

**PSYCHOEDUCATIONAL PROGRAM TO IMPROVE
MEDICATION ADHERENCE IN ADULT PATIENTS WITH
BIPOLAR DISORDER: EVIDENCE-BASED NURSING**

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Thematic Paper
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ABSTRACT

The purpose of this study was to summarize evidence related to a psychoeducational program to improve medication adherence in adult patients with bipolar disorders. The research evidence was searched from electronic databases and the quality and the strength of the evidence were evaluated. The quality of the evidence was evaluated using three characteristics: validity, reliability, and applicability. Seven studies met the inclusion criteria: one was a systematic review of randomized controlled trials, five were randomized controlled trials and one was a pretest-posttest study design. After analysis and summary of the evidence, recommendations were proposed.

The results found that the appropriate form of the psychoeducational program to improve the medication adherence for patients with bipolar disorders is either for individuals or in a group form. Regarding the group form, there were two types of group psychoeducational programs: The Barcelona Bipolar Disorder Program group psychoeducation, which consisted of 21 structure sessions and the brief group psychoeducation, which consisted of 6-12 sessions. The components of the psychoeducational program consisted of structured information about illness awareness, treatment compliance, early detection of prodromal symptoms and recurrences and life style regularity. The individual psychoeducation is a short form of the Barcelona Bipolar Disorder Program and consisted of eight weekly sessions. The individual intervention continued using scheduled monthly telephone contact for the subsequent 18 months. Both group and individual psychoeducation were conducted during the time the patients were being euthymic. The outcome of the psychoeducational program was measured using the Medication Adherence Rating Scale (MARS). The interventions of these programs can be implemented in the clinical setting in the Bangladeshi context. The healthcare setting should prepare personnel through training and develop a manual for the psychoeducation program in Bangladesh.

KEY WORDS: BIPOLAR DISORDER/MANIA/PSYCHOEDUCATIONAL PROGRAM/ MEDICATION ADHERENCE/ EVIDENCE-BASED NURSING

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CHAPTER I

INTRODUCTION

1.1 Background and significance of the clinical problem

1.1.1 Prevalence of bipolar disorders among adults

Bipolar disorder (BD) is an extensive disorder with persistent mental problems manifested through major impairment of cognitive function and damaged quality of life, despite the periods of euthymia (Saunders, Novick, Fernandez-Mendoza, Kamali, & McInnis et al, 2013).

Around the world, approximately 1% of the global population is affected by bipolar disorder (BD) (Belmaker, 2004). The WHO reveals the estimated rate of bipolar affective disorder to be 4.1 million in the USA, 4.4 million in Europe, 7.2 million in South East Asia, 2.7 million in Africa and 8.9 million in the Western pacific region (WHO, 2004). One study recently found that 7.5 million adults are affected by bipolar disorder in the USA (Lage & Hassan, 2009). In Canada, a community health survey found the lifetime prevalence rate of (BD) to be 2.2% (Schaffer, Cairney, Cheung, Veldhuizen, & Levitt, 2006). In the United Kingdom (UK), a cross-sectional study revealed the estimated prevalence of bipolar disorder to be 1.3% (Smith et al, 2013). In Korea, the incidence of bipolar I disorder has been found to range from 0.16% to 0.44%, which is extensively lower than the rate stated in western countries (Bae et al, 2013). In Egypt, a study showed bipolar disorder to be one of the most important lifelong psychiatric disorders with a lifetime prevalence of 0.3–1.6% and equal occurrence among men and women (El-Hadidy, Abdeen, Abd El-Aziz, & Al-Harrass, 2014). In Singapore, Singapore Mental Health Study (SMHS) a population-based survey revealed the incidence of lifetime major depressive disorder (MDD) to be 5.8% and 1.2% for BD (Chong et al, 2012).

In Bangladesh, in the author's health care setting, particularly in the psychiatric field where there are no specific data on BD. According to the World Health Organization (WHO, 2007, statistics from a National Mental Health Review in 2003-2005 indicated that 16.05% of the adult population in the state is suffering from psychological disorders Health Bulletin (2013) revealed that 39.61% of bipolar affective disorder patients are admitted to tertiary level hospitals, especially to the psychiatric unit. Another study revealed that 12.17% of bipolar mood disorder patients are admitted to the mental health institute in Dhaka. Furthermore, in the same Mental Health (NIMH) study, Dhaka revealed that 11.19% of patients were suffering from major depressive disorder (MDD) and 8.95% from BD (Fahmida, Wahab, & Rahman, 2009).

Bipolar disorder is characterized by the occurrence of at least one manic episode during the patient's lifetime. The diagnosis criteria for manic episodes are as follows (DSM-IV-TR, 1994):

A. A distinct period of abnormally and persistently elevated, expansive, or irritable moods lasting approximately one week.

B. Three (or more) of the following symptoms persisting during the period of mood disturbance:

1. Inflated self-esteem or grandiosity.
2. Decreased need for sleep.
3. More talkative than usual or pressure to keep talking.
4. Flight of ideas or subjective experience that thoughts are racing.
5. Distractibility.
6. Increases in goal-directed activity or psychomotor agitation.
7. Excessive involvement in pleasurable activities that have a high potential for painful consequences.

In addition, most patients have also experienced one or more depressive episodes at one time or another. In the intervals between these episodes, the majority of patients return to their normal states of well-being. Thus, bipolar disorder is a "cyclic" or "periodic" illness with patients cycling "up" into a manic or mixed-manic episode, then returning to normal and cycling "down" into a depressive episode from which they also eventually more or less recover (DSM-IV-TR, 1994).

1.1.2 The impacts of bipolar disorder on patients, families, society, global populations and economies are as follows

Impact on patients

It has been shown that people with BD experience purposeful impairment. Patients with BD complain about the complexity of their services and approximately 20% of these patients have no ability to carry out their activities of daily living (ADL) permanently. Furthermore, patients with BD state fewer social connections with friends and family, poor interest or enjoyment in leisure time activities, inadequate ability to maintain personal duties and poor cognitive performance (Vazquez, Kapczynski, Magalhães, Cordova, Lopez and Tohen et al, 2010)

Impact on families

Patients with BD and their family members suffer from a vast amount of stress. Family members can provide essential help in favor of younger persons along with manic depression. However, familiarity can also create a great deal of tension. Bipolar disorders frequently increase at the same period when young person are self-regulating from their families and taking on adult responsibilities (daily activities). For example, the young people of a family might be maturing and seeking employment outside the home. While they feel uneasy and would like to go back home to live for a longer period of time, these young people also need support/care from family members, because BD can be occasionally shameful and annoying as well as upsetting for youthful individuals in a family (Macneil, Hasty, Conus, Berk, & Scott, 2010).

Social impact

BD is a lifetime illness manifested by stages of frame of mind alterations, occasional excessiveness and ongoing psychotic episodes. Consequently, patients are determinedly and repeatedly sick. Bipolar disorder patients express considerable loads of social destruction with high rates of marital separation and occupational disadvantages. The financial costs of manic depression are important and comprise treatment expenditures used for the illness, management of its psychiatric and non-

psychiatric co-morbidities, psychological health check-up expenses, alcohol and pharmacological treatment expenses (Ostacher, 2006).

Global impact

The destruction of global functioning seems to be strongly associated with higher numbers of episodes among patients with BD and long-term illness. Most bipolar patients with long duration of illness report lower employment qualifications and occupational status. It is possible that the high number of episodes may determine long-lasting biochemical changes in the brain that could have some consequences on global functioning in bipolar patients. Patients with BD and multi-episodes are more susceptible to cognitive destruction with potential consequences of poor social and occupational adaptation (Di Marzo et al, 2006).

Economic impact

Inadequate management of patients with BD is likely to increase the cost of care, as well as the burden of disease on daily life, families, care-givers and society as a whole (Stimmel, 2004).

In the USA, one study examined and recognized the economic impact of BD as a major psychological health problem. In the UK, however, the calculated national annual costs of treatment for BD are 4.59 billion pounds, while the costs of unemployment and suicide are 1,510 million to 1,579 million pounds, respectively with hospitalization during acute episodes on behalf of the major element at 1999/2000 prices (Fajutrao, Locklear, & Hayes, 2009).

1.1.3 Prevalence of drug non-adherence

Worldwide, the medication non-adherence rate for BD is 48.1% (Lage & Hassan, 2009). Another study conducted in the USA found the estimated rates for non-adherence in bipolar illness to differ significantly among study inhabitants and apparatus used to evaluate the compliance. Conversely, it is anticipated that 20% to 60% (mean = 40%) of people with manic depression are frequently non-adherent with their prescribed medications at any particular moment (Depp, Moore, & Jeste, 2008). In the USA, approximately 21% to 50% of the population with manic episodes carries the

highest risk of non-adherence to recommended treatment regimens (Foster, Sheehan, & Johns, 2011).

More recent studies report the estimated rate of medication non-adherence nationwide to be 48.4% in the USA, 11.8% in Australia, 40.3% in Nigeria, 30% in France and 58.4% in Norway. According to findings, the highest non-adherence rate for BD occurred in Norway and the second highest happened in the USA. Australia had the lowest rate of medication non-adherence due to caregiver awareness and patient participation in interventional programs and taking medication regularly supervised by a psychiatrist (Kane, Kishimoto & Correll, 2013)._ The occurrence of medical non-adherence remains a difficult crisis in dealing with bipolar disorder patients. A recently published review of psychiatric specialists from eight European countries estimated that 57% of patients with bipolar are partly or totally non-compliant with prescribed medications (Montes, Maurino, deDios & Medina, 2013), And in Germany, 52% of hospitalized BD patients were initially diagnosed through mania or varied episodes in which they were partially or totally non-adherent to medication (Kraemer et al, 2013). Medication non-adherence is a common problem among bipolar patients. A prospective and longitudinal study in Iran showed the rate of medication non-adherence to be more than 60% of all patients with BD who are at least incompletely non-adherent to medications (Sharifi, Shabani, & Ahmadzad-Asl, 2009). In India, a study revealed the estimated rate of medication non-adherence to be 41% of people with BD. A similar study in Pakistan showed the rate of medication non-adherence to be approximately 39%; the study was conducted at a tertiary care level hospital (Tesfay, Girma, & Dehning, 2013).

In Bangladesh, there are no exact data on the drug non-adherence of BD patients. Basically, drug non-adherence is a major clinical problem in the psychiatric field in Bangladesh. When psychiatrists take history from hospitalized patients they diagnose that most of the patients are suffering relapse. Therefore, in the field of psychiatry in Bangladesh, psychiatrists should take necessary action toward preventing relapse and improving adherence among the patients with BD.

1.1.4 Factors associated with drug non-adherence among patients with bipolar disorder

More or less than 50% of patients are non-adherent in developed countries because the patients do not take medications regularly as prescribed by physicians. Drug adherence, however, is absolutely not an issue of accountability for the sufferer. Compliance trends can yield better health outcomes than developments into definite medical treatment. Medication adherence behaviors are multi-dimensional with engaged patients and doctors as well as method of mechanisms (Brown and Bussell, 2011).

Medication non-adherence is predictive or prognostic of a number of unhelpful effects in patients with BD and is accountable for the gap of efficacy-effectiveness of the disorder and the discontinuation of mood stabilizers which places these patients at high risk for relapse or recurrence. During the manic episodes of bipolar disorder, the patient always stays away from psychiatric drugs due to thoughts that taking medicine will result in depression due to the side effects of drugs and a feeling of lost enjoyment with friends and family members in daily life. Medication adherence is a very significant issue among patients with BD because treatment compliance plays an important role in acquiring the best outcomes in treatment (Gaudiano, Weinstock, a Miler, 2008). The World Health Organization defines drug adherence broadly as the extent to which a person's behavior results in taking medication, following a diet, and/or executing lifestyle changes in concurrence with recommendations from a healthcare provider (WHO Report, 2003). Hence, there is an urgent need to recognize gainful, successful and essential interventions for improving medication adherence in patients with bipolar disorder. Medication adherence helps to reduce the rate of relapse or recurrence and maintain quality of life style.

