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Management of social anxiety in clients who stutter

Submission date
05/07/2013

Recruitment status
No longer recruiting

Registration date
05/07/2013

Overall study status
Completed

Last Edited
29/01/2019

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
About 1% of adults continue to experience stuttering (stammering) that began in childhood. For many of these adults, severe social anxiety (social phobia) is a serious problem. Social phobia involves a fear of situations where the person has to speak to others, in places such as work or education as well as social occasions, or where they fear that others will form negative views of them. This project aims to develop a new treatment for social phobia in adults who stutter. The treatment builds on the observation that, compared with an average person, people who are very socially anxious are more likely to focus on signs of disapproval in others (such as disapproving facial expressions). This tendency to look for negative signals is what causes and maintains the anxiety. Earlier research has shown that this tendency can be corrected by getting people with high levels of social anxiety to take part in a simple computer task. In previous studies, doing the task has lowered occurences of social anxiety disorder. If this treatment is to be used in the NHS for people who stutter, we must first make sure that it works, that it is safe and acceptable to people who use it, and whether it has any other benefits such as improving the speech fluency of people who stutter. We also need to know about its cost to the NHS. The study described here is a first step towards answering these questions.

Who can participate?
People aged 18 or over who stutter, who are not currently receiving speech treatment for their stutter (and have not been having such treatment in the past 6-12 months). Participants need to meet initial screening criteria about their stutter and their level of social anxiety, and must understand English to a level where they can make informed decisions about the study and understand the task instructions. They should not have been involved in other stuttering or social anxiety research in the previous 12 months. They should not have a mental disability. They should not be taking benzodiazepine medication (for anxiety), and if they are taking other mood-altering medication they need to be willing to continue to take these during the course of the study.

What does the study involve?
Participants would be randomly allocated to the treatment condition, the computer task (that is, the one that we think may improve social anxiety) or to a placebo (dummy) condition where they carry out a similar-looking computer task. We need to look at how people respond in both

conditions because this is the only way that we can tell whether the treatment really works. The simple 5-minute computer task should be performed 8 times in a 4-week period. The task consists of a set of trials. On each trial, the person first sees a pair of faces presented very briefly. The faces then disappear and a letter appears in the place where one of the faces was previously. The person has to press a button as fast as possible to indicate what letter it was. Participants need to visit the University of East Anglia three times in a 5-month period, to have a conversation with a clinically-trained researcher, make a recording of their speech and fill in some questionnaires. Travel expenses up to a maximum of £55 per trip will be paid. If travelling to the University is inconvenient, it may be possible for the researcher to visit the participant instead.

What are the possible benefits and risks of participating?
Participants will receive a £20 gift voucher to thank them for participating. Although an individual participant may not benefit directly from taking part in the study, they would be contributing to the development of a potentially worthwhile treatment for people who stutter. It is possible that participants may become upset when talking about their experience of stuttering with the clinically-trained researcher.

Where is the study run from?
The University of East Anglia (UK)

When is the study starting and how long is it expected to run for?
May to November 2013

Who is funding the study?
The Research for Patient Benefit Programme of the National Institute for Health Research (NIHR), UK.

Who is the main contact?
Dr Jan McAllister
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Contact information

Type(s)
Scientific

Contact name
Dr Jan McAllister

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
12924

Study information

Scientific Title
Addressing social anxiety in adults who stutter: a pilot study

Acronym
MOSAICS

Study objectives
This is a pilot study investigating the use of a computer task to treat social anxiety in adults who stutter. The mechanism of the intervention is attentional bias modification. The computer task trains people to pay less attention to disapproving faces. In earlier studies this approach has been shown to result in substantial decreases in social anxiety as measured on standard clinical assessments.

Ethics approval required
Old ethics approval format

Ethics approval(s)
12/EE/0272; First MREC approval date 06/08/2012

Study design
Randomised; Interventional; Design type: Treatment

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet
http://www.uea.ac.uk/documents/244682/0/PIS+V3+18.3.13.doc/4f58817d-a2be-4a62-b124-6a1d1b6cb32d

Health condition(s) or problem(s) studied
Topic: Mental Health Research Network, Primary Care Research Network for England; Subtopic: Anxiety, Not Assigned; Disease: Anxiety, All Diseases

Interventions
Attentional bias modification. Participants carry out a computer task in which they see pairs of faces (one with a disapproving expression, the other neutral) followed by a probe letter to which they respond. In the treatment condition the letter always replaces the neutral face. In the placebo control condition the letter may replace either face. Each participant carries out 8 x 5-10 minute sessions in a 4-week period.; Follow Up Length: 4 month(s); Study Entry : Single Randomisation only

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Diagnostic and Statistical Manual, Structured Clinical Interview for DSM Disorders (DSM-IV SCID); Timepoint(s): Baseline, first follow-up (after 4 weeks), second follow-up (after 4 months).
The interview follows a set protocol and leads to diagnostic decisions about a range of mental health conditions including social anxiety disorder.

Secondary outcome measures
1. Attentional bias task; Timepoint(s): Baseline, first follow-up (after 4 weeks), second follow-up (after 4 months).
2. EuroQol (EQ-5D) questionnaire; Timepoint(s): Baseline, first follow-up (after 4 weeks), second follow-up (after 4 months)
3. Health Service Resource Use Questionnaire; Timepoint(s): Baseline, second follow-up
4. Liebowitz Social Anxiety Scale; Timepoint(s): Baseline, first follow-up (after 4 weeks), second follow-up (after 4 months)
5. Social Phobia and Anxiety Inventory (SPAI); Timepoint(s): Baseline, first follow-up (after 4 weeks), second follow-up (after 4 months)
6. Speech recording; Timepoint(s): Baseline, first follow-up (after 4 weeks), second follow-up (after 4 months)
7. State-Trait Anxiety Inventory (STAI); Timepoint(s): Baseline, first follow-up (after 4 weeks), second follow-up (after 4 months)
8. User feedback questionnaire; Timepoint(s): First follow-up (after 4 weeks), second follow-up (after 4 months)
9. Unhelpful Thoughts and Beliefs about Stuttering (UTBAS); Timepoint(s): Baseline, first follow-up (after 4 weeks), second follow-up (after 4 months).

Overall study start date
03/05/2013

Completion date
02/11/2013

Eligibility

Key inclusion criteria
1. Eighteen years of age or older
2. Stuttering rate greater than 2% syllables stuttered when measured over the telephone
3. Score of 19 or more on the Social Phobia Inventory
4. English proficiency to the level required for informed consent and taking part in the study.
Target Gender: Male & Female ; Lower Age Limit 18 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 60; UK Sample Size: 60

Key exclusion criteria
1. Cognitive behavioural therapy (CBT) during the previous 6 months
2. Speech treatment during the previous 12 months
3. Involvement in stuttering or social anxiety research during the previous 12 months
4. Serious risk of self-harm, evaluated during interview at baseline
5. Intellectual disability
6. Current use of benzodiazepines
7. Unwillingness or inability to maintain a stable dose of any extant psychotropic medication for the duration of the trial

Date of first enrolment
03/05/2013

Date of final enrolment
02/11/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of East Anglia
Norwich

United Kingdom
NR4 7TJ

Sponsor information

Organisation
NHS South Norfolk Clinical Commissioning Group (UK)

Sponsor details
Lakeside 400
Old Chapel Way
Broadland Business Park
Thorpe St Andrew
Norwich
England
United Kingdom
NR7 0WG

Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Government

Funder Name
NIHR Research for Patient Benefit (RfPB) (UK); Grant Codes: PB-PG-0610-22225

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	22/10/2017	29/01/2019	Yes	No