

Relating Therapy for voices: Evaluating a relationally-based therapy for people who hear distressing voices

Submission date 17/06/2013	Recruitment status No longer recruiting	☐ Prospectively registered ☒ Protocol
Registration date 17/06/2013	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 05/10/2018	Condition category Mental and Behavioural Disorders	☐ Individual participant data

Plain English summary of protocol

Background and study aims

The experience of hearing voices is a defining feature of schizophrenia and is reported by 60% of service users. NHS guidance recommends that psychological therapy (Cognitive Behaviour Therapy for psychosis - CBTp) should be offered to all service users with a diagnosis of schizophrenia. However, the effect of CBTp specifically on voices is being questioned and a symptom-based approach may be warranted. An evolving body of literature is exploring the experience of hearing voices from interpersonal perspectives. Dr Hayward has developed and tested the feasibility of a therapy for distressing voices that is derived from this literature. This study aims to evaluate this relationally-based individual therapy for people hearing distressing voices.

Who can participate?

Male and female patients aged over 18 years who have been hearing treatment-resistant and distressing voices for at least one year.

What does the study involve?

The trial will compare outcomes for 15 service users receiving the therapy and their usual treatment with 15 service users receiving their usual treatment.

What are the possible benefits and risks of participating?

Not provided.

Where is the study run from?

Nevill View Hospital (UK).

When is the study starting and how long is it expected to run for?

The study will run from June 2013 to August 2014.

Who is funding the study?

The study is funded by the British Academy and Sussex Partnership NHS Foundation Trust.

Who is the main contact?
Dr Mark Hayward
mark.hayward@sussexpartnership.nhs.uk

Contact information

Type(s)
Scientific

Contact name
Dr Mark Hayward

Contact details
Nevill View Hospital
Hove
United Kingdom
BN3 7HZ
-
mark.hayward@sussexpartnership.nhs.uk

Additional identifiers

Protocol serial number
14628

Study information

Scientific Title
Relating Therapy for voices: A pilot randomised trial evaluating a relationally-based therapy for people who hear distressing voices

Acronym
R2V

Study objectives
The primary aim of the study is to generate an effect size to inform the power calculation for a full randomised controlled trial (RCT).

More details can be found at: <http://public.ukcrn.org.uk/search/StudyDetail.aspx?StudyID=14628>

Further reading:
Hayward, M. (2003). Interpersonal relating and voice hearing: To what extent does relating to the voice reflect social relating? Psychology and Psychotherapy: Theory, Research and Practice, 76, 369-383.

Hayward, M., Berry, K. & Ashton, A. (2011). Applying interpersonal theories to the understanding of and therapy for auditory hallucinations: A review of the literature and directions for further research. Clinical Psychology Review, 31, 1313-1323.

Hayward, M., Denney, J., Vaughan, S. & Fowler, D. (2008). The Voice and You: Development and psychometric evaluation of a measure of relationships with voices. *Clinical Psychology & Psychotherapy*, 15, 45-52.

Hayward, M., Overton, J., Dorey, T. & Denney, J. (2009). Relating Therapy for people who hear voices: a case series. *Clinical Psychology & Psychotherapy*, 16, 216-227.

Ethics approval required

Old ethics approval format

Ethics approval(s)

NRES Committee South East Coast Surrey, 18/03/2013, ref: 12/LO/2045

Primary study design

Interventional

Study design

Randomised interventional treatment trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Topic: Mental Health Research Network; Subtopic: Schizophrenia, Psychosis; Disease: Schizophrenia, Psychosis

Interventions

Intervention = Relating Therapy offered in an individual format over a maximum of 16 sessions (+ treatment as usual)

Control = treatment as usual

Study Entry : Single Randomisation only

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Psychotic Symptoms Rating Scale (PSYRATS: Auditory hallucinations scale AHRs) - an 11-item rating scale designed to measure the severity of different dimensions of the voice hearing experience (Haddock et al, 1999). Items include frequency, duration, loudness, intensity of distress and controllability. Each item is measured by the rater on a 5-point scale ranging from 0-4. The items relating to intensity of distress and controllability of voices on the AHRs are the most often cited in the voice hearing literature and will be the focus of this study.

Assessment data at Time 0 (baseline) will be collected pre-randomisation by a research assistant. Assessments at Times 1 (post-therapy) and 2 (3-month follow-up) will be collected by a research assistant who is blind to allocation.

Key secondary outcome(s)

1. CHOICE (Greenwood et al, 2009) - a 21 item self report questionnaire developed with service users to assess goals for CBT for psychosis that are relevant to recovery, e.g. self confidence, ways of dealing with unpleasant feelings and emotions, positive ways of relating to people, knowing I am not the only person who has unusual experiences, a positive purpose and direction in life. CHOICE has been found to be reliable and valid (Greenwood et al, 2009).
2. Voice and You (VAY) - the VAY is a 28-item measure of interrelating between the hearer and their predominant voice (Hayward et al, 2008). Relating is measured across four scales; two concerning the hearer's perception of the relating of the voice - voice dominance and voice intrusiveness; and two concerning the relating of the hearer - hearer distance and hearer dependence. Each item is measured on a four-point scale (0-3) generating the following range of scores for each scale: Voice Dominance 0-21; Voice Intrusiveness 0-15; Hearer Distance 0-21; and Hearer Dependence 0-27. The VAY has good internal consistency ($\alpha > .80$ for all scales) and acceptable test-retest reliability ($r > .7$ for all scales).
3. Persons Relating to Others Questionnaire (PROQ3) - the PROQ3 is a 40 item questionnaire that assesses relating across eight scales which correspond to the relating positions within Birtchnell's Interpersonal Octogan . Response options are 'Nearly always true', 'Quite often true', 'Sometimes true' and 'Rarely true', which carry a score of 3, 2, 1 or 0. Thus each scale has a score range of 0 -15, and there is a maximum total score of 120 (Birtchnell et al, in press).
4. Hospital anxiety and depression scale (HADS) the HADS is a 16 item measure of symptoms of anxiety and depression that has well established psychometric properties (Zigmond & Snaith, 1983).

Assessment data at Time 0 (baseline) will be collected pre-randomisation by a research assistant. Assessments at Times 1 (post-therapy) and 2 (3-month follow-up) will be collected by a research assistant who is blind to allocation.

Completion date

31/08/2014

Eligibility

Key inclusion criteria

1. Inclusion criteria will require that participants have been hearing treatment resistant and distressing voices for at least one year, irrespective of diagnosis.
2. Target Gender: Male & Female ; Lower Age Limit 18 years

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

People will be excluded on the grounds of:

1. Organic illness
2. A primary diagnosis of substance misuse
3. Currently receiving psychological therapy for distressing voice

Date of first enrolment

04/06/2013

Date of final enrolment

31/08/2014

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

Nevill View Hospital

Hove

United Kingdom

BN3 7HZ

Sponsor information**Organisation**

Sussex Partnership NHS Foundation Trust (UK)

ROR

<https://ror.org/05fmrjg27>

Funder(s)**Funder type**

Other

Funder Name

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	01/05/2017		Yes	No
Protocol article	protocol	16/08/2014		Yes	No
HRA research summary			28/06/2023	No	No