

## SPECIAL ISSUE

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# Psychological treatment for bipolar disorders

## A review of randomised controlled trials

**Abstract** The increased acceptance of stress-vulnerability models of severe mental disorders and of brief evidence-based psychological treatments in their treatment has finally led to increased interest in the role of psychotherapies in bipolar disorders. This paper reviews the results from randomised controlled trials of psychological therapies as an adjunct to standard medications. The evidence suggests that the addition of a psychological therapy may significantly reduce symptoms, enhance social adjustment and functioning, and reduce relapses and hospitalisations in patients with bipolar disorder. However, the methodological problems in the published randomised controlled trials and the heterogeneity in the outcomes achieved (some therapies reduce manic but not depressive relapses, others have the opposite effect) suggests that further studies are required to fully establish the place of these approaches in day to day practice.

**Keywords** psychological treatments · psychotherapy · mood disorders · manic depression · bipolar disorders · randomized controlled trials

### Introduction

Bipolar disorder (BP) has a lifetime prevalence rate of 1–2% (Goodwin and Jamison 1990; Tohen and Angst 2002). It is a severe mental disorder characterised by recurrent affective episodes (Angst et al. 2003). Relapse rates after a manic episode are reported to be around 50% at one year and 70–85% at five years (Gitlin, Swendsen, Heller and Hammen 1995). The disorder is

associated with substantial morbidity and high mortality even in patients prescribed appropriate mood stabilising medication (Priem and Potter 1990; Angst F et al. 2002). However, for many decades there was a widely held belief that psychological therapies had little to add to the treatment of BP because the disorder is primarily biologically determined (Scott 1995). The increasing emphasis on stress diathesis models of BP has gradually changed this view and in the last years a number of large scale randomised controlled trials (RCTs) have commenced or been completed (Scott and Todd 2002). Although these trials employ different psychotherapy models, they all explore the possible health gain of providing psychological treatments as an adjunct to usual clinical management (usually medication plus outpatient support) to individuals with BP.

There have been several reviews of literature examining the efficacy of psychotherapy in BP (e.g. Scott 1995; Craighead and Miklowitz 2000). However, many of these pre-dated the publication of the most recent, larger scale RCTs. So far, there has been no systematic review focusing exclusively on RCTs. For this reason, this paper only explores the outcomes of RCTs of psychological treatments for BP.

### Psychosocial interventions

The following types of therapy will be reviewed:

- Psychoeducation
- Family Focused Therapy (FFT)
- Group Therapy
- Cognitive Behavioural Therapy (CBT)
- Interpersonal and Social Rhythm Therapy (IPSRT)

It is important to note that this categorisation is somewhat arbitrary as there is substantial overlap in the techniques used in the therapies and some approaches, e.g. group psychoeducation or relapse prevention packages (which employ CBT techniques) could be classified into more than one category. If the manuals for each specific

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therapy are compared it is clear that there are four shared components in all the psychotherapies. These common interventions are: education and awareness about BP and its symptoms, regularizing daily activities and reducing substance misuse, enhancing medication adherence, and identifying and managing the early stages of BP relapse. The relative emphasis on these common elements may vary between therapies, and there are also some therapy-specific components. However, the similarities between these brief structured approaches are more striking than the differences and there appears to be some consensus on the basic issues that need to be tackled. The outcomes from the available RCTs are now reviewed and Table 1 highlights the key studies.

## ■ Psychoeducation

Psychoeducation approaches are primarily aimed at providing information about the causes and likely course of BP, the rationale for the treatments provided and the development of individual skills that enable effective self-management of life stressors and early prodromal symptoms of impending relapse. However, the approach often includes components specific to other interventions such as behavioural techniques and similarly, psychoeducation is a key element of almost all other psychotherapeutic approaches (Scott and Todd 2002). Psychoeducation has been delivered in individual, family and group formats.

