

Cognitive mechanisms of change in delusions

Submission date 28/05/2010	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 28/05/2010	Overall study status Completed	☐ Protocol
Last Edited 01/12/2017	Condition category Mental and Behavioural Disorders	☐ Statistical analysis plan
		☒ Results
		☐ 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

Protocol serial number
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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s))

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

United Kingdom

England

Study participating centre

Institute of Psychiatry

London

United Kingdom

SE5 8AF

Sponsor information

Organisation

Kings College London (KCL) (UK)

ROR

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

Funder(s)

Funder type

Charity

Funder Name

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

Results and Publications

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	01/03/2015		Yes	No
Results article	results	01/07/2015		Yes	No

