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Increasing access to CBT for psychosis patients

Submission date
28/01/2019

Recruitment status
No longer recruiting

Registration date
05/02/2019

Overall study status
Completed

Last Edited
14/09/2021

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Current plain English summary as of 10/01/2020:
Background and study aims
Psychosis is a type of mental health problem. People with psychosis usually experience distressing delusional beliefs and/or voice hearing. The National Institute for Health & Care Excellence (NICE) recommends Cognitive Behaviour Therapy (CBT) as one of the best treatments for psychosis, but only 10% of people with psychosis have the chance to receive CBT. CBT is scarce because it can be quite long and needs to be delivered by highly trained therapists. The researchers want to see if a shorter version of CBT that is delivered by therapists with less training will be helpful for people who hear voices. Their research aims to give more people with psychosis the chance to receive a helpful talking therapy. The long-term aim of this research is to increase access to CBT for psychosis patients; this will be achieved by evaluating the clinical and cost effectiveness of a brief and targeted CBT intervention that can be delivered by a less costly and widely available workforce of assistant psychologists (AP) following a brief training in the delivery of the intervention. This is a feasibility study. The findings will tell us if it is possible to run a larger version of this study. We will only find out if the therapy works when we run this larger study.

Who can participate?
Psychosis patients aged 16 or older in NHS community secondary care adult mental health services who are currently experiencing distressing voice hearing

What does the study involve?
Participants are randomly allocated into one of three groups to receive eight sessions of Guided self-help CBT intervention for distressing VoicEs (GiVE), or eight sessions of Supportive Counselling that is not specifically about hearing voices, or to continue with their usual care.

What are the possible benefits and risks of participating?
The CBT being evaluated within this study is being delivered in a novel way. For this reason, it is not known whether it will be helpful to patients. Participants who part in the study will be helping to determine whether CBT is helpful when delivered in this way, and this will help mental health services when they are planning what therapies they offer. Participant's care team (including their Care Co-ordinator or Lead Practitioner) would know that the participant is taking part in the study. All participants will continue to receive their usual care, including those offered the therapy. Participants may potentially experience transient distress when asked to

talk about their mental health difficulties which might include hearing voices or other experiences. This will be managed by asking therapists and researchers to remind participants that they are under no pressure to discuss topics or situations that they don't feel comfortable disclosing. Participants should feel able to discuss any issues at their own pace. It is thought that participant distress will be more likely to occur during the interventions (GiVE or Supported Counselling) rather than during contact with the research team (at consent meeting or assessment meetings). The process of developing a supportive therapeutic relationship between the therapist and participant will alleviate some of this distress and will be carefully considered during therapist training. Assistant Psychologists who will be delivering therapy will have experience of this patient group and will be supervised by highly trained therapists (clinical and counselling psychologist). The study will involve participants giving up some of their time to take part. To reimburse them for their time they are paid £20 per assessment (at the start of the study and two follow-up assessments). All participants can potentially earn £60 over the course of the study. It is hoped that the CBT will be helpful, but this can't be guaranteed. This research will provide information about whether CBT delivered by briefly trained therapists is helpful for people who hear distressing voices. This will help mental health services to make decisions about what therapies should be provided for people who hear voices. All participants will be reminded of their right to withdraw throughout the study, especially if they become too distressed. If concerns regarding the participants safety arise, the Trust's risk procedures shall be followed.

Where is the study run from?
1. Sussex Partnership NHS Foundation Trust (UK)
2. Pennine Care NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
September 2018 to August 2020

Who is funding the study?
National Institute of Health Research (NIHR) (UK)

Who is the main contact?
Mark Hayward (Chief Investigator), mark.hayward@sussexpartnership.nhs.uk

Previous plain English summary:
Background and study aims
Psychosis is a type of mental health problem. People with psychosis usually experience distressing delusional beliefs and/or voice hearing. The National Institute for Health & Care Excellence (NICE) recommends Cognitive Behaviour Therapy (CBT) as one of the best treatments for psychosis, but only 10% of people with psychosis have the chance to receive CBT. CBT is scarce because it can be quite long and needs to be delivered by highly trained therapists. The researchers want to see if a shorter version of CBT that is delivered by therapists with less training will be helpful for people who hear voices. Their research aims to give more people with psychosis the chance to receive a helpful talking therapy. The long-term aim of this research is to increase access to CBT for psychosis patients; this will be achieved by evaluating the clinical and cost effectiveness of a brief and targeted CBT intervention that can be delivered by a less costly and widely available workforce of assistant psychologists (AP) following a brief training in the delivery of the intervention. This is a feasibility study. The findings will tell us if it is possible to run a larger version of this study. We will only find out if the therapy works when we run this larger study.