### Individual psychoeducation

Peet & Harvey (1991) developed a standardised brief educational intervention for euthymic BP patients. They

**Table 1** Key randomized controlled trials of psychological treatments as an adjunct to medication in bipolar disorders

Study	Sample size	Experimental intervention	Control intervention	Outcomes
Frank et al. 1997, 1999	N = 82 IPSRT/IPSRT (n = 18) IPSRT/CM (n = 25) CM/CM (n = 22) CM/IPSRT (n = 17)	Acute phase <i>IPSRT</i> Weekly sessions until stabilisation achieved  Preventative phase <i>IPSRT or CM</i> Biweekly sessions for 12 weeks then monthly sessions for 2 years	Acute phase <i>Clinical Management (CM)</i> Weekly sessions until stabilisation achieved  Preventative phase <i>IPSRT or CM</i> Biweekly sessions for 12 weeks then monthly sessions for 2 years	Participants remaining in the same treatment for both acute and preventative phases had lower rates of recurrence <b>Study Duration: 24 months</b>
Perry et al. 1999	N = 69 Relapse Prevention = 35 Control = 34	<i>Relapse Prevention</i> 7–12 sessions of one hour each aimed at identifying early warning signs of relapse and developing and rehearsing action plans	<i>Treatment as usual</i>	Reduction in manic but not depressive relapses Improved overall social functioning and employment <b>Study Duration: 18 months</b>
Miklowitz et al. 2000	N = 101 FFT = 30, Control = 71	<i>FFT</i> 21 family sessions of about one hour duration delivered over 9 months	<i>Crisis Management</i> <b>Consisted of:</b> 2 family education sessions Follow-up crisis management as required	Fewer relapses and longer delays before relapses Improvements in depressive but not manic symptoms More positive nonverbal interactional behaviour <b>Study Duration: 24 months</b>
Scott et al. 2001	N = 42 CBT 21, WLC = 21	<i>CBT</i> 22 sessions of one hour each over 6 months	<i>Waiting list control (WLC)</i> Usual treatment from the psychiatric team	Improvement in symptoms and functioning. 60 % reduction in relapse rates in the 18 m after commencing CBT compared with the 18 m prior to CBT. <b>Study Duration: 18 months</b>
Colom et al. 2003	N = 120 PsychoEd 60, Control = 60	<i>Group PsychEducation</i> 21 group sessions of 90 minutes duration	<i>Nonstructured group meetings</i> 21 sessions over 9 months	Significant reduction in number of relapsed patients and recurrences per patient. Number and length of hospitalisations per patient <b>Study Duration: 24 months</b>
Lam et al. 2003	N = 103 CBT 52 Psychiatric Care 51	<i>CBT</i> 14–20 sessions of one hour each over 6 months	<i>Treatment as usual</i>	Significantly fewer bipolar episodes and fewer hospitalisations higher social functioning. <b>Study Duration: 12 months</b>

randomly assigned 60 participants with BP to either a waiting list control group or to a group receiving an intervention providing access to educational materials (videotaped and written information about lithium), followed by a home visit by a community psychiatric nurse to discuss the material. In comparison to control group, the experimental group showed a statistically significant improvement in their knowledge about lithium (which had been poor in both groups at baseline) and a statistically significant improvement in attitudes towards the use of lithium. The intervention group also demonstrated a higher mean level of red blood cell lithium levels (possibly indicating improved adherence). The trial demonstrated that a simple brief low cost intervention could be beneficial in ways that might enhance engagement with, understanding and acceptance of treatments, but there were no follow-up data available to allow any conclusions about whether there was any impact on clinical or social functioning or on overall relapse rates. This is unfortunate, and there is a case to be made for a replication of this intervention study with a larger sample with a view to exploring its effect on clinical and social outcomes.

### Family psychoeducation

Studies of psychoeducation for individuals with BP and their families are underdeveloped and the interpretation of the available data is hampered by the fact that the studies often include heterogeneous samples of patients with unipolar, BP or schizophrenia (as described in the section on family therapy) and the BP subgroup is often small ( $n < 20$ ). The outcomes for individuals with BP and the benefits to their families have to be extracted from the published papers and potential gains may be obscured by the lack of power in these studies. The most useful evidence is provided by Clarkin and colleagues who published a small series of papers (e.g. Clarkin et al. 1998) that explored the value of 25 sessions of psychoeducation for 19 patients and their spouses over an 11-month period, and compared this to 23 control subjects who received standard medication only. They conclude that, compared to subjects in the control group, BP patients receiving family psychoeducation showed significantly greater improvement in overall functioning and increased feelings of well-being. However, there were no statistically significant between group differences in symptoms ratings.

