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A pilot randomised controlled trial of guided self-help cognitive behaviour therapy for distressing voices

Submission date
17/07/2015

Recruitment status
No longer recruiting

Registration date
23/07/2015

Overall study status
Completed

Last Edited
21/05/2019

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims:
Research has shown that cognitive behavioural therapy (CBT) can work well at reducing the distress associated with hearing voices (auditory hallucinations). Current psychological therapies are time and resource intensive meaning very few people who hear voices have access to them. One way that access to therapy can be increased is by delivering the therapy using a low intensity format i.e. using less resources. This study aims to see whether a low intensity therapy, namely guided self-help CBT, can be an effective therapy for those who hear distressing voices.

Who can participate?
Participants aged over 18 that hear voices that they find distressing.

What does the study involve?
All participants receive the therapy if they take part in this study. We are using a wait list control condition. This means that people who enter the study either receive the therapy immediately or they may have to wait 12 weeks. This is allocated at random. The therapy that both groups receive is the same. The therapy they receive is guided self-help CBT for distressing voices. This therapy involves some self-help using a book and workbook, and support by a clinical psychologist. The therapy is delivered over 8 weekly sessions.

What are the possible benefits and risks of participating?
Taking part will help us to find out whether guided self-help CBT is a helpful therapy for people who hear distressing voices. Taking part will have no effect on the participant's current care provision. All participants will also have the opportunity to try a brand new therapy, and provide their opinions as to whether they think it is something that should be offered in the NHS. All participants will be given a copy of the self-help book this therapy is based upon to keep, and all of travel expenses incurred during the study can be reimbursed. As this is a new therapy we do not know if it will work or not. We think it will help but cannot be sure. Also talking about people' s experiences with voices may be distressing at times; however we believe it can be helpful to talk about these experiences. Also the members of the research team are there to support the participants to do this in a way that they can feel comfortable with. Moreover all participants will

also be able to access the help that is offered by their usual care team. The study will involve giving up some of the participant's time to take part. None of the stages of the research process are too long, so we hope taking part will not be a burden. It is estimated that completing the questionnaires will take approximately 1.5 hours; although the first one will probably take a bit longer as this will involve completing a few extra forms (around 2 hours). To reimburse participants for their time we will pay participants £10 per set of questionnaires/interview they complete (not including the baseline questionnaires). All participants can potentially receive a compensation of £20 over the course of the study. Also all participants will have the option of completing the questionnaires within one session, taking breaks throughout the session or completing the questionnaires over more than one session.

Where is the study run from?
Sussex Partnership NHS Foundation Trust (UK)

When is study starting and how long is it expected to run for?
July 2015 to October 2016

Who is the main contact?
Miss Cassie Hazell
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
V1: 20.1.15

Study information

Scientific Title
Guided self-help CBT intervention for voices Evaluated (GiVE): an external pilot randomised controlled trial

Acronym
GiVE

Study objectives
This study is an external pilot with the aim of determining the following indices for a definitive trial:
1. The between-group effect size on the primary outcome (distress related to voices)
2. Recruitment rates
3. Retention rates to the study and to the intervention
4. Acceptability of the intervention

Research questions for the definitive trial will be:
Primary Question: Does guided self-help CBT for distressing voices lead to improvements in the distress associated with voices in comparison to a wait list control?
Secondary Questions: Does guided self-help CBT for distressing voices lead to improvements in depression, anxiety, voice hearing characteristics and voice hearing impact in comparison to a wait list control?

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee North West - Lancaster, 15/07/2015, ref: 15/NW/0575

Study design
Single-centre randomised controlled external pilot trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
The intervention being trialed is specifically for people who hear distress voices (also know as auditory hallucinations). This may be in the context of a psychosis or another mental health problem.

Interventions
The intervention in this trial is guided self-help using cognitive behavioural techniques. The intervention using the self-help book 'Overcoming Distressing Voices' by Hayward, Strauss and Kingdon (2012) as its basis. This will be compared to a wait list control group. Both groups will continue to receive their usual care throughout the trial.

Intervention Type
Behavioural

Primary outcome measure
Hamilton Program for Schizophrenia Voices Questionnaire (HPSVQ) distress subscale. The HPSVQ is a self-report questionnaire. This outcome will be measured at baseline (before randomisation) and at 12 weeks (post therapy for those in the intervention group).