Who can participate?
Psychosis patients aged 18 or older in NHS community secondary care adult mental health services who are currently experiencing distressing voice hearing

What does the study involve?
Participants are randomly allocated into one of three groups to receive eight sessions of Guided self-help CBT intervention for distressing VoicEs (GiVE), or eight sessions of Supportive Counselling that is not specifically about hearing voices, or to continue with their usual care.

What are the possible benefits and risks of participating?
The CBT being evaluated within this study is being delivered in a novel way. For this reason, it is not known whether it will be helpful to patients. Participants who part in the study will be helping to determine whether CBT is helpful when delivered in this way, and this will help mental health services when they are planning what therapies they offer. Participant's care team (including their Care Co-ordinator or Lead Practitioner) would know that the participant is taking part in the study. All participants will continue to receive their usual care, including those offered the therapy. Participants may potentially experience transient distress when asked to talk about their mental health difficulties which might include hearing voices or other experiences. This will be managed by asking therapists and researchers to remind participants that they are under no pressure to discuss topics or situations that they don't feel comfortable disclosing. Participants should feel able to discuss any issues at their own pace. It is thought that participant distress will be more likely to occur during the interventions (GiVE or Supported Counselling) rather than during contact with the research team (at consent meeting or assessment meetings). The process of developing a supportive therapeutic relationship between the therapist and participant will alleviate some of this distress and will be carefully considered during therapist training. Assistant Psychologists who will be delivering therapy will have experience of this patient group and will be supervised by highly trained therapists (clinical and counselling psychologist). The study will involve participants giving up some of their time to take part. To reimburse them for their time they are paid £20 per assessment (at the start of the study and two follow-up assessments). All participants can potentially earn £60 over the course of the study. It is hoped that the CBT will be helpful, but this can't be guaranteed. This research will provide information about whether CBT delivered by briefly trained therapists is helpful for people who hear distressing voices. This will help mental health services to make decisions about what therapies should be provided for people who hear voices. All participants will be reminded of their right to withdraw throughout the study, especially if they become too distressed. If concerns regarding the participants safety arise, the Trust's risk procedures shall be followed.

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September 2018 to August 2020

Who is funding the study?
National Institute of Health Research (NIHR) (UK)

Who is the main contact?
Kate Arnold (Trial Manager)
Kate.arnold2@sussexpartnership.nhs.uk

Study website
https://www.sussexpartnership.nhs.uk/sussex-voices-clinic

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
40571

Study information

Scientific Title
Increasing access to CBT for psychosis patients: a feasibility, randomized controlled trial evaluating brief, targeted CBT for distressing voices delivered by Assistant Psychologists

Acronym
GiVE 2

Study objectives
The long-term aim of this research is to increase access to cognitive behavioral therapy (CBT) for psychosis patients; this will be achieved by evaluating the clinical and cost effectiveness of a brief and targeted CBT intervention that can be delivered by a less costly and widely available workforce of assistant psychologists (AP) following a brief training in the delivery of the intervention.

The current study aims to explore the feasibility of conducting a three-arm randomized controlled trial (RCT) of a Guided, self-help CBT intervention for distressing VoicEs (GiVE), delivered by APs. The research question considers if it would be feasible to conduct an RCT to evaluate the clinical and cost-effectiveness of GiVE when delivered by APs to psychosis patients.

The secondary aims for this study will be to determine the following indices for a definitive RCT: referral rates; recruitment rates; retention rates to the study and intervention; acceptability of the GiVE intervention and Supportive Counselling as an active control; adherence to therapy and supervision protocols; and estimates of effects to inform the calculation of the sample size.

