ISRCTN62304114 https://doi.org/10.1186/ISRCTN62304114

A multicentre, randomised controlled trial of cognitive therapy to reduce harmful compliance with command hallucinations

Submission date	Recruitment status	[_] Prospectively registered
04/12/2007	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
27/03/2008	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
18/10/2019	Mental and Behavioural Disorders	

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
MRC ref: G0500965

Study information

Scientific Title
A multicentre, randomised controlled trial of cognitive therapy to reduce harmful compliance with command hallucinations

Acronym
COMMAND

Study objectives
Main hypothesis: The group receiving the cognitive therapy (CTCH group) will show a lower level of compliance and appeasement behaviour and an increase in resistance compared with the control group

Secondary hypotheses: The CTCH group will show lower levels of conviction in the power of the voice and reduction in distress and depression compared to the control group

Publication from pilot study: http://www.ncbi.nlm.nih.gov/pubmed/15056575

More details can be found at: http://www.mrc.ac.uk/ResearchPortfolio/Grant/Record.htm?GrantRef=G0500965&CaseId=5966

Ethics approval required
Old ethics approval format

Ethics approval(s)
West Midlands Multi-centre Research Ethics Committee, 05/01/2007, ref: 06/MRE07/71

Study design
Multicentre single-blind randomised controlled trial with intention to treat

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Command hallucinations

Interventions
Three UK sites will be taking part: Birmingham, London and Manchester.

Participants will be randomly allocated to two groups:
1. Cognitive Therapy for Command Hallucinations + Treatment As Usual (CTCH + TAU)
2. TAU only

The CTCH + TAU group will receive an average of 15 sessions (maximum 25 sessions in all) of cognitive therapy delivered by qualified clinical psychologists who will be regularly supervised by consultant psychologists. This cognitive therapy uses Cognitive Behavioural Therapy (CBT) to assess and modify conviction in four beliefs linked to the construct of voice power: i) that the voice has absolute power and control; ii) that the client must comply or appease or be severely punished; iii) the identity of the voice (e.g. the Devil) and iv) the meaning attached to the voice experience (e.g., the client is being punished for past bad behaviour).

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Compliance behaviour, assessed using the Cognitive Assessment of Voices Interview Schedule combined with the Revised Voice Compliance Scale. This is an observer rated scale to measure the level of compliance/resistance with each command, using information from the participant and at least one of three other informants (parent, spouse, keyworker). Each behaviour is then classified as:
1. Neither appeasement nor compliant
2. Symbolic appeasement, i.e. compliant with innocuous and/or harmless commands
3. Actual appeasement i.e. preparatory acts or gestures
4. Partial compliance with at least one severe command
5. Full compliance with at least one severe command

The ratings are taken at baseline, 9 and 18 months.

Secondary outcome measures
Beliefs about voices, distress and symptoms assessed at baseline, 9 and 18 months follow-up as follows:
1. Voice power is measured using the Voice Power Differential Scale (VPD) which measures the power differential between voice and voice hearer
2. Distress associated with delusions about voices is measured using the Psychotic Symptoms Rating Scales (PSYRATS)
3. Psychosis symptoms are rated using the Positive and Negative Symptom Scale (PANSS)
4. Beck Hopelessness scale & Beck Scale for Suicidal Ideation
5. Calgary Depression Scale
6. Personal Knowledge Questionnaire
7. Beliefs about voice questionnaire
8. Suicide and self-injury scale (SASII)
9. Childhood trauma questionnaire

Overall study start date

17/09/2007

Completion date
31/01/2011

Eligibility

Key inclusion criteria
1. Aged 16-65
2. Primary diagnosis of International Statistical Classification of Diseases and Related Health Problems (ICD-10) schizophrenia or related disorder
3. History of experiencing command hallucinations (minimum 6 months) with risk of harm to self or others

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
180 (60 participants from each of the three site)

Total final enrolment
197

Key exclusion criteria
1. Over 65 years of age
2. Primary diagnosis of organic brain disorder
3. Primary diagnosis of addictive substance misuse
4. Insufficient command of the English language

Date of first enrolment
17/09/2007

Date of final enrolment
31/01/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Birmingham
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Sponsor information

Organisation
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Sponsor type
University/education

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http://www.bham.ac.uk

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Government

Funder Name
Medical Research Council (UK)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type

Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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?
Protocol article	protocol	30/09/2011		Yes	No
Results article	results	01/06/2014		Yes	No
Results article	results	15/06/2018	18/10/2019	Yes	No