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Brief Report

Beating Bipolar: exploratory trial of a novel internet-based psychoeducational treatment for bipolar disorder

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Objectives: Psychoeducational approaches are promising interventions for the long-term management of bipolar disorder. In consultation with professionals, patients, and their families we have developed a novel web-based psychoeducational intervention for bipolar disorder called *Beating Bipolar*. We undertook a preliminary exploratory randomized trial to examine efficacy, feasibility and acceptability.

Methods: This was an exploratory randomized controlled trial of *Beating Bipolar* (current controlled trials registration number: ISRCTN81375447). The control arm was treatment-as-usual and the *a priori* primary outcome measure was quality of life [measured by the brief World Health Organization Quality of Life (WHOQOL–BREF) scale]. Secondary outcomes included psychosocial functioning, insight, depressive and manic symptoms and relapse, and use of healthcare resources. Fifty participants were randomized to either the *Beating Bipolar* intervention plus treatment-as-usual or just treatment-as-usual. The intervention was delivered over a four-month period and outcomes were assessed six months later.

Results: There was no significant difference between the intervention and control groups on the primary outcome measure (total WHOQOL–BREF score) but there was a modest improvement within the *psychological* subsection of the WHOQOL–BREF for the intervention group relative to the control group. There were no significant differences between the groups on any of the secondary outcome measures.

Conclusions: *Beating Bipolar* is potentially a safe and engaging intervention which can be delivered remotely to large numbers of patients with bipolar disorder at relatively low cost. It may have a modest effect on psychological quality of life. Further work is required to establish the impact of this intervention on insight, knowledge, treatment adherence, self-efficacy and self-management skills.

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Psychoeducation has emerged recently as an effective intervention for preventing relapse in the long-term management of bipolar disorder. The goals of psychoeducation include providing patients and their families with accurate and reliable information about the diagnosis, causes and treatment of bipolar disorder, as well as teaching patients a range of self-management skills, such as effective mood monitoring, early relapse recognition and pragmatic relapse prevention strategies (1). Many of the trials of psychoeducational

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interventions carried out so far have focused on symptom reduction and relapse prevention as primary outcomes. There has been very little systematic assessment of the impact of psychoeducation on quality of life, psychosocial functioning, treatment adherence, personal insight and self-management skills.

Psychoeducational treatments can be delivered in a number of formats, including individually (2), in groups (3), to patients' families, and/or carers (4, 5), and as part of systematic care programmes (6). To date, there is evidence that group-based psychoeducation is effective for preventing relapse in some (7, 8) but not all (4) clinical trials. Potential disadvantages of group approaches include the considerable cost in terms of therapist time, the likelihood that some patients will not be comfortable in group settings and the need for patients to travel to group sessions. We therefore set out to develop and test a novel internet-based psychoeducational treatment for bipolar disorder, called *Beating Bipolar*, which translates the content of group psychoeducation and, to some degree, the experience of peer-group support, for use on the internet. Based on feedback from individuals with bipolar disorder, their families and mental health professionals, we decided that our primary focus in terms of outcome should be the degree to which this new treatment improved quality of life (9). The development process for *Beating Bipolar* and the protocol for its evaluation have been described in detail elsewhere (9, 10). Here we report the findings from a phase II exploratory trial of the *Beating Bipolar* intervention.

Patients and methods

This was a phase II randomized controlled trial carried out between March 2009 and September 2010 (current controlled trials registration number: ISRCTN81375447) (10). It was approved by the South East Wales NHS Research Ethics Committee. In total, 80 participants with bipolar disorder were screened for inclusion in this study and 50 were randomized to either the *Beating Bipolar* intervention plus treatment-as-usual (TAU) or just TAU. Outcome was assessed six months after the end of the intervention.

