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Research paper

The long-term outcomes of an effectiveness trial of group versus individual psychoeducation for bipolar disorders

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ABSTRACT

Background: In this effectiveness trial we compared the long-term effects on hospitalizations of group psychoeducation (GP) versus individual psychoeducation (IP) for a heterogeneous sample of patients with BD recruited from general clinical settings.
Methods: Eighty-five patients with BD were randomized to receive 10 weekly sessions of GP followed by 8 booster-sessions over the next two years, or three sessions of IP. Time to first admission over the course of GP was the primary outcome measure, with additional outcomes examining the use of psychiatric services over about 8 years.
Results: Patients allocated to GP had longer survival time compared to IP over 27 months ($p < 0.05$). There were also group differences in survival time over 8 years, but treatment allocation alone was no longer a significant predictor of survival time ($p=0.07$). There was an interaction between group (GP/IP) and harmful substance use (HSU), such that GP cases with comorbid HSU had the shortest survival time, whilst GP cases without HSU survived the longest ($p=0.02$). Also, GP cases had a small but significant reduction in hospital use compared with IP ($p=0.04$).
Limitations: We did not have a 'pure' treatment as usual group. Wide confidence intervals for some of the odds ratios suggest that the findings need to be treated with some caution. Insufficient sample size for more detailed subgroup analyses.
Conclusions: GP is superior to IP in delaying hospitalizations in a clinically representative population. However, GP did not prevent or delay admissions in BD patients with HSU.

1. Introduction

It is well-established that individuals with bipolar disorder (BD) are at high risk of *syn*dromal episode recurrences (Winokur et al., 1993). The treatment of choice is mood stabilizers to prevent relapses, but there is a widespread recognition that pharmacological treatment alone may be insufficient and/or the benefits of medication may be undermined by reduced adherence (Scott et al., 2007). In addition, treatment benefits and illness are adversely affected by the presence of comorbid disorders, especially alcohol and substance use problems (Scott et al., 2007; Yatham et al., 2013). To address many of these issues, the first line recommended maintenance treatments in clinical practice guidelines have increasing suggested the use of adjunctive psychosocial interventions such as psychoeducation (Malhi et al., 2015; Yatham et al., 2013).

The primary reason for recommending the use of psychoeducation is the evidence that has accrued from a number of efficacy trials, e.g. Colom et al. (2003). Such studies have demonstrated both the short-term and long-term benefits of group psychoeducation, not least the reduction in admission rates for all types of BD episodes, although the treatment seems to be less effective for patients in an advanced stage of illness (Bond and Anderson, 2015; Colom, 2014; Colom et al., 2009b; Luciano et al., 2015; Miziou et al., 2015; Scott et al., 2007). However, as psychoeducation is increasingly offered to cases treated in routine clinical practice, it is clear that some issues remain to be resolved about its generalizability. For example, some patients find the time and meeting pattern for standard group psychoeducation (GP) courses difficult

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to adhere to and request a more flexible program (Coulthard et al., 2013). Second, it is not clear whether the same GP course should be offered for BD II and BD I cases (Colom et al., 2009a) or if a briefer course of GP and/or individual psychoeducation (IP) are as potent as the original model (Parikh et al., 2012). Third, by definition, efficacy trials often employ more rigorous inclusion criteria (to enhance sample homogeneity) which can be difficult to apply in day to day practice. For example, many individuals seen in routine clinical practice with BD would be excluded from efficacy studies because they do not meet the requirement of being euthymic for an extended period of time or because of comorbid alcohol or substance misuse. Indeed, a recent report by Hoertel and colleagues indicated that only 50% of patients with BD treated in general clinical settings would be eligible for inclusion in published treatment efficacy trials (Hoertel et al., 2013).

A small number of studies have examined the effectiveness of GP in more naturalistic clinical settings and/or have adapted the GP model to meet local needs (Candini et al., 2013; Castle et al., 2010; de Barros Pellegrinelli et al., 2013). For example, a recent trial that tested an eight-week intervention failed to find an effect of GP on mood, level of functioning or quality of life (de Barros Pellegrinelli et al., 2013). The authors speculated that the sample characteristics of long duration of illness and many previous episodes might have influenced the outcomes achieved with this brief GP intervention (de Barros Pellegrinelli et al., 2013). Interestingly, a trial of a 12-week GP program that provided three additional booster sessions (one per month) significantly reduced relapse rates at nine months follow-up compared to treatment as usual (Castle et al., 2010). Also, that study did not explicitly exclude cases with drug or alcohol problems (Castle et al., 2010). In a non-randomized study in routine clinical practice in Italy, Candini et al. (2013) found that GP was successful in reducing number and duration of psychiatric admissions. Overall, these studies provide some support for the use of GP in general as well as specialist or research orientated services. However, some of the studies were small or non-randomized, and most of the findings suggest worse outcomes in patients with multiple previous episodes or complex illness profiles. Several of the studies have limited follow-up periods (e.g. 6–9 months), indicating a need for randomized effectiveness trials with longer term follow-ups.