Risk predictors linked with medical non-adherence in bipolar disorder include the following different categories:

Socio-demographic factors: Age, education, age at onset of BD, number of manic episodes, health care professionals, doctor-patient relationships, mental health, social health, gender and ethnicity are all included. This type of factors is responsible for non-adherence to medication in the treatment of BD (Col, Caykoylu,

Ugurlu and Ugurlu 2014; Rosa, Marco, Fachel, Kapczinski, Stein and Barros, 2007; Javadpour, Hedayati, Dehbozorgi and Azizi, 2013; Wang and Henning, 2010; and Sylvia et al, 2013)

Personal factors: Self efficacy for drug avoidance, level of patients' knowledge about the disorder, patients' attitudes about treatment, negative attitudes toward drugs in general, depression scores, manic scores, attitudes toward medication, less satisfaction about treatment and experiences of feeling neglected with lower lithium levels, bipolar disorder, severity index, range of impaired functioning and insight (Magura, Rosenblum, and Fong, 2011; Sajatovic et al, 2009; Javadpour, Hedayati, Dehbozorgi and Azizi, 2013; Wang and Henning, 2010; and Sylvia et al, 2013).

Social and environmental factors: Recovery support, peer support for abstinence, recovery-promoting behaviors and quality of therapeutic alliance all constitute risk factors (Magura, Rosenblum, and Fong, 2011; and Sylvia et al, 2013).

Clinical/medication-related factors: Medication side effects, fear of side effects, complexity of medical regimens, medication interactions, difficulties with medication routines, incidence and intensity of side effects, and adverse effects are the clinical risk factors for medication non-adherence (Rosa et al, 2007; & Sylvia et al, 2013).

Physical factors: Physical healths are closely associated with risk factors for medication non-adherence of BD such as weight gain, metabolic syndrome, smoking and diabetes contributing to cardiovascular disease and early death (Young and Grunze, 2013).

According to the above research studies, various predictors are linked with the medication non-adherence of patients with BD, including socio-demographic factors, personal factors, social/environmental factors, clinical/medication-related factors, and physical factors.

1.1.5 Mental Health services for psychiatric patients in Bangladesh

Bangladesh is a developing country divided into 64 executive districts and 496 sub-districts (Upazila). The people of every district receive services from the District General Hospital and every Upazila Health Complex as well as several Rural Health Centers providing services for people in certain areas. At the community level, the primary health care providers are accountable for providing services with primary health care for the inhabitants living in the communities under their jurisdiction. There is no definite mental health regulatory body, and mental health services are not available in Bangladesh. The same shortage affects the orders of conditions in catchment/service areas. For each 100,000 people in the general population, approximately 26 service users have 50 outpatient psychological health treatment conveniences in the countryside. A small number of patients are covered by government facilities and accept a number of psychiatric medications from the services. There is no scope covering mental illness by providing social insurance systems. In the country, there is no review body of human rights to supervise mental health services. From 2003–2005 the National Mental Health in Bangladesh review indicated that 16.05% of the adult population in the countryside is affected by psychological disorders in which the incidence is considerably associated with socio-economical dispossession at rates of 19% in females and 12.9% in males. Hence, the prevalence is higher in females than males. Primarily, 20% of patients are diagnosed with mood disorder, 30% with schizophrenia and 20% with neurotic disorder requiring care from outpatient services. Only a small quantity of medical appointments is given to MHP together with medical-based and non-medical-based primary health-service centers. Nurses and other non-medical health workers in primary health-care have no authority to prescribe psychiatric drugs.

The people of Bangladesh have always had a tendency to visit with various kinds of service/care providers to check-up on psychological and non-psychological problems. People usually go to consult with intimate acquaintances, family members, local or spiritual healers, health care centers, local practitioners and other health practitioners. The community inhabitants of Bangladesh show different kinds of treatment choices for trained health practitioners, religious healers and conventional healers or ayurvedhic practitioners. The categories of treatment facilities vary from

modern medicine to conventional medicine or personal beliefs from a rural perspective. From the perspective of Bangladeshi private practitioners, individual common health practitioners include licensed doctors achieving essential medical degrees (MBBS) from the Bangladesh Medical & Dental Council (BMDC). The villagers of Bangladesh in certain area are deprived from doctor's visits or appointments with specialists (like the GP system in the UK). Relatively, patients can choose from primary, secondary or tertiary level care centers, depending on their comfort and facility. A local healer is generally known as 'Ojha' and a spiritual healer is usually known as 'Fakir Baba' or 'Pirr' or 'Sufi' or 'Huzur' in Bangladeshi rural community traditions. There is a common faith that carrying out rituals or great verses will free people from psychological diseases. In Bangladesh, most of the general primary care providers are private practitioners at 44% followed by spiritual healers at 22%, other medical facilities at 12% and general hospital facilities at 4% (Giasuddin et al, 2012).

In Bangladesh, most people live in villages and come to visit the doctor when the condition of their health becomes more serious. They do not have proper education, knowledge about illness or available resources, especially mental health services. Rather they believe in social stigma and do not always have familial support, depending on traditional healers. Traditional treatment is not appropriate for patients with bipolar disorder. Without proper psychiatric treatment, these patients do not take psychiatric medications as regularly prescribed by psychiatrists. Consequently, the patients become non-adherent and suffer relapse with BD. Most patients even maintain suicidal thoughts or ideas about death.

1.1.6 Management of bipolar disorder from clinical practice guidelines

The basic problem for persons with BD is that their characteristic mood sequences are more excessive: they may be euphoric for phases of time and engage in thoughtless behaviors during manic periods. This may be followed by a grinding depression that may also be characterized by self-destructive impulses or behaviors. Bipolar I disorder requires a history of at least one manic episode, whereas bipolar II disorder may carry similar mood extremes without a history of mania. It is important to distinguish BD from substance use disorders (e.g. cocaine abuse) or other medical

conditions (e.g. hyperthyroidism) that may mimic a similar course of mood swings. The medical management of BD consists of a broad array of interventions and activities. Regardless of the modalities selected, it is important to provide medical management through all phases of treatment.

Acute treatment phases of bipolar disorder

Severe manic or mixed episodes: Antipsychotic drugs such as lithium plus or valproate plus are the first line of pharmacological treatment for more severe manic or mixed episodes. Monotherapy with lithium, valproate, or an antipsychotic drug such as olanzapine may be sufficient treatment for less severely ill patients with BD. Short-term adjunctive treatment with a benzodiazepine may also be helpful. For mixed episodes, valproate may be preferred over lithium. Atypical antipsychotics are favored over typical antipsychotics due to more benign side effect reports.

Bipolar depression: The first-line of treatment for bipolar depression is lithium or lamotrigine. Antidepressant monotherapy is not recommended. Selective Serotonin Reuptake Inhibitors (SSRIs) are believed to sometimes precipitate manic episodes. Lithium with an antidepressant is an alternative to antidepressant monotherapy.

Rapid cycling: Rapid cycling refers to the occurrence of four or more mood disturbances within a single year that meet criteria for a major depressive, mixed, manic, or hypomanic episode. These episodes are demarcated either by partial or full remission for at least two months or a switch to an episode of opposite polarity (e.g., from a major depressive to a manic episode). The initial intervention in patients who experience rapid cycling is to identify and treat any medical conditions, such as hypothyroidism or drug or alcohol use that may contribute to cycling. Certain medications, particularly antidepressants, may also contribute to cycling and should be tapered or eliminated, if possible. The initial treatment for patients who experience rapid cycling should include lithium or valproate; an alternative treatment is lamotrigine. For many patients, combinations of medications are required.

Work-up: While applying lithium, carbamazepine or valproic acid are used, and careful monitoring is required to assure safe and useful dosing. Before taking the medication, clinical indications such as pregnancy should be ruled out by taking a pregnancy test, etc. Every agent has serum plasma concentration, complete blood count, blood chemistries, ECG, urinalysis, PT/PTT, and thyroid function test baseline and routine monitoring protocols.

Following the remission of an acute episode, patients may remain at particularly high risk for relapse over a period of up to 6 months.

Maintenance Treatment Phase of Bipolar Disorder

Maintenance regimens of medication are recommended following a manic episode. The medications with the best empirical evidence to support use in maintenance treatment include lithium and valproate; possible alternatives include lamotrigine, carbamazepine or oxcarbazepine. If one of these medications is used to achieve remission from the most recent depressive or manic episode, it generally should be continued through the maintenance phase of treatment. Maintenance sessions of ECT may also be considered for patients whose acute episodes responded to ECT.

For patients treated with antipsychotic medication during the preceding acute episode, the need for ongoing antipsychotic treatment should be reassessed upon entering maintenance treatment (Harvard Pilgrim Health Care, 2009).

Education: The following themes should be communicated with the patients and their caregivers (Amerigroup Real Solutions in health care, 2009).

- BD is a no-fault illness
- BD is responsive to medication
- Medication may take time to become effective
- Medication adherence must be continued, even when the patient is feeling better.

1.1.7 Strategies to make patients become more adherent to medication

Medication adherence is a significant part of treatment for patients with BD. The improvement of adherence to pharmacotherapy is a universal remedial intention linking non-adherence with higher relapse rates, re-hospitalization and health care costs among people with BD. Hence, medication adherence is essential to a positive outcome because it helps to reduce the rate of relapse, re-hospitalization and decreases or minimizes national health care costs among patients with BD (Deep, Moore, and Jeste, 2008).

Currently emerging psychotherapies for BD (e.g. psycho-education and motivational interviewing) comprise four vital mechanisms: 1. message in relation to the illness (PE in a narrow sense); 2. Suggesting lifestyle regularity (including decrease in substance use); 3. Improving drug adherence; 4. Early identification and managing the features of relapses. Psycho-education should contain information regarding high repetition rates linked with the disease, possible drugs with adverse-effects, recognition of prodromal symptoms from the early and management phases, the effects of avoiding illegal substances and alcohol, the effects continuing schedules, stress management and certain statements regarding problems such as pregnancy and BD, suicide risks, superstition and social problems of bipolar patients correlated with the illness. The most important major targets of psycho-education involve apprehension about the improvement of medication adherence, which is generally extremely unfortunate for bipolar patients while they remain euthymic (Grabski, Mączka, & Dudek, 2007).

Motivational interviews

Motivational Interviewing is defined as a “Client-centered directive method for improving basic motivation to modify by investigating and determining ambivalence. The concept of modification within motivational interviewing is viewed as a procedure involving the following steps: pre-consideration, consideration, preparation, action and continuation. The essential steps of motivational interviewing engage expressing understanding for patients, supporting self-efficacy with a solid approach, focusing on inconsistencies among the patient’s current health behaviors and center importance as well as rising and falling with resistance (the clinician does

not challenge the patient's resistance to medications, but explores the resistance in order to improve recognition of the patient's viewpoint instead (Ehret & Wang, 2013).

The Motivational Interviewing approach is an effective intervention for use with patients who have BD. Featuring the multipart character of bipolar disorder and the unstable stages of mood conditions on the diagonal bipolar range, this study focuses on applying the ideologies and plans of motivational interviewing with bipolar patients who communicate a few stages of ambivalence and are competent in balanced decision-making. Bipolar patients in severe manic or depressive episodes may show psychotic, paranoid or bizarre behavior and frequently require dissimilar interventions with a main concern for protection and self-care. Although the balanced decision-making method was previously re-established, Motivational Interviewing may also be successfully used with this population of patients to improve medication adherence. Motivational Interviewing may be mostly useful for patients with BD who are medication non-adherent due to ambivalence about the advantages and disadvantages of taking prescribed medications or persons who have not completely accepted their mental illness (Laakso, 2012).

Psycho-educational strategy for improving medication adherence and reducing bipolar disorder relapse

Some multimodal psychotherapeutic interventions have been developed for BD such as motivational interviews (MI) and cognitive-behavioral therapy (CBT). All of these treatment approaches include patient psychoeducation (PE). More recent research has also begun to deal with the efficacy of PE as a separate treatment for BD and manual-based standardized PE interventions are currently being developed. As the usefulness of PE in improving treatment compliance and enhancement of long-term outcome in several health situations (cardiac illness, diabetes, asthma) PE can be inspected as a key component of a good medical practice. PE covers basic rights for patients and the right to be informed regarding their illness (Grabski, Mączka, & Dudek, 2007)

PE alone or PE combined with other interventions can reduce the risk of relapse and re-hospitalization with improved medication adherence (Foster, Sheehan & Johns, 2011). The effectiveness of some psychological treatments in reducing relapses has lead

to a relevant pattern change in the treatment of BD, switching from a totally pharmacological therapeutic approach to a combined yet hierarchical representation in which pharmacotherapy plays a vital role and psychological interventions help to cover the gap existing between theoretical efficacy and real life effectiveness. Most of the psychotherapeutic studies recently published and reported to have yielded positive results on maintenance when used as an accurate treatment with efficacy in the treatment of depressive episodes. Interestingly, several groups from all over the world have reported similar positive results and reached very similar conclusions; nearly every intervention tested contained important psycho-educative elements, including both compliance enhancement and early identification of prodromal signs stressing the importance of life style regularity and exploring patients' health beliefs and illness-awareness (Colom & Lam, 2005).

