ISRCTN62761948 https://doi.org/10.1186/ISRCTN62761948

Group psychoeducation versus group support using expert patients and clinical staff in the management of bipolar disorder

Submission date	Recruitment status
06/07/2009	No longer recruiting
Registration date	**Overall study status**
18/09/2009	Completed
Last Edited	**Condition category**
03/10/2016	Mental and Behavioural Disorders

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
09006

Study information

Scientific Title
Randomised controlled trial of group psychoeducation versus group support using both expert patients and clinical staff in the management of bipolar disorder

Acronym
PARADES

Study objectives
1. To determine the clinical and cost effectiveness of joint expert patient and health professional-led group psychoeducation for bipolar disorder
2. To demonstarte that such group psychoeducation is feasible and sustainable across different NHS sites
3. To determine that group psychoeducation is clinically and cost effective compared to group support
4. To identify barriers and potential solutions to barriers to the implementation of effective group psychoeducation

Ethics approval required
Old ethics approval format

Ethics approval(s)
National Research Ethics Service Nottingham Research Ethics Committee 2, 20/03/2009, ref: 09/H0408/33

Study design
Multicentre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Bipolar disorder

Interventions

1. Bipolar Group Psychoeducation Intervention:
The group will be run by three facilitators, two health professionals (usually one experienced and one in training), specially trained for the purpose; and one expert patient, also specially trained. The group psychoeducation programme will have 21 sessions, running for 90 minutes:
1.1. Meeting the group and what is bipolar disorder
1.2. Causes of bipolar disorder and triggers for relapse
1.3. Symptoms 1: Mania and hypomania
1.4. Symptoms 2: Depression and mixed episodes
1.5. Course of illness and prognosis
1.6. Overview of available interventions
1.7. Treatment 1: mood stabilisers
1.8. Treatment 2: antimanic drugs
1.9. Treatment 3: antidepressants
1.10. Pregnancy, genetic counselling and effects on families
1.11. Risks associated with treatment withdrawal
1.12. Alcohol, smoking, diet and street drugs
1.13. Early detection of mania and hypomania 1
1.14. Early detection of mania and hypomania 2
1.15. Early detection of depression and mixed episodes 1
1.16. Early detection of depression and mixed episodes 2
1.17. What to do when a new phase is detected
1.18. Regularity of habits
1.19. Stress control techniques
1.20. Problem solving strategies
1.21. Finalising a care plan and course

The group will be a closed one, ideally starting with 17 - 18 participants. In practice 25% of patients will not attend so that the average group size will be 12 - 14 participants. Any participant who misses a session will be provided printed materials for the session and an opportunity to discuss the materials before the next session. However, absence of five consecutive sessions will be considered a drop-out from treatment and these participants will be excluded from further groups. They will be offered a complete set of handouts for all group sessions. The work in the psychoeducation group builds on earlier sessions so the involvement of participants who had not attended earlier sessions would be disruptive to the other participants in the group. The same rule will apply to the bipolar group support arm so that there is internal consistency within the RCT and the RCT remains internally valid.

A manual will be produced for the therapists. The content and conduct of each session will be recorded on written forms by the therapists and participants (with the therapists not present) using the treatment fidelity checklist. Participants will also be asked for consent to audio-tape the group. If all consent, this will be used to assess fidelity. If one or more participants do not wish to be recorded only the fidelity checklist will be used for that group. Where groups are recorded and checklist used, this data will be used to evaluate the validity of the checklist as a proxy measure of fidelity.

As part of the group, participants will produce a care plan. This will include a list of people this can be shared with including family members and clinicians. A final version will be signed by the participants and therapists and sent to relevant members of the clinical team to aid communication. Patients will receive in addition their usual treatment which will be unconstrained and recorded from case notes and at the CSRI interview.

2. Bipolar Group Support Intervention:
Meeting other service users with bipolar disorder and discussing collective experience can be a powerful form of support and information giving in its own right. To ensure that the content of the group psychoeducation programme is effective, we need to control for the effects of meeting together. Therefore, two health professionals and an expert patient (the same people conducting the psychoeducation group), will meet in groups of 18 participants. In practice due to attrition the group will be around 12 - 14 participants. The group will have 21 weekly sessions running from 90 minutes.

In this group the topics for discussion will be entirely determined and led by the service users in the group. The health professionals and expert patient will be more passive, being there to facilitate discussion, encourage participation and prevent unhelpful group behaviour such as bullying or scapegoating. They will be instructed not to provide information on bipolar disorder. To limit this possibility, the content and conduct of each session will be recorded by each therapist and each participant (with the therapist not present) as a quality check and to record how the bipolar support group different in form and content form the bipolar psychoeducation group. A manual on the conduct of the bipolar support group will be produced for the therapists. Patients will receive in addition their usual treatment which will be unconstrained and recorded from case notes and at the CSRI interview.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Time to next bipolar episode and average weekly symptom score, both established using four monthly SCID LIFE interviews to generate weekly scores of mania and depression on 1 - 6 scale of severity
2. Primary economic measure of incremental cost per quality adjusted life year gained

Follow-up of each patient will be for 24 months from randomisation. Patients who had not relapsed at 24 months will be censored on the time to next episode outcome. The peak effect of psychoeducation on time to next bipolar episode have been observed at 24 months after randomisation. Baseline interview using the SCID will assess the presence of axis 1 and axis 2 comorbid psychopathology and the number of previous bipolar episodes.

Secondary outcome measures
1. Assessment of weekly symptoms using the LIFE
2. Assessment of function using the Social Adjustment Scale, and Social and Occupational Functioning Assessment Scale (SOFAS)
3. Observer and self-rated measures of mood: 17-item Hamilton Depression Scale (HDRS), Bech-Raphaelson Mania Scale (MAS), Beck Depression Inventory (BDI) and PHQ-9 (Personal Health Questionnaire)
4. Medication adherence

Schedule of assessment:
At baseline, 12 and 24 months (face to face assessments): SAS, Economic Interview (CSRI), EuroQol

At 4, 8, 16, and 20 months (telephone assessments): LIFE, HDRS, MAS, SOFAS, MedAd, BDI version 1(by post), PHQ-9 (by post)

Overall study start date
01/03/2009

Completion date
01/09/2013

Eligibility

Key inclusion criteria
1. Structured Clinical Interview for Diagnostic and Statistical Manual of Mental Disorders, 4th Edition (SCID-DSM-IV) verified diagnosis of primary bipolar disorder
2. Increased risk of relapse (at least one episode in the last 24 months)
3. Age over 18 years, either sex

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
10 groups of 18 subjects in each arm, 179 per arm, 358 in total

Key exclusion criteria
1. Presence of a current manic, hypomanic, mixed affective or major depressive episode currently or within the previous 8 weeks
2. Current suicide plans or high suicide intent
3. Inability or unwillingness to give written informed consent to the study
4. Participants would have to be able to communicate in written and verbal English to a sufficient level to allow them to complete the measures and take part in the groups

Date of first enrolment
01/03/2009

Date of final enrolment
01/09/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Nottingham
Nottingham
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NG7 2TU

Sponsor information

Organisation
University of Nottingham (UK)

Sponsor details
Research Innnovation Services
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Sponsor type
University/education

Website
http://www.nottingham.ac.uk/

ROR
https://ror.org/01ee9ar58

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK) - Programme Grant for Applied Research (PGfAR) (ref: RP-PG-0407-10389)

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?
Protocol article	protocol	21/07/2011		Yes	No
Results article	results	01/11/2016		Yes	No