

# A randomised controlled trial of cognitive therapy for command hallucinations

<b>Submission date</b> 23/01/2004	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 23/01/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 29/01/2010	<b>Condition category</b> 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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**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?
<a href="#">Results article</a>	results	01/04/2004		Yes	No