Inclusion and exclusion criteria

The main inclusion criteria for this study were age between 18 and 65 and a diagnosis of DSM-IV bipolar disorder [including type I and type II/not otherwise specified (NOS)] currently in clinical remission. Diagnosis was confirmed using the Mini International Neuropsychiatric Interview (MINI) (11) and clinical remission was defined as not fulfilling diagnostic criteria for a depressive, manic or mixed affective episode during the preceding three-month period, plus a current Montgomery–Åsberg Depression Rating Scale (MADRS) (12) score of ≤ 10 and a Young Mania Rating Scale (YMRS) (13) score of ≤ 8. These MADRS and YMRS threshold scores are widely accepted correlates of symptomatic remission in bipolar disorder. The exclusion criterion was an inability to engage fully in the psychoeducational programme, for example, because of cognitive impairment or not having English language ability of sufficient level. Given that this was an exploratory trial, no other exclusion criteria were specified.

Recruitment

Recruitment was from multiple sources across South Wales, including Primary Care Practices and Community Mental Health Teams (CMHTs). Potential participants in this study were identified from case files by Clinical Studies Officers from the Mental Health Research Network Cymru (Wales) and invitations to take part were sent to patients on behalf of the research team from general practitioners and consultant psychiatrists. Members of the Manic Depression Fellowship in Wales were also invited to take part by their local group co-ordinators. Written informed consent was obtained from all participants.

Intervention

Beating Bipolar was developed in a three-stage process (9). In stage 1, a literature search was conducted to identify data and other information which could help to inform the design and content of a web-based psychoeducational programme for bipolar disorder (1). This included searching for information related to the design of e-learning environments, learner engagement, interactivity, presentation and instructional design. In stage 2, a multidisciplinary team including a psychiatrist, two psychologists (one with expertise in designing online learning programmes), and an educational web designer convened to draft ideas for content, delivery and interactivity based on the available literature and professional experience. In stage 3 we convened three focus groups with the goal of iteratively developing the content and format of the intervention. The draft ideas from stage 2 acted as an initial stimulus for discussions. The focus groups were made up of a combination of service users, carers and mental health professionals in order to achieve a

balance between users' subjective needs and recommendations based on clinical experience. The finalized *Beating Bipolar* intervention involves a blending of different delivery mechanisms, with initial face-to-face delivery, followed by written and web-based interactive delivery of factual content and ongoing support via a web forum (9).

The key areas covered in the package are: (i) the accurate diagnosis of bipolar disorder; (ii) the causes of bipolar disorder; (iii) the role of medication; (iv) the role of lifestyle changes; (v) relapse prevention and early intervention; (vi) psychological approaches; (vii) gender-specific considerations, and (viii) advice for family and carers. This content has a similar focus to the content within Phase I of Bauer and McBride's Life Goals Program (which also includes information on the nature of bipolar disorder, triggers and early symptoms of relapse, and self-management strategies for relapse) (14). It also has some similarities with Colom and Vieta's group psychoeducation intervention for bipolar disorder (15), although in greatly abbreviated form given that the Colom and Vieta intervention comprises 21 sessions. The programme was not designed in such a way as to be able to address individual differences (for example, patients who tend to experience more depression than mania or vice versa).

The eight modules were delivered online on a fortnightly basis over a four-month period. There was an initial face-to-face introductory meeting led by a consultant psychiatrist (DJS) to demonstrate how to use the programme. Thereafter, participants logged onto the website and completed the modules. Within each of the modules there was approximately a 50:50 mix of didactic video-based delivery of information and interactive exercises for participants to complete (for example, completing an online life-chart). In order for participants to progress through each of the modules it was necessary for them to complete each of the subsections in turn. Throughout the trial there was an opportunity for participants in the intervention group to discuss the content of the material with each other within a secure discussion forum moderated by DJS. A reminder email inviting participants to access the content was sent by the moderator (DJS) one week before each of the eight modules was made available.

Participants who were randomized to the intervention also continued to receive TAU whereas those not randomized to the intervention received just TAU. TAU for all participants comprised usual care delivered in a collaborative model between general practitioners and local multidisciplinary community mental health teams.

Randomization

Using dynamic block allocation, participants were randomized remotely using computer-generated number lists (16). The balanced variables were age, gender and bipolar disorder subtype.

