

Cognitive behavioural therapy (CBT) for dysphonia: a trial platform

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| Submission date 19/05/2010 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 19/05/2010 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 12/02/2018 | Condition category Ear, Nose and Throat | <input type="checkbox"/> Individual participant data |

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
4588; G0501875

Study information

Scientific Title

Training a speech and language therapist in cognitive behavioural therapy to treat functional dysphonia: a randomised controlled trial

Acronym

CBT for dysphonia

Study objectives

The principle purpose of this trial is to see if giving a speech and language therapist a brief training in cognitive behavioural therapy (CBT), and then having that therapist deliver CBT "enhanced" voice therapy, can improve the quality of life of people suffering from medically unexplained hoarseness and voice loss. This voice problem, known as "functional dysphonia", is associated with increased anxiety and depression, and with poor general health. Voice therapy alone improves voice, but seems to have no impact on this associated distress. Our hypothesis therefore is that the addition of CBT skills to conventional voice therapy will improve anxiety and depression in this patient group more than voice therapy alone.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Newcastle and North Tyneside REC, 27/07/2007, ref: 07/H0906/118

Study design

Single-centre randomised interventional treatment trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

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

Topic: Ear; Subtopic: Ear (all Subtopics); Disease: Ear, nose & throat

Interventions

Voice Therapy:

This "treatment as usual" will aim to be as close to standard voice therapy practice as possible.

Patients will be offered 6 - 8 sessions, weekly to fortnightly, of approximately one hour's voice therapy. This represents an average length of a voice therapy course in the UK. The content will typically have the following elements:

1. Voice care and education on use
2. Elimination of voice misuse and abuse
3. Breath control, breathing and speaking coordination

Voice Therapy plus CBT:

The approximate number and timing of sessions will be the same as in the voice therapy alone arm. The treatment will be couched within an overarching CBT framework, the key component of this being that an explanatory model of the patient's condition will be collaboratively established, and the key factors maintaining both vocal problems and distress will be identified. This model will then be used to structure the treatment.

Length of treatment will be six to eight sessions, fortnightly and patients will be followed up to six months post-discharge from treatment.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Psychological distress, measured using the Hospital Anxiety and Depression Scale (HADS). Outcomes will be taken at baseline, discharge and six months post-discharge

Secondary outcome measures

1. Psychological distress, measured using the General Health Questionnaire
2. The Chalder Fatigue Scale
3. The Work and Social Adjustment Scale
4. Voice, measured using the Voice Performance Questionnaire (VPQ)

Outcomes will be taken at baseline, discharge and six months post-discharge.

Overall study start date

29/10/2007

Completion date

30/09/2009

Eligibility

Key inclusion criteria

1. Patients of either sex who are over 16 years
2. Diagnosed by an expert speech and language therapist as having functional dysphonia
3. Clinical assessment involving larygoscope to exclude other causes

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

Planned sample size: 62

Key exclusion criteria

1. Previous experience of cognitive behavioural therapy (CBT) for voice problem
2. Acute or ongoing serious medical illness
3. Suffer from a severe mental health problem (for example major depression, psychotic illnesses, or alcohol dependence)
4. Learning disability
5. Vocal condition that does not merit a full course of treatment
6. Score of less than 1 on a standardised measure of voice quality (the Grade, Roughness, Breathiness, Aesthenia, Strain [GRBAS] Scale)
7. Do not speak English

Date of first enrolment

29/10/2007

Date of final enrolment

30/09/2009

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

Institute of Health and Society

Newcastle Upon Tyne

United Kingdom

NE2 4AA

Sponsor information**Organisation**

Newcastle upon Tyne Hospitals NHS Trust (UK)

Sponsor details

Queen Victoria Road
Newcastle Upon Tyne
England
United Kingdom
NE1 4LP

Sponsor type

Hospital/treatment centre

Website

<http://www.newcastle-hospitals.org.uk/>

ROR

<https://ror.org/05p40t847>

Funder(s)

Funder type

Research council

Funder Name

Medical Research Council (MRC) (UK) (ref: G0501875)

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? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| Results article | results | 01/12/2018 | | Yes | No |