosocial interventions are effective in improving compliance to treatment used at out-patients settings for schizophrenic patients**

Medication management training for Community Mental Health Nurses (CMHNs) is effective in improving schizophrenic patients’ compliance to mental health treatments as it leads to improvement in overall psychopathology, attitude towards antipsychotic treatment and compliance. The training focused on teaching CMHNs the compliance therapy approach detailed in the treatment manual. The training program included training in the use of a range of standardised measures to assess the side-effects of medication and patients’ beliefs and feelings about treatments, and psychopharmacology components that consider effective treatment strategies for schizophrenia and the management of common side-effects. A multi-disciplinary team that included clinical nurse specialists, psychologists and psychiatric pharmacist provided the training. The findings of this study demonstrated that medication
management training for CMHNs is effective in improving clinical outcomes in people with schizophrenia and significant improvement in clinical skills. The training also equips nurses with the clinical skills and knowledge that is needed to improve psychiatric patients’ compliance to mental health treatment. Therefore, it is important that community mental health nurses attend medication management training to promote psychiatric patients’ compliance to mental health treatment in the community (Gray et al, 2004:157-162).

Antipsychotic medications combined with psychosocial intervention have proven effective in improving compliance to mental health treatment for patients with early stage schizophrenia. Psychosocial interventions have also lowered the rate of treatment discontinuation or change, the risk of relapse and hospitalisation, and improved insight, quality of life, and social/occupational functioning. The psychosocial intervention strictly followed a detailed treatment manual and included 4 evidence-based practices namely: psycho-education, family intervention, skills training, and cognitive behaviour therapy. Medication and psychosocial treatments occurred on the same day each month for patients, allowing the psychiatrists and other care providers to reinforce the importance of participation in all components of the treatment. The findings of this study has indicated that psycho-education, family intervention, skills training, and cognitive therapy have proved to be effective in treating patients with schizophrenia, and can be implemented at the clinics (Guo et al., 2010:895-904).

4.2.4.5 Finding 5: Home care support and use of long-acting injectable treatments, and atypical antipsychotic treatment, are effective to promote compliance to treatment

Long-acting injection (LAI) and the provision of home care may lead to continue treatment. This Home care services include psychosocial interventions delivered by a community-based multidisciplinary team, linking patients to community resources. Home care visitors offer active services, such as encouraging the patients to seek medical advice and to keep in contact with their physicians. Therefore, it is important to make certain that patients receiving RLAI interventions must also have provision of home care to improve their compliance to mental health treatment (Chang et al., 2010:16-19).

Furthermore psychotic out-patients with prescriptions of atypical antipsychotic treatment (risperidone, olanzapine and quetiapine) are more compliant to mental health treatment compared to patients with prescriptions of typical agents (haloperidol and perphenazine). Therefore, using interventions of atypical antipsychotic treatment has proven to reduce the side effects of antipsychotics and can be used as it improves psychiatric patients’ compliance to mental health treatment (Dolder et al., 2002:103-108).
4.3 SUMMARY

In this chapter, the realisation of the data extraction and data synthesis according to the steps of a systematic review were explained and characteristics of the final sample were provided. In order to answer the review question, a summary of findings was provided of the reviewed studies.

The final chapter includes the conclusions, limitations and recommendations for clinical practice and research.
CHAPTER 5: CONCLUSIONS, LIMITATIONS AND RECOMMENDATIONS

5.1 INTRODUCTION

This chapter offers the concluding statements regarding interventions to promote psychiatric patients’ compliance to mental health treatment, as well as an evaluation of rigour and a discussion of limitations. Recommendations for research education and clinical practice are also suggested.

5.2 CONCLUSIONS

Primary studies have been identified that meet the review criteria. According to the discussion in Chapter 4, there is evidence on interventions that can improve psychiatric patients’ compliance to mental health treatment. The researcher draws her conclusion for the evidence gathered from findings of the studies to answer the research question namely:

- What is the current evidence on interventions to promote psychiatric patients’ compliance to mental health treatment?

The conclusions are summaries or interpretations on the recurrent themes, e.g., interventions, target group and settings.

Concluding statement 1

Adherence Therapy (AT) and motivational interviewing techniques have the potential of improving compliance to treatment and overall psychotic symptoms for schizophrenic patients. Adherence Therapy strategies emphasize patients’ engagement and enable patients to make joint decisions in cooperation with professionals. Health professionals, particularly nurses who spend more time with the patients should be able to deliver such intervention in the hospital settings. However, adherence therapy alone cannot improve compliance to treatment, therefore further research needs to be done on Adherence therapy and/or Compliance therapy to improve psychiatric patients compliance to treatment.