From the above types of interventions, the author selected only PE because PE is a highly important and helpful intervention for patients with BD. Medical treatment supports in the management of bipolar illness in any case of age and psychosocial interventions including PE have been planned as an accessory to medication adherence in the treatment of BD. Psycho-educational intervention is very important for patients and family members/care givers because this type of intervention is provided by psychiatric nurses to patients with BD whereas other interventions such as CBT are provided by expert psychologists or other health care personnel. Psychiatric nurses always serve the patients in the inpatient and outpatient units, including the provision of psycho-educational programs. Hence, it is extremely helpful for patients with BD who can realize or understand psycho-educational programs easily. If patients and family members accept and maintain PE regularly and in compliance with the rules of the intervention sessions, PE will be very helpful and beneficial for both BD patients and families.

1.2 Clinical problem of the study

Drug non-adherence as a clinical problem of bipolar disorder

In the Bangladeshi context, there is only one 500-bed mental hospital at Pabna district and one National Institute of Mental Health & Research (NIMH&R) at Sher-e-Bangla Nagar in Dhaka, the capital city of Bangladesh. There is no specific mental health authority in the country and mental health services are not organized in terms of catchment/service areas. Medication non-adherence is a clinical problem for BD patients in the clinical settings of the author's country, but there is no exact data on the medication non-adherence of BD in the field of psychiatry in Bangladesh. Self-reported experience is the main evidence as follows:

From self-reported experience during the period of visits to the mental health institute & hospital in Dhaka, Bangladesh, the author noticed that doctors identified the reasons for medication non-adherence among BD patients by taking history from the patients and family members/caregivers. Doctors found the leading causes of medication non-adherence among BD patients to be that patients did not take medicine regularly due to the side effects of psychiatric drugs, no proper monitoring and supervision, inadequate caregiver observation of drugs taken by the patients, nursing workloads and poor nursing services in the psychiatric ward, caregiver negligence, no proper family support and ignorance among adult bipolar patients who were at risk for relapse.

Routine care in the author's health care setting

In the Psychiatric Department of the hospital where the author is employed, there are no trained psychiatric nurses, only general nurses providing routine care to patients with BD. Nurses always follow the prescriptions of the psychiatrists and comply with the prescriptions, providing medication for patients, monitoring patients' behaviors and reporting to the doctor on the patients' daily routines. The aforementioned constitute routine care for nurses for patients in the psychiatric unit of the hospital. Nurses in the hospital are unavailable to give extra time to monitor the patients' timely medication adherence due to the shortage of nurses in the hospital. In the author's health care setting, nurses do not know how to provide therapeutic intervention for bipolar patients. Only psychologists provide therapeutic intervention to the patients in the Outpatient Department, not only in the Inpatient Department as in group counseling. Under the aforementioned circumstances, this type of routine care provided by nurses in the hospital

is insufficient for the treatment of bipolar patients. Medical treatment combined with therapeutic intervention can enhance medication adherence among bipolar patients.. For this reason, patients with BD without proper care are non-adherent to prescribed medications.

Medication adherence usually refers to whether or not patients take medications as prescribed in addition to whether or not they continue to take those prescribed medication. As the foundation of many interventions used to improve medication adherence, PE can improve adherence to medication in real life settings (Berk et al, 2010). These strategies involve individual or group sessions with or without the use of written or audiovisual materials on psychiatric diagnoses, medications and potential side effects. Studies have demonstrated that PE is used as the only method for improving adherence. When intervention techniques are used to promote behavior modification, skills and attitudes are used, and increased adherence has been observed in BD patients (Ehret & Wang, 2013).

Psycho-educational intervention has been assessed in clinical trials in large health care systems in the United States and Europe. The content and strength of these interventions may be different. PE can be carried out in either group-based or individual therapy. The number of sessions varies from three sessions to 20 sessions. The content of psycho-educational program generally covers the improvement of self-management skills in handling the illness, providing education regarding the illness and the significance of medication adherence, increasing ability in recognizing early warning signs and avoiding high-risk activities such as substance abuse. Participants are taught to monitor their moods using charts, identify early warning signs of episode onset and connect in action stages in an effort to alter full-blown of mania or depression. A bipolar program in Barcelona, Spain evaluated 21 sessions of a psycho-educational program and found improvement in terms of recurrence, time to depressive symptoms, hypomanic states, and manic episodes as well as lower hospitalization rates (Deep, Moore, and Jeste, 2008).

In summary, the above circumstances describe currently unsatisfactory results and the dearth of knowledge patients have about BD. Findings from the literature review and the above reasons have inspired the author to review the evidence regarding psycho-educational programs for improving medication adherence and

reducing relapse among adult patients with BD in order to eventually improve quality of life.

1.3 Purpose of the study

To summarize the scientific evidences related to psychoeducational programs to improve medication adherence among adult patients with bipolar disorder.

1.4 Expected benefits of the study

It is anticipated that the results of this study will be used as evidence for developing guidelines on psychoeducational programs with the aim of improving medication adherence among adult patients with bipolar disorder.

CHAPTER II

METHODOLOGY

This study was conducted with the objective of summarizing current evidence for psychoeducational program on drug compliance amongst adult patients with bipolar disorder. The author applied the process of searching for evidence-based practice. Search strategy was used to look for and choose the best evidence. Appropriate data of psychoeducational program were evaluated for their important and possibility in terms of considering setting and circumstances, health care resources, and patient favorites and importance. In order to obtain reliable studies, the author described search strategy and set the working process in accordance with the following steps:

2.1 Search Strategy

2.1.1 Search framework

The PICO Framework (Melnik & Fineout-Overholt, 2011) was used to search and select evidence for the effect of psychoeducational program on medication adherence among adult patients with bipolar disorder. Details of this PICO Frameworks are as following:

- P (Population) = adult patients with bipolar disorder.
- I (Intervention) = psychoeducational program
- C (Comparison) = none.
- O (Outcome) = medication adherence.

2.1.2 Scope of search

The effect of psychoeducational program on medication adherence among adult patients with bipolar illness on the basis of authenticates evidence-based practice was searched from the following scope:

1) Keywords were used according to the PICO Framework in the searching

P (Population) = bipolar disorder, manic depression.

I (Intervention) = psychoeducational program.

C (Comparison) = none

O (Outcome) = medication adherence, drug compliance, treatment compliance, level of lithium.

A Boolean Operator was a simple word used in the searching for each PICO component, the investigators collected any synonyms by connecting terms with “OR”, then placed citations which are appropriate for every PICO components by connecting through “AND

2) The databases/sources used for the search

Researchers searched for evidences from studies published internationally as well as from different sources as follows:-

The investigator used electronic databases/sources of Mahidol University library system and searched from many databases such as- Pub Med (Public or publisher Medline), ProQuest, Journal of Ovid full text, Science Direct, Best practice, SpringerLink, SCOPUS, Wiley Online Library and Cumulative Index to Nursing and Allied Health (CHINHAL). Databases from systematic reviews such as the Cochrane Library and from other databases gathering nursing and health science research and evidence based practice, such as Google scholar etc.

3) Type of evidence: The author searched for full text studies such as systematic reviews, randomized single-blind trials and randomized controlled trials and a semi-experimental design (pretest-posttest, randomized control groups) published in English from 2002 to 2013.

4) Selection criteria for evidence-based practice: In order to cover the studies about psychoeducational intervention to improve medication adherence among adults patient with bipolar disorder, the author set the following inclusion criteria;

4.1 Selection of research studies in the form of systematic reviews or meta-analysis from randomized controlled trials (RCTs) or studies with RCTs and quasi experimental design.

4.2 Search for evidence-based practice published in English language during the period from 2003-2014, duration 12 years.

4.3 Selection of only full text articles.

2.2 Appraisal method and levels of evidence

The investigator applied techniques and rules as proposed by Melnyk and Fineout- Overholt (2011) to evaluate the quality, reliability and usefulness of the evidences. The researcher also originate essential substances and examine and make the contents from each evidence-based article through validate research objectives, sampling criteria, sample size the research setting, following methodology, utilization of measurements tools to assess the outcome for the outline of management, data collection method or procedures and valuable idea. Three questions were used to appraise the collected empirical evidences as follows;

2.2.1 Appraisal for research evidence

The author used the following three questions to evaluate the research evidence

1) Are the results of the study valid? (Validity)

Validity means the capacity of an experiment to measure what it tends to measure. The strength of experimental evidence refers to whether the evidence was carried out in the course of scientific method and able to scientifically answer the raising questions. It is expected to answer the question and solve the problems. It is distinguished that some of the factors may be responsible to create unfairness and influence the result of the study or not. To diminish the influencing factors, randomization is a significant part of parcel for the validation of a study and it helps to

make possible result of the evidence-based research to be valid. Participants of most of the studies were randomized into the experimental and control group after recruitment. Some of the studies found that some subjects did not complete their study and reasons were explained. All studies conducted follow-up assessment sessions for the effect of the intervention. Validity is a significant part of an evidence-based research for the reason that it helps to evaluate what types of test/instrument the researcher used and make it sure that using processes are not only principled and cost effective but also accurately assesses the capability to convene all of the necessities and solve the medical problems. In the context of the evidence-based nursing practice the validity of evidence is a key instrument of measurement.

2) What are the results? (Reliability)

Reliability means the capability of assessment to obtain the same result after frequent testing. Reliability should be considered after having the validity of the research findings. The reliability depend on the accuracy, integrity, stability, realization and repeatability of an any kinds of evidence-based research so that anybody can do the similar experiment by using similar apparatus, condition and acquire precisely the same result. The findings of the researches are required to examine and evaluate the validity of the test results. The reliability can be measured by providing intervention effectively. The reliability consists of two parts internal and external reliability. The internal reliability measured in accordance with the consistency and the external reliability measured according to the varieties from the uses of one to another for example, from the research setting referred to the setting in the other context.

3) Will the results help locally? (Applicability)

Applicability means the usefulness of the results in a given situation. The target of any evidence-based research is to apply to the results of the patient individually or in a group participation. For the duration of application the outcome in clinical situation validity, reliability and usefulness for clinical decision making are considered. Usually the randomized control trials studies are treated to the most appropriate research design to compare the effectiveness of dissimilar management to recognize which one is better. The participants are randomly assigned in the RCTs to a particular management is known as the key of a study. These types of evidences are

considered as reliance for applicability in clinical background with skills of the health care professionals, benefits of patients and caregivers or families, support by the authority.

2.2.2 Appraisal for systematic reviews

The author used three questionnaires to appraise the systematic reviews as follows:

1) Are the results of the review valid? (Validity)

Randomized controls trials are usually treated the most appropriate research design to compare the effectiveness of different treatment to identify which is appropriate. Inclusion and exclusion criteria were absolutely met in this systematic review. PubMed and SCOPUS were searched for the RCTs articles were published in English language, without date limits using the key words psychoeducation and bipolar disorder. Most of the randomized controlled trials with reliable methodology fund in this review were published in recent years. Authors identified 13 pioneering studies from 161 articles of randomized controlled trials on the efficacy of psychoeducation are fully met the inclusion criteria. Authors evaluate the efficacy of psychoeducation in the clinical course, treatment adherence and psychosocial functioning of bipolar patients and collected data from controlled trials that used only psychoeducation as a psychosocial approach. After all this review extracted data by using a standard procedure concerning target population, sample size, program provider, content of the PE program, process and outcome. These are appropriate methods of reviewing RCTs, so the results of the review should be valid.

2) What were the results? (Reliability)

The reliability of any systematic review the evidence depend on the accuracy, consistency, achievement and repeatability as any can perform the same experiment with using similar equipment, condition and achieve the exactly same outcome. In the review, the effectiveness of any treatment program largely depends on its ability to target selective problems of the study. Psychoeducational program also appears to be intervention in the enhancement of treatment adherence and improvement of long term outcome of the study. So, the result of the study is reliable.

