A pilot study into a role for subvocal speech production in the perception and reduction of AVH

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Ethical review	Approved WMO
Status	Pending
Health condition type	Disturbances in thinking and perception
Study type	Interventional

Summary

ID

NL-OMON55146

Source
ToetsingOnline

Brief title
Pilot study subvocal speech in AVH

Condition

- Disturbances in thinking and perception

Synonym
auditory verbal hallucinations, hearing voices

Research involving
Human

Sponsors and support

Primary sponsor: Rijksuniversiteit Groningen
Source(s) of monetary or material Support: Brain and Behaviour Research Foundation

Intervention

Keyword: Auditory verbal hallucinations, Biofeedback, Electromyogram, Speech production

Outcome measures

Primary outcome

The main parameter of the current study is EMG activation during AVH.

Study part 1 compares EMG during AVH with baseline (rest) and behavioural tasks

(humming, whistling and reading out loud).

Study part 2 measures the success of interruption of AVH related EMG activation

through behavioural tasks.

Secondary outcome

A secondary study parameter pertains the difference in EMG activation in

participants experiencing AVH and a control group who do not experience AVH.

This is measured in study 1 by comparing baseline activation patterns and task

related EMGs between the AVH+ and AVH- groups.

Study description

Background summary

Around 16% of the general population hears voices in the absence of speaker. This is called an Auditory Verbal Hallucination (AVH). For part of the hallucinating population the hallucinations cause great distress, lead to a lower global functioning, and result in psychiatric disorder. Despite the high prevalence of AVH, the underlying cognitive mechanisms are largely unknown. A promising cognitive theory regarding the origin of AVHs is the *deficit in forward model production* theory. Deficits in the production of the forward models results in self-produced actions being perceived as if some external force controls them. In the case of auditory hallucinations, it is hypothesized that self-produced speech is perceived as speech produced by someone else due to the lack of attenuation.One avenue of support for this theory comes from research in the 1950*s demonstrating that during the perception of AVH,

involvement of articulatory muscles was observed through EMG. The speech remained inaudible unless amplified (subvocal speech). Importantly, although the speech production was measurable, the person perceiving the AVH did not perceive the speech as self-produced. The current proposal seeks to decrease AVH by training the participant to interrupt the production of subvocal speech. In a first step we will test whether subvocal speech production is measurable through EMG, and different from people who do not experience AVH. In a second study we will visualise the subvocal speech by measuring the activation in muscles engaged during AVH with EMG, and displaying that muscle activation in real time on a screen. The participant is trained to link the visual display with their own muscle activity during humming, whistling and speaking. In a next step the participant sees the engagement of the muscles during AVH, and is trained to interrupt the AVH by performing the tasks that use the same muscles or by intentionally relaxing these muscles. Through the visual feedback the participant can again identify a role for their own articulators during AVH, bypassing the failure in the forward model production system, and regain control. Having a sense of control over AVH is a major improvement in the lives of these participants. Relatively short training on articulatory muscles with similar biofeedback mechanisms has been shown to have lasting effects.

Study objective

The current research project investigates whether subvocal speech production can be measured using EMGs during AVH. If such subvocal speech is visible in the EMGs, as previous research suggests, this visualization can be used to develop biofeedback training. With biofeedback training the participant sees the muscle activation, thereby correcting incorrect interpretation. The participant is trained to use this visualization to stop subvocal speech production, which in turn results in a halt of the AVH. If the biofeedback training works as proposed, this technique has the potential to form a novel therapeutic tool.
The objective of the current research project is to pilot whether EMG-based biofeedback can be used as a novel therapeutic tool to reduce AVH.

