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Facilitated integrated mood management (FIMM) versus manualised integrated mood management (MIMM) in bipolar disorder

Submission date
31/08/2011

Recruitment status
No longer recruiting

Registration date
31/08/2011

Overall study status
Completed

Last Edited
27/11/2015

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Bipolar disorder, previously known as “manic depression”, is a serious mental disorder characterised by extreme mood swings, alternating between mania (extreme highs) and depression (extreme lows). Bipolar disorder can look very different in different people, and so specific types have been proposed. Two of the most common types are known as bipolar I and II. Bipolar I is characterised by severe manic episodes, and bipolar II is characterised by severe depression alternating with episodes of hypomania (a very mild form of mania). Bipolar disorder can be managed using a combination of different treatments, such as with medication and therapy. Studies have shown that a particularly effective treatment is by teaching sufferers ways manage their moods day-to-day (integrated mood management). It is thought that this is most successful when a person is guided through the process by a trained facilitator (support worker). One of the cornerstones of this treatment is through routine “mood monitoring”, in which the sufferer keeps a log of their moods and the effects of different activities. “True Colours” is an online system that helps people to monitor their moods and experiences using text messages or e-mail. The aim of this study is to find out whether using “True Colours” is more effective when it is accompanied by support from a trained facilitator (Facilitated Integrated Mood Management, FIMM), or independently (Manualised Integrated Mood Management, MIMM).

Who can participate?
Adults with bipolar disorder I or II.

What does the study involve?
Participants are randomly allocated into one of two groups. The first group are given written information about how best to use True Colours and manage their symptoms day-to-day (MIMM). The second group are given five individual face-to-face sessions with a trained facilitator (FIMM), as well as several telephone calls to give additional support. Participants in both groups are asked to update True Colours every day for 12 months, as well as completing a questionnaire every week about how they are managing their moods.

What are the possible benefits and risks of participating?
Not provided at time of registration.

Where is the study run from?
Department of Psychiatry, Warneford Hosptial (UK)

When is the study starting and how long is it expected to run for?
September 2011 to September 2012

Who is funding the study?
National Institute of Health Research (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
10233

Study information

Scientific Title

Randomised controlled trial of facilitated integrated mood management (FIMM) versus manualised integrated mood management (MIMM) in bipolar disorder

Acronym
OXTEXT-6

Study objectives
A randomised controlled trial (RCT) of the impact of different modes of delivery of Integrated Mood Management when delivered to bipolar patients together with True Colours, a symptom self-monitoring system which uses text messaging or e-mail. The two arms of the RCT will compare the efectiveness of Facilitated Integrated Mood Management (with support from a trained facilitator) with Manualised Integrated Mood Management (with no direct facilitator input).

Ethics approval required
Old ethics approval format

Ethics approval(s)
South Central Oxford C approved on 21 April 2011, ref: 11/SC/0068

Study design
Randomised; Interventional and Observational; Design type: Treatment, Qualitative

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please contact oxtext@psych.ox.ac.uk to request a patient information sheet

Health condition(s) or problem(s) studied
Topic: Mental Health Research Network; Subtopic: Bipolar affective disorder; Disease: Bipolar affective disorder

Interventions
A new therapeutic intervention for use in bipolar disorder, known as Integrated Mood Management (IMM), has been developed by the research team. This is composed of five sessions which aim to educate patients to achieve better symptom control. IMM can be delivered either through individual face-to-face sessions with a facilitator (Facilitated Integrated Mood Management FIMM), or by allowing the patient to work through the written materials independently (Manualised Integrated Mood Management MIMM)

The randomised controlled trial examines the impact of the different modes of delivery of IMM, when used in conjunction with weekly symptom monitoring using True Colours, an electronic self-mood monitoring service which uses text messaging or E-mail. Patients using True Colours are requested to respond weekly to prompts using validated questionnaires that measure depressive symtoms using the Quick Inventory of Depressive Symptomology patient-rated version (QIDS-SR16) and manic symptoms using the Altman Self-Rating Mania Scale (ASRM). The two arms of the trial will compare the effectiveness of:
a) True Colours monitoring plus MIMM (no direct facilitator input); versus
b) True Colours monitoring plus FIMM (face-to-face support from a trained facilitator and several telephone contact boosters-sessions)

Both control and intervention arms are selected from patients aged 16 years or over who have a diagnosis of DSM-IV bipolar I or II and have demonstrated reliable participation in True Colours mood monitoring for >=4 weeks.

Follow Up Length: 12 month(s); Study Entry : Single Randomisation only

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Quick Inventory of Depressive Symptomatology; Timepoint(s): 3 and 12 months after randomisation.

Secondary outcome measures
1. Altman Self-Rating Mania Scale; Timepoint(s): 3 and 12 months after randomisation
2. EuroQol EQ-5D; Timepoint(s): Monthly post randomisation
3. ICECAP-A questionnaire; Timepoint(s): Baseline and 3, 6,9 and 12 months
4. Medicines and health resource use questionnnaire; Timepoint(s): Baseline then 3,6,9 and 12 months
5. OxCAP-MH; Timepoint(s): Baseline and 12 months post randomisation
6. Self-management knowledge, understanding and action; Timepoint(s): Baseline and 3,6,9 and 12 months post randomisation
7. Time to recurrence; Timepoint(s): 3,6,9 and 12 months post randomisation

Overall study start date
19/09/2011

Completion date
19/09/2012

Eligibility

Key inclusion criteria
1. Participant in OXTEXT-1, and has opted into considering participation in further research studies
2. Participant is willing and able to give informed consent for participation in the study.

3. Diagnosis of Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) bipolar I or II
4. Aged 16 or over
5. Reliable participation in True Colours mood monitoring for >=4 weeks (at least 3 out of 4 responses received for both Quick Inventory of Depressive Symptoms (QIDS) and Altman Self-Rating Mania (ASRM) over the last 4 weeks prior to invitation to participate).
6. Understanding of verbal and written English that is sufficient to participate in trial procedures, including integrated mood management (IMM).; Target Gender: Male & Female ; Lower Age Limit 16 years

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 156; UK Sample Size: 156;

Key exclusion criteria
1. Current participant in OXTEXT- 2(because delivery of an additional intervention would confound the results of this pre- vs post-monitoring cost comparison study)
2. Treating psychiatrist or research team judge prospective participant to be acutely unwell to the extent that they cannot participate in IMM
3. Treating psychiatrist considers IMM to be inappropriate

Date of first enrolment
19/09/2011

Date of final enrolment
19/09/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Psychiatry
Warneford Hospital
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Sponsor information

Organisation
University of Oxford (UK)

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Nuffield Dept. Obstetrics and Gynaecology
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Sponsor type
University/education

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
National Institute of Health Research (NIHR) (UK) - Programme for Applied Research (Grant Codes: RP-PG-0108-10087)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2012		Yes	No