Concluding statement 2

A Treatment adherence program (TAP) with health care professionals trained on monitoring patients’ compliance to treatment, can lead to improvement in compliance of patients with severe and mental illness. Therefore training on TAP should be done for health care
professionals working at the community health care centres to monitor patients who failed to come for their treatment and improve patient’s compliance to mental health treatment. Further research is encouraged to involved pharmacist in the notification process to improve patients’ compliance to mental health treatment.

In addition, A pharmacy-based intervention called Meds-Help intervention has been proven to improve psychiatric patients’ compliance to mental health treatment for severe mentally ill patients in out-patient settings. Therefore, pharmacy based interventions should be used to improve psychiatric patients’ compliance to mental health treatment.

**Concluding statement 3**

The Treatment Initiation Participative Program (TIP) has the ability to improve early compliance to antidepressants therapy provided at the clinics and primary care settings. The TIP model offers a framework for exploring and improving adherence in different settings were depression in older adults is being treated.

The use of a flow sheet coupled with patient education and diligent follow-up are effective to improve compliance to treatment. The use of a depression management flow sheet coupled with patient education; checklist for co-morbid disorders; a medical reference guide; a major depression guide and diligent follow-up can dramatically improve the rate of treatment compliance for depressed patients at the clinic. The use of a Patient Health Questionnaire (PHQ-9s) is useful in assessing medication side effects. Compliance to mental health treatment can also be improved by health education given by pharmacists giving patients information material to explain the disease and the necessity of compliance to the prescribed regimen. The registered nurse can also do follow up telephonically for patients who failed to keep their appointment to improve compliance to treatment. Further research is required on telephone following alone as intervention to improve compliance to treatment.

**Concluding statement 4**

Training in medication management for Community Mental Health Nurses (CMHNs) has proved to improve compliance to mental health treatment, clinical outcome and attitude to treatment of patients living in the community. Therefore a medication management training manual package can be made available for CMHNs so that they can be trained and equipped with skills that can help to improve psychiatric patients’ compliance to mental health treatment in the community.
Furthermore, Medication combined with psychosocial interventions has the ability to improve compliance to mental health treatment. The psychosocial interventions should follow 4 evidence-based practices namely: psycho-education, family intervention, skills training, and cognitive behaviour therapy.

In addition, treatment with atypical treatment and long-acting injections, rather than oral treatment, combined with home care interventions improves compliance to psychiatric patients’ mental health treatment. Further research is encouraged to monitor the effectiveness of the intervention in improving psychiatric patients’ compliance to treatment.

5.3 EVALUATION OF RIGOUR

Systematic reviews are scientific studies, so they must use scientifically rigorous methods. According to Whittemore and Knafl (2005:548-552) rigour can be increased in systematic reviews by motivating all research decisions during the different stages of the review namely the problem-identification stage, the literature search stage, the critical appraisal stage, the data synthesis stage and the presentation.

5.3.1 Problem-identification stage

The problem statement and purpose of this systematic review were clearly stated and supported by literature review in chapter 1. The review question for this study was formulated according to the PICOT format, namely:

- Population;
- Interventions;
- Comparison;
- Outcome; and
- Time frame (adopted from ADA, 2008:6) (see Table 2.1).

Clarification of terminology was systematically done in Table 1.1. The model of Botes (Botes, 1995:34) and the model of evidence-based clinical decisions (Haynes et al., 2002:135) were used. A systematic review was chosen and was used to answer a review question as stated in paragraph 1.7. Since scientifically rigorous methods are used in this systematic review to summarise the best current information, conclusions derived from the systematic review are considered as high-quality evidence. The information obtained can be used to inform clinical practice and in making decisions regarding interventions to improve the compliance of psychiatric patients to treatment.
5.3.2 Literature search stage

The literature search was conducted to identify all the best available evidence relevant to the research question. A comprehensive search was used as it is important to ensure that all the relevant studies are identified and to minimise selection bias (Akobeng, 2005:847). In order to retrieve a set of studies on a topic, several different sources were searched to identify relevant studies relating to interventions on promoting psychiatric patients’ compliance to mental health treatment. The multiple sources that were used in this study included electronic databases, grey literature and manual searches to reduce public bias (Henymay & Brereton, 2009:04). The researcher covered all literature, including non-English sources, in order to reduce language bias (Henymay & Brereton, 2009:04). An experienced librarian at the Ferdinand Postma Library at North-West University in Potchefstroom assisted with the literature search.

5.3.3 Critical appraisal

In this study, all articles selected for critical appraisal were critically evaluated to find out whether they answer the review question and meet the inclusion criteria. The evidence of primary studies selected for this review were analysed in accordance to the evidence class rating recommended by the ADA to enhance the rigour of the study (ADA 2008:30) (see Table 3.5).

