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# The acceptability and effectiveness of cognitive behavioural therapy for the treatment of post-traumatic stress disorder within schizophrenia

**Submission date**
23/04/2010

**Recruitment status**
No longer recruiting

**Registration date**
23/04/2010

**Overall study status**
Completed

**Last Edited**
07/12/2017

**Condition category**
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

## Plain English summary of protocol

Background and study aims
The NHS spends over £2 billion a year on treating schizophrenia, including expensive in-patient care. Consequently the development of cost-effective psychological therapies for schizophrenia is an NHS priority. Although government guidelines recommend cognitive behavioural therapy (CBT) as a treatment, the NHS struggles to meet this demand. Due to the wide range of presentations associated with a diagnosis of schizophrenia, the relevant CBT training is still generic and lengthy. There is a need for treatment protocols which target specific forms of schizophrenic presentation. These interventions are easier to disseminate within the NHS, and are likely to be more cost-effective. People diagnosed with schizophrenia are particularly likely to have suffered traumatic life events, and up to 40% may suffer from symptoms of posttraumatic stress disorder (PTSD). This 'co-morbid' condition is associated with severe symptoms, abusing illicit drugs and alcohol, and frequent hospital admissions. There have been no studies of any treatment for PTSD within this group. As standard CBT for PTSD is considered to be unsuitable for people with schizophrenia, a CBT package has been carefully designed for this purpose. A pilot study suggests a high level of patient acceptability. The potential for benefits in patient wellbeing and reduced healthcare costs suggest that the intervention should be evaluated within an NHS setting. The aim of this study is to test whether CBT, delivered to patients with co-morbid schizophrenia and PTSD, in addition to standard psychiatric care will result in a reduced level of PTSD and psychotic symptoms.

Who can participate?
Patients aged between 18 and 65 diagnosed with schizophrenia and PTSD

What does the study involve?
Participants are randomly allocated to receive either the CBT package or standard psychiatric care. Existing NHS clinicians are trained to conduct the CBT package as part of their routine clinical work. Assessments are carried out at the beginning of the treatment, the end of treatment and after a 6-month follow-up. Levels of symptoms and health care use are compared between the two groups. The acceptability of the intervention to the patients is assessed through an interview conducted at the end of treatment.

What are the possible benefits and risks of participating?
There are no perceived risks, whilst the CBT programme may provide the benefit of a reduction within the symptoms of posttraumatic stress.

Where is the study run from?
University of Reading (UK)

When is the study starting and how long is it expected to run for?
January 2010 to September 2011

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Dr Craig Steel

# Contact information

### Type(s)
Scientific

### Contact name
Dr Craig Steel

### Contact details
Department of Psychology
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# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
6683

# Study information

### Scientific Title
The acceptability and effectiveness of cognitive behavioural therapy for the treatment of post-traumatic stress disorder within schizophrenia: a randomised interventional treatment trial

### Study objectives

Sixty-two participants who are diagnosed with schizophrenia/schizo-affective disorder /schizophreniform disorder and post-traumatic stress disorder (PTSD) will be randomly allocated to receive either the proposed cognitive behavioural therapy (CBT) package or routine psychiatric care. The CBT package includes 16 sessions to be conducted within a 6-month period. Currently employed NHS clinicians will be trained to conduct the intervention as part of their routine clinical practice. Symptoms and level of use of NHS services will be assessed at baseline (week 0), end of therapy (6 months) and after a 6-month follow-up period (12 months). The primary outcome will be level of PTSD symptoms at end of treatment, as measured by the Clinician Administered PTSD scale (CAPS). Acceptability of the intervention will be assessed through a service-user led interview.

The principal research questions to be addressed:
The main hypothesis to be tested is that CBT, delivered to patients with co-morbid schizophrenia and PTSD, in addition to standard psychiatric care will result in a reduced level of PTSD symptomatology. The subsidiary hypothesis is that reduction in PTSD symptoms will mediate a reduction in psychotic symptomatology and service-use.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Berkshire Research Ethics Committee (REC), 01/03/2010, ref: 09/H0505/85

## Study design
Randomised interventional treatment trial

## Primary study design
Interventional

## Secondary study design
Randomised controlled trial

## Study setting(s)
Hospital

## Study type(s)
Treatment

## Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

## Health condition(s) or problem(s) studied
Topic: Mental Health Research Network; Subtopic: Schizophrenia; Disease: Schizophrenia, post-traumatic stress disorder (PTSD);

## Interventions
The trial compares standard psychiatric care alone with CBT treatment in addition to standard care.

Standard psychiatric care in the UK is based on the care programme approach to case management and includes antipsychotic medication, outpatient and community follow-up, and access to community-based rehabilitative activities such as day centres and drop ins.

CBT intervention consists of several important parts.
1. Establish safety: Issues such as suicidality, self-harming behaviour

### Intervention Type
Other

### Phase
Not Applicable

### Primary outcome measure
PTSD symptoms, assessed through the Clinician Administered PTSD Scale (CAPS), measured at baseline, 6 months and 12 months

### Secondary outcome measures
Post-traumatic Cognitions, assessed using the Post-traumatic Cognitions Inventory (PTCI), measured at baseline, 6 months and 12 months

### Overall study start date
01/01/2010

### Completion date
30/09/2011

## Eligibility

### Key inclusion criteria
1. Provides consent
2. Current Diagnostic and Statistical Manual, Fourth Edition (DSM-IV) diagnosis of schizophrenia or schizo-affective disorder
3. Present with symptoms consistent with a DSM-IV diagnosis of PTSD
4. Aged between 18 and 65 years, either sex

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
Planned Sample Size: 62; UK Sample Size: 62

### Key exclusion criteria
1. Organic disorder
2. Unable to read and write in English
3. Learning disability

### Date of first enrolment
01/01/2010

### Date of final enrolment
30/09/2011

## Locations

### Countries of recruitment
England

United Kingdom

### Study participating centre
**University of Reading**
Reading
United Kingdom
RG6 6AL

## Sponsor information

### Organisation
University of Reading (UK)

### Sponsor details
Winnicott Rsearch Unit
School of Psychology
PO Box 238
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### Sponsor type
University/education

### Website
http://www.reading.ac.uk/

### ROR

https://ror.org/05v62cm79

# Funder(s)

**Funder type**
Government

**Funder Name**
Research for Patient Benefit Programme

**Alternative Name(s)**
NIHR Research for Patient Benefit Programme, RfPB

**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 | results | 01/01/2017 | | Yes | No |