

The effects of reducing worry in patients with persecutory delusions: finding out if worries can be reduced by brief cognitive therapy

Submission date 07/03/2011	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input checked="" type="checkbox"/> Protocol
Registration date 20/04/2011	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 18/12/2017	Condition category Mental and Behavioural Disorders	<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

09/160/06

Study information

Scientific Title

The effects of reducing worry in patients with persecutory delusions: An explanatory randomised controlled trial

Acronym

Worry Intervention Trial (WIT)

Study objectives

1. A worry intervention will reduce levels of worry in individuals with persecutory delusions
2. A worry intervention will reduce persecutory delusions, especially levels of distress
3. The improvements will be maintained at follow-up

Ethics approval required

Old ethics approval format

Ethics approval(s)

NHS Research Ethics Service Oxford REC B, application ref 11/SC/0001 - approval pending as of 09/03/2011

Study design

Single-blind randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Persecutory delusions in the context of schizophrenia or related diagnosis

Interventions

1. Six sessions of CBT for worry over 2 months for patients randomised to intervention arm 2. This is in addition to their standard psychiatric care
3. The control condition is standard psychiatric care

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

1. Penn State Worry Questionnaire (PSWQ; Meyer et al, 1990)
2. Psychotic Symptoms Rating Scale - Delusions (PSYRATS; Haddock et al, 1999)

Key secondary outcome(s)

1. Paranoid Thoughts Scale (Green et al, 2008)
2. Positive and Negative Symptom Scale (PANSS; Kay, 1991).
3. EQ-5D (Brooks et al, 2003)

Completion date

01/03/2014

Eligibility

Key inclusion criteria

1. A current persecutory delusion as defined by Freeman and Garety (2000); scoring at least 3 on the conviction scale of the PSYRATS (Haddock et al, 1999)
2. That the delusion has persisted for at least one month
3. A clinical diagnosis of schizophrenia, schizoaffective disorder or delusional disorder (i.e. diagnosis of non-affective psychosis (F2) in the International Classification of Diseases and Diagnostic and Statistical Manual IV)
4. A clinically significant level of worry, as indicated by scores above 44 on the Penn State Worry Questionnaire (see Startup and Erickson, 2006)
5. Aged between 18 and 65
6. Where major changes in medication are being made, entry to the study would not occur until at least a month after stabilisation of dosage

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. A primary diagnosis of alcohol or substance dependency
2. Organic syndrome or learning disability
3. A command of spoken English inadequate for engaging in therapy
4. Currently having individual cognitive behavioural therapy (CBT) (though previous CBT experience is not an exclusion)

Date of first enrolment

01/09/2011

Date of final enrolment

01/03/2014

Locations

Countries of recruitment

United Kingdom

England

Study participating centre
Oxford University
Oxford
United Kingdom
OX3 7JX

Sponsor information

Organisation

The Efficacy and Mechanism Evaluation Programme (MRC/NIHR) (UK)

ROR

<https://ror.org/0187kwz08>

Funder(s)

Funder type

Government

Funder Name

National Institute for Health Research

Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

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	pilot study results	01/03/2010		Yes	No
Results article	results	01/04/2015		Yes	No
Protocol article	protocol	21/11/2012		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes