

# Cognitive mechanisms of change in delusions

<b>Submission date</b> 28/05/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 28/05/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 01/12/2017	<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

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
5048; 085396

## Study information

**Scientific Title**

Cognitive mechanisms of change in delusions: a multicentre randomised investigation of two experimental interventions

**Study objectives**

Psychosis is acknowledged to be a complex disorder, with multiple causes. Recent advances in understanding, using cognitive models and epidemiological research have identified new candidate cognitive, social and emotional processes as causes of symptoms, identified with greater specificity and a firmer basis in evidence than five years ago. Increased understanding of the factors leading to better outcomes is of huge potential importance, in terms both of individual suffering and disability, and of burden on families and societies. This is well recognised by the NHS, and the proposed research should pave the way for developing more effective psychological treatments leading to important improvements in individual patient management.

The aim of this project is to conduct research to bridge the gap between experimental research into theoretically derived hypotheses concerning mechanisms of psychotic symptoms and clinical development, leading to the development of new more effective components of cognitive behavioural approaches. The research is based on a cognitive model of psychosis from which specific hypotheses are derived.

We propose to concentrate on selected key cognitive, emotional, and social processes which are causally implicated in persecutory delusions and hallucinations: jumping to conclusions reasoning bias, anxiety, negative beliefs, and social exposure.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

South West London REC 3 (formerly Wandsworth REC) 17/10/2007, ref: 07/H0803/140

**Study design**

Multicentre 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****Health condition(s) or problem(s) studied**

Topic: Mental Health Research Network; Subtopic: Schizophrenia, Psychosis; Disease: Psychosis

**Interventions**

1. Computer package: designed to change particular thinking styles
2. Manipulating anxiety: to investigate the impact on cognitive processes associated with paranoia

Both interventions have an active control.

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome measure**

Change in anxiety and cognitive processes associated with paranoia, measured immediately post-intervention.

**Secondary outcome measures**

Change in thinking style and cognitive processes associated with unusual and distressing beliefs, measured immediately post-intervention.

**Overall study start date**

20/03/2009

**Completion date**

30/09/2011

**Eligibility****Key inclusion criteria**

1. Psychosis, non-affective (International Classification of Diseases version 10 [ICD-10], chapter F2)
2. Current delusion on Schedules for the Clinical Assessment in Neuropsychiatry (SCAN) (for study 2: a persecutory delusion)
3. Rated greater than 0 on visual analogue distress
4. Aged 18 - 65 years, either sex
5. Symptoms stable (no major relapse or crisis in last 3 months) before allocation
6. Sufficient grasp of English to complete measures and participate in manipulations

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

Planned sample size: 200; UK sample size: 200

**Key exclusion criteria**

1. Primary diagnosis of alcohol or drug dependency
2. Organic syndrome
3. Learning disability

**Date of first enrolment**

20/03/2009

**Date of final enrolment**

30/09/2011

**Locations****Countries of recruitment**

England

United Kingdom

**Study participating centre**

Institute of Psychiatry

London

United Kingdom

SE5 8AF

**Sponsor information****Organisation**

Kings College London (KCL) (UK)

**Sponsor details**

Institute Of Psychiatry

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England

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SE5 8AF

**Sponsor type**

University/education

**Website**

<http://www.kcl.ac.uk/>

ROR

<https://ror.org/0220mzb33>

## Funder(s)

### Funder type

Charity

### Funder Name

The Wellcome Trust (UK) (grant ref: 085396)

## 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	01/03/2015		Yes	No
<a href="#">Results article</a>	results	01/07/2015		Yes	No