Secondary outcome measures
1. Visual Analogue Scales (VAS) measuring beliefs about personal control when voices are active, beliefs about the self, assertiveness, and ability to cope with voices. This measure will be used to track changes in what are hypothesised to be the mechanisms of change and to see if these correspond with the topics of the therapy sessions i.e. do beliefs about the self improve after the self module of therapy
2. The Hospital Anxiety and Depression Scale (HADS) . The changes in distress related to the voice hearing experience that is hypothesised may actually reflect a more global reduction in distress – therefore this measure will allow us to capture this.
3. Short Warwick-Edinburgh Mental Well-Being Scale (SWEMWBS). A measure of well-being will give us a more global assessment of how the participants believe their mental health currently is and if this has changed at all
4. Choice of Outcome In Cbt for psychosES (CHOICE) . It is important for this study to include a measure that reflects the outcomes that are important to patients; the CHOICE was developed in partnership with service users and therefore meets this criteria
5. The Brief Core Schema Scale (BCSS) self scale . One of the modules within the therapy focuses on beliefs about the self; this measure gives an assessment as to the degree of positive and negative beliefs the person has about themselves
6. Voice and You (VAY). One of the modules within the therapy looks at relationships, both socially and relationships with the voice; this measure gives an assessment of the nature of the relationship between the voice and hearer, and can measure any changes that might occur in relation to this
7. Beliefs about voices questionnaire- revised (BAVQ-R). One of the modules within the therapy targets beliefs about voices; the present measure is able to measure the degree to which these beliefs are positive or negative, and can therefore track any changes in this
8. Persons relating to other questionnaire (PROQ3). As mentioned, one of the modules within the therapy looks at relationships, both socially and relationships with the voice; this measure aims to capture any changes in social relationships
9. Rosenberg self-esteem scale (RSES). As mentioned, one of the modules within the therapy

focuses on beliefs about the self; the therapy looks at how these beliefs relate to self-esteem, and this measure will allow us to see if any change in beliefs do correspond to a change in self-esteem.
10. Hamilton Program for Schizophrenia Voices Questionnaire (HPSVQ) phenomenology subscale. It is common place within trials that include populations who experience the symptoms of psychosis for there to be a measure of the symptom severity. This measure will allow us to compare the results to other trials and see if participants do experience a change in the nature or frequency of their voices

All of the above measures are questionnaires that will be completed at (before randomisation) and at 12 weeks (post therapy for those in the intervention group).

11. Patient Experience Questionnaire based on the questionnaire used in IAPT services. This questionnaire is a way of ascertaining patient satisfaction in a quantitative manner, in addition to the exit interview; this data will also allow for comparison between this study and IAPT services
12. Qualitative exit interview based on the 'Change Interview' . The qualitative part of this research study will help to identify any other changes that participants experienced after the therapy that the quantitative measures were not able to identify. It will also give participants a space to give the research team suggestions that can be utilised in future research studies

Overall study start date
20/07/2015

Completion date
01/10/2016

Eligibility

Key inclusion criteria
1. Aged 18 years or over
2. Currently distressed by hearing voices (as defined by scoring at least 3 on questions 5, 6 or 7 on the HPSVQ)
3. Experienced distressing voices for the preceding one year period
4. Be able to understand and communicate in English i.e. have the reading and writing ability of an 11 year old

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants

30

Total final enrolment
28

Key exclusion criteria
Participants must not:
1. Have an organic illness
2. A current primary diagnosis of substance misuse
3. Be currently receiving or have confirmed plans to begin a psychological therapy for any mental health problem

Date of first enrolment
01/09/2015

Date of final enrolment
01/07/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Sussex Partnership NHS Foundation Trust
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Sponsor information

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ROR
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Funder(s)

Funder type
Research council

Funder Name
Economic and Social Research Council

Alternative Name(s)
ESRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
Sussex Partnership NHS Foundation Trust

Results and Publications

Publication and dissemination plan
The between group results of the trial are intended to be published in a clinical psychology journal. The research team also plans to publish a paper that will look at any changes in

symptoms over course of the therapy sessions using visual analogue scales, and identify whether these changes map onto the content of the therapy session. A paper will also be produced that analysed the qualitative data that will be obtained through interviews with the participants.

Intention to publish date
01/06/2016

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	26/07/2016		Yes	No
Results article	results	01/05/2018	21/05/2019	Yes	No
HRA research summary			28/06/2023	No	No