3) Will the results help in caring for the patients? (Applicability)

During the period of application the results in clinical settings validity, reliability and the usefulness for clinical decision making are considered. The findings from the review are useful about the type of providers and the components of the interventions of bipolar disorder outcomes. Expenditures were not reported but the outcomes of given interventions were significant for the improvement of medication adherence for the patients with bipolar disorder. This type of evidence is assessed as valuable for applicability in clinical settings with abilities of the health care providers, benefits of patients and families/caregivers as well as support by the authority.

Table 2.1 Level of research and empirical evidence according to criteria of Melnyk & Fineout-Overholt, (2011)

Level of evidences	Source of empirical evidences
Level I	Evidence from a systematic review or a meta-analysis of all studies that are RCT, or evidence from guidelines developed from a systematic review of research evidence from randomized control trials.
Level II	Evidence obtained from at least one RCT.
Level III	Evidence obtained from at least one well-designed controlled trials without randomized assignment.
Level IV	Evidence from well-designed case controlled and cohort studies.
Level V	Evidence from a systematic review of descriptive and qualitative study.
Level VI	Evidence from a descriptive or qualitative study.
Level VII	Evidence from the opinions, attitudes of experts on the issues or and/or a report written by expert committee.

CHAPTER III

FINDINGS

3.1 Search results

In the course of searching electronic database of Mahidol University, after searching author identified 23 research articles and after primary screening selected 7 evidences. Among 23 evidences 16 were excluded because 6 of which did not measure the medication adherence, 5 of which did not report relationship with adherence and 5 of which did not focus on psychoeducational intervention. After all 7 evidence-based articles those were to have a specific focus on psychoeducational program to improve medication adherence among adult patients with bipolar disorder. These research articles were interventionally published from 2003 to 2014, duration 12 years and focused in psychoeducational program on medication adherence among adult patients with bipolar disorder.

Table 3.1 List of evidences with their type, level of strength and database

Order	Authors, years, title and publication/source	Type of evidence	Level of evidence /Data base
1	Batista, T.A., Baes, C.V.W., & Juruena, M.F.(2011). Efficacy of psychoeducation in bipolar patients: Systematic review of randomized trials. <i>Psychology & Neuroscience</i> , 4 (3), 409-416.	Systematic review of randomized control trial study	Level=I
2	Bahredar, M.J., Asghamejad-Farid, A.A., Ghanizadeh, A., & Birashk, B. (2014). The efficacy of psycho-educational group program on medication adherence and global functioning of patients with bipolar disorder type-1 <i>IJBNM</i> , 2 (1), 12-19.	Experimental study (RCT)	Level=II/ Google scholar

Table 3.1 List of evidences with their type, level of strength and database (Con't)

Order	Authors, years, title and publication/source	Type of evidence	Level of evidence /Data base
3	Colom, F., Vieta, E., Martinez-Aran, A., Reinares, M., Goikolea, M., Benabarre, A., & Corominas, J. (2003). A randomized trial on the efficacy of group psychoeducation in the prophylaxis of recurrences in bipolar patients whose disease is in remission. <i>Arc Gen Psychiatry</i> , 60, 402-407	Randomized single blind trial study	Level=III./ ProQuest
4	Colom, F., Vieta, E., Sanchez-Moreno, J., Martinez-Aran, A., Reinares, M., & Scott, J. (2005). Stabilizing the stabilizer: group psychoeducation enhances the stability of serum lithium levels. <i>Bipolar Disorder</i> , 7 (5), 32-36.	Randomized single blind trial study	Level=III/Wiley Online Library
5	D'Souza, R., PisKulic, D., & Sundram, S. (2010). A brief dyadic group based psychoeducation program improves relapse rates in recently remitted bipolar disorder: A pilot randomized trial. <i>Journal of Affective Disorder</i> , 120, 272-276.	A pilot randomized control trial study (RCT)	Level=II/ PubMed
6	Javadpur, A., Hedayati, A., Dehbozorgi, G.R., & Azizi, A. (2013). The impact of a simple individual psychoeducation program on quality of life, rate of relapse and medication adherence in bipolar disorder patients. <i>Asian Journal of Psychiatry</i> , 6, 208-213.	Randomized control trial study	Level=II/ SCOPUS
7	Eker, A., & Harkin, S. (2012). Effectiveness of six-week psychoeducation program on adherence of patients with bipolar affective disorder. <i>Journal of Affective Disorders</i> , 138, 409-416.	A semi-experimental design. (pretest-posttest, randomized control groups)	Level=III/ Science Direct

Summary content from each evidence

Article # 1

Title of the article: Efficacy of psychoeducation in bipolar patients: systematic review of randomized trials.

Authors: Batista, T.A., Baes, C.V.W., & Juruena, M.F.

Publication & year: Psychology & Neuroscience, 2011.

Objective: To evaluate the efficacy of psychoeducation in the clinical course, treatment adherence and psychosocial functioning of bipolar patients by collecting data from control trials that used solely psychoeducation as a psychosocial approach.

Method: Systematic review of randomized controlled trials study.

Subject: 13 articles are randomized controlled trials included.

Inclusion criteria

- RCTs used PE.
- Individual with type I or type II BD.
- Combination of the two or their family/caregivers.
- PE included children, adolescents and elderly disorder and;
- Review articles included

Exclusion criteria:

- PE in other psychiatric disorders
- Other medical conditions,
- The duplicate articles excluded

Intervention: Psychoeducation: Different study groups used varying numbers of sessions ranging between 5 and 21, with a follow-up that ranged from 6 months to 5 years. For more details about the methodology employed included in this review and their main results.

Dependent variable

- Treatment adherence.
- Clinical course.
- Psychosocial functioning.

Results: From 13 to 9 articles give their results after psychoeducation increases medication adherence and the rest of the articles after psychoeducation increase psychosocial functioning.

Article # 2

Title of the article- The efficacy of Psycho-Educational Group Program on Medication Adherence and Global Functioning of Patients with Bipolar Disorder Type 1.

Authors: Bahredar, M.J., Asgharnejad Farid, A.A., Ghanizadeh, A., & Birashk, B.

Publications & years: International Journal of Community Based Nursing and Midwifery (IJCBNM), 2013.

Objective: To investigate the effectiveness of the psychoeducational group program on medication adherence and global functioning of patients with bipolar disorder type 1.

Method: Experimental study (RCT).

Subjects

-45 participants with bipolar type 1 disorders were selected and categorized into three groups

-The experimental groups (n=15) received psychoeducation with pharmacotherapy.

-The control groups (n=15) received pharmacotherapy and;

-The placebo groups (n=15) received only pharmacotherapy.

The inclusion criteria were

-Diagnostic interview and SCID-1 test results are used for the diagnosis of type I bipolar disorder.

-Age range between 18-50 years.

-Euthymic mood score should be less than 7 or equal measured by the Hamilton scale and score less than 6 or equal measured by the Young Mania Scale.

-The participants without receiving any psychological treatment before and written informed consent as a agreement should be needed.

The exclusion criteria were

- Participants who had acute phase of the disease
- Active drug abuser
- Borderline personality disorder.
- Person's with the presence of serious physical health problems.
- Mental retardation.
- Being in the age range of below 18 and above 50 years.

Settings: Psychiatric private clinic and governmental centers of Shiraz University of Medical Sciences, Hafez and Ibn Sina hospitals.

Interventions- Psychoeducation

- The experimental group: received psychoeducational programs were performed in nine weekly sessions according to psychoeducational program (Colom et al, 2006).
- The control group:-received continued their routine treatment includes monthly regular visits with a psychiatrist and taking medication.
- The placebo group:-received in addition to drug therapy, had about 15-20 minutes sessions with a clinical psychologist for 5 weeks.

The component of the psychoeducation

1. The definition and causes of bipolar illness.
2. An introduction to the clinical features of bipolar illness.
3. An introduction to the symptoms about the depression and mixed conditions of the illness.
4. The process of the disease and its prognosis.
5. The medications about the mood stabilizer
6. Medicines are used for the treatment of depression and mania.
7. Education about the early recognition of illness.
8. The patients should do the activities at the beginning of the illness and drug use wrongly.
9. The final session.

Dependent variable

- Medication adherence.

-Global Functioning.

Measurements- Medication Adherence Rating Scale (MARS) was used to evaluate the medication adherence.

Data analysis- Randomized control trial study (RCT) data was analyzed according to the age, onset of disease and education. For the comparison of medication adherence and global functioning of patients in the three groups (experimental, control and placebo) ANOVA was performed to examine the data, and also for the analysis of data was performed using SPSS 16 statistical program.

Results: In accordance with the 1st & 2nd assessment of these study, medication adherence and global functioning mean score for patients in the psychoeducational group was significantly higher than that in the placebo and control groups where ($p=0.001$). Medication adherence score of the psychoeducational group was increased from 6.27 (0.88) to 7.92 (1.38), while the mean score of the psychoeducational group increased from 56.6 (3.58) to 64.17 (2.12) where $p=0.0001$. The mean score of global functioning in the control group reduced from 56.27 (3.17) to 54.17 (5.08) and in the placebo group reduced from 56.67 (3.58) to 56.0 (4.36) wherever $p= 0.0001$.

Article # 3

Title of the article: A Randomized Trial on the efficacy of Group Psychoeducation in the Prophylaxis of Recurrences in Bipolar Patients Whose Disease Is in Remission.

Author: Colom, F., Vieta, E., Martinez-Aran, A., Reinares, M., Goikolea, M., & Benabarre, A.

Publication & year: Archives of General Psychiatry, 2003.

Objective: To demonstrate the efficacy of group psychoeducation to prevent recurrences in patients with bipolar I and II disorder.

Method: Randomized single-blind trial study.

Subjects: 120 bipolar I and II outpatients in remission phase fulfilling DSM-IV criteria were engaged and enrolled in the naturalistic prospective follow-up visit of the Bipolar Disorders Program of the Hospital Clinic at the University of Barcelona (Spain).

Inclusion criteria

- Lifetime identification of bipolar illness type I or II.
- Age range between 18 to 65 years.
- Being euthymic (Young Mania Rating Scale (YMRS) score <6, Hamilton Depression Rating scale (HDRS)-17 score <8) for at least 6 months;
- Having adequate data on the previous course of the disease collected from a prospective follow-up visit of at least 24 months.

Exclusion criteria

- DSM-IV Axis 1 comorbidity
- Caffeine and nicotine dependence;
- Mental retardation (IQ <70;
- Organic brain damage or deafness.

Settings: Bipolar disorders program of the hospital clinic of Barcelona (Barcelona, Spain).

Interventions: Psychoeducation: A psychoeducative program composed of 21 sessions and each session lasted for 90 minutes aimed at improving 4 main issues: awareness of illness, drug compliance, early detection of prodromal symptoms, recurrences and maintaining life-style regularity. The structure of every session consisted of a 30-40 minutes. The experimental group (n=60) received standard psychiatric care and psychoeducative program. The control group (n=60) received standard pharmacological treatment and group meetings for 20 weeks.

Psychoeducation program: The Content of the psychoeducative program (Barcelona Bipolar Disorders Program) are following:-

1. Introduction.
2. What is bipolar illness?
3. Causal and triggering factors.
4. Symptoms (I) Mania and hypomania.
5. Symptoms (II); Depression and mixed episodes.
6. Course and outcome.
7. Treatment (I); mood stabilizers.
8. Treatment (II); antimanic agents.
9. Treatment (III); antidepressants.

10. Serum levels; lithium, carbamazepine and valporate.
11. Pregnancy and genetic counseling.
12. Psychopharmacology vs. alternative therapies.
13. Risks linked with treatment withdrawal.
14. Alcohol and street drug: risks in bipolar illness.
15. Early detection of manic and hypomanic episodes.
16. Early detection of depressive and mixed episodes.
17. What to do when a new phase is identified?
18. Regularity.
19. Stress management practice.
20. Crisis solving practice.
21. Final session.

Outcome

-Compliance.

-Recurrence.

Measurements: The Hamilton Depressive Rating Scale (HDRS) were administered to measure the depressive recurrence above or equal score <8 . The Young Mania Rating scale (YMRS) were administered to measure the manic recurrence and hypomanic recurrence above or equal score <6 .

Data analysis: In this randomized single-blind trial study, free from recurrence curve analysis was carried out by applying the Kaplan Meier survival analysis. The different analysis at follow-up visit of the number of patients who relapsed for every situation was by an χ^2 test. The assessment of the mean number of recurrences through the treatment and the follow-up phase was made using the Mann-Whitney U test. Statistical significance was set for all cases at $p < .05$.

