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Research paper

Psychoeducation and online mood tracking for patients with bipolar disorder: A randomised controlled trial ☆

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ABSTRACT

Background: Psychoeducation is an effective adjunct to medications in bipolar disorder (BD). Brief psychoeducational approaches have been shown to improve early identification of relapse. However, the optimal method of delivery of psychoeducation remains uncertain. Here, our objective was to compare a short therapist-facilitated vs. self-directed psychoeducational intervention for BD.
Methods: BD outpatients who were receiving medication-based treatment were randomly assigned to 5 psychoeducation sessions administered by a therapist (Facilitated Integrated Mood Management; FIMM; n=60), or self-administered psychoeducation (Manualized Integrated Mood Management; MIMM; n=61). Follow-up was based on patients' weekly responses to an electronic mood monitoring programme over 12 months.
Results: Over follow-up, there were no group differences in weekly self-rated depression symptoms or relapse/readmission rates. However, knowledge of BD (assessed with the Oxford Bipolar Knowledge questionnaire (OBQ)) was greater in the FIMM than the MIMM group at 3 months. Greater illness knowledge at 3 months was related to a higher proportion of weeks well over 12 months.
Limitations: Features of the trial may have reduced the sensitivity to our psychoeducation approach, including that BD participants had been previously engaged in self-monitoring.
Conclusions: Improved OBQ score, while accelerated by a short course of therapist-administered psychoeducation (FIMM), was seen after both treatments. It was associated with better outcome assessed as weeks well. When developing and testing a new psychosocial intervention, studies should consider proximal outcomes (e.g., acquired knowledge) and their short-term impact on illness course in bipolar disorder.

1. Introduction

Current treatment guidelines for bipolar disorder (BD) recommend combining pharmacological with psychosocial interventions (Goodwin et al., 2016; Yatham et al., 2009). Psychoeducation appears to be a common element in most successful psychosocial interventions for BD (Miklowitz et al., 2012b; Vallarino et al., 2015); interventions based on psychoeducational approaches can enhance relapse prevention and improve medication adherence over periods of 1–2 years (Candini et al., 2013; Colom et al., 2003a, 2003b, 2005; Kessing et al., 2014). The brevity of most psychoeducational models makes them an economically attractive alternative. An intervention of 7–12 individual sessions to improve identification of early symptoms of relapse and facilitate help-seeking behaviour was associated with reduced rates of manic (but not depressive) relapse compared with treatment as usual over 12 months (Perry et al., 1999). In remitted patients, 6 sessions of group psychoeducation appeared to be as efficacious as 20 sessions of individual cognitive behaviour therapy (CBT) in terms of symptom burden and relapse likelihood (Parikh et al., 2012).

Whether psychoeducational interventions are best delivered by group, family, individual instruction, or self-direction, remains uncertain. In addition, in testing new approaches, it is unclear

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which outcomes will be most informative. Relapse is often difficult to define and usually requires prolonged follow-up. Additionally, a relapse may not indicate treatment failure in a patient who is otherwise well for the majority of weeks of follow-up.

The current study used a randomised design to compare the effects of a 5-session Facilitated Integrated Mood Management (FIMM) intervention against a self–administered Manualised Integrated Mood Management (MIMM) intervention. Our primary focus was on depressive and manic symptoms reported weekly by patients in both groups, collected electronically via the True Colours platform (Bopp et al., 2010; Miklowitz et al., 2012a). Our hypothesis was that the FIMM approach would be more effective than the self-administered MIMM approach in reducing mood symptoms, particularly depression. We also reasoned that increased knowledge of recommended actions when experiencing prodromal symptoms of relapse (e.g., contacting one's physician) would be an important correlate of any effects of FIMM or MIMM on symptoms. We used the Oxford Bipolar Knowledge Questionnaire (OBQ) to measure knowledge of illness at baseline and follow-up visits.

2. Methods

The relevant protocols were reviewed and approved by UK NHS Ethics Committees (REC references: OXTEXT-1, 11/SC/0068; OXTEXT-6, 10/H0604/13). Written informed consent was obtained from all participants.

