

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

<b>Submission date</b> 05/09/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 07/10/2005	<b>Overall study status</b> Completed	<input checked="" type="checkbox"/> Protocol
<b>Last Edited</b> 10/04/2012	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Fiona Lobban

**Contact details**  
Department of Clinical Psychology  
Ground Floor  
The Whelan Building  
The Quadrangle  
Brownlow Hill  
Liverpool  
United Kingdom  
L69 3GB  
+44 (0)151 794 5528  
fiona.lobban@liv.ac.uk

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

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 from 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

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

Not specified

**Study type(s)**

Prevention

**Participant information sheet**

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

**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 measure**

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.

## Secondary outcome measures

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

## Overall study start date

10/01/2005

## 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

## Age group

Adult

## Sex

Both

## Target number of participants

120 people with bipolar disorder, 40 CCs, 10 CMHTs

## 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**

England

United Kingdom

**Study participating centre**

**Department of Clinical Psychology**

Liverpool

United Kingdom

L69 3GB

## **Sponsor information**

**Organisation**

The University of Liverpool (UK)

**Sponsor details**

P.O. Box 147

Liverpool

England

United Kingdom

L69 3BA

+44 (0)151 794 2000

claire.chandler@liv.ac.uk

**Sponsor type**

University/education

**Website**

<http://www.liverpool.ac.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, 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

### 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?
<a href="#">Protocol article</a>	protocol	02/02/2007		Yes	No

<a href="#">Other publications</a>	qualitative investigation	09/02/2009	Yes	No
<a href="#">Results article</a>	results	01/01/2010	Yes	No
<a href="#">Other publications</a>	multi-perspective qualitative study	01/11/2011	Yes	No