Outcome measures

Outcome was assessed six months after the end of the intervention by two members of the research team (RP and AdF) who were blinded as to whether participants had received the intervention or not. The primary outcome was improvement in quality of life as measured by the World Health Organization Quality of Life, Brief version (WHOQOL–BREF) questionnaire (17). Quality of life was chosen as the primary outcome measure in response to feedback from individuals with bipolar disorder, their families and mental health professionals (9). These groups identified a need for new psychoeducational interventions to impact on broad areas of everyday functioning (particularly quality of life) which go beyond a focus on symptoms of depression and/or mania or episodes of illness. The WHOQOL–BREF is comprised of scores within four separate domains (physical health, psychological health, social relationships and environment). It is a reliable, valid and widely used measure of quality of life in psychiatric out-patient settings (18). When this study began there was no specific quality of life measure for use in bipolar disorder but the WHOQOL has been recommended as suitable for use in this population (19).

Secondary outcomes included the Global Assessment of Functioning (GAF) scale (20), the Functioning Assessment Short Test (FAST) (21), and insight measured using a modified Schedule for Assessment of Insight (SAI) (22). Current depressive symptoms according to the MADRS (23) and current manic symptoms according to the YMRS (13) were also compared between the two groups. Using the MINI (11), the number and severity of depressive and manic symptoms and number and timing of episodes of depression and mania or hypomania experienced during the 10-month period since the beginning of the trial were compared between groups.

Statistical analyses

The primary analysis was an intention-to-treat analysis comparing the WHOQOL–BREF scores between the intervention and control groups while controlling for baseline WHOQOL–BREF scores using analysis of covariance (ANCOVA). Secondary outcome analyses were performed similarly,

also controlling for baseline scores. Categorical and non-normally distributed data were analysed using the chi-squared and Mann–Whitney *U* tests, respectively, and the Cohen's *d* effect size was calculated for the intervention group (24). An exploratory analysis excluding those who did not comply with the intervention was also carried out.

Results

Eighty potential participants were assessed for inclusion but only 50 satisfied the inclusion and exclusion criteria (Fig. 1). Randomization resulted in 24 participants in the intervention group and 26 in the control TAU group. Full outcome data were available on 17 participants from the intervention arm and 20 from the control arm. Baseline characteristics of trial participants are detailed in Table 1. Randomized participants were well matched in terms of baseline sociodemographic and clinical characteristics and there were no differences between groups on current medication use (Table 1).

Primary outcome measure

In terms of changes from baseline on the total WHOQOL–BREF score, there was no significant difference between the intervention and control groups (Table 2). Although there were no differences between groups on the *physical, social relationships,* and *environment* subsections of the WHOQOL–BREF, within the *psychological* subsection, there was a marginally significant difference without correction for multiple testing: an increase of 8.1 units from 52.7 at baseline to 60.8 at follow-up within the intervention group compared to a decrease of 5.0 units from 61.9 at baseline to 56.9 at outcome within the control group ($p = 0.05$; 95% confidence interval 0.24 to 22.6). This represents a medium level (Cohen's *d*) effect size for the treatment group of 0.43. The psychological quality of life subsection of the WHOQOL–BREF assesses several areas, including: body image/appearance; negative feelings; positive feelings; self-esteem; spirituality/religion/personal beliefs and thinking; and learning, memory and concentration.