The primary studies selected for critical appraisal were appraised for methodology and quality using standard checklists. Objectively structured instruments were used to reduce the researcher’s bias. The instruments used during the critical process were from the Critical Appraisal Skills Program (CASP) and the John Hopkins Nursing Evidence-Based Practice research evidence appraisal tool (JHNEBP) (Newhouse et al., 2007:206).

The tools were chosen based on their ability to fit the design of the included studies. They were all validated and tested for reliability, and have all been utilised in previous research studies. The critical appraisal process was conducted by both the reviewer and an independent reviewer under the supervision of experienced researchers to prevent inconsistency. Inconsistencies can come from a lack of skill on the part of the reviewers to critically assess and interpret the design/studies. It was important that there should be two reviewers in order to ensure that only studies that contain high-quality evidence would be included (see paragraph 3.4). To ensure transparency and repeatability, the entire search strategy was documented (including decisions concerning including/excluding data and reasons), and these are presented in tables and a flow chart (see paragraph 3.3; Table 3.3 and Flow Chart 3.1).
5.3.4 Data synthesis stage

The data analysis process was thoroughly discussed in the text (see paragraph 4.2.4). All primary studies included, randomised control trials, non-experimental studies and quasi experimental studies included were carefully considered.

5.3.5 Presentation

The conclusions, recommendations and limitations of the study are well presented in chapter 5. Furthermore, the outcome of the systematic review will be submitted for publication in a peer-reviewed journal. The entire systematic review was presented as transparently as possible using tables and flow charts where applicable. In addition, reporting was done as thoroughly as possible to prevent the omission of any relevant information.

5.4 LIMITATIONS

The heterogeneity of the studies and interventions outcome measure prevented the possibility of comparing results between the studies directly by means of meta-analysis. Different interventions were identified, but there were more studies that looked at effective interventions for schizophrenia. These cannot be generalised to other psychiatric conditions.

The systematic review was conducted on studies presenting with both high and neutral quality ratings, a mixture of class A and C evidence, therefore generalisation is limited to specific settings and not all findings can be generalised to the wider population.

Only the electronically databases subscribed to by North-West University were used. This is a limitation (as for instance other universities might have more/different database) as relevant data may have been missed. However, this was overcome by using multiple sources to obtain studies, such as electronic databases and gray literature. A comprehensive search was conducted as it is important to ensure that many studies are identified and to minimise selection bias (Akobeng, 2005:847).

In order to minimise selection bias, abstracts or hard copies (where applicable) of the articles were obtained. It was not always possible to obtain the full text of a publication. Those studies that could not be obtained (including reasons) were recorded, and outlined in Table 3.4.

In this review, blinding was not used during the search or critical appraisal step, as there was no conflict of interest. This could be a limitation with regard to validity of appraisal.
5.5 RECOMMENDATIONS

The findings of the systematic review helps to provide recommendations for nursing practice, nursing education and nursing research on best available evidence (Khan et al., 2003:4) on interventions to promote psychiatric patients’ compliance to mental health treatment. There is a problem that psychiatric patients often do not comply with mental health treatment.

Health professionals should be able to integrate the current research evidence on interventions to promote psychiatric patients’ compliance to treatment, clinical expertise, and patients’ preferences and characteristics during clinical decision-making. The following recommendations are made:

5.5.1 Recommendations for nursing practice

Information on interventions to promote psychiatric patients’ compliance to mental health treatment should be made available in nursing practice to improve patients’ compliance to treatment in different health care settings.

Integrating comprehensive therapy (psycho-education, family intervention, skills training, and cognitive therapy) with medication treatment in the early stage of schizophrenia is critically important to improve compliance to mental health treatment and should be implemented in outpatients settings.

Community mental health nurses (CMHNs) should be trained on medication management to equip them with skills to be effective in delivering compliance therapy and promote psychiatric patients’ compliance to mental health treatment in the community.

Schizophrenic patient receiving RLAI intervention must also have provision of home care to improve psychiatric patients’ compliance to mental health treatment.

Long-acting injectable antipsychotic treatment has proven to improve psychiatric patients’ compliance to mental health treatment more than oral medication in out-patients with schizophrenia, therefore long-acting injectables can be used more that oral medication for out-patients.

Interventions of atypical antipsychotic treatment have proven to reduce the side effects of antipsychotics and can be used as it improves psychiatric patients’ compliance to mental health treatment.
5.5.2 Recommendations for nursing education

The current available evidence on interventions that promote psychiatric patients' compliance to treatment can be included in nursing curricula to inform, educate, and equip nurses with special skills to safely and effectively deliver nursing care in community health care centres and the hospitals.

5.5.3 Recommendations for research

Further research is needed on interventions to promote psychiatric patients' compliance to mental health treatment as most of the research identified was only recommended for specific settings and have small samples.

