Correspondence

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Group-based psychosocial intervention for bipolar disorder

Castle et al’s study provides further evidence that psychosocial treatments can supplement pharmacological treatments and improve the course and outcome of bipolar disorder. It is a well-conceived and well-implemented study. However, I would like to raise three pertinent issues.

First, the authors reported a significant baseline difference between the two groups in respect of comorbidity with anxiety and eating disorders, and reported a P value of 0.04. The P value denotes the possibility of finding the difference by chance. In a randomised controlled trial, any difference between the groups is by chance. The CONSORT guideline advises against carrying out significance tests for baseline imbalances in randomised controlled trials. Hence, we should stop doing significance tests for baseline differences in randomised controlled trials.

Second, the primary outcomes were three parameters of relapse of any mood episode (mania, depression, hypomania, mixed and other). The authors reported a significant difference between the two groups, favouring the treatment, for the combined outcome. On further analysis, they found significant differences with regard to depressive, and manic and mixed relapses. The rationales for combining manic with mixed episodes and excluding hypomanic episodes are not clear. More patients in the treatment group suffered from hypomanic episodes than in the control group (9 v. 5). Had the authors combined mania with hypomania, or mania, hypomania and mixed episodes, they would have reached a different conclusion. Therefore the authors’ conclusion that the intervention would reduce the number and duration of relapses of any type is not entirely supported by the data. In a review of psychosocial interventions in bipolar disorder, Miklowitz & Scott emphasised the need to report adverse effects along with the beneficial effects. However, the authors have primarily focused on positive and beneficial effects of the intervention.

Lastly, both groups had high relapse rates. In the treatment group, 28.1% of participants (9/32) had experienced one or more relapses. In the control group, the comparative figure was 55% (22/40). The difference between the treatment and control groups was most obvious for depression (4 v. 15). However, at face-to-face interviews (both at 3 months and 12 months), no difference was found on the Montgomery–Åsberg Depression Rating Scale. Apart from the authors’ explanation, other reasons could be the method of assessment and ascertainment bias because participants and assessors were not masked to treatment. The telephone assessments might have identified more patients with borderline depression as depressed in the control group than in the treatment group.

Authors’ reply

We are pleased that Gupta found our study of interest. As he says, the findings provide further evidence that psychosocial treatments can supplement pharmacological treatments and improve the course and outcome of bipolar disorder.

Regarding the three issues he raises: first, we agree that given the rigorous randomisation process the reporting of P values for baseline differences between ‘treatment’ and ‘control’ groups is not essential. However, many studies do report these P values and we have followed this convention in our article. Reporting P values also allows a ‘check’ on the randomisation. Here we posit that the idea of randomisation is to obtain ‘comparable’ comparison groups. If randomisation ‘fails’ in any particular way, this seems important to be aware of in both the conduct of the analyses and the interpretation of the results.

Second, regarding the outcomes, we were particularly interested to see whether we could deliver an intervention that addressed both poles of the illness, hence our strategy to define the primary outcomes in the way we did. With regard to the pooling of mixed and manic episodes, that is the most commonly used convention in clinical trial reporting.

Lastly, the rate of relapse in itself is not as important as the difference in rates between the intervention and the control group. Relapse is the most commonly used primary outcome measure in comparable trials. Our definition of relapse as the primary outcome was dictated by the fact that in bipolar disorder it is relapse that matters most for clinical care rather than symptomatic differences at any single point in time. We should also point out that the lower relapse rate in the intervention group was mirrored by a reduction in emergency psychiatric contacts and hospital admissions, lending support to the clinical utility of the intervention.


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