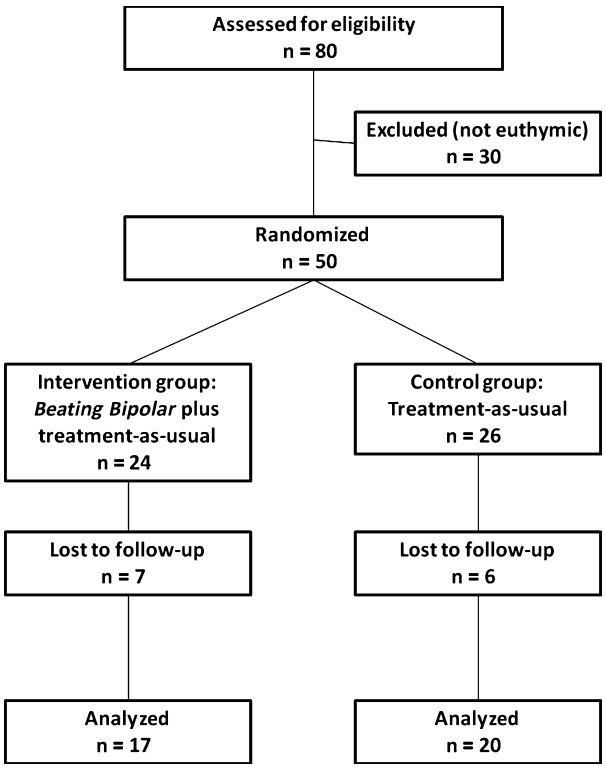

Fig. 1. CONSORT diagram.

Secondary outcome measures

There were no significant differences between groups on any of the secondary outcome measures (Table 2).

Compliance with the *Beating Bipolar* intervention

Figure 2 illustrates the use of the *Beating Bipolar* programme by each of the 24 participants within the intervention group. We were able to collect data on whether participants had completed (rather than simply accessed) the subsections within each of the eight modules. All but one of the modules had 6 subsections (the remaining module had 5) so that the total number of subsections available for completion was 47. Compliance with the intervention is defined as the proportion of these 47 subsections completed by participants (Fig. 2). Although three participants did not access any of the programme during the trial, 16/24 (66.6%) completed at least 75% of the programme. Usage of the discussion forum was variable. Only 13/24 (54.2%) of participants posted at least one message on the board and four individuals accounted for 92 out of a total of 127 messages posted (72.4%). Having said this, many of the messages posted were very positive regarding the content and format of *Beating Bipolar* and in general participants posted comments to each other which were supportive and constructive.

As an exploratory analysis, we excluded the three participants in the intervention arm who did not access any of the programme (and therefore did not receive the intervention) and re-analysed the outcome data. This analysis did not identify any differences between the groups in primary or secondary outcomes.

Table 1. Baseline characteristics

	Treatment group (n = 24)	Control group (n = 26)	p-value
Diagnosis, n (%)			
BP-I	19 (79.2)	24 (92.3)	0.34[a]
BP-II	4 (16.7)	2 (7.7)	
BP-NOS	1 (4.2)	0 (0)	
Age, years, mean (SD)	42.7 (11.4)	44.7 (9.9)	0.51[b]
Males, n (%)	11 (45.8)	8 (30.8)	0.27[a]
Caucasian ethnicity, n (%)	23 (95.8)	26 (100)	0.29[a]
Educated to A-level or above, n (%)	12 (50.0)	12 (46.2)	0.79[a]
Currently employed, n (%)	14 (58.3)	16 (61.5)	0.82[a]
Current medication, n (%)			
Antidepressant	13 (54.2)	10 (38.5)	0.27[a]
Mood stabilizer	16 (66.7)	20 (76.9)	0.42[a]
Antipsychotic	10 (41.7)	10 (38.5)	0.82[a]
Other	11 (47.8)	13 (52.0)	0.77[a]
MADRS score, mean (SD)	4.0 (3.0)	3.5 (2.8)	0.51[b]
YMRS score, mean (SD)	1.4 (2.0)	0.9 (1.7)	0.39[b]
WHOQOL–BREF total, mean (SD)	228.7 (75.0)	254.7 (81.3)	0.25[b]
Physical	56.1 (19.2)	59.5 (16.3)	0.50[b]
Psychological	52.7 (22.9)	61.9 (21.6)	0.15[b]
Social relationships	53.6 (27.8)	61.5 (31.1)	0.35[b]
Environment	66.3 (19.6)	71.9 (23.1)	0.37[b]
GAF score, mean (SD)	68.3 (13.3)	73.4 (15.1)	0.21[b]
FAST score, mean (SD)	27.5 (15.0)	21.0 (16.3)	0.15[b]
SAI score, mean (SD)	5.6 (2.2)	5.2 (1.7)	0.44[b]