Ethics approval required
Old ethics approval format

Ethics approval(s)
London - Surrey Research Ethics Committee, Health Research Authority, Bristol HRA Centre, Level 3, Block B, Whitefriars, Lewins Mead, Bristol BS1 2NT, Tel: +44 (0)2071048053, Email: nrescommittee.secoast-surrey@nhs.net, 21/01/2019, ref: 18/LO/2091

Study design
Randomised; Interventional; Design type: Treatment, Psychological & Behavioural

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Schizophrenia or other psychosis

Interventions
Current intervention as of 10/01/2020:
The study will recruit up to 90 people with psychosis who will be randomly allocated into one of three groups:
1. 30 participants will receive 8 sessions of Guided self-help CBT intervention for distressing VoicEs (GiVE)
2. 30 participants will receive 8 sessions of Supportive Counselling that is not specifically about hearing voices
3. 30 participants will continue with their usual care
Participants will be enrolled in the study for 28 weeks in total

Previous intervention:
The study will recruit 90 people with psychosis who will be randomly allocated into one of three groups:
1. 30 participants will receive 8 sessions of Guided self-help CBT intervention for distressing VoicEs (GiVE)
2. 30 participants will receive 8 sessions of Supportive Counselling that is not specifically about hearing voices
3. 30 participants will continue with their usual care
Participants will be enrolled in the study for 28 weeks in total

Intervention Type
Behavioural

Primary outcome measure
1. Distress associated with hearing voices measured using a subscale of the Psychotic Symptoms Rating Scale – Auditory Hallucinations (PSYRATS-AH) at T0, T1, T2
2. The negative impact of voices measured using a subscale of the Hamilton Program for Schizophrenia Voices Questionnaire (HPSVQ) at -t1, T1, T2

Timepoint(s): Screening/Eligibility (-t1), Baseline: T0, 16 week follow up: T1, 28 week follow up: T2

Secondary outcome measures
Screening measures:
1. Symptoms and experiences assessed using Structured Clinical Interview for DSM-5 Disorders (SCID-5) at -t1
2. Intellectual functioning assessed using Test of Premorbid Functioning – UK (TOPF-UK) at -t1

Clinical measures:
3. Impact of voice-hearing experiences, assessed using the Voice Impact Scale (VIS) at T0, T1, T2
4. Emotional distress assessed using the Hospital Anxiety and Depression Scale (HADS) at T0, T1, T2
5. Outcomes that are important to patients assessed using Choice of Outcome In Cbt for psychosES (CHOICE) at T0, T1, T2
6. Beliefs about the self, assessed using the Brief Core Schema Scale (BCSS) - self scale at T0, T1, T2
7. Relationship between the voice and hearer, assessed using Voice and You (VAY) at T0, T1, T2
8. Social relationships assessed using Persons relating to others questionnaire (PROQ3) at T0, T1, T2
9. Beliefs about voices assessed using Beliefs about voices questionnaire - revised (BAVQ-R) at T0, T1, T2
10. Paranoid delusions assessed using Paranoid Thoughts Scale at T0, T1, T2
11. Therapeutic relationship assessed using Scale to Assess Therapeutic Relationships (in community mental health care) (STAR) at T1
12. Participants' expectancy about the effectiveness of the therapeutic intervention, assessed using Therapy Credibility and Expectancy Questionnaire at Session 1 of therapy intervention (GiVE and SC arms of the trial)

Non-clinical measures:
13. Demographics information assessed using survey at T0
14. Completion of 'homework' tasks assessed using a diary between sessions

Social functioning measures:
15. Ability to engage in meaningful activity, assessed using Work and Social Adjustment Scale (WSAS) at T0, T1, T2
16. Social functioning assessed using Social and Occupational Functioning Scale (SOFAS) at T0, T1, T2

Health economic measures:
17. Resource use and support costs, assessed using Client Service Receipt Inventory (CSRI-UK) at T0, T1, T2
18. Health-related quality of life, assessed using EQ5D-5L at T0, T1, T2
19. Functional health and well-being, assessed using SF-12 at T0, T1, T2

Timepoint(s): Screening/Eligibility (-t1), Baseline: T0, 16 week follow up: T1, 28 week follow up: T2

Overall study start date
01/09/2018

Completion date
31/08/2020

Eligibility

Key inclusion criteria
Current inclusion criteria as of 10/01/2020:
Participants must:
1. Be aged 16 years or older
2. Be in contact with Secondary Care Mental Health Services (under the care of a Consultant Psychiatrist)
3. Be currently experiencing voice hearing; operationalized by participants having a score of at least 1 on item 1 (How frequently did you hear a voice or voices?) on the Hamilton Program for Schizophrenic Voices Questionnaire (HPSVQ) - indicating that the participant has experienced at least one episode of voice hearing in the past week
4. Be distressed by hearing voices; operationalized by participants scoring at least 8 out of 16 on the 'negative impact' scale of the HPSVQ
5. Meet DSM-5 Research criteria for Schizophrenia Spectrum or Other Psychotic Disorders (assessed by the Structured Clinical Interview for DSM-5 disorders, SCID-5)
6. Be willing and able to provide written, informed consent