Results: Group psychoeducation significantly reduced the number of relapsed patients and the number of recurrences per patient, and increased the time to depressive, manic, hypomanic, and mixed recurrences. The number and length of hospitalizations per patients were also lower for patients who received psychoeducation. Adherence was measured by the combination of a compliance-

focused interview with the patient, a compliance-focused interview with significant first degree relatives or a partner and by plasma concentrations of mood stabilizer.

Survival analyses of patients remaining in remission for each condition. The event curves for the control and treatment groups were significantly different for time to any recurrence (log rank1=13.45, $p<.001$); time to manic, mixed or depressive episode (log rank1=9.3, $p<.004$); time to depressive recurrence (log rank1=15.47, $p<.001$); time to mixed recurrence (log rank1=7.95, $p<.05$); and time to manic or hypomanic recurrence (log rank1=7.79, $p<.006$).

Article # 4

Title of the article: Stabilizing the stabilizer: group psychoeducation enhances the stability of serum lithium levels.

Authors: Colom, F., Vieta, E., Sanchez-Moreno, J., Martinez-Aran, A., Reinares, M., & Goikolea, J.M.

Publication & year: Bipolar disorder, 2005.

Objectives:

-To determine the effect of 21 –session structured group psychoeducation on lithium levels in a sample of euthymic bipolar (I or II) patients over a period of 2 years.

-To determine serum lithium level variability within and between groups.

Method: Randomized single-blind trial.

Subjects: 93 subjects are included.

In the experimental group- n=49 (82%) received additional psychoeducation and;

In the control group- n=44 (73%) met weekly support sessions.

Inclusion criteria

-Lifetime identification of bipolar disorder type 1 or 11.

-Being euthymic (Young Mania Rating scale-17 <6, Hamilton Depression Rating Scale-17 <8) for at least 6 months.

-Adequate data on the previous course of disease obtained from a prospective follow-up visit of at least 24 months.

Exclusion criteria

-DSM-IV axis 1 comorbidity-except caffeine and nicotine dependence,

-Mental retardation (IQ<70),

-Organic brain damage or deafness.

Settings: Psychoeducational program conducted in the hospital.

Interventions: Psychoeducation program was performed in 21 group sessions with 8-12 patients per groups. The structure of each session consisted of a presentation that lasted 30-40 minutes. The content of the psychoeducational program (Barcelona Bipolar Disorder Program in Spain) already discussed in the previous original article. These programs are same as article 3.

Dependent variable: Compliance was evaluated by the combination of a compliance-focused interview with the patient, a compliance-focused interview with significant first-degree relatives or partner and by plasma concentrations of mood-stabilizers

Measurements: Plasma levels of lithium were obtained from Biochemistry Laboratories.

Data analysis: Panel data were used to observe the whole, interclass and intraclass variability of lithium levels regarding time and treatment condition. Panel studies evaluate the similar sample of respondents at different points in time. Additionally, panel studies can reveal shifting attitudes and patterns of behavior that might go unnoticed with other research approaches. Additionally, panel study is useful in predicting long-term or cumulative effects which are normally hard to analyze in a one-shot case study (or cross-sectional study).

Results: Mean serum lithium levels were significantly greater for patients getting psychoeducation when compared with the control group patients at 6, 18 and 24 months. Mean serum lithium levels for the experimental group were fairly constant (range 0.75 -0.79 mEq/L) and were all the time greater than the mean baseline levels at the same time as mean levels in the control group demonstrated better unpredictability (0.64–0.72 mEq/L) and were at their maximum at baseline. Panel data analysis demonstrates no variations intragroup regarding lithium levels throughout the follow-up, but it does show global distinctions between groups, with patients selected

psychoeducation including greater global lithium levels than the control group ($p < 0.03$).

Article # 5

Title of the article: A brief dyadic group based psychoeducation program improves relapse rates in recently remitted bipolar disorder: A pilot randomized controlled trial.

Authors: D'Souza, R., PisKulic, D., & Sundram, S.

Publication & years: Journal of Affective Disorder, 2010.

Objective: To test in recently remitted BD if a combined group based psychoeducation program involving patient-companion days decreased relapse.

Method: A randomized controlled trials.

Subjects:

-58 consecutive patients of late remission phase of BD out-patients were randomized;

-In the control group (TAU, n=31) and

-In the experimental group (SIMSEP, n=27).

Inclusion criteria

-In recent times patients in the remission phase (Young Mania Rating Scale (YMRS) score <10 and Montgomery-Asberg Depression Rating Scale (MADRS) score <8 were recruited.

Exclusion criteria

-Patient with comorbid axis I disorders or present substance dependence disorders.

Setting: Community.

Interventions: Psychoeducation:-Patients were randomly assigned in a non-stratified method to take delivery of SIMSEP-BD or treatment as natural (TAU). The SIMSEP-BD was controlled in a group setting as 12 weekly sessions of 90 min by four mental health clinicians led and experienced by one of the authors (RD'S). Supervision and monitoring of the training was performed three-weekly by RD'S. The elements of the SIMSEP-BD are listed below:

Description of the sessions comprising the group based psychoeducation program involving patients with bipolar 1 disorder and their nominated companions-

Week-1=Introduction; patient and companion perspectives on illness.

Week-2=Program familiarization; knowledge of the disorder.

Week-3=Symptoms-mania, depression, mixed states and psychosis.

Week-4=Symptoms-biological rhythms, episodes and stress.

Week-5=Pharmacotherapy-role of medications and types of medications.

Week-6=Pharmacotherapy-adherence, ambivalence, combinations and monitoring.

Week-7=Psychotherapy-illness models, stressors, drug and alcohol as well as sexuality.

Week-8=Psychotherapy-life charts, personal learning, risks and coping strategies.

Week-9=Signals-relapse signature, emergency planning and help options.

Week-10=Signals-work, study, legal, financial, relationship issues and strategies.

Week-11=Fine tuning-further resources and groups, mood charts as well as residual symptoms.

Week-12=Review and assessment-warning signs, help actions, management plan, feedback and “commencement”.

The TAU (control group) was a community based case management model involving a educated mental health clinician appraise weekly with the patient for just about 45 minutes and a medical evaluation monthly.

Dependent variable

-Medication adherence

-Relapse.

Measurements: In recent times patients in the remission phase (Young Mania Rating Scale (YMRS) score <10 and Montgomery–Asberg Depression Rating Scale (**MADRS**) score <8) were needed within 1 month following release from hospital for relapse of bipolar disorder. Medication adherence assessed by ARS. The ARS was scored 0 for non-adherence, 1 for partial adherence and 2 for full adherence based on pill count and need for repeat medication prescription.

Data analysis: The primary outcome variable, relapse, was compared between the two groups using Kaplan-Meier and Cox regression survival analysis. Two separate Kaplan-Meier survival analyses were performed to ascertain group differences in survival time, following the SIMSEP program or TAU weeks 1-12 and post intervention weeks 13-60. Likewise, two separate Cox regression survival analyses were carried out for the time intermission revealed over, to assess the usefulness of SIMSEP after regulating for two covariates which were found to be significantly different between the two groups: medication type and medication adherence.

Results: Medication adherence was significantly better in the Systematic Management Skills Enhancement program (SIMSEP) group (M=1.2, SD=1.0) compared to the Treatment As usual (TAU) group (M=0.4, SD=0.7=233, p=0.001).

Article # 6

Title of the article: The impact of a simple individual psycho-education program on quality of life, rate of relapse and medication adherence in bipolar disorder patients.

Author, year: Javadpour, A., Hedayati, A., Dehbozorgi, G.R., & Azizi, A.

Publication & year: Asian Journal of Psychiatry, 2013.

Objective: To find out the effectiveness of simple individual psychoeducation with pharmacotherapy compared with pharmacotherapy alone on the quality of life, adherence to psychiatric medication and prevention of recurrence in patients with bipolar disorder (BD).

Method: Randomized controlled trial (RCT).

Subjects: 108 subjects are divided into two groups similarly and were randomly assigned; in the experimental groups (n=54) received psychoeducation along with pharmacotherapy treatment and; in the control groups (n=54) received pharmacotherapy alone.

Inclusion criteria

- Age 18–60 years.
- The previous history of at least two episodes of relapse and last 5 years, two or three episodes.

-Patients in euthymic state (the Hamilton Depression Rating Scale score < 8 and Bech Rafaelsen Mania Rating Scale score < 9).

Exclusion criteria

- Patients age range below 18 and above 60 years.
- Patients with first episode of BD
- Acute phase of BD.

Settings: These eight weekly scheduled sessions were conducted face to face in the clinic of psychology at Hafez Hospital.

Interventions: The psychoeducational program consisted of eight sessions and each session consisting of a 50 minutes per week in a short form of psychoeducation course. The intervention group received standard pharmacotherapy for BD and enrolled for simple, individual psychoeducation. The control group received continuing standard pharmacotherapy and also received written scheduled appointment for follow-up assessment in the next 6, 12 and 18 months. Psychoeducation program and discussions were presented to the patients in the eight sessions:

The content of the psychoeducational sessions are described below:-

1. Understanding BD and its etiology.
2. Familiarization with symptoms of mania and hypomania,
3. Understanding signs of depression and other psychological episodes,
4. Awareness of causes and prognosis,
5. Education about the function,
6. Types and adverse side effect of mood stabilizer medication, functions,
7. Types and adverse effects of antimanic and antidepressant medications.
8. The final sessions.

Dependent variable: Medication adherence

Medication adherence **or** Pharmacotherapy compliance assessment was performed by patients' completion of validated questionnaire forms of "medication adherence rating scale" (Fialko, Garety & Kuipers 2008). The Medication Adherence Rating Scale is a ten-item self-report assess of drug compliance in an affective and psychotic illness. (This questionnaire is translated from the original English text to Farsi by researchers.

Measurements: Medication adherence was assessed by (MARS) Medication Adherence Rating Scale. The Medication Adherence Rating scale is a ten-item self-report measure of medication adherence in affective and psychotic disorders.

Data analysis: All collected data were statistically analyzed using T-test, Chi-square test and repeated measures. The similarity of the mean quantity of recurrences throughout the study was made by means of Mann–Whitney U test. P value of <05 was considered as statistically significant.

Results: The result indicated that patients in the experimental group had a statistically significant improvement in drug adherence (P-value = 0.008).

Article # 7

Title of the article: Effectiveness of six-week psychoeducation program on adherence of patients with bipolar affective disorder.

Authors: Eker, A., & Harkin, S.

Publication & year: Journal of Affective Disorders, 2012.

Objective: To examined the effectiveness of a six week psychoeducation program on the adherence of patients with Bipolar Affective Disorder.

Method: Pretest–posttest design randomized controlled groups.

Subjects: Finally, total subjects are 63 patients: 30 intervention and 33 control patients.

Inclusion criteria

-The subject met DSM-IV diagnosis criteria of bipolar affective disorder.

-Age range between 20-55 years

Settings: Meeting room of the psychiatry ambulatory medical center in Zonguldak Karaelmas University Hospital mood disorder outpatient clinic in Turkey.

Interventions: Psychoeducational intervention is provided to the experimental group then the control group patients were trained by the doctor regarding the medicines in an outpatient department for a highest of 5–10 minutes. Psychoeducational program comprised of six sessions. Each group session lasted 90–120 minutes for 10–12 persons and was held one time per week. Every session divided into two parts that continued 45–50 minutes and time of break 10–15 minutes.

Elements of psychoeducational course

1. Introduction
2. Definition, reasons and symptoms of bipolar affective disorder
3. Treatments for bipolar disorder and importance of treatment adherence
4. Medications used for bipolar affective disorder, their effects and side effects
5. Detecting and controlling prodromal symptoms
6. Coping with stress, problem solving strategies and evaluation.

Dependent variable:

-Medication adherence.

Measurements: Medication adherence rating scale (MARS). It is a rapid and simple scale that comprises of 10 questions to be answered as “yes” or “no” and it assesses the compliance to medication in psychiatric patients. The scale demonstrates the compliance value below 0-7 show low adherence and above 8-10 show high adherences.

Data analysis: Two different types of analyses were carried out: investigation for completers only and last-observation-carried-forward (LOCF). A chi-test, an independent sample t test and a paired t test were used.

Results: The psychoeducational program appreciably enhanced patients' compliance after six weeks. The medication adherence rate in the experimental group improved from 40.0% (14 patients on pre-test), to 86.7% (26 patients on post-test). In the meantime, the medication adherence rate in the control group was 38.9% (14 patients on pre test) and 24.2% (8 patients on post test).