BP-I = bipolar I disorder; BP-II = bipolar II disorder; BP-NOS = bipolar disorder not otherwise specified; MADRS = Montgomery–Åsberg Depression Rating Scale; YMRS = Young Mania Rating Scale; WHOQOL–BREF = World Health Organization Quality of Life, Brief version; GAF = Global Assessment of Functioning; FAST = Functioning Assessment Short Test; SAI = Schedule for Assessment of Insight; SD = standard deviation.
[a]Chi-squared test.
[b]*t*-test.

Discussion

To our knowledge, this is the first exploratory randomized controlled trial of a web-based psychoeducational treatment for bipolar disorder. The primary outcome measure (total WHOQOL–BREF score) was not significantly different between the intervention and control groups. There was a marginally statistically significant improvement ($p = 0.05$) within the psychological quality of life subsection of the WHOQOL–BREF. The intervention group increased by 8.1 points whereas the control group decreased by 5.0 points, with a Cohen's *d* effect size within the medium range at 0.43. It should be noted that this finding is not statistically significant when corrected for multiple testing. On balance, it is possible that the *Beating Bipolar* intervention has a modest positive impact on the quality of life of individuals with bipolar disorder, particularly within the domain of psychological quality of life.

Although there were no statistically significant improvements between groups on the secondary outcome measures, it is likely that the small sample size (n = 50) and the relatively brief follow-up period of six months make it difficult to draw any firm conclusions about the likely impact of the intervention on these domains, which included rates of relapse into depression, hypomania and mania, measures of psychosocial functioning, insight, and contact with health and social care services.

Over two-thirds of those in the intervention group completed at least 75% of the programme, suggesting that this was an acceptable and engaging experience for the majority of participants, although only half of participants posted messages on the discussion forum.

Strengths and limitations

This was a small study of 50 randomized patients with bipolar disorder. The majority of participants had bipolar I disorder (n = 43, 86%) (Table 1). Possible limitations include a very high proportion of participants of Caucasian ethnicity (98%) and a relatively high proportion of participants who were currently in employment (60%). As a phase II exploratory trial, strengths of this study include a clear *a priori* protocol for conducting the study and analysing the findings (10) and the recruitment of participants from real-world NHS settings in the UK. Ideally, a longer follow-up period than six

