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Research paper

A study of the real-world effectiveness of group psychoeducation for bipolar disorders: Is change in illness perception a key mediator of benefit?

B. Etain[a,b,c,d,e,*,1], J. Scott[b,e,f,1], B. Cochet[g,1], F. Bellivier[a,b,c,d], C. Boudebesse[g,h,i], N. Drancourt[g], S Lauer[g], I. Dusser[g], L. Yon[g], D. Fouques[j], J.R. Richard[i], M. Lajnef[i], M. Leboyer[d,g,h,i], C. Henry[d,g,h]

[a] AP-HP, GH Saint-Louis - Lariboisière - F. Widal, Département de Psychiatrie et de Médecine Addictologique, Paris, France
[b] Université Paris Diderot, Sorbonne Paris Cité, Paris, France
[c] Inserm, UMR-S1144, Paris, France
[d] Fondation FondaMental, Créteil, France
[e] Centre for Affective Disorders, Institute of Psychiatry, London, UK
[f] Academic Psychiatry, Institute of Neuroscience, Newcastle University, UK
[g] AP-HP, Hôpitaux Universitaires Henri Mondor, DHU Pepsy, Pôle de Psychiatrie, Créteil, France
[h] Université Paris Est, Faculté de Médecine, Créteil, France
[i] INSERM U955, IMRB, Créteil, France
[j] Université Paris Ouest Nanterre La Défense, France

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ABSTRACT

Background: Findings from efficacy trials of group psychoeducation (PE) for bipolar disorders (BD) led to its inclusion in evidence-based guidelines as a first-line mandatory treatment. However, pragmatic trials and observational studies are needed to determine its real-world effectiveness, impact on outcomes deemed important to patients and to clarify potential mediators of any benefits.

Methods: Individuals with BD were offered the opportunity to participate in 20 h of PE and asked to complete pre- and post-intervention ratings of symptoms, knowledge about BD, medication adherence, and illness perception. *A priori*, two key patient outcomes were identified (social functioning and self-esteem); sample attrition due to dropout or relapse was recorded.

Results: Of 156 individuals who completed the pre-PE assessments, 103 completed the program and post-PE assessments. Only 4 of 53 dropouts were associated with BD relapse. Post-intervention, the PE completers demonstrated a statistically significant improvement in social functioning ($p = 0.003$, Effect Size (ES) = 0.26) and a trend towards improved self-esteem (ES = 0.14). Whilst there were significant changes in medication adherence ($p = 0.002$, ES = 0.28), knowledge of BD ($p < 0.001$, ES = 1.20), and illness perception ($p < 0.001$, ES = −0.37), mediational analysis demonstrated that only change in illness perception was associated to change in functioning ($p = 0.03$) with no contribution from changes in knowledge of BD or medication adherence.

Conclusions: In real-world settings, over 60% individuals completed 10-session course of PE. After controlling for demography and baseline clinical state, change in illness perception, rather than change in knowledge or medication adherence, emerged as a potential mediator of some benefits of PE.

1. Introduction

Bipolar disorders (BD) affect 1–4% of the population, causing significant mortality, morbidity and psychosocial adversity (Goodwin, 2009; Murray and Lopez, 2013). It is acknowledged that optimal treatment of BD cannot rely on pharmacotherapy alone, and clinical practice guidelines recommend the use of psychological interventions, such as psychoeducation (PE) as a first line maintenance treatment (Yatham et al., 2013). These recommendations arose because randomized controlled trials (RCTs) repeatedly demonstrated the efficacy of group PE in preventing BD relapses in individuals who commenced therapy during euthymia.

* Correspondence to: Centre Expert Troubles Bipolaires, Département de Psychiatrie et de Médecine Addictologique, Hôpital Fernand Widal, 200 rue du Faubourg Saint Denis, 75010 Paris, France.
E-mail address: bruno.etain@inserm.fr (B. Etain).
[1] Equal contribution.

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Whilst many elements of efficacy RCTs help to minimize confounding and bias (e.g. recruitment of homogeneous samples of euthymic cases) and maximize opportunities to detect treatment effects (Carroll and Rounsaville, 2003), the consequences can be a loss of external validity and generalizability (Scott, 2008). For example, (Hoertel et al., 2013) demonstrated that more than 50% individuals with BD would be excluded from most efficacy RCTs (58–64% for depression; 56% for mania), and that excluded cases were those that were least likely to respond to the experimental treatment. Also, the endpoints and outcome measures employed in efficacy studies primarily focus on targets that are of most concern to health care providers (e.g. relapses, admissions, cost) (Camacho et al., 2017), rather than benefits that are the most meaningful to patients (e.g. concerns about functioning and self-esteem, etc.) (Jonas et al., 2012). Lastly, knowledge of the clinical predictors or moderators of response to PE and other therapies (such as prior number of BD episodes) does not always shed light on the mediators of any therapeutic effects (in contrast to studies of putative mechanisms of action of medications) (Calabrese and Kemp, 2008). Given these issues, it is important to continue to evaluate interventions after they are transferred to general psychiatry settings to understand any efficacy-effectiveness gaps (Blanco et al., 2013).