3.1.1 Summary of seven evidences appraisal

Seven research evidences as an abovementioned were significantly evaluated for their validity, reliability by using the criteria of Melnyk and fineout-overholt (2011) as acknowledged in chapter two confirm with the accuracy of this appraisal by the major advisor and co-advisor. The results of the appraisal related to all evidences were conducted in scientific procedure. The results of each research evidences were relevant with the clinical issues of this study and can be practically applied in the author's clinical/health care settings.

Table 3.2 Collective table of seven evidences

Article No-	Evidence 1:Level I	Evidence 2: Level II	Evidence 3: Level III	Evidence 4: Level III
Author & year	Batista et al, 2011	Bahredar et al, 2013	Colom et al, 2003	Colom et al, 2005
Objectives	-To evaluate the efficacy of (PE) psychoeducation in the clinical course, treatment adherence and psychosocial functioning of bipolar patients by collecting data from control trials that used solely psychoeducation (PE) as a psychosocial approach	-To investigate the effectiveness of the psychoeducational group program on medication adherence and global functioning of patients with bipolar disorder type I	-To demonstrate the efficacy of group psychoeducation to prevent recurrences in patients with bipolar I and II disorder	-To determine the effect of 21-session structured group psychoeducation on lithium levels in a sample of euthymic bipolar (I or II) patients over a period of 2 years -To determine serum lithium level variability within and between groups
Methods/study design	Systematic review of randomized control trials study	RCT	Randomized single-blind trial study	Randomized single-blind trial study

Table 3.2 Collective table of seven evidences (cont.)

Article No-	Evidence 1:Level I	Evidence 2: Level II	Evidence 3: Level III	Evidence 4: Level III
<p>Characteristics of the participants</p>	<p>13 randomized control trials are included. Inclusion criteria: -RCTs used PE -Individuals with either type I or type II bipolar disorder -Combination of the two and/or their family or caregivers -PE included children, adolescents or the elderly with bipolar disorder Exclusion criteria: -PE in other psychiatric disorders -Other medical conditions. -Duplicate articles</p>	<p>45 participants with bipolar type 1 disorders were selected and categorized into three groups: -The experimental groups (n=15) received psychoeducation with pharmacotherapy -The control groups (n=15) received pharmacotherapy and; -The placebo groups (n=15) received only pharmacotherapy Inclusion criteria were: - type I bipolar disorder. - Age range between 18-50 years. -During the study euthymic mood score should be less than 7 or equal measured by the</p>	<p>-Participants 120 -Bipolar I and II outpatients in remission fulfilling DSM-IV criteria. Inclusion criteria were: - Aged between 18 to 65 years was recruited -A life-time diagnosis of bipolar disorder types I or II -Being euthymic Young Mania Rating Scale (YMRS) score <6, Hamilton Depression Rating scale (HDRS)-17 score <8) for at least 6 months; -Having prior course of illness</p>	<p>Subjects were a total of 93. -Bipolar I and II who were on lithium during the trial Inclusion criteria; - A lifetime diagnosis of bipolar disorder type 1 or 11. - Being euthymic (Young Mania Rating scale-17 <6, Hamilton Depressive Rating Scale -17 score <8) for at least 6 months -Prior course of illness Exclusion criteria were: DSM-IV axis 1 comorbidity- except caffeine and nicotine dependence. -</p>

Table 3.2 Collective table of seven evidences (cont.)

Article No-	Evidence 1:Level I	Evidence 2: Level II	Evidence 3: Level III	Evidence 4: Level III
		<p>Hamilton scale and score less than 6 or equal measured by the Young Mania Scale</p> <p>Exclusion criteria were:</p> <ul style="list-style-type: none"> - Acute phase of the disease or drug abuser and full criteria for borderline personality disorder -Person’s with the presence of serious physical health problems. -Mental retardation -Age range between less than 18 and more than 50 years 	<p>Exclusion criteria were: - DSM-IV Axis 1 comorbidity except for caffeine and nicotine dependence;</p> <ul style="list-style-type: none"> - Mental retardation (IQ <70; -Organic brain damage or deafness <p>The experimental group (n=60) received standard psychiatric care and psychoeducation program.</p> <p>The control group (n=60) received standard pharmacologic treatment and 20 weekly group meetings</p>	<ul style="list-style-type: none"> - Mental retardation (IQ<70), - Organic brain damage or deafness -Patients currently receiving any kind of psychotherapy or enrolled in any pharmacological trial were also excluded <p>The experimental group- n=49 received additional psychoeducation and the control group- n=44 met every week for support sessions</p>

Table 3.2 Collective table of seven evidences (cont.)

Article No-	Evidence 1:Level I	Evidence 2: Level II	Evidence 3: Level III	Evidence 4: Level III
Characteristics of the therapist.		Psychiatrist and trained persons.	Psychiatrist who had four years minimum clinical and research experience in bipolar disorder.	Experienced psychologists who had specific training and previous experience leading with bipolar patients.
Characteristics of the intervention.	Used varying numbers of sessions ranging between 5 and 21, with a follow-up that ranged from 6 months to 5 years	Group psychoeducational programs were nine weekly sessions according to (Colom et al, 2006). The control group received continued their routine treatment The placebo group received in addition to drug therapy, had about 15-20 minutes sessions with a clinical psychologist for 5 weeks	Group psychoeducation program composed of 21 sessions of 90 minutes according to the Barcelona bipolar disorder psychoeducational program The control group received standard pharmacologic treatment and 20 weekly group meetings	Group psychoeducational program was Barcelona bipolar disorder psychoeducational program same as evidence 3
Settings		Psychiatric private clinic and government centers of Shiraz University of Medical Science, Hafez and Ibn Sina hospital	Bipolar disorders program of the hospital clinic of Barcelona (Barcelona, Spain)	Same as evidence-3 Hospital

Table 3.2 Collective table of seven evidences (cont.)

Article No-	Evidence 1:Level I	Evidence 2: Level II	Evidence 3: Level III	Evidence 4: Level III
Dependent variable/outcomes	-Treatment adherence -Clinical course -Psychosocial functioning	Medication adherence -Global Functioning	-Compliance - Recurrence	Compliance
Measurement		Medication Adherence Rating Scale (MARS) evaluate the medication adherence The questionnaire consists of 10 questions with yes/ no responses which can be easily answered by the patient or therapist. The test-retest reliability coefficient for this test was 0.91	-The Hamilton Depressive Rating Scale (HDRS) -Young Mania Rating scale (YMRS)	
Results of the study	Psychoeducational program increases medication adherence and the rest of the articles after psychoeducation increase psychosocial functioning	Medication adherence and global functioning mean score for patients in the psychoeducational group was significantly higher than that in the placebo and control groups	Group psychoeducation significantly reduced the number of relapsed patients and the number of recurrences per patient, and increased the time to depressive, manic,	Mean serum lithium levels were significantly greater for patients getting psychoeducation when compared with the control group patients

Table 3.2 Collective table of seven evidences (cont.)

Article No-	Evidence 1:Level I	Evidence 2: Level II	Evidence 3: Level III	Evidence 4: Level III
			<p>hypomanic, and mixed recurrences. The number and length of hospitalizations per patients were also lower for patients who received psychoeducation</p> <p>The event curves for the control and treatment groups were significantly different for time to any recurrence</p>	

Table 3.2 Collective table of seven evidences (cont.)

Article Number	Evidence 5: Level II	Evidence 6: Level II	Evidence 7: Level III
Author & year	D'Souza et al, 2010	Javadpour et al, 2013	Eker & Harkin.2012
Objectives	To test in recently remitted BD if a combined group based psychoeducation program involving patient-companion days decreased relapse	To find out the effectiveness of simple individual psychoeducation with pharmacotherapy compared with pharmacotherapy alone on the quality of life, adherence to psychiatric medication and prevention of recurrence in patients with bipolar disorder (BD)	To examined the effectiveness of a six week psychoeducation program on the adherence of patients with Bipolar Affective Disorder
Methods/Study design	RCT	RCT	A semi-experimental design. (Pretest–posttest, randomized control groups)
Characteristics of the participants	58 patients recently remitted BD out-patients were randomized; in the control group Treatment As Usual (TAU, n=31) and; in the experimental group the Systematic Illness Management Skill Enhancement Program (SIMSEP, n=27) Inclusion criteria;	108 patients, divided equally into two groups, were randomly assigned; in the experimental groups (n=54) received psychoeducation along with pharmacotherapy treatment and; in the control groups (n=54) received pharmacotherapy alone Inclusion criteria:	A total of 71 participants age range of between 20-55 years were randomly assigned. The final study group consisted of 63 patients: 30 intervention and 33 control patients Inclusion criteria: -met the bipolar affective disorder DSM-IV diagnosis criteria, and; - In the remission period

Table 3.2 Collective table of seven evidences (cont.)

Article Number	Evidence 5: Level II	Evidence 6: Level II	Evidence 7: Level III
	<p>- Recently remitted patients (Young Mania Rating Scale (YMRS) score <10 and Montgomery-Asberg Depression Rating Scale (MADRS) score <8 were recruited</p> <p>Exclusion criteria:</p> <p>-comorbid axis 1 disorder or a current substance dependence disorder</p>	<p>-Age range of 18–60 years. History of at least two episodes of relapse in the past two or three episodes in last five years</p> <p>-Euthymic state (the Hamilton Depression Rating Scale score < 8 and Bech Rafaelsen Mania Rating Scale score < 9)</p> <p>Exclusion criteria:</p> <p>-Age below 18 and above 60 years.</p> <p>- First episode of BD or with a history of interepisode intervals more than two years,</p> <p>-Acute phase of BD or presence of some residual symptoms of BD</p>	
Characteristics of the therapists	Mental health clinicians trained by one of the authors	Psychologist	Doctorate educated in psychiatric mental health nursing and; the therapist who had seven years of psychiatric clinical experience in the care of patients with mood disorders

Table 3.2 Collective table of seven evidences (cont.)

Article Number	Evidence 5: Level II	Evidence 6: Level II	Evidence 7: Level III
Characteristics of the interventions	The experimental group received- Systematic Illness Management Skill Enhancement Program- Bipolar Disorder (SIMSEP-BD) The control group received-the TAU was a community based case management model involving a trained mental health clinician review weekly with the patient for approximately 45 minute and a medical review monthly.	The experimental group received standard pharmacotherapy for BD and enrolled for simple, individual psychoeducation The control group received continuing standard pharmacotherapy	The experimental group received-psychoeducation program consisted of six sessions. The control group patients were trained by the doctor about the medication in an outpatient setting for a maximum of 5–10 minutes
Settings	Community	The eight weekly scheduled sessions were conducted face to face in the clinic of psychology at Hafez Hospital	Meeting room of the psychiatry Ambulatory medical center in Zonguldak Karaelmas University Hospital mood disorder outpatient clinic
Dependent variable/outcomes	Medication adherence	Medication adherence: Assessment Scale (Bech, 2002) at baseline, 6, 12 and 18 months	Medication adherence

Table 3.2 Collective table of seven evidences (cont.)

Article Number	Evidence 5: Level II	Evidence 6: Level II	Evidence 7: Level III
Measurements	Medication adherence. Young Mania Rating Scale (YMRS) score<10 and Montgomery-Asberg Depression Rating Scale (MADRS) score <8	Medication adherence was assessed by (MARS) Medication Adherence Rating Scale. The Medication Adherence Rating scale is a ten-item self-report measure of medication adherence in affective and psychotic disorders	Medication adherence rating scale (MARS). It is a quick and easy scale that includes 10 questions to be answered as “yes” or “no” and it measures the adherence to medication in psychiatric patients. Low values (0–7) on the scale show low adherence and high values (8–10) on the scale show high adherence
Results of the study	Medication adherence was significantly better in the Systematic Illness Management Skills Enhancement program (SIMSEP) group compared to the Treatment As usual groups	The result indicated that patients in the experimental group had a statistically significant improvement in drug adherence (P-value = 0.008)	The psychoeducational program appreciably enhanced patients' compliance after six weeks. The medication adherence rate in the experimental group improved from patients on pre-test and post-test

Table 3.3 The comparison content of the psychoeducational program of the 7 evidence-based practices

Evidence Number	Evidence No 1: Level I	Evidence No 2:Level II	Evidence No 3: Level III	Evidence No 4: Level III
Name of the PE program	Psychoeducation Program	Group based psychoeducation program	Group based psychoeducation program (Barcelona Bipolar Disorder Program)	Group based psychoeducation program (Barcelona Bipolar Disorder Program)
Components of psychoeducation		1) The definition and causes of bipolar illness 2) An introduction to the clinical features of bipolar illness 3) An introduction to the symptoms about the depression and mixed conditions of the illness 4) The process of the disease and its prognosis 5) The medications about the mood stabilizer 6) Medicines are used for the treatment of depression and mania 7) Education about the early recognition of illness.	1) Introduction 2) What is bipolar illness? 3) Causal and triggering factors 4) Symptoms (I) Mania and hypomania 5) Symptoms (II); Depression and mixed episodes 6) Course and outcome. 7) Treatment (I); mood stabilizers 8) Treatment (II); antimanic agents 9) Treatment (III); antidepressants valporate	The components of the psychoeducation programs are same as the original article 3

Table 3.3 The comparison content of the psychoeducational program of the 7 evidence-based practices (cont.)