Table 2. Primary and secondary outcomes

	Treatment group (n = 17)	Control group (n = 20)	*F*-statistic	Chi-squared	Mann–Whitney *U*	p-value
Primary outcome, mean (SD)						
WHOQOL–BREF total	256.6 (52.7)	259.2 (63.2)	1.29	–	–	0.27
Physical	62.3 (19.0)	62.6 (16.5)	0.36	–	–	0.56
Psychological	60.8 (17.8)	56.9 (16.4)	4.31	–	–	0.05
Social relationships	55.5 (20.9)	62.7 (25.4)	0.01	–	–	0.93
Environment	78.1 (14.9)	77.0 (19.8)	1.75	–	–	0.19
Secondary outcomes						
MADRS score, mean (SD)	9.1 (8.4)	11.1 (13.6)	0.46	–	–	0.50
YMRS score, mean (SD)	2.4 (2.9)	3.9 (7.7)	1.03	–	–	0.32
GAF score, mean (SD)	70.8 (14.8)	65.9 (21.8)	0.95	–	–	0.34
FAST total score, mean (SD)	22.8 (12.3)	19.4 (13.6)	0.08	–	–	0.78
Autonomy	2.0 (2.3)	1.9 (2.6)	0.001	–	–	0.97
Occupational functioning	8.2 (4.8)	6.2 (5.8)	0.20	–	–	0.66
Cognitive functioning	4.5 (4.0)	4.8 (3.1)	0.44	–	–	0.51
Finances	1.5 (1.6)	1.5 (1.9)	0.08	–	–	0.78
Relationships	4.4 (4.2)	3.6 (3.6)	0.05	–	–	0.82
Leisure	2.2 (1.6)	1.7 (1.5)	0.05	–	–	0.83
SAI score, mean (SD)	5.4 (2.1)	5.7 (1.9)	3.07	–	–	0.09
Depressive episode during study period, n (%)	10 (55.6)	9 (45.0)	–	0.42	–	0.52
Episodes of depression, median [range]	1 [0–4]	0.5 [0–4]	–	–	180.0	1.00
Total number of months with depression, median [range]	0.25 [0–6]	0.25 [0–10]	–	–	174.5	0.87
Hypomanic episode during study period, n (%)	3 (17.6)	6 (30.0)	–	0.76	–	0.38
Episodes of hypomania, median [range]	0 [0–8]	0 [0–5]	–	–	150.0	0.42
Total number of months with hypomania, median [range]	0 [0–2.5]	0 [0–9]	–	–	150.5	0.43
Manic episode during study period, n (%)	4 (22.2)	5 (25.0)	–	0.04	–	0.84
Episodes of mania during study period, median [range]	0 [0–1]	0 [0–10]	–	–	144.5	0.44
Total number of months with hypomania, median [range]	0 [0–2.5]	0 [0–9]	–	–	150.5	0.43
Contacts with psychiatric services, median [range]	3 [0–30]	5 [0–52]	–	–	150.0	0.54
Contacts with primary care services, median [range]	6 [0–11]	7 [4–41]	–	–	132.0	0.25
Contacts with social services, median [range]	0 [0–12]	0 [0–0]	–	–	150.0	0.12
Contacts with other services (e.g., A & E), median [range]	1 [0–10]	0 [0–14]	–	–	110.0	0.06

WHOQOL–BREF = World Health Organization Quality of Life, Brief version; MADRS = Montgomery–Åsberg Depression Rating Scale; YMRS = Young Mania Rating Scale; GAF = Global Assessment of Functioning; FAST = Functioning Assessment Short Test; SAI = Schedule for Assessment of Insight; SD = standard deviation

months would have been preferable in order to assess any sustained benefit in the medium to longer term. Given that this was an exploratory study we did not correct for multiple testing.

Clinical implications

Our findings are in keeping with a growing body of work which suggests that psychoeducational approaches are acceptable and effective interventions in the long-term management of bipolar disorder (1). This study suggests that *Beating Bipolar* is potentially a safe and engaging intervention which can be delivered remotely to large numbers of patients with bipolar disorder and which may have a modest effect on psychological quality of life (including areas such as body image/appearance, the experience of negative and positive emotions, self-esteem, spirituality and learning/concentration). It is unclear at present which of these areas is most improved by *Beating Bipolar*. Further work is required to

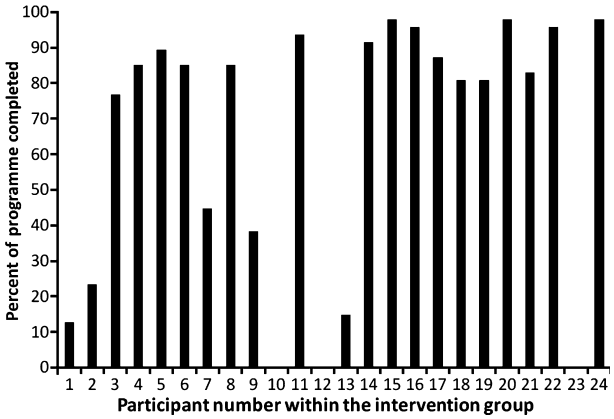

Fig. 2. Compliance of participants with the *Beating Bipolar* intervention.

establish the impact of this intervention on areas such as insight, knowledge, self-efficacy and self-management skills. This is likely to inform the design of a formal randomized controlled trial and particularly the most appropriate choice of outcome measures. The delivery of *Beating Bipolar* via the internet represents a potentially cost-effective means of providing high-quality psychoeducational material to large numbers of individuals at relatively low cost.

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