Recent studies of PE have begun to address the above concerns, demonstrating practical barriers to delivering group PE in day to day practice (Biseul et al., 2016; Coulthard et al., 2013), and/or patient preferences for shorter duration of therapy (Kallestad et al., 2016). Furthermore, PE may be less effective when offered to heterogenous BD populations with complex or unstable (non-euthymic) presentations, and/or if delivered by less able therapists (Biseul et al., 2016; Bond and Anderson, 2015; Kallestad et al., 2016; Morriss et al., 2016). These findings do not detract from the importance of offering group PE in routine clinical settings, but attest to the need for comparative effectiveness research (CER) (National Research Council, 2009), which encompasses a range of methodologies including prospective observational monitoring of patient-related outcomes and use of self-ratings in broader clinical samples than recruited to RCTs (Berger et al., 2009; Marko and Weil, 2010). Although these CER approaches are gaining acceptance in psychiatry (Friedman et al., 2014), their role with therapies is underexplored compared to medications (Lambert, 2017; Porzsolt et al., 2015). As such, we report a feasibility, or 'proof of principle' study that assessed individuals with BD from the point of acceptance of an invitation to participate in PE through to dropout from or completion of a group programme delivered in a day-to-day clinical setting and that included patient-focused outcomes. We specifically explored:

1. Adherence / Attrition: How many cases that completed the pre-PE assessments and commenced the course of therapy also completed the programme and the post-PE assessments? What are the baseline characteristics associated with dropout and the commonest reasons for sample attrition?
2. Therapy Outcomes: How many relapses are observed during the intervention period? Are there any significant pre- to post-PE changes in mood and anxiety symptoms or in the two patient-focused outcomes, namely social functioning and self-esteem?
3. Mediators: Is it possible to identify any full or partial mediators of therapeutic effects of PE on the patient-orientated outcome measures? The mediators were selected after a review of the empirical literature published during the last decade. This identified that knowledge about BD, medication adherence and illness perception have all been specifically targeted in PE programs and have been identified or proposed as putative mediators of the effects of PE (see Appendix 1). For example, it was noted that PE could enhance medication adherence (Gonzalez-Pinto et al., 2004; Miklowitz and Scott, 2009; Vieta, 2005), but also that PE can also be beneficial in individuals who show high levels of medication adherence (Colom et al., 2003b), leading to investigations of the potential importance of health beliefs and illness-awareness (Colom and Lam, 2005).

2. Methods

As group PE and monitoring of outcome are part of routine clinical practice in the service where the study was undertaken, the local ethical committee gave approval for this project as a 'treatment as usual' study (for additional details about this classification see (Biseul et al., 2016)). Individuals offered to option of participation in group PE were first provided with an information sheet about the programme, after which they had to demonstrate their interest in PE by 'opting-in' (i.e. initiating a preliminary appointment to discuss joining a PE group). Individuals identified as eligible for PE were then given a letter explaining that, unless they refused to give consent, their de-identified assessment data would be included in an evaluation of the benefits of PE. The ethical committee does not permit data collection about, nor any contact with: (i) clinic attendees with BD who were not referred to the group PE programme, or (ii) individuals who did not 'opt-in' to a discussion about PE participation.

2.1. Participants

2.1.1. Sample recruitment

Local psychiatrists working in the public and private sector in the catchment area surrounding the Creteil district of Paris were invited to refer individuals with a primary diagnosis of BD for potential participation in PE. The period of data collection was 2008–2015. During the same period, we received around 450 letters from psychiatrist who would like to refer their patients to the psychoeducation programme. All of these referred patients have received a letter for an invitation to contact us for their participation. Of these, only 156 effectively came to participate, leading an estimate of around 35%. For the 450 potential participants, ethical constraints precluded retrieval of further information.

2.1.2. Eligibility

The only exclusion criteria for group PE were: (i) deafness or other impairments to communication (e.g. difficulties in comprehending the French language); and (ii) a current diagnosis of social phobia, severe alcohol or substance misuse, severe antisocial or borderline personality disorder, and/or impaired intellectual capacity. Participation in PE was delayed for about three months (to allow a period of stabilization) for individuals with a Young Mania Rating Scale score $>=8$ (YMRS) (Young et al., 1978), and/or a Montgomery Asberg Depressions Scale (MADRS) score $>=15$ (Montgomery and Åsberg, 1979), and/or if the individual had experienced a recent acute BD episode. Whilst all PE participants were encouraged to continue with ongoing prescribed interventions (e.g. pharmacotherapy and social support, etc.), failure to do so was not an exclusion criterion.

2.2. Psycho-education intervention

The PE intervention closely followed the programme described in the manual by Colom and Vieta (Colom et al., 2006), but was modified to allow completion over 10 sessions (of 120 min each) which were delivered over three months and supplemented by between-session learning exercises and homework assignments (additional details in Appendix 1). Each PE group comprised of 7–11 individuals with BD and sessions were conducted by a psychologist and a psychiatrist (with > 5 years of clinical experience of working with BD, and specific training in groups and CBT).

2.3. Assessments

Participants were asked to attend three individual meetings. During two pre-intervention meetings, individuals received information about