Evidence Number	Evidence 1: Level I	Evidence 2:Level II	Evidence 3: Level III	Evidence 4: Level III
		9) The final session	10) Serum levels; lithium, carbamazepine and valporate 11) Pregnancy and genetic counseling 12) Psychopharmacology vs. alternative therapies 13) Risks linked with treatment withdrawal 14) Alcohol and street drug: risks in bipolar illness 15) Early detection of manic and hypomanic episodes 16) Early detection of depressive and mixed episodes 17) What to do when a new phase is identified? 18) Regularity 19) Stress management practice 20) Crisis solving practice. 21) Final session	

Table 3.3 The comparison content of the psychoeducational program of the 7 evidence-based practices (cont.)

Evidence Number	Evidence 1: Level I	Evidence 2:Level II	Evidence 3: Level III	Evidence 4: Level III
Duration and length of the program		The group psychoeducational programs were nine weekly sessions according to Colom et al, 2006	Group psychoeducation programs composed of 21 sessions and each session consists of 90 minutes according to the Barcelona Bipolar Disorder Program	Duration and length of the program was same as the original article 3
Materials/process		Simple questionnaire consists of 10 questions with yes or no responses were used which can be easily answered by the patients or therapist	Speech on the topic of the day, followed by an exercise related to the issue (e.g, drawing a life chart, writing a list of potential triggering factors) and a discussion	Using educational materials are same as evidence 3

Table 3.3 The comparison content of the psychoeducational program of the 7 evidence-based practices (cont.)

Evidence Number	Evidence 5: Level II	Evidence 6: Level II	Evidence 7: Level III
Name of the PE program	Group based psychoeducation program involving patients with bipolar 1 disorder and their nominated companions	Individual psychoeducation program	Group based psychoeducation program
Components of psychoeducation	Component of psychoeducation: Week-1=Introduction; patient and companion perspectives on illness Week-2=Program familiarization; knowledge of the disorder Week-3=Symptoms-mania, depression, mixed states and psychosis Week-4=Symptoms-biological rhythms, episodes and stress Week-5=Pharmacotherapy-role of medications and types of medicines Week-6=Pharmacotherapy-adherence, ambivalence, combinations and monitoring	The content of the psychoeducational sessions are described below: 1. Understanding BD and its etiology 2. Familiarization with symptoms of mania and hypomania, 3. Understanding signs of depression and other psychological episodes 4. Awareness of causes and prognosis 5. Education about the function, 6. Types and adverse side effect of mood stabilizer medication, functions	Contents of psychoeducative program: 1. Introduction 2. Definition, reasons and symptoms of bipolar affective disorder 3. Treatments for bipolar disorder and importance of treatment adherence 4. Medications used for bipolar affective disorder, their effects and side effects 5. Detecting and controlling prodromal symptoms 6. Coping with stress, problem solving strategies and evaluation

Table 3.3 The comparison content of the psychoeducational program of the 7 evidence-based practices (cont.)

Evidence Number	Evidence 5: Level II	Evidence 6: Level II	Evidence 7: Level III
	Week-7=Psychotherapy-illness models, stressors, drug and alcohol as well as sexuality Week-8=Psychotherapy-life charts, personal learning, risks and coping strategies Week-9=Signals-relapse signature, emergency planning and help option Week-10=Signals-work, study, legal, financial, relationship issues and strategies Week-11=Fine tuning-further resources and groups, mood charts as well as residual symptoms Week-12=Review session	7. Types and adverse effects of antimanic and antidepressant medications. 8. The final sessions	
Duration and length of the session	The group program was 12 weekly sessions and the length of the each session was 90 minutes	The individual program consisted of eight sessions and length of the sessions 50 minutes	Duration of the group program session was six weeks and length of the sessions 90-120 minutes

Table 3.3 The comparison content of the psychoeducational program of the 7 evidence-based practices (cont.)

Evidence Number	Evidence 5: Level II	Evidence 6: Level II	Evidence 7: Level III
Materials/process	Description of the sessions comprising the assessment warning signs, help actions management plan feedback and graduation.	Psychoeducation program and discussions were presented to the patients in the eight sessions Eight weekly scheduled sessions were conducted face to face simple individual education; the intervention continued using scheduled monthly telephone contact consisted of ten minutes question and answer session to remind the patients of their next appointment	Teaching instruments: Leaflets, blackboard and projector were used as educational materials in the psychoeducation program

3.2 Recommendations

The objective of this study was to summarize the scientific evidence related to psychoeducational programs for improving medication adherence among adult patients with bipolar disorder. The author obtained seven samples of evidence-based practice from different databases. Of these, only one was a systematic review of randomized controlled trials; two were randomized single-blind studies; three were randomized controlled trials and one was a semi structured pre-test post-test controlled trial. All of the samples of evidence-based practice focused on medication adherence among adult patients with bipolar disorder. According to the findings of the samples of evidence-based practice, psychoeducational programs can improve the medication adherence of patients with bipolar disorder. Based on the analysis and summary of the seven samples of evidence-based practice, the psychoeducation programs can be based on either group or individual models. Moreover, group psychoeducation consists of two types, namely, the Barcelona Bipolar Disorder Program and brief group psychoeducational programs. All of the psychoeducation programs mentioned in the samples of evidence-based practice were conducted in hospitals or clinics. The group and individual models of the psychoeducation programs are described as follows:

3.2.1 Group psychoeducation: Group psychoeducation is very helpful and suitable for inpatients and outpatients who have already been diagnosed with Type I or II bipolar disorders and received pharmacological treatment. From the five samples of evidence-based practice, two were group psychoeducation models based on the Barcelona Bipolar Disorder Program in Spain (Colom et al, 2003: Level III; Colom et al, 2005: Level III) while the remaining three samples of evidence-based practice were also group psychoeducation but with shorter numbers of sessions and program lengths (Bahredar, Asgharnejad Farid, Ghanizadeh & Birashk, 2014: Level II; D'Souza, PisKulic, & Sundram, 2010: Level II; Eker & Harkin, 2012: Level III). The following section discusses recommendations for using two types of group psychoeducation:

3.2.1.1 Barcelona Bipolar Disorder Program Group

Psychoeducation

The Barcelona Bipolar Disorder Program was conducted according to Colom et al, 2003. The program was aimed at improving the following four main issues: illness awareness, treatment compliance, early detection of prodromal symptoms-recurrences and life style regularity.

1) Patients' Characteristics

i) Patients diagnosed with lifetime Type I or II bipolar disorder based on the DSM-IV TR criteria and in the euthymic phase evaluated by using the Young Mania Rating Scale (YMRS) score <6, Hamilton Depressive Rating Scale (HDRS) -17 score <8 for at least six months (Colom et al, 2003: Level III; 2005: Level III).

ii) Patients aged between 18-65 years with prior courses of bipolar disorders (Colom et al, 2003: Level-III; Colom et al, 2005: Level III).

iii) Patients with no comorbidities of DSM-IV Axis I, no history of substance abuse, no organic brain damage or deafness and no mental retardation (IQ<70) (Colom et al, 2003: Level III; Colom et al, 2005: Level III).

2) Therapists' qualifications

The therapists who provided the group psychoeducation were psychiatrists and psychologists. The psychiatrists had a minimum four years' clinical experience in bipolar disorder and the psychologists had specific training and prior experience with bipolar patients (Colom et al, 2003: Level III; Colom et al, 2005: Level III).

3) Settings:

The group psychoeducation was conducted in hospitals. Psychoeducation could be provided with two types of education: group education and individual education.

4) Procedure, duration and length of group psychoeducation

Group psychoeducation should be provided every week for a total number of 21 sessions with 90 minutes for each session. Each session should start with an introduction and continue for 30-40 minutes to teach the planned lesson, followed by practice/exercise and group discussion. An effective group psychoeducation program should have 8-12 participants in each group (Colom et al, 2003: Level III; Colom et al, 2005: Level III).

5) Content

The content of the psychoeducation in the Barcelona Bipolar Disorder Program is composed of the following 21 topics:

1. Introduction.
2. What is bipolar illness?
3. Causal and triggering factors.
4. Symptoms (I) Mania and hypomania.
5. Symptoms (II); Depression and mixed episodes.
6. Course and outcome.
7. Treatment (I); mood stabilizers.
8. Treatment (II); antimanic agents.
9. Treatment (III); antidepressants.
10. Serum levels; lithium, carbamazepine and valproate.
11. Pregnancy and genetic counseling.
12. Psychopharmacology vs. alternative therapies.
13. Risks linked with treatment withdrawal.
14. Alcohol and street drugs: risks for bipolar illness.
15. Early detection of manic and hypomanic episodes.
16. Early detection of depressive and mixed episodes.
17. What to do when a new phase is identified,
18. Regularity.
19. Stress management practice.
20. Crisis-solving practice.
21. Final session.

3.2.1.2 Brief group psychoeducation - Brief group psychoeducation is also suitable for both inpatients and outpatients among the three research samples of evidence-based practice conducting brief group psychoeducation. The first samples of evidence-based practice described the brief group psychoeducation for inpatients who had been diagnosed with Type I bipolar disorder based on diagnostic interviews and Structured Clinical Interviews for DSM-IV Axis I disorders (SCID-I) (Bahredar et al, 2014: Level II). The second sample of evidence-based practice was a brief group psychoeducation for outpatients recently readmitted and patients within one month following discharge from hospital for relapse of bipolar disorder (D'Souza et al, 2010: Level II). The third sample of evidence-based practice was brief group psychoeducation for outpatients; all of the patients were diagnosed with bipolar affective disorder and receiving ambulatory treatment fulfilling the DSM-IV criteria (Eker & Harkin, 2012: Level III).

1)Patients' Characteristics

i) Diagnosis with Type I bipolar disorder based on diagnostic interviews and SCID-I; age ranging from 18-50 years; a euthymic mood score of less than or equal to seven points for the Hamilton Scale and a score of less than or equal to six points for the Young Mania Scale (Bahredar et al, 2014: Level II).

ii) Recently readmitted patients {Young Mania Rating Scale (YMRS) score <10 and Montgomery-Asberg Depression Rating Scale (MADRS) score <8} within one month following discharge from hospital for relapse of bipolar disorder were the subjects. The patients had no comorbid axis I disorder or any current substance dependence disorders (D'Souza et al, 2010: Level II).

iii) All of the patients were diagnosed with bipolar affective disorder and receiving ambulatory treatment fulfilling the DSM-IV criteria (Eker & Harkin, 2012: Level III).

2)Therapist Characteristics

Psychiatrists (Bahredar et al, 2014: Level II), mental health clinicians trained by one of the experts (D'Souza et al, 2010: Level II), and psychiatric mental health nurses who had psychiatric clinical experience in the care of patients with mood disorders (Eker & Harkin, 2012: Level III) can all be therapists.

3) Settings

The settings that is suitable for conducting interventions include mood disorder outpatient clinics (Eker, & Harkin, 2012: Level III), hospitals (Bahredar et al, 2014: Level II) and communities (D'Souza et al, 2010: Level II).

4) Program Content

The content of the brief group psychoeducation among the three samples of evidence-based practice included nine weekly sessions, twelve weekly sessions and eight weekly sessions. The content of the group psychoeducation from the three samples of evidence-based practice as described shared both differences and similarities. The content of the psychoeducational program may also be varied according to the disease condition of the study participants. The components of the PE are as follows (Bahredar et al, 2014: Level II; D'Souza et al, 2010: Level II; Eker & Harkin, 2012: Level III):

The content of brief group psychoeducation programs is as follows: ((Bahredar et al, 2014: Level II).