- Adherence Therapy and motivational interviewing can improve schizophrenic patients’ compliance to treatment and in hospital settings. Further research is recommended on the effectiveness of compliance therapy to improve psychiatric patients’ compliance to treatment in all settings.
- The Treatment Initiation and Participative (TIP) Program has proven to have the ability to improve early compliance to antidepressants therapy provided at the urban clinics. More research is needed on the effectiveness of Treatment initiation and participative program in different settings.
- Further research is needed on the use of atypical antipsychotic treatment to improve psychiatric patients’ compliance to mental health treatment compared to typical antipsychotic medication.
- Further research is needed on the use of adherence therapy to improve compliance to mental health treatment in community settings.
- Further research is needed on a brief high-intensity structured telephone intervention to improve compliance to treatment for patients on antidepressant medication treated in psychiatric outpatient settings.
- Compliance therapy alone as an intervention to improve compliance to psychiatric patients' treatment has proven to be not effective; therefore further research is needed on this topic.

5.6 IN CONCLUSION

The objective of the review was to critically synthesise the best available evidence on interventions to promote psychiatric patients' compliance to mental health treatment. This objective was reached through conducting a systematic review. The findings of the systematic
review were then used to draw conclusion and formulate recommendations for nursing practice, nursing education and research.
REFERENCES


ADA see AMERICAN DIETETIC ASSOCIATION.


Date of access: 11 January 2012.


CASP see CRITICAL APPRAISAL SKILLS PROGRAMME.

CEBC see CENTRE FOR EVIDENCE-BASED CONSERVATION.

CNA see CANADIAN NURSES ASSOCIATION.


CRD see CENTRE FOR REVIEWS AND DISSEMINATION.


Critical Appraisal Skill Programme. 2006. Evidence-based health care. 2nd ed. USA.


Critical Appraisal Skills Programme (CASP)

making sense of evidence

10 questions to help you make sense of randomised controlled trials

How to use this appraisal tool

Three broad issues need to be considered when appraising the report of a randomised controlled trial:

- Is the trial valid?
- What are the results?
- Will the results help locally?

The 10 questions on the following pages are designed to help you think about these issues systematically.

The first two questions are screening questions and can be answered quickly. If the answer to both is "yes", it is worth proceeding with the remaining questions.

You are asked to record a "yes", "no" or "can't tell" to most of the questions. A number of italicised prompts are given after each question.

These are designed to remind you why the question is important. Record your reasons for your answers in the spaces provided.

The 10 questions are adapted from Guyatt GH, Sackett DL, and Cook DJ. Users' guides to the medical literature. II. How to use an article about therapy or prevention. JAMA 1993; 270 (21): 2698-2601 and JAMA 1994; 271(1): 59-63

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Screening Questions

1. Did the study ask a clearly-focused question?  □ Yes  □ Can't tell  □ No

   Consider if the question is 'focused' in terms of:
   - the population studied
   - the intervention given
   - the outcomes considered

2. Was this a randomised controlled trial (RCT) and was it appropriately so?  □ Yes  □ Can't tell  □ No

   Consider:
   - why this study was carried out as an RCT
   - if this was the right research approach for the question being asked

Is it worth continuing?

Detailed Questions

3. Were participants appropriately allocated to intervention and control groups?  □ Yes  □ Can't tell  □ No

   Consider:
   - how participants were allocated to intervention and control groups. Was the process truly random?
   - whether the method of allocation was described. Was a method used to balance the randomization, e.g. stratification?
   - how the randomization schedule was generated and how a participant was allocated to a study group
   - if the groups were well balanced. Are any differences between the groups at entry to the trial reported?
   - if there were differences reported that might have explained any outcome(s) (confounding)
4. Were participants, staff and study personnel ‘blind’ to participants’ study group?  
   Consider:  
   – the fact that blinding is not always possible  
   – if every effort was made to achieve blinding  
   – if you think it matters in this study  
   – the fact that we are looking for ‘observer bias’

5. Were all of the participants who entered the trial accounted for at its conclusion?  
   Consider:  
   – if any intervention-group participants got a control-group option or vice versa  
   – if all participants were followed up in each study group (was there loss-to-follow-up?)  
   – if all the participants' outcomes were analysed by the groups to which they were originally allocated (intention-to-treat analysis)  
   – what additional information would you liked to have seen to make you feel better about this

6. Were the participants in all groups followed up and data collected in the same way?  
   Consider:  
   – if, for example, they were reviewed at the same time intervals and if they received the same amount of attention from researchers and health workers. Any differences may introduce performance bias.

7. Did the study have enough participants to minimise the play of chance?  
   Consider:  
   – if there is a power calculation. This will estimate how many participants are needed to be reasonably sure of finding something important (if it really exists and for a given level of uncertainty about the final result).
8. How are the results presented and what is the main result?

