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Neurofeedback treatment of auditory verbal hallucinations

Submission date
16/01/2014

Recruitment status
No longer recruiting

Registration date
10/02/2014

Overall study status
Completed

Last Edited
31/01/2019

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 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 January2014 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
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Additional identifiers

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 (Psyrats)-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

Primary study design
Interventional

Study design
Single-centre randomized placebo controlled pilot study

Study type(s)
Treatment

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(s)
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.

Key secondary outcome(s)
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).

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
45 Years

Sex
All

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)

ROR
https://ror.org/04h670p07

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Hospital of Psychiatry, Bern (Switzerland)

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 results	18/05/2017	31/01/2019	Yes	No

Results article	01/11/2018	31/01/2019	Yes	No