

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

<b>Submission date</b> 07/03/2011	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
<b>Registration date</b> 20/04/2011	<b>Overall study status</b> Completed	<input checked="" type="checkbox"/> Protocol
<b>Last Edited</b> 18/12/2017	<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

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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?
<a href="#">Results article</a>	pilot study results	01/03/2010		Yes	No
<a href="#">Results article</a>	results	01/04/2015		Yes	No
<a href="#">Protocol article</a>	protocol	21/11/2012		Yes	No