Consider:
- If, for example, the results are presented as a proportion of people experiencing an outcome, such as risks, or as a measurement, such as mean or median differences, or as survival curves and hazards
- How large this size of result is and how meaningful it is
- How you would sum up the bottom-line result of the trial in one sentence

9. How precise are these results?

Consider:
- If the result is precise enough to make a decision
- If a confidence interval was reported. Would your decision about whether or not to use this intervention be the same at the upper confidence limit as at the lower confidence limit?
- If a p-value is reported where confidence intervals are unavailable

10. Were all important outcomes considered so the results can be applied?  ☐ Yes  ☐ Can't tell  ☐ No

Consider whether:
- The people included in the trial could be different from your population in ways that would produce different results
- Your local setting differs much from that of the trial
- You can provide the same treatment in your setting

Consider outcomes from the point of view of the:
- Individual
- Policy maker and professionals
- Families/carers
- Wider community

Consider whether:
- Any benefit reported outweighs any harm and/or cost. If this information is not reported can it be filled in from elsewhere?
- Policy or practice should change as a result of the evidence contained in this trial

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ANNEXURE 2: Johns Hopkins Nursing Evidence-Based Practice Research Evidence Appraisal

Johns Hopkins Nursing Evidence-Based Practice Research Evidence Appraisal

Strength of Evidence

Level I (Strong)

Experimental Study (Randomized Controlled Trial or RCT)
- Study participants (subjects) are randomly assigned to either a treatment (TX) or control (non-treatment) group
- May be:
  - Blind: subject does not know which TX subject is receiving
  - Double-blind: neither subject nor investigator knows which TX subject is receiving
  - Non-blind: both subject and investigator know which TX subject is receiving; used when it is felt that the knowledge of treatment is unimportant

Meta-Analysis of RCTs
- Quantitatively synthesizes and analyzes results of multiple primary studies addressing a similar research question
- Statistically pools results from independent but comparable studies
- Summary statistic (effect size) is expressed in terms of direction (positive, negative, or zero) and magnitude (high, medium, small)

Level II

Quasi-Experimental Study
- Always includes manipulation of an independent variable
- Lack either random assignment or control group
- Findings must be considered in light of threats to validity (particularly selection)

Level III

Non-Experimental Study
- No manipulation of the independent variable
- Can be descriptive, comparative, or correlational
- Often uses secondary data
- Findings must be considered in light of threats to validity (particularly selection, lack of severity or co-morbidity adjustment)

Qualitative Study
- Expansive in nature, such as interviews, observations, or focus groups
- Starting point for studies of questions for which little research currently exists
- Sample sizes are usually small and study results are used to design stronger studies that are more objective and quantifiable

Meta-Synthesis
- Research technique that critically analyzes and synthesizes findings from qualitative research
- Identifies key concepts and metaphors and determines their relationships to each other
- Aim is not to produce a summary statistic, but rather to interpret and translate findings

Quality of Evidence (Scientific Evidence)

A High: consistent results, sufficient sample size, adequate control, and definitive conclusions; consistent recommendations based on extensive literature review that includes thoughtful reference to scientific evidence

B Good: reasonably consistent results, sufficient sample size, some control, and fairly definitive conclusions; reasonably consistent recommendations based on fairly comprehensive literature review that includes some reference to scientific evidence

C Low/Major flaw: little evidence with inconsistent results, insufficient sample size, conclusions cannot be drawn

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### Johns Hopkins Nursing Evidence-Based Practice Research Evidence Appraisal

**Evidence Level:**

<table>
<thead>
<tr>
<th>Article Title</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Author(s)</td>
<td>Date</td>
</tr>
<tr>
<td>Journal</td>
<td>Sample (Composition)</td>
</tr>
</tbody>
</table>

**SUTING:**

- Experimental
- Meta-analysis
- Qualitative
- Meta-synthesis

**Does this study apply to the population targeted by my practice question?**

- Yes
- No

**Strength of Study Design**

- Was sample size adequate and appropriate? □ Yes □ No
- Were study participants randomized? □ Yes □ No
- Was there an intervention? □ Yes □ No
- Was there a control group? □ Yes □ No
- If there was more than one group, were groups equally treated, except for the intervention? □ Yes □ No
- Was there adequate description of the data collection methods? □ Yes □ No

**Study Results**

- Were results clearly presented? □ Yes □ No
- Was an interpretation/analysis provided? □ Yes □ No

**Study Conclusions**

- Were conclusions based on clearly presented results? □ Yes □ No
- Were study limitations identified and discussed? □ Yes □ No

**Pertinent Study Findings and Recommendations**

**Will the results help in caring for my patients?** □ Yes □ No

**Evidence Rating (scales on back)**

<table>
<thead>
<tr>
<th>Strength of Evidence</th>
<th>Quality of Evidence (check one)</th>
</tr>
</thead>
<tbody>
<tr>
<td>High (A)</td>
<td>Good (B)</td>
</tr>
</tbody>
</table>
### ANNEXURES 3: Quality Criteria Checklist: Primary Research

#### Appendix B: Quality Criteria Checklist: Primary Research

**Symbols Used**
- **Positive**: Indicates that the report has clearly addressed issues of inclusion/exclusion, bias, generalizability, and data collection and analysis.
- **Negative**: Indicates that these issues have not been adequately addressed.
- **Neutral**: Indicates that the report is neither exceptionally strong nor exceptionally weak.

#### Quality Criteria Checklist Primary Research

<table>
<thead>
<tr>
<th><strong>RELEVANCE QUESTIONS</strong></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patient/patient population group? (NA for some Eti studies)</td>
<td>Yes</td>
<td>No</td>
<td>Unclear</td>
</tr>
<tr>
<td>2. Did the authors study an outcome (dependent variable) or topic that the patient/patient population group would care about?</td>
<td>Yes</td>
<td>No</td>
<td>Unclear</td>
</tr>
<tr>
<td>3. Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to clinicians/practitioners?</td>
<td>Yes</td>
<td>No</td>
<td>Unclear</td>
</tr>
<tr>
<td>4. Is the intervention or procedure feasible? (NA for some epidemiological studies)</td>
<td>Yes</td>
<td>No</td>
<td>Unclear</td>
</tr>
</tbody>
</table>

If the answers to all of the above relevance questions are "Yes," the report is eligible for designation with a plus (+) on the Evidence Quality Worksheet, depending on answers to the following validity questions.

<table>
<thead>
<tr>
<th><strong>VALIDITY QUESTIONS</strong></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Was the research question clearly stated?</td>
<td>Yes</td>
<td>No</td>
<td>Unclear</td>
</tr>
<tr>
<td>1.1 Was the specific intervention(s) or procedure (independent variable(s)) identified?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.2 Was the outcome(s) (dependent variable(s)) clearly identified?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.3 Were the target population and setting specified?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Was the selection of study subjects/patients free from bias?</td>
<td>Yes</td>
<td>No</td>
<td>Unclear</td>
</tr>
<tr>
<td>2.1 Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?</td>
<td>Yes</td>
<td>No</td>
<td>Unclear</td>
</tr>
<tr>
<td>2.2 Were criteria applied equally to all study groups?</td>
<td>Yes</td>
<td>No</td>
<td>Unclear</td>
</tr>
<tr>
<td>2.3 Were health, demographics, and other characteristics of subjects described?</td>
<td>Yes</td>
<td>No</td>
<td>Unclear</td>
</tr>
<tr>
<td>2.4 Were the subjects/patients a representative sample of the relevant population?</td>
<td>Yes</td>
<td>No</td>
<td>Unclear</td>
</tr>
<tr>
<td>3. Were study groups comparable?</td>
<td>Yes</td>
<td>No</td>
<td>Unclear</td>
</tr>
<tr>
<td>3.1 Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)</td>
<td>Yes</td>
<td>No</td>
<td>Unclear</td>
</tr>
<tr>
<td>3.2 Were distributions of disease status, prognostic factors, and other factors (e.g., demographic) similar across study groups at baseline?</td>
<td>Yes</td>
<td>No</td>
<td>Unclear</td>
</tr>
<tr>
<td>3.3 Were concurrent controls used? (Concurrent preferred over historical controls.)</td>
<td>Yes</td>
<td>No</td>
<td>Unclear</td>
</tr>
<tr>
<td>3.4 If cohort study or cross-sectional study, were groups comparable on important confounding factors and if so, were interactions differences accounted for by using appropriate adjustments in statistical analysis?</td>
<td>Yes</td>
<td>No</td>
<td>Unclear</td>
</tr>
<tr>
<td>3.5 If case-control study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some case-control studies.)</td>
<td>Yes</td>
<td>No</td>
<td>Unclear</td>
</tr>
<tr>
<td>3.6 If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., &quot;gold standard&quot;)?</td>
<td>Yes</td>
<td>No</td>
<td>Unclear</td>
</tr>
<tr>
<td>4. Method of handling withdrawals described?</td>
<td>Yes</td>
<td>No</td>
<td>Unclear</td>
</tr>
<tr>
<td>4.1 Were follow-up methods described and the same for all groups?</td>
<td>Yes</td>
<td>No</td>
<td>Unclear</td>
</tr>
<tr>
<td>4.2 Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and response rate (cross-sectional studies) described for each group?</td>
<td>Yes</td>
<td>No</td>
<td>Unclear</td>
</tr>
<tr>
<td>4.3 Were all enrolled subjects/patients in the original sample accounted for?</td>
<td>Yes</td>
<td>No</td>
<td>Unclear</td>
</tr>
<tr>
<td>4.4 Were reasons for withdrawals similar across groups?</td>
<td>Yes</td>
<td>No</td>
<td>Unclear</td>
</tr>
</tbody>
</table>
### APPENDICES

