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

Submission date
04/12/2007

Recruitment status
No longer recruiting

Registration date
27/03/2008

Overall study status
Completed

Last Edited
18/10/2019

Condition category
Mental and Behavioural Disorders

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Max Birchwood

Contact details
School of Psychology
University of Birmingham
Early Intervention Service
1 Miller Street
Aston
Birmingham
United Kingdom
B6 4NF
+44 (0)121 301 1850
birchmjz@bham.ac.uk

Additional identifiers

Protocol serial number
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

Primary study design
Interventional

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

Study type(s)
Treatment

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(s)
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.

Key secondary outcome(s)
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

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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
United Kingdom

England

Study participating centre
University of Birmingham
Birmingham
United Kingdom
B6 4NF

Sponsor information

Organisation
University of Birmingham (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, Medical Research Committee and Advisory Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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