Previous inclusion criteria:
Participants must:
1. Be 18 years or older
2. Be in contact with Secondary Care Mental Health Services (under the care of a Consultant Psychiatrist)
3. Be currently experiencing voice hearing; operationalized by participants having a score of at least 1 on item 1 (How frequently did you hear a voice or voices?) on the Hamilton Program for Schizophrenic Voices Questionnaire (HPSVQ) - indicating that the participant has experienced at least one episode of voice hearing in the past week
4. Be distressed by hearing voices; operationalized by participants scoring at least 8 out of 16 on the 'negative impact' scale of the HPSVQ
5. Meet DSM-5 Research criteria for Schizophrenia Spectrum or Other Psychotic Disorders

(assessed by the Structured Clinical Interview for DSM-5 disorders, SCID-5)
6. Be willing and able to provide written, informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 90; UK Sample Size: 90

Total final enrolment
79

Key exclusion criteria
Current exclusion criteria as of 10/01/2020:
Participants must not:
1. Have an established organic cause for distressing voices (e.g. brain disease or injury)
2. Have a primary diagnosis of substance misuse
3. Have completed a full course (minimum of 16 hours) of CBT for psychotic symptoms during the past year
4. Be currently participating, or be confirmed to participate in another interventional study in which they are receiving an intervention which utilizes psychological therapy
5. Be non-English speaking to the degree that the participant is unable to fully understand and answer assessment questions or give informed consent
6. Have severe learning disability (mild to moderate will not be excluded) assessed using the TOPF-UK
7. Be at immediate and serious risk to self or other (assessed at the point of referral/eligibility review)
8. Be detained in hospital under a section of the Mental Health Act

Previous exclusion criteria:
Participants must not:
1. Have an established organic cause for distressing voices (e.g. brain disease or injury)
2. Have a primary diagnosis of substance misuse
3. Have completed a full course (minimum of 16 hours) of CBT for psychotic symptoms during the past year
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6. Have severe learning disability (mild to moderate will not be excluded) assessed using the

TOPF-UK
7. Be at immediate and serious risk to self or other (assessed at the point of referral/eligibility review)

Date of first enrolment
31/01/2019

Date of final enrolment
29/02/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Sussex Partnership NHS Foundation Trust (lead site)
Swandean
Arundel Road
Worthing
United Kingdom
BN13 3EP

Study participating centre
Pennine Care NHS Foundation Trust
225 Old Street
Ashton-under-Lyne
United Kingdom
OL6 7SR

Sponsor information

Organisation
Sussex Partnership NHS Foundation Trust

Sponsor details
c/o Taffy Bakasa
Governance Manager
Assessment and Treatment Centre
Chapel Street
Chichester

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PO19 1BX
+44 (0)300 304 0088
researchgovernance@sussexpartnership.nhs.uk

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05fmrjg27

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF); Grant Codes: PB-PG-0317-20029

Results and Publications

Publication and dissemination plan
Findings will be written up and submitted for open-access publication in high-impact academic journals. Three peer-reviewed papers are planned:
1. The trial protocol will be submitted for publication in a peer reviewed journal before recruitment ends (December 2019)
2. A paper reporting on the main findings in relation to the feasibility questions will be submitted to a peer reviewed journal (September 2021)
3. A paper reporting the findings from the process evaluation on barriers and facilitators to the delivery of the GiVE intervention by APs will be submitted to a peer reviewed journal (September 2021)

Findings will be disseminated to participants and patient organizations. If a participant is unwell at the conclusion of the study (i.e. they continue to meet the study inclusion criteria for the distress associated with hearing voices), the findings will be sent to their Lead Practitioner/Care Co-ordinator who can offer some feedback to the participant at an appropriate time. LEAP members will participate in dissemination including use of social media to disseminate findings, producing leaflets for wide distribution and submitting a summary of findings to the non-academic journal. This will enable the findings to be widely shared within the mental health community of interest. Findings will be presented at patient events and at local, national and international conferences including the annual conference of the British Association of Behavioural and Cognitive Psychotherapies and the annual scientific meeting of the International Consortium on Hallucinations Research.

Intention to publish date
01/09/2021

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	01/04/2020	03/04/2020	Yes	No
Results article		19/08/2021	14/09/2021	Yes	No
HRA research summary			28/06/2023	No	No