<p>| | | | | | |</p>
<table>
<thead>
<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>4.5</td>
<td>If diagnostic test, was decision to perform reference test not dependent on results of test under study?</td>
<td>Yes</td>
<td>No</td>
<td>Unclear</td>
<td>N/A</td>
</tr>
<tr>
<td>5.</td>
<td>Were <strong>blinding</strong> used to prevent introduction of bias?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.1</td>
<td>In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?</td>
<td>Yes</td>
<td>No</td>
<td>Unclear</td>
<td>N/A</td>
</tr>
<tr>
<td>5.2</td>
<td>Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)</td>
<td>Yes</td>
<td>No</td>
<td>Unclear</td>
<td>N/A</td>
</tr>
<tr>
<td>5.3</td>
<td>In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?</td>
<td>Yes</td>
<td>No</td>
<td>Unclear</td>
<td>N/A</td>
</tr>
<tr>
<td>5.4</td>
<td>In case control study, was case definition explicit and case ascertainment not influenced by exposure status?</td>
<td>Yes</td>
<td>No</td>
<td>Unclear</td>
<td>N/A</td>
</tr>
<tr>
<td>5.5</td>
<td>In diagnostic study, were test results blinded to patient history and other test results?</td>
<td>Yes</td>
<td>No</td>
<td>Unclear</td>
<td>N/A</td>
</tr>
<tr>
<td>6.</td>
<td>Were <strong>intervention/therapy</strong> regimen/exposure factor or procedure and any comparators described in detail? Were <strong>intervention factors</strong> described?</td>
<td>Yes</td>
<td>No</td>
<td>Unclear</td>
<td>N/A</td>
</tr>
<tr>
<td>6.1</td>
<td>In RCT or other intervention trial, were protocols described for all regimen studied?</td>
<td>Yes</td>
<td>No</td>
<td>Unclear</td>
<td>N/A</td>
</tr>
<tr>
<td>6.2</td>
<td>In observational study, were interventions, study settings, and clinicians/provider described?</td>
<td>Yes</td>
<td>No</td>
<td>Unclear</td>
<td>N/A</td>
</tr>
<tr>
<td>6.3</td>
<td>Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?</td>
<td>Yes</td>
<td>No</td>
<td>Unclear</td>
<td>N/A</td>
</tr>
<tr>
<td>6.4</td>
<td>Was the amount of exposure and, if relevant, subject/patient compliance measured?</td>
<td>Yes</td>
<td>No</td>
<td>Unclear</td>
<td>N/A</td>
</tr>
<tr>
<td>6.5</td>
<td>Were complications (e.g., ancillary treatments, other therapies) described?</td>
<td>Yes</td>
<td>No</td>
<td>Unclear</td>
<td>N/A</td>
</tr>
<tr>
<td>6.6</td>
<td>Were extra or unplanned treatments described?</td>
<td>Yes</td>
<td>No</td>
<td>Unclear</td>
<td>N/A</td>
</tr>
<tr>
<td>6.7</td>
<td>Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?</td>
<td>Yes</td>
<td>No</td>
<td>Unclear</td>
<td>N/A</td>
</tr>
<tr>
<td>6.8</td>
<td>In diagnostic study, were details of test administration and replication sufficient?</td>
<td>Yes</td>
<td>No</td>
<td>Unclear</td>
<td>N/A</td>
</tr>
<tr>
<td>7.</td>
<td>Were <strong>outcome</strong> clearly defined and the measurements valid and reliable?</td>
<td>Yes</td>
<td>No</td>
<td>Unclear</td>
<td>N/A</td>
</tr>
<tr>
<td>7.1</td>
<td>Were primary and secondary endpoints described and relevant to the question?</td>
<td>Yes</td>
<td>No</td>
<td>Unclear</td>
<td>N/A</td>
</tr>
<tr>
<td>7.2</td>
<td>Were outcome measures appropriate to question and outcomes of concern?</td>
<td>Yes</td>
<td>No</td>
<td>Unclear</td>
<td>N/A</td>
</tr>
<tr>
<td>7.3</td>
<td>Was the period of follow-up long enough for important outcome(s) to occur?</td>
<td>Yes</td>
<td>No</td>
<td>Unclear</td>
<td>N/A</td>
</tr>
<tr>
<td>7.4</td>
<td>Were the observations and measurements based on standard, valid, and reliable data collection instruments/test procedures?</td>
