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

Submission date	Recruitment status	[X] Prospectively registered
07/03/2011	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
20/04/2011	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
18/12/2017	Mental and Behavioural Disorders	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Daniel Freeman

Contact details
Department of Psychiatry
Oxford University
Warneford Hospital
Oxford
United Kingdom
OX3 7JX

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

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

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

Overall study start date
01/09/2011

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
150

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
England

United Kingdom

Study participating centre
Oxford University
Oxford
United Kingdom
OX3 7JX

Sponsor information

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

Sponsor details
NETSCC - Efficacy and Mechanism Evaluation
Alpha House
University of Southampton Science Park
Southampton
United Kingdom
SO16 7NS

Sponsor type
Government

Website
http://www.eme.ac.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

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