

Neurofeedback treatment of auditory verbal hallucinations

Submission date 16/01/2014	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 10/02/2014	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 31/01/2019	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

About 80% of schizophrenia patients suffer from auditory verbal hallucinations (AVH) (hearing one or more talking voices). The most conventional method of treatment is the use of antipsychotic drugs; however, in about 20-30% of patients AVH are not improved. Therefore, our aim is to investigate an alternative treatment method.

AVHs are assumed to be internal generated inner thoughts misidentified as an external stimulus by activation of the primary auditory cortex (PAC) (part of the brain that processes auditory information). As we know from electroencephalography (EEG) studies, schizophrenia patients show a reduction of the EEG N100 component. An even more pronounced reduction in the N100 component is seen in schizophrenia patients during the very moment they notice AVH. This has led to the assumption that the PAC has a crucial role in AVHs.

The main goal of our study is to investigate a new non-invasive treatment for schizophrenia patients with AVH. The aim is to investigate whether schizophrenia patients are able to increase the response to the amplitude of the N100 component following external auditory stimulation with neurofeedback (NFB) training.

Who can participate?

Chronic schizophrenia patients aged between 18 and 45 years who are likely to develop AVH.

What does the study involve?

Participants are randomly allocated to either the intervention or the placebo group. Both groups are participating in the neurofeedback training: a visual feedback will be given to the intervention group and a dummy feedback will be given to the placebo group.

What are the possible benefits and risks of participating?

All participating patients contribute to examining a non-invasive treatment for patients with AVHs. There are no risks of participating in this study. In case that our training is effective and patients show a significant improvement of the subjective wellbeing or a reduction of auditory verbal hallucinations, we offer those patients who were treated with a dummy feedback to undergo the neurofeedback training that we used in the treatment group (instead of a dummy-feedback), to give them the same possibility of an effective treatment like the patients who trained with the "real" feedback in the first place.

Where is the study run from?

The neurofeedback training as well as the evaluations will take place in the University Hospital of Psychiatry Bern, Department of Psychiatric Neurophysiology, Switzerland.

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

The study started in January 2014 and is expected to run until June 2016.

Who is funding the study?

University Hospital of Psychiatry Bern, Department of Psychiatric Neurophysiology, Switzerland.

Who is the main contact?

Prof. Dr Thomas Koenig

Contact information

Type(s)

Scientific

Contact name

Prof Thomas Koenig

Contact details

University Hospital of Psychiatry Bern
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Neurofeedback treatment of auditory verbal hallucinations: a randomized placebo controlled pilot study

Study objectives

H1: There is an unequal difference in the post-pre comparison of the Psychotic Symptom Rating Scale (Pysrats)-Auditory Hallucination Subscale in the treatment group compared to the placebo group.

H2: We expect that it is possible that schizophrenia patients with Auditory Verbal Hallucinations

(AVH) can learn to up regulate the amplitude of the auditory evoked potential N100 component by using the NFB method.

H3: After the NFB training, patients are able to modulate the N100 without feedback (transfer effect).

H4: We hypothesize that augmentation of control of the N100 component leads to reduced AVH.

H5: Also, the achieved changes due to Neurofeedback (NFB) have a positive impact on the subjective controllability of AVH and well-being.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Cantonal Ethics Committee Bern (Kantonale Ethikkommission Bern) (KEK), 07/01/2014, Ref.: 193 /13

Study design

Single-centre randomized placebo controlled pilot study

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 below to request a patient information sheet

Health condition(s) or problem(s) studied

Schizophrenia patients (ICD-10: F20 and/or F25) with auditory verbal hallucinations

Interventions

30 patients with auditory verbal hallucinations will be randomly assigned to one of two groups:

15 patients in the intervention group

15 in a placebo group

A total of 20 sessions of neurofeedback training during 2 weeks with 2 sessions a day will be completed. During training, beep tones will be used to evoke auditory N100 potentials. In the intervention group an intuitive visual feedback will be given that depends on the amplitude of the immediately preceding N100 potential.

In the placebo group, this feedback will be independent of the N100 amplitude, but will have a similar statistical distribution as in the intervention group.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Individual difference in the post-pre (last-first session) comparison of the PsyRats-Auditory Hallucinations Subscale will be compared between treatment and placebo group. Comparison 1st vs. 20th session.

Secondary outcome measures

1. The ability to modulate the N100 component (with feedback) within session, in the training against the placebo group. Every single session will be compared in both groups (session 1-20)
2. A learning effect, i.e. an increase of modulation of the N100 across sessions, in the training against the placebo group will be calculated with a regression analysis. The training will take place over two weeks every day from Monday to Friday with 2 sessions a day
3. A transfer effect, showing that participants in the training group can modulate the N100 component without feedback. Comparison 1st vs. 20th session.
4. A change in the psychopathology of the positive symptoms, the subjective controllability and well being is assessed. After each session a questionnaire will be filled out (1-20 comparison).

Overall study start date

30/01/2014

Completion date

30/06/2016

Eligibility

Key inclusion criteria

1. Male and female, age 18-45 years
2. ICD-10: in-patients of the University Hospital of Psychiatry in Bern with schizophrenia (F20) or schizoaffective disorder (F25) , prone to AVH in the acute phases of the disorder (the medication has to be stable during the training as defined in the exclusion criteria)
3. AVH in the present phase of disorder
4. Able to give written informed consent and to participate in 2 weeks of NFB training

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

45 Years

Sex

Both

Target number of participants

30 patients

Key exclusion criteria

1. Psychiatric or neurologic disease (except for ICD-10: F20/F25)
2. Hearing problems
3. Vision problems (uncorrected)
4. Substance abuse during the previous 2 weeks (except THC)
5. Change in medication (type and quantity) during the 2 weeks of training
6. Pregnancy and nursing mothers
7. Suicidal risk
8. Not capable of judgment or capacity to consent

Date of first enrolment

30/01/2014

Date of final enrolment

30/06/2016

Locations

Countries of recruitment

Switzerland

Study participating centre

University Hospital of Psychiatry Bern

Bern 60

Switzerland

3000

Sponsor information

Organisation

University Hospital of Psychiatry Bern (Switzerland)

Sponsor details

c/o Thomas Dierks

Head of the Department of Psychiatric Neurophysiology Research

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3000

Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/04h670p07>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

University Hospital of Psychiatry, Bern (Switzerland)

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	18/05/2017	31/01/2019	Yes	No
Results article	results	01/11/2018	31/01/2019	Yes	No