1. Definition and causes of bipolar illness.
2. Introduction to the clinical features of bipolar illness.
3. Introduction to the symptoms of depression and mixed conditions of the illness.
4. Process and prognosis of the disease.
5. Mood stabilizer medications
6. Medications used for the treatment of depression and mania.
7. Education about early recognition of illness.
8. Patients should perform the activities at the beginning of the illness and learn about misusing drugs.
9. Final session.

The components of brief psychoeducation programs are as follows (D'Souza et al, 2010: Level II):

Week-1=Introduction; patient and companion perspectives on illness.

Week-2=Program familiarization; knowledge of the disorder.

Week-3=Symptoms-mania, depression, mixed states and psychosis.

Week-4=Symptoms-biological rhythms, episodes and stress.

Week-5=Pharmacotherapy-role of medications and types of medicines.

Week-6=Pharmacotherapy-adherence, ambivalence, combinations and monitoring.

Week-7=Psychotherapy-illness models, stressors, drug and alcohol as well as sexuality.

Week-8=Psychotherapy-life charts, personal learning, risks and coping strategies.

Week-9=Signals-relapse signature, emergency planning and help options.

Week-10=Signals-work, study, legal, financial, relationship issues and strategies.

Week-11=Fine tuning-further resources and groups, mood charts as well as residual symptoms.

Week-12=Review session.

The contents of psychoeducative programs are as follows: (Eker & Harkin, 2012: Level III).

1. Introduction
2. Definition, reasons and symptoms of bipolar affective disorder
3. Treatments for bipolar disorder and importance of treatment adherence
4. Medications used for bipolar affective disorder, their effects and side effects
5. Detecting and controlling prodromal symptoms
6. Coping with stress, problem solving strategies and evaluation

5) Duration and length of brief group psychoeducation

i) The brief group psychoeducational programs involved 6-12 weekly sessions. Each session lasted 45-120 minutes (Eker, & Harkin, 2012; Level III; Bahredar et al., 2014: Level II; D'Souza et al, 2010: Level II).

ii) The SIMSEP-BD administered 12 weekly sessions of 90 minutes each. (D'Souza et al, 2010: Level II).

iii) The program consisted of six sessions with each session lasting 90-120 minutes; members of groups are 10-12 persons and sessions were held weekly. Each session consisted of two parts that lasted 45-50 minutes each with a 10-15-minute break (Eker & Harkin, 2012: Level III).

3.2.2 Individual psychoeducation

Individual psychoeducation is a short form of psychoeducation courses adapted from studies by Colom and Vieta (2006). In most cases, individual psychoeducation is conducted at the same time as the pharmacological intervention. The program was personalized to particularly benefit patients admitted to the hospital.

3.2.2.1 Patients' Characteristics

The patients with bipolar disorder who are suitable for the intervention were in the remission phase of recovery after being discharged from the hospital. The patients' ages ranged from 18 to 60 years and their history of illness involved at least two episodes of relapse in the past two or three episodes over the last five years. Furthermore, the patients were in the euthymic phase (with Hamilton Depressive Rating Scale scores of < 8 and Bech Rafaelsen Mania Rating Scale scores of <9) (Javadpour, Hedayati, Dehbozorgi & Azizi, 2013: Level II).

3.2.2.2 Therapists Qualifications

The therapists who performed individual psychoeducation were psychologists (Javadpour et al, 2013: Level II).

3.2.2.3 Settings

The simple individual psychoeducation was conducted face-to-face in the hospital.

3.2.2.4 Duration and length of psychoeducational sessions

The simple individual psychoeducational program consisted of eight sessions in which each session lasted for 50 minutes and was held on a weekly basis in a short version of the psychoeducation course. After eight sessions of face-to-face simple individual education, the intervention continued by using scheduled monthly telephone contact to remind the patients of their next appointment. Each telephone contact consisted of a 10-minute question and answer session when the patient's queries were thoroughly answered. Follow-up telephone contact for each patient was then scheduled over the next 18 months (Javadpour et al, 2013: Level II).

3.2.2.5 Simple individual psychoeducation content

The psychoeducation program and discussion were presented to the patients in the following eight sessions:

1. Understanding bipolar disorder and its etiology.
2. Familiarization with symptoms of mania and hypomania.
3. Understanding signs of depression and other psychological episodes.
4. Awareness of causes and prognosis.
5. Education about function.
6. Types and adverse effects of antimanic and antidepressant medications.
7. Patients also received information about the risk of discontinuation of these medications.
8. Learning how to detect any future episodes of relapse as well as strategies and plans on which to base early detection of symptoms with ability to be self-directed toward new situations (Javadpour et al, 2013: Level II).

Outcomes: Among the seven articles selected, the primary outcome was medical adherence (Batista et al, 2011: Level I; Bahredar et al, 2014: Level II; D'Souza et al, 2010: Level II; Javadpour et al, 2013: Level II; Eker & Harkin et al, 2012: Level III) and the secondary outcome was compliance (Colom et al, 2003: Level III; Colom et al, 2005: Level III).

Outcome measurement: Among the seven research samples of evidence-based practice, five were focused on the outcome of medication adherence measured by the Medication Adherence Rating Scale (Batista et al, 2011: Level I; Bahredar et al, 2014: Level II; D'Souza et al, 2010: Level II; Javadpour et al, 2013: Level II; Eker & Harkin et al, 2012: Level III). Two samples of evidence-based practice focused on the outcome of compliance measured by the Hamilton Depressive Rating Scale (HDRS) and the Young Mania Rating Scale (YMRS) (Colom et al, 2003: Level III). Furthermore, plasma levels of lithium were obtained from Biochemistry Laboratories (Colom et al, 2005: Level III).

CHAPTER IV

CONCLUSION AND SUGGESTIONS

4.1 Conclusion

Bipolar disorder or manic depression is a national and global public health problem that increases daily. Bipolar disorder also has a significant impact on the health of people with the condition. Patients with bipolar disorder lose their daily routines in various aspects of life such as physical activities, sleep patterns and behaviors as well as social and psychological activities, lifestyles and health care expenditures/costs etc. Globally, the burden of this disease is increasing for patients, families and health services as well as governmental organizations. Bipolar disorder is a lifelong disorder and the world's sixth leading non-curable disease (Wang & Henning, 2010). According to the author's personal experience, medication non-adherence is a clinical issue for patients with bipolar disorder. This issue can be controlled by providing both pharmacological and non-pharmacological treatments. Additionally, medication non-adherence may be a challenging problem among patients with bipolar disorder, because the prevalence of unusual forms of the disorder is increasing and more people with bipolar illness have co-morbid substance use disorders. In today's world, medication adherence enhancement is the focal point of clinical bipolar illness management. Improvement of medication adherence refers to reducing symptoms, using medication and minimizing possible risk factors of avoidance as well as lifestyle regularity. Improvement of medication adherence can be achieved through providing psychoeducational strategy. Psychoeducation is an effective and helpful strategy for improving treatment outcomes and also provides adequate knowledge regarding bipolar illness, risk factors and proper use of medication for patients with bipolar disorder. Inadequate literacy of bipolar patients and an overall dearth of proper knowledge about illness and the absence of evidence-based nursing practice are significant issues in Bangladesh. In mental health care settings and from the perspectives of bipolar disorder patients in Bangladesh, brief group psychoeducation would be very suitable and helpful because the duration is

short and the content is easy. The evidence clearly shows that psychoeducational strategy can improve medication adherence, patients' health status, quality of life and self care-efficacy while reducing relapse or recurrence of bipolar symptoms among adult patients with the disorder.

The purpose of this study is to summarize the scientific evidence related to psychoeducational programs to improve medication adherence among adult patients with bipolar disorder. The PICO framework and electronic databases of the Mahidol University Library system were used to search and select evidence for systematic reviews from the Cochrane Database. In addition, PubMed, ProQuest, Wiley Online Library, Science Direct and SCOPUS journals online were used to search for single research studies. The author also conducted a manual search by looking for citations from reference lists from systematic reviews. Next, the author searched further in other libraries and electronic databases. The author searched for systematic reviews of randomized controlled trials (RCTs), single-blind randomized controlled trials, a semi-experimental design (pretest-posttest control groups) acquired from full text studies published in English language over a period of 12 years from 2003 to 2014. The searching terms/keywords used for the PICO framework were adult patients with bipolar disorder, manic depression, psychoeducational programs, medication adherence, drug adherence, treatment compliance and level of lithium. The author selected seven quality evidence-based practices. Of these, one was a systematic review (Level I), four were randomized control trials (Level II) and two were single-blind randomized control trial studies (Level III). The samples of evidence-based practice were summarized to gain knowledge regarding psychoeducational programs for improving medication adherence among adult patients with bipolar disorder.

The findings of the samples of evidence-based practice can be summarized as follows:

Among the seven samples of research on evidence-based practiced focused on psychoeducational programs to increase medication adherence among adult patients with bipolar disorder, two main types of psychoeducation emerged, namely, group psychoeducation and individual psychoeducation. Group psychoeducation is composed of two types: the Barcelona Bipolar Disorder Program with 21 sessions on

psychoeducation and brief group psychoeducation with 6-12 sessions. Individual psychoeducational programs are composed of eight sessions for patients during hospitalization and continue with a follow-up schedule of phone contacts lasting 10 minutes each on a monthly basis to answer patients' queries.

4.1.1 The psychoeducational program years in the systematic review was based on teaching activities as well as different numbers of sessions used by different study groups ranging between 5-12 and follow-up periods ranging from six months to five years.

4.1.2 The majority of the studies provided teaching activities based on the contents of the psychoeducational programs for bipolar disorder comprising 6 to 21 sessions lasting for 45 to 120 minutes and consisting of 8-12 persons in group settings aimed at improving awareness about the illness and medication adherence, teaching patients about early detection of prodromal symptoms and recurrences as well as promoting life-style regularity

4.1.3 Most of the studies provided teaching materials and demonstrations such as role play, problem-solving exercises, homework, drawing life charts, writing a list of potential triggering factors and discussions about improving medication adherence among patients with bipolar disorder. After the intervention, the researchers continued by using scheduled monthly telephone contact with question and answer sessions for the patients over the next 18 months.

4.1.4 The outcome was medication adherence which could be measured by the Medication Adherence Rating Scale (MARS).

4.2 Suggestions

In accordance with the summary of linked evidence-based practice, it would be suggested that the psychoeducational programs among adult patients with bipolar disorder were effective at enhancing medication adherence and should be implemented based on the following suggestions:

4.2.1 Implications for practice:

1. From the mental health perspective in Bangladesh, brief group psychoeducational programs should be developed using 8-10 sessions. Brief group psychoeducational programs are easy, short and cost-effective. In the Bangladeshi context, bipolar patients and their family members will not accept long-term programs because most of the patients' families are poor and not educated. Furthermore, the families have no time to participate in long-term psychoeducation programs. They have to spend time working for a living; hence, they cannot participate in long, drawn-out programs. That's why the author would like to develop a brief group psychoeducational program.

2. A psychoeducational manual should be constructed as a clinical practice guideline for use in clinics with inpatients and outpatients to train the psychiatric nurses in order to implement the program.

3. The content and process of the psychoeducational program should be simple and connected to patient goals as well as acceptable to patients. In addition, patients and caregivers should be provided easy, verbal and written orders and information on drug treatment

4. The Medication Adherence Rating Scale (MARS) that is used to measure medication adherence should be translated into a Bengali version.

5. To increase medication adherence, psychoeducational programs should be included for adult patients with bipolar disorder to ensure that every patient and family member has opportunities to participate to the program easily.

6. In the selected samples of evidence-based practice, nurses did not provide psychoeducation. Nurses can, however, be trained to conduct psychoeducation interventions.

4.2.2 Implications for research

1 Research should be conducted to evaluate the outcomes of bipolar disorder patients after attaining a psychoeducational program or follow-up session.

2. Before implementing psychoeducation programs in patients with bipolar disorders, a pilot study should be done in order to adjust the program appropriately for the Bangladeshi context.

3. Apart from medication adherence, other varieties should be studied concerning the outcomes from providing psychoeducation programs to patients with bipolar disorder.

4. Multidisciplinary teams including nurses, physicians, psychologists, psychiatrists, occupational therapists and social workers should be prepared to provide psychoeducational programs in hospitals with inpatient and outpatient settings.

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