Study design

The current study is a pilot study with a two-part design. Part 1 is a case control observational study, Part 2 is a clinical trial study with a behavioural intervention

In part 1 we measure EMG activation in articulatory muscles while the participants passively watch a nature movie without sound. Wet-gel electrodes are strategically placed on articulatory muscles (orbicularis oris superior, orbicularis oris inferior and sternocleidomastoid with a bipolar electrode montage). Additionally two electrodes are placed on a reference site (brachioradialis) to ensure measured orofacial muscle activations are

associated with speech and not generalized muscle contractions. We also record EMG activation of articulatory muscles during humming, whistling and reading out loud. Participants who hallucinate are asked to report the perception of AVH via a button press.
Before the experimental tasks, a few additional measures of importance to the interpretation and validity of the findings are taken. Firstly, the Questionnaire for Psychotic Experiences (QPE) will be administered to assess the presence, severity, and phenomenology of delusions and hallucinations. Second, a diagnostic interview (M.I.N.I) will be performed with the participants to assess the current state of the participant*s mental health, unless a diagnostic interview was been performed in the month preceding the testing date, in which case those data will be used. Third, to have an estimate of the IQ of the participant, they perform the Dutch Adult Reading Test (DART). Additionally, a shadowing procedure is followed where the participant is asked to repeat out loud what the voices are telling them, to allow for a characterisation of the verbal hallucinations.

In part 2 we ask the AVH+ patients from part 1 to return. The setting of the experiment is identical to session 1. In this session we display muscle activation of that participant in real time on a screen. The participant is then trained to link the visual display of EMG activation with his/her own muscle activity during humming, whistling or speaking. In a next step the participant and experimenter identify the engagement of the muscles during AVH, and the participant is trained to interrupt the AVH by performing the tasks that use the same muscles or by intentionally relaxing the muscles. The outcome measure of this task is the number of successful AVH interruptions as function of the number of interruption attempts.

Intervention

The current study aims to investigate whether biofeedback can be used to interrupt AVH perception. Part 1 of the study observes which, if any, sites demonstrate a correlation with EMG activity during AVH perception. In part 2 a behavioural intervention takes place in the form of biofeedback training. During the session participants are seated in a comfortable chair. Electrodes are placed on their articulatory muscles. A real-time visualization of the EMG activation is displayed on a monitor in front of the participant (biofeedback). The experimenter explains the visualization to the participant. The participant performs simple behavioural tasks (relaxing, humming, whistling, talking out loud) to see how this affects the visual display. The biofeedback is subsequently used to interrupt AVH. The experimenter asks the participant to indicate the experience of AVH. The experimenter demonstrates to the participant how the AVH is linked to the visualisation. Experimenter and participant discuss strategies to engage the AVH relevant musculature using a behavioural task, and put this in practice. If successful, the participant continues the training using this strategy. If unsuccessful after multiple attempts a different strategy is employed; either the behavioural engagement

task is changed or instead of engagement, the relaxation of relevant musculature is trained.
The experimenter notes which strategies were successful, how many attempts to interrupt AVH were made, and how many were successful.

Study burden and risks

The current study sets out to test whether a novel therapeutic tool can be developed that would give patients who experience AVH more control over the perception. To this aim, it is necessary that we test participants who experience AVH. AVHs are most commonly associated with schizophrenia, but are also observed in other psychiatric disorders including bipolar disorder, post-traumatic stress disorder, in some neurological disorders (e.g., temporal lobe epilepsy) and in healthy individuals. For the current study to be successful it is necessary to recruit participants who perceive AVH at a high frequency. As a result, a substantial of participants in the current study will be psychiatric patients.

The number of participant visits are limited (2 max.) and mainly requires time investment for questionnaires and behavioural testing sessions.There are no risks associated with taking part in this study beyond normal every-day living.

Potential benefits for the participants who experience AVH is that if the mechanism and therapy work as proposed, the participant might be able to have more control over the AVH perception, however this is uncertain. Participants who do not experience AVH will have no personal benefit from participation.

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
-Able to understand procedures and agree to participate in the study by giving written informed consent
-Report having heard voices, measured through the Questionnaire for Psychotic Experiences.
And who report that:
(1) voices are distinct from thoughts and had a *hearing* quality and
(2) voices are experienced daily
-Or in the case of control participants, report NOT having heard voices through the Questionnaire for Psychotic Experiences.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
• Below 18 years of age
• IQ below 80 as measured by highest completed education and DART (Dutch adult reading test)

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2021
Enrollment:	50
Type:	Anticipated

Ethics review

Approved WMO

Date:	26-05-2021
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL73953.042.20