

A randomised controlled trial of cognitive therapy for command hallucinations

Submission date 23/01/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 23/01/2004	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 29/01/2010	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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
RGC00391

Study information

Scientific Title

Study objectives

The objective is to evaluate whether a form of cognitive therapy (CT) developed by the applicants is an effective form of treatment for command hallucinations. The researcher's cognitive model asserts that high risk behaviours of command hallucinators are a consequence of core beliefs, namely a conviction in the power of their voices and a belief that they are compelled to comply with and appease these voices.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Schizophrenia and other psychoses

Interventions

1. Cognitive therapy
2. Control

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

1. Voices:
 - 1.1. Content - Cognitive Assessment Schedule (Chadwick & Birchwood, 1995)
 - 1.2. Topograph - Frequency, volume, audibility, affect (Hustig & Hafner, 1992)

1.3. Beliefs and evidence

1.3.1. Beliefs About Voices Questionnaire (Chadwick & Birchwood, 1995)

1.3.2. Maudsley Assessment of Delusions Schedule (Buchanan et al 1993)

1.4. Compliance (Beck-Sander et al 1997)

2. Affect:

2.1. Depression, hopelessness (Calgary Depression Scale for Schizophrenia: Addington & Addington, 1993)

3. Mental State:

3.1. Positive and Negative Syndrome Scale (PANSS) (Kay, 1997)

3.2. Previous episodes of 'risk' behaviours

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/10/1999

Completion date

01/10/2001

Eligibility

Key inclusion criteria

The sample will be drawn from the case registers of patients receiving treatment from South and North Birmingham Mental Health Trusts. From this sample base the researchers will draw a cohort of patients conforming to International Statistical Classification of Diseases and Related Health Problems, Tenth revision (ICD-10) schizophrenia who have experienced auditory command hallucinations for a minimum of six months. There will be 26 patients in each of the groups.

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

52

Key exclusion criteria

1. Current drug and alcohol misuses

2. Primary organic disorder

This is to ensure that the auditory hallucinations are a symptom of schizophrenia rather than induced by drugs or the result of organic impairment.

Date of first enrolment

01/10/1999

Date of final enrolment

01/10/2001

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

University of Birmingham / South Bham Mental Health Trust

Birmingham

United Kingdom

B15 2TT

Sponsor information

Organisation

NHS R&D Regional Programme Register - Department of Health (UK)

Sponsor details

The Department of Health

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dhmail@doh.gsi.org.uk

Sponsor type

Government

Website

<http://www.doh.gov.uk>

Funder(s)

Funder type

Government

Funder Name

NHS Executive West Midlands (UK)

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	01/04/2004		Yes	No