<td>Yes</td>
<td>No</td>
<td>Unclear</td>
<td>N/A</td>
</tr>
<tr>
<td>7.5</td>
<td>Was the measurement of effect at an appropriate level of precision?</td>
<td>Yes</td>
<td>No</td>
<td>Unclear</td>
<td>N/A</td>
</tr>
<tr>
<td>7.6</td>
<td>Were other factors accounted for (measured) that could affect outcomes?</td>
<td>Yes</td>
<td>No</td>
<td>Unclear</td>
<td>N/A</td>
</tr>
<tr>
<td>7.7</td>
<td>Were the measurements conducted consistently across groups?</td>
<td>Yes</td>
<td>No</td>
<td>Unclear</td>
<td>N/A</td>
</tr>
<tr>
<td>8.</td>
<td>Was the <strong>statistical analysis</strong> appropriate for the study design and type of outcome indicators?</td>
<td>Yes</td>
<td>No</td>
<td>Unclear</td>
<td>N/A</td>
</tr>
<tr>
<td>8.1</td>
<td>Were statistical analyses adequately described the results reported appropriately?</td>
<td>Yes</td>
<td>No</td>
<td>Unclear</td>
<td>N/A</td>
</tr>
<tr>
<td>8.2</td>
<td>Were correct statistical tests used and assumptions of test not violated?</td>
<td>Yes</td>
<td>No</td>
<td>Unclear</td>
<td>N/A</td>
</tr>
<tr>
<td>8.3</td>
<td>Were statistical reported with levels of significance and/or confidence intervals?</td>
<td>Yes</td>
<td>No</td>
<td>Unclear</td>
<td>N/A</td>
</tr>
<tr>
<td>8.4</td>
<td>Was &quot;intent to treat&quot; analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a close-response analysis)?</td>
<td>Yes</td>
<td>No</td>
<td>Unclear</td>
<td>N/A</td>
</tr>
<tr>
<td>8.5</td>
<td>Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?</td>
<td>Yes</td>
<td>No</td>
<td>Unclear</td>
<td>N/A</td>
</tr>
<tr>
<td>8.6</td>
<td>Was clinical significance as well as statistical significance reported?</td>
<td>Yes</td>
<td>No</td>
<td>Unclear</td>
<td>N/A</td>
</tr>
<tr>
<td>8.7</td>
<td>If negative findings, was a power calculation reported to address type 2 error?</td>
<td>Yes</td>
<td>No</td>
<td>Unclear</td>
<td>N/A</td>
</tr>
<tr>
<td>9.</td>
<td>Are conclusions supported by results with biases and limitations taken into consideration?</td>
<td>Yes</td>
<td>No</td>
<td>Unclear</td>
<td>N/A</td>
</tr>
<tr>
<td>9.1</td>
<td>Is there a discussion of findings?</td>
<td>Yes</td>
<td>No</td>
<td>Unclear</td>
<td>N/A</td>
</tr>
<tr>
<td>9.2</td>
<td>Are biases and study limitations identified and discussed?</td>
<td>Yes</td>
<td>No</td>
<td>Unclear</td>
<td>N/A</td>
</tr>
<tr>
<td>10.</td>
<td>Is bias due to study's funding or sponsorship unlikely?</td>
<td>Yes</td>
<td>No</td>
<td>Unclear</td>
<td>N/A</td>
</tr>
<tr>
<td>10.1</td>
<td>Were sources of funding and investigators' affiliations described?</td>
<td>Yes</td>
<td>No</td>
<td>Unclear</td>
<td>N/A</td>
</tr>
<tr>
<td>10.2</td>
<td>Was there no apparent conflict of interest?</td>
<td>Yes</td>
<td>No</td>
<td>Unclear</td>
<td>N/A</td>
</tr>
</tbody>
</table>

**NITNAS/NEGATIVE (X)**

If most (or more) of the answers to the above validity questions are "No," the report should be designated with a minus (-) symbol on the Evidence Table.
### APPENDICES

<table>
<thead>
<tr>
<th>NEUTRAL (0)</th>
<th>If the answers to validity criteria questions 2, 3, 6, and 7 do not indicate that the study is exceptionally strong, the report should be designated with a neutral (0) symbol on the Evidence Worksheet.</th>
</tr>
</thead>
<tbody>
<tr>
<td>PLUSPOSITIVE (+)</td>
<td>If most of the answers to the above validity questions are &quot;yes&quot; (including criteria 2, 3, 6, 7 and at least one additional &quot;yes&quot;), the report should be designated with a plus symbol (+) on the Evidence Worksheet.</td>
</tr>
</tbody>
</table>