Most of the above studies were unable to examine whether the presence of 'harmful' alcohol or substance use adversely affected outcomes from psychoeducation. This is important as such problems may affect as many as 60% of BD patients (depending on how the alcohol or substance problem is defined) (Regier et al., 1990). These patients are repeatedly reported to have a poor prognosis with more hospitalizations, increased suicidality, lower medication adherence, and slower recovery from mood episodes (Weiss et al., 2007). A series of papers by Weiss and colleagues has shown that a specialized and integrated group intervention (which includes many elements of psychoeducation) can successfully reduce the number of days with substance abuse, though not BD severity in cases with 'dual diagnosis' (Weiss et al., 2000, 2007). Other research with patients with severe mental disorders such as psychosis has suggested that the use of brief Motivational Interviewing (MI) as an adjunct to cognitive therapy or psychoeducation may enhance the motivation to change 'substance-related' behaviors and improve outcomes (Bagoien et al., 2013; Barrowclough et al., 2014).

Taken as a whole, it is timely to examine the short- and long-term effectiveness of brief, IP and an extended GP program (delivered in a format that meets local patient preferences) to individuals with BD. To ensure this was a pragmatic trial, individuals with repeated psychiatric admissions and/or with *syn*dromal or sub*syn*dromal symptoms (i.e. those who are not currently euthymic) were all eligible for inclusion. Furthermore, those with 'harmful' substance use (drugs and/or alcohol) could be included, with those randomized to GP being offered two sessions of MI before starting the course of GP. The aims of this study are to compare the long-term effectiveness of GP (27 months intervention) and IP (three sessions) in a general clinical setting where patients with repeated psychiatric admissions, syndromal or subsyndromal symptoms, and 'harmful' substance use could be included. Time to first hospitalization over the first 27 months was the primary outcome measure, with additional long-term outcomes examining time to hospitalization, and hospital use, 8 years post randomization.

2. Methods

2.1. Trial design

This was a pragmatic, parallel group RCT of GP plus treatment as usual (TAU) compared with IP plus TAU for BD, with a balanced randomization between the two groups. The primary outcome measure was time to first psychiatric admission after randomization. The recruitment period for the RCT was 2005–2007, and the final follow-ups were completed during 2013–14. Ethical approval for the study was obtained from the Regional Committee for Medical and Health Research Ethics of Central Norway (approval number: 4.2005.94) and the study was registered at ClinicalTrials.gov (NCT00159562).

2.2. Participants

The trial was undertaken at the Bipolar Clinic at the Østmarka Department of Psychiatry, in Trondheim, Norway. The department is the only public provider of mental health services for the inhabitants of Sør-Trøndelag County (catchment area=290000). Given the pragmatic design, inclusion criteria were broad and exclusion criteria were minimal. Individuals were eligible for inclusion if they were aged >18 years, and were receiving ongoing treatment by a general practitioner, psychiatrist, psychologist or health care worker (supervised by a psychiatrist) for a BD I or BD II disorder that met DSM-IV diagnostic criteria (American Psychiatric Association and American Psychiatric Association Task Force on DSM-IV, 2000). The only exclusion criteria were: unable or unwilling to give written informed consent, clinical evidence of substantial cognitive impairments or acutely elevated risk of suicide, and/or insufficient understanding of Norwegian language to allow participation in the therapy sessions.

2.3. Procedures and study timeline

2.3.1. Recruitment and inclusion

Recruitment started in fall 2005 and lasted until spring 2007. The study participants were recruited via referrals from general practitioners and from in- and outpatient facilities at the Department of Psychiatry, St. Olav's University Hospital. All potential participants were given both oral and written information about the study, and signed a consent form. A clinical psychologist undertook a clinical interview using a structured clinical schedule (see next section) that confirmed the diagnosis (BD I or II) and assessed if the patient was eligible for inclusion.

2.3.2. Pre-treatment assessments

After inclusion, a clinical psychologist assessed key clinical characteristics and the participants completed a series of self-ratings.