2.1. Participants

Participants registered for research under an observational protocol (the OXTEXT-1 study: (Bourne et al., 2015)) were invited to take part in the OXTEXT-6 trial. As part of OXTEXT-1, participants had completed a diagnostic interview, adapted from the Mini International Neuropsychiatric Interview (Sheehan et al., 1998), conducted and audio-recorded by trained Research Assistants. OXTEXT-1 also included completion of a battery of cognitive tasks (data to be published elsewhere; includes (Bourne et al., 2015)) and weekly assessment for depression and mania via the True Colours system (see Assessments, below). All diagnostic interviews were reviewed by a Research Psychiatrist for diagnostic confirmation using DSM-IV-TR criteria.

Eligibility criteria were (i) age 16 years or over; (ii) a diagnosis of DSM-IV-TR Bipolar I (BD I) or Bipolar II (BD II) disorder, but not in a current mood episode; (iii) current and reliable participation in True Colours mood monitoring for ≥ 4 weeks, with at least 3 out of 4 responses in the 4 weeks as a requirement for participation, (iv) a current patient of Oxford Health NHS Foundation Trust; (v) able to give informed consent; (vi) understanding of verbal and written English sufficient to participate in trial procedures; and (vi) a treating psychiatrist deemed a psychoeducational intervention with mood monitoring to be appropriate, and there was no need for more acute treatment.

2.2. Study design

The study was a two-arm RCT in which participants were randomised to engage with FIMM (standard medication management+weekly mood monitoring +5 sessions of facilitator integrated mood management), or MIMM (standard medication management+weekly mood monitoring+a self-care manual with instructions regarding mood management). Medication and case management was provided by NHS teams.

2.3. Treatment facilitators

Nine female facilitators were involved in delivering the FIMM arm of the study. Six had formal clinical qualifications or professional registration as a therapist and 3 worked in mental health research with clinical populations.

Prior to the trial, all facilitators underwent a 6-hour workshop delivered by DJM (a specialist in psychological interventions for BD) that included guidance on how to use the FIMM manual with participants. During the trial, facilitators continued to receive regular support from DJM and JP (a consultant psychiatrist) through supervision and monitoring of individual session tapes. Feedback was given for audio-recorded FIMM sessions 2 and 5 for the facilitators' first two participants, as well as for additional sessions when requested by the facilitator. In cases where clinicians received below average fidelity ratings (below 4 on the 1–7 point scale of overall fidelity), they were given additional supervision until ratings improved.

2.4. Assessments

2.4.1. Mood assessment

All participants were asked to complete weekly, remote symptom assessments of depression and (hypo)mania via the True Colours system (www.truecolours.nhs.uk). In brief, True Colours is an online system which schedules and prompts (via email and/or text message) self-report questionnaires, as well as curating the collected data (an example email prompt as delivered by the True Colours system is provided in Supplemental Fig. 1). The system provides a graphical representation (e.g. a line graph) of symptoms over time, and individuals can share access to their account with their treating clinicians.

As part of the current trial, participants were asked to submit weekly ratings of depression with the Quick Inventory of Depressive Symptomology patient-rated version (QIDS-SR16; Rush et al., 2003) and mood elevation with the Altman Self-Rating Mania scale (ASRM; Altman et al., 1997), both of which were implemented in the True Colours system. Symptom scores were extracted from the True Colours system for the week in which participants were randomised (week 0, or W0), and for the subsequent 52 weeks (i.e. W0 to W52).

2.4.2. The Oxford Bipolar Knowledge Questionnaire (OBQ)

The OBQ was developed as a self-report measure of the knowledge and behaviour relevant to self-management in BD. It comprises 10 items, each with 4 statements, which ask about participants' knowledge of risk factors and early warning signs that may indicate mood changes, and behavioural plans, sleep/wake routines, and medicines that may promote mood stability. The full OBQ questionnaire is provided in Supplementary Information. Participants rated their level of agreement with each statement on a 3-point scale, scored as 0=disagree, 1=neither agree nor disagree and 2=agree. A higher total OBQ score (range 0–80) is indicative of better knowledge of bipolar mood management. Participants completed the questionnaire at baseline (during face-to-face assessments with a researcher) and again at 3 months and 12 months (with pen-and-paper questionnaires sent by post).

2.5. Randomisation

A computerised system was used to randomise participants. Allocation was stratified by diagnostic subtype (BPI vs. BPII) and whether patients were in full recovery (defined as 4 consecutive weeks with minimal or no mood symptoms [QIDS-SR16 < 10 and ASRM ≤ 5]) or not at the time of randomisation.

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