### Group psychoeducation

In the largest and best study of psychoeducation undertaken so far, Colom et al. (2003) randomly allocated 120 currently euthymic BP patients receiving standard psychiatric care to either 21 sessions of group psychoeducation (each session was 1.5 hours in duration) or 21 sessions of non-structured support group meetings provided for the equivalent time period. Over two years, group psychoeducation was found to be significantly

more effective than the non-structured intervention in preventing relapses of both mania and depression. The number and length of hospitalisations per patient were also lower in the psychoeducation as compared to the control group (35% in the control versus 25% in the treatment group respectively were hospitalised). It is possible that the benefits of psychoeducation are largely mediated through its impact on medication adherence. To explore this notion, the research team undertook a smaller RCT ( $n = 40$ ) using the same interventions with individuals with BP who demonstrated high levels of medication adherence prior to participation in the study. The findings showed that those receiving group psychoeducation still showed significantly better clinical outcomes than those receiving the control intervention even when medication adherence was taken into account.

### Family therapy

Several studies (e.g. Miklowitz et al. 1986; Priebe et al. 1989; Simoneau et al. 1999) found that high levels of expressed emotion (EE) in parents or spouses are associated with high rates of relapse and/or poor symptomatic outcomes in BP patients. These data parallel the findings in the literature on relapse in schizophrenia and encouraged the development of family interventions in BP that built on the behavioural family therapy model that was shown to be effective in improving clinical outcomes in individuals with schizophrenia. Interventions aimed at reducing levels of EE are the most frequently evaluated family therapy models in the published RCTs.

Clarkin et al. (1998) developed an inpatient family intervention (IFI) that they delivered to patients with severe mental disorders including schizophrenia and major affective disorders (Haas et al. 1988; Spencer et al. 1988; Clarkin et al. 1990; Glick et al. 1991, 1993). In comparison to a treatment as usual control group, female patients with BP who were randomised to IFI showed significantly greater clinical improvements.

The FFT model developed by Goldstein and Miklowitz is the most widely researched family intervention in BP (Goldstein and Miklowitz 1997). The goal of treatment is to improve family functioning using a combination of communication, problem solving and coping strategies training, psychoeducation and relapse rehearsal. Miklowitz et al. (2000) conducted a RCT of 21 sessions of FFT ( $n = 31$ ) compared with standard care and a brief two session family intervention ( $n = 70$ ). Subjects receiving FFT showed a greater improvement in depressive symptoms than the control group, but no between group differences were observed in levels of manic symptoms. The benefits of FFT were greatest in individuals with BP living in a high EE environment. At two-year follow-up, the FFT group experienced fewer relapses than the standard care group (71% versus 47%). Interestingly, the original hypothesis was that FFT would be particularly effective in reducing manic re-

lapses as a direct consequence of reducing high EE. In fact the predominant benefits of FFT were that the individuals with BP showed increased rates of medication adherence compared to the control group and that the strongest observable effect was on depressive symptoms and episodes.

### ■ Group therapy

Although group therapy for individuals with BP was used quite widely in community mental health settings in the 1970s and 1980s, there are no published RCTs. Recently, more clearly delineated models of group therapy have been described and two large-scale RCTs are nearing completion. Bauer et al. (2001) introduced a structured, manual based 'Life Goals' program that aims to improve patients' illness management skills and their functional status. The program, incorporating group work and access to support and early treatment through a key worker system, is the subject of a large scale RCT in Veterans Hospitals in the USA (due to be reported in 2004). Simon and colleagues (2002) employed a similar approach in an RCT ( $n > 400$ ) conducted with individuals from a health maintenance organization in California. A key difference from the previous study is that the patients in Bauer et al.'s trial were assessed using structured diagnostic assessment tools, whilst in Simon et al.'s study the participants were recruited from those individuals who had previously been informed that they had BP. This difference in sampling may provide a useful insight into the benefits of a similar treatment programme to individuals with different types of and experiences of BP. Early reports from the Simon et al. study suggest that the intervention group as compared to the control group showed significantly greater reductions in the occurrence of manic symptoms and were significantly more likely to use additional medication to treat the symptoms of BP.

### ■ Cognitive behavioural therapy

Standardised CBT for BP (Basco and Rush 1996; Lam et al. 1999; Scott 2001) is usually delivered over 20–25 sessions and targets some or all of the following: psychoeducation, relapse prevention, stabilisation of social rhythms, medication adherence, dysfunctional thoughts and beliefs, identification and management of stressful life events and the identification and modification of mood instability. However, the literature on the use of CBT in other disorders demonstrates that it is sometimes valuable to abbreviate CBT to allow key techniques to be incorporated into the day to day clinical practice of staff who do not have formal training in this psychotherapy (Scott et al. 2004). The latter strategy is attractive as it may increase the number of individuals with BP who receive psychological input and, if clinically beneficial it may prove to be a highly cost-effective

method of delivery. The RCTs undertaken so far demonstrate these different approaches to using cognitive and behavioural strategies. The two earliest studies selectively utilised specific behavioural or cognitive techniques combined with simple problem-solving to target one specific difficulty (either medication non-adherence, or recognising and managing early symptoms of relapse). The later studies employed the classic CBT approach that incorporates the use of case formulation and clearly represents an elaboration of the existing CBT intervention employed successfully in unipolar disorders.

