

Psychological Prevention of Relapse in Psychosis

Submission date 25/06/2003	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 25/06/2003	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 19/04/2013	Condition category 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

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Additional identifiers

Protocol serial number
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

Study type(s)

Treatment

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(s)

Relapse and days in hospital over 24 months.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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**

United Kingdom

England

Study participating centre

Department of Psychology

London

United Kingdom

SE5 8AF

Sponsor information**Organisation**

King's College London (UK)

ROR

<https://ror.org/0220mzb33>

Funder(s)

Funder type

Charity

Funder Name

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

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	01/09/2006		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