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Feasability study of Enhanced Relapse Prevention (ERP) delivered by Care Coordinators (CCs) to people with Bipolar Disorder (BD) - a cluster randomised controlled trial

Submission date	Recruitment status
05/09/2005	No longer recruiting
Registration date	**Overall study status**
07/10/2005	Completed
Last Edited	**Condition category**
10/04/2012	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

Protocol serial number

TP165; G0301042

Study information

Scientific Title

Study objectives
Aim:
To develop a brief Enhanced Relapse Prevention (ERP) for people with Bipolar Disorder which can be offered by Care Co-ordinators (CCs) in the NHS and to gather specific information required to inform the design of a large multi-site trial to test its effectiveness in comparison to treatment as usual.
Objectives:
1. To devise a manual for brief Enhanced Relapse Prevention (ERP)
2. To refine a methodology to train (CCs) in ERP
3. To assess the effectiveness of the training package by assessing CC skills
4. To gain feedback form CCs receiving training in order to identify barriers and solutions in offering such training in a large trial
5. To calculate an estimate of the relationship of between to within cluster variance needed to design a cluster RCT for ERP
6. To compare outcome of patients receiving ERP and those receiving treatment as usual to estimate the effect size of the intervention
7. To estimate rates of recruitment and dropout for a large trial of this intervention
8. To gain feedback from people receiving the intervention in order to identify barriers and solutions to offering this intervention in a large trial

Ethics approval required
Old ethics approval format

Ethics approval(s)
Added as of 30/07/2007: Ethical approval through Central Office for Research Ethics Committees (COREC) and Research & Development (R&D) approval at each Trust has been given.

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Bipolar Disorder (Type I and II)

Interventions
ERP versus TAU

1. A training package for ERP delivered to CCs who are part of Community Mental Health Teams (CMHTs) and who have current active caseloads of people with BD. The training will include theoretical background and rationale for the approach, detailed analysis of the content of each session in the manual and videoed role play using trained actors. Written materials will accompany all aspects of training, and will take place over six 2-h sessions.
2. Following training, CCs will offer ERP to patients who have a diagnosis of BD. This involves patients and CCs working together to identify prodromal signs of manic and depressive relapse separately and developing and rehearsing an action plan for responding to such signs.

As of 14/02/2007: Please note that the anticipated end date of this trial has been extended to 20 /01/2007.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
1. The effectiveness of the training intervention with CCs assessed by training and CC ratings
2. An estimate of the effect size of the ERP intervention by CCs will be made by comparing patients receiving ERP with those receiving treatment as usual on:
a. Time to recurrence to an episode of illness of sufficient severity to reach Diagnostic and Statistical Manual of Mental Disorders (DSM) criteria for major depressive, manic, or mixed episode, based on the Structured Clinical Interview for Depression (SCID) interview
b. Assessment of coping using the Coping with Manic and Depressive Prodromes checklist
c. The Client Service Receipt Schedule (CSRI) to estimate the use of primary, inpatient, outpatient, day patient, community and emergency services

The feasibility will be assessed using quantitative and qualitative data.

Quantitative data:
1. Recruitment rates of CMHTs: proportion of teams approached who agreed to take part
2. Attendance rates: the number of training and supervision sessions attended by each care coordinator
3. Care coordinator feedback ratings of training and supervision
4. Service user recruitment rates: number of service users recruited within each group - ERP and TAU
5. Service user retention rates: number of service users that completed follow-up at each point
6. Number of relatives taking part (ERP only)

Qualitative data:
1. Interview feedback from care coordinators (ERP and TAU)
2. Feedback from service users and relatives (ERP only) identifying barriers to the intervention.

An estimate of the effect size of the intervention will be made using time from baseline to recurrence of an episode of major depression , hypomania, mania, or mixed, satisfying DSM-IV criteria, as the main outcome. All outcomes will be reported allowing for design effect.

Key secondary outcome(s))

1. Longitudinal analysis of symptom severity using the Longitudinal Interval Follow-up Evaluation (LIFE-II) modified to DSM criteria
2. An estimate of recruitment and drop-out rates
3. Qualitative interviews to gather detailed information from CCs of their experience of training and offering ERP, and from patients with BD and their friends/relatives of their experience of therapy

Completion date
09/01/2007

Eligibility

Key inclusion criteria
1. Lifetime diagnosis of Bipolar Disorder (I or II)
2. Two or more relapses ever and at least one in the last year or two in the last 3 years
3. Currently in contact with healthcare professional attached to a CMHT
4. Working understanding of English language

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Substantial cognitive impairment, i.e. moderate/severe learning disability
2. Drug/alcohol abuse/dependence a primary diagnosis, i.e people who use drugs/alcohol are not excluded unless the severity of this would make them unable to engage with the intervention
3. No working understanding of the English language

Date of first enrolment
10/01/2005

Date of final enrolment
09/01/2007

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Department of Clinical Psychology
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United Kingdom
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Sponsor information

Organisation
The University of Liverpool (UK)

ROR
https://ror.org/04xs57h96

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (MRC) (UK) (ref: G0301042)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
Mersey Care NHS Trust 2004/28 (UK)

Results and Publications

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	01/01/2010		Yes	No
Protocol article	protocol	02/02/2007		Yes	No
Other publications	qualitative investigation	09/02/2009		Yes	No
Other publications	multi-perspective qualitative study	01/11/2011		Yes	No