### Brief technique-driven interventions

Cochran (1984) conducted the first RCT of CBT in patients with BP who were newly referred to a lithium clinic. In a small-scale study, she assigned 28 subjects to standard treatment or standard treatment plus six sessions of CBT at weekly intervals. At post treatment assessment and six months follow-up, patients in the CBT group had significantly fewer relapses, better adherence and were less likely to have discontinued lithium (21 % v 57 %) than individuals receiving standard treatment alone. Unfortunately no data were provided on the rates of mania or depression in each group or time to relapse. Nevertheless, given the simplicity of the intervention it would be useful to replicate this study in a larger sample.

Perry et al. (1999) undertook an RCT of a sample of 69 patients at high risk of BP relapse. The intervention (median number of sessions = 9) taught patients to use cognitive and behavioural strategies to recognise and manage BP prodromes. The subjects met regularly with a psychology graduate with minimal experience of mental health work to learn the key early warning signs and symptoms that indicated they may be at high risk of relapse (termed the relapse signature). After identifying the relapse signature the patient and psychologist developed a treatment plan of how to self-manage symptoms (e.g. through the use of additional medication) and also how and when they should seek the help of key mental health professionals. Over an 18-month period, the intervention had a significantly greater impact than the control treatment on manic relapses (relapse prevention v treatment as usual: 30 % reduction in manic episodes, longer time to first manic episode, shorter and less frequent hospitalisations for mania). However, the relapse prevention intervention had no effect on rates of depressive relapse and the only between group difference was that the intervention group was significantly more likely to receive antidepressant medication.

### Cognitive behaviour therapy

Scott, Garland & Moorhead (2001) randomly allocated 42 BP patients to 22 sessions of CT or a six-month waiting list control condition. All patients received their usual medication. Patients in the experimental group

experienced statistically significant improvements in global functioning and reductions in depressive symptoms. The impact of CT on manic symptoms was less marked, but there was evidence of fewer episodes of mania and depression during CBT and the one year after CBT was completed.

Lam et al. (2000, 2003) conducted a pilot RCT ( $n = 25$ ) followed by a larger scale RCT ( $n = 103$ ) of CBT for BP. All participants received mood stabilisers and psychiatric follow-up, but half were also randomised to about 20 sessions of CBT over six months. The main study demonstrated that the CBT group had significantly fewer episodes of BP, fewer hospitalisations, higher social functioning and better adherence with medication. The proportion of patients experiencing a relapse over one year was 44 % in the CBT group and 75 % in the control group. The CBT group was also significantly better at coping with manic prodromes at the six and 12 month follow-up.

### ■ Interpersonal and social rhythm therapy

Interpersonal and social rhythm therapy (IPSRT) was developed by Frank et al. (2000) and represents a modification of the IPT intervention that is known to be effective in the treatment of acute major depression. As well as the established interpersonal and role functioning targets, IPSRT also seeks to regulate both social and circadian rhythms. The main components of therapy are psychoeducation, social rhythm regulation, cognitive and behavioural interventions and strategies to manage interpersonal events and problems.

Frank and colleagues (1997, 1999) published the results of an ongoing two stage RCT that explored the benefits of IPSRT as compared to Clinical Management (comprising support, education and a review of symptoms and treatment). In the preliminary or acute phase, patients who were currently in a BP episode were randomly allocated to IPSRT (high intensity psychological treatment) as compared to Clinical Management (low intensity psychological treatment). After the acute phase, those patients who were stabilised then entered phase two of the RCT. The randomisation process was then repeated so that some participants were reassigned to continue with their previous therapy (IPSRT-IPSRT or CM-CM) whilst others were now allocated to the alternative therapy (i. e. IPSRT followed by CM or CM followed by IPSRT). The design is a complex one that obviously attempts to answer a number of key questions about the benefits of psychological therapies in the treatment of the acute and the maintenance phases of BP, but also explores whether using therapies of different intensities have any advantages for patients in either illness phase.

Results published so far indicate that IPSRT plus medication helps patients achieve more stable social rhythms than those receiving CM and medication. There is also a trend in the IPSRT group for individuals

to recover more quickly from a major depressive episode compared to those receiving CM. However, there were no differences in relapse rates in those receiving IPSRT in both phases (IPSRT-IPSRT) or receiving CM in both phases (CM-CM). The most notable finding was that participants who changed therapy in phase two (IPSRT-CM or CM-IPSRT) had significantly higher rates of BP relapse and symptoms over two years of monitoring compared to those receiving the same therapy continuously (IPSRT-IPSRT or CM-CM). One explanation of the findings is that stability and continuity of the therapy package may be more important for individuals with BP than which specific therapy they receive. However, it should also be noted that all treatment groups in this trial had good outcomes and it may be that the nature of the sample or the quality of the medication management and the control treatment obscured or eliminated any subtle differences in outcome that might be attributable to the therapies. This in itself would be an important result as it would suggest that high quality prescribing and appropriate basic support and clinical management may alone improve the clinical outcome of BP.

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### Conclusion

Several psychosocial approaches have been used as an adjunct to pharmacotherapy in the treatment of BP. All therapies employ psycho-education and promote self-management of various aspects of BP. Differences among the treatments relate to the underlying theoretical model which dictates the relative emphasis placed on various components of the interventions (IPSRT emphasises social rhythms and role changes etc), the method of delivery (individual, family or group), and the phase of the illness in which they are implemented (the RCTs of IFI and IPSRT began with patients currently in an acute BP episode). Despite this heterogeneity, almost all the studies examined have found some benefits from adjunctive psychotherapy. Positive outcomes include increased medication adherence, improved attitudes towards and knowledge about treatments, decreased number and length of hospitalisations, fewer relapses or extended symptom-free periods, improved social functioning, increased work productivity, improved sense of well-being, improved family functioning, and improved marital relationships. However, comparisons between studies expose some inconsistencies. For example, Perry et al. (1999) showed that a brief approach incorporating CBT techniques prevented or delayed the onset of mania but not of depression. This is contrary to other studies where a longer course of CBT prevented both manic and depressive episodes (Scott et al. 2001; Lam et al. 2003). It may be that briefer therapies teach the individual relapse prevention skills that avoid the evolution of manic prodromes into a full blown episode. However, a more extensive course of CBT may be needed to reduce sub-

syndromal depressive symptoms, to enable the individual to recognise the subtle shift from a subsyndromal state into a major depressive episode and to implement effective interventions to treat BP depression. If an individual experiences isolated manic symptoms it is possible to use behavioural strategies and early modifications of the medication regime to quickly avert the risk of manic relapse. The resolution of depressive symptoms and/or prevention of depressive relapse require more therapy time, whilst the introduction and use of antidepressants to treat BP depression needs greater attention to ensure that the risk of a switch into mania is avoided. However, the hypothesis that these differences in the evolution and treatment of manic and depressive prodromes account for the RCT findings cannot be accepted without question. Other therapies, notably FFT and IPSRT, were developed from theoretical models that suggested these approaches would particularly prevent manic relapses and yet both interventions appear to have a greater impact on depressive symptoms and/or depressive relapses than on mania (Miklowitz et al. 2000; Frank et al. 1997).

Further research and more high quality large scale RCTs are needed to enable us to understand the differential reductions in the risk of manic and depressive relapses with different therapy models. However, for clinicians, the clear message from this review is that offering psychological treatments as an adjunct to medication for individuals with BP are beneficial. Given that the brief technique driven interventions (adherence therapy and relapse prevention packages) and the group psychoeducation model is probably easier for mental health professionals to master there would appear to be a strong argument for these to be part of our basic treatment of BP. The results of RCTs using the most recent models of group therapy are eagerly awaited as these seem to combine brief psychoeducation and a skills-based group work with a systematic approach to chronic disease management. Again this may prove to be a cost-effective way of delivering a better service to individuals with BP. Until the findings from these studies are available, the only alternative to the simpler interventions are the extended courses of specific psychological therapies that were all developed from effective models applied to populations of individuals with unipolar disorders. The training and skill level required to deliver FFT, IPSRT and CBT vary, but all three approaches are likely to remain as more selective options, used primarily for those individuals at high risk of relapse or with complex problems who do not benefit from a combination of pharmacotherapy with basic psychological approaches. There is no clear evidence as to which of these three therapies (IPSRT, FFT, CBT) should be employed in any given situation, as there are no data on how they perform when compared directly with each other. As such, decisions about which model to use will largely be governed by patient and clinician preferences, or most probably the availability of a suitably skilled exponent of one of the approaches outlined.

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