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Psychological Prevention of Relapse in Psychosis

Submission date	Recruitment status
25/06/2003	No longer recruiting
Registration date	**Overall study status**
25/06/2003	Completed
Last Edited	**Condition category**
19/04/2013	Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] 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
062452

Study information

Scientific Title
A randomised controlled trial of cognitive behavioural therapy and family intervention for the prevention of relapse and reduction of symptoms in psychosis

Acronym
PRP

Study objectives
The trial is designed to answer questions both about outcome and about mechanisms of treatment change of Cognitive Behaviour Therapy (CBT) and Family Intervention (FI) for psychosis. The trial consists of two pathways (for those with carers and those without) incorporating randomisation within each pathway, after stratification by treatment centre and whether the participant is an inpatient at the time of recruitment.

Trial I has two conditions: CBT and Treatment As Usual (TAU).
Trial II has three conditions: CBT, FI and TAU.

Primary Outcome hypotheses:
1. In Trial Pathway I, CBT will reduce rates of relapse and total days in hospital in the two year follow up compared to TAU, and that CBT will be cost neutral.
2. In Trial Pathway II, Both CBT and FI will reduce relapse and days in hospital at two year follow up compared with TAU, and that CBT and FI will be cost neutral.

Secondary outcome hypotheses:
1. CBT and FI will both reduce relapse and psychotic and emotional symptoms at 12 months (end of treatment) compared with TAU. The main change in psychotic symptoms will be in delusions and hallucinations.
2. FI, but not CBT, will increase social functioning compared to TAU at 24 months.
3. CBT, but not FI, will reduce psychotic and emotional symptoms at 24 months compared with TAU.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Added 03/03/2009: South East Multi-Centre Research Ethics Committee gave approval on the 4th June 2001 (ref: MREC01/1/24). All local research ethics committees also subsequently approved the study.

Study design
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 below to request a patient information sheet

Health condition(s) or problem(s) studied
Psychosis

Interventions
For participants with carers:
1. Cognitive behavioural therapy (CBT) and treatment as usual (TAU)
2. Family intervention (FI) and TAU
3. TAU only

For participants with no carers:
1. CBT and TAU
2. TAU only

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Relapse and days in hospital over 24 months.

Secondary outcome measures
1. Pattern of symptom change (PANSS total scores and subscale scores, Psychotic SYmptom RATing Scales [PSYRATS], Beck Depression Inventory [BDI], Beck Anxiety Inventory [BAI]) over 12 and 24 months
2. Social functioning (time budget) at 24 months

Overall study start date
01/12/2001

Completion date
31/10/2006

Eligibility

Key inclusion criteria
Participants are recruited from identified psychiatric teams in four NHS Trusts.

Entry criteria:
1. Current diagnosis of psychosis
2. Non-affective (International Statistical Classification of Diseases and Related Health Problems, Tenth edition [ICD-10], F20)
3. Aged 18 to 65 years, either sex
4. Second or subsequent episode, which started not more than three months before entry
5. Rated at least four (moderate severity) on the Positive and Negative Syndrome Scale (PANSS) on at least one positive psychotic symptom

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
301

Key exclusion criteria
Added 03/03/2009:
1. Primary diagnosis of alcohol or substance dependency, organic syndrome or learning disability
2. Inadequate command of English to engage in psychological therapy
3. Unstable residential arrangements and so unlikely to be available for therapy and/or assessments over period of trial

Date of first enrolment
01/12/2001

Date of final enrolment
31/10/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Department of Psychology
London
United Kingdom
SE5 8AF

Sponsor information

Organisation
King's College London (UK)

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Institute of Psychiatry
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Sponsor type
University/education

Website
http://www.iop.kcl.ac.uk

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Charity

Funder Name
The Wellcome Trust (UK) (grant ref: 062452)

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	01/09/2006		Yes	No
Results article	results	01/06/2008		Yes	No
Results article	subgroup analysis results	01/05/2012		Yes	No
Results article	results	01/05/2013		Yes	No
Results article	results	01/05/2013		Yes	No