

Cognitive mechanisms of change in delusions

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

Contact name
Ms Suzanne Jolley

Contact details
Institute of Psychiatry
Department of Psychology (PO77)
16 De Crespigny Park
London
United Kingdom
SE5 8AF
-
s.jolley@iop.kcl.ac.uk

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

16 De Crespigny Park

London

England

United Kingdom

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? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| Results article | results | 01/03/2015 | | Yes | No |
| Results article | results | 01/07/2015 | | Yes | No |