

The effect of biofeedback therapy in psychiatric rehabilitation

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| Submission date 06/04/2021 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| Registration date 18/05/2021 | Overall study status Completed | <input checked="" type="checkbox"/> Protocol |
| Last Edited 07/07/2025 | Condition category Mental and Behavioural Disorders | <input type="checkbox"/> Statistical analysis plan |
| | | <input checked="" type="checkbox"/> Results |
| | | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol

Background and study aims

Schizophrenia is characterized by distortions in thinking, perception, emotions, language, sense of self and behaviour. The aim of this study is to find out whether neurofeedback can be a new form of therapeutic/rehabilitation intervention for people with schizophrenia. The study involves comparing an existing form of standard rehabilitation with a new galvanic skin response neurofeedback (GSR-NF) therapy.

Who can participate?

Male patients aged 18 to 65 with a diagnosis of schizophrenia, in remission for 1.5 years or more

What does the study involve?

Participants are randomly allocated to three groups. Group 1 receive standard rehabilitation interventions. Group 2 receive a standard rehabilitation program according to an established schedule. Group 3 undergo GSR-NF training. The rehabilitation measures are carried out over a period of 3 months. The initial and final measurements are compared in each group.

What are the possible benefits and risks of participating?

Biofeedback therapy may be an alternative solution to standard rehabilitation activities carried out in patients with mental illness.

Where is the study run from?

Medical University of Lublin (Poland)

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

February 2016 to January 2021

Who is funding the study?

Ministry of Science and Higher Education (Poland)

Who is the main contact

Renata Markiewicz

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

Grant number 550

Study information

Scientific Title

Improving clinical, cognitive, and psychosocial dysfunction in patients with schizophrenia: a neurofeedback study

Acronym

RehBF-Schizophrenia

Study objectives

According to the research hypothesis, neurofeedback training improves the functioning of people with schizophrenia to a greater extent than standard rehabilitation alone, which can be demonstrated by:

1. Reduction of the severity of psychopathological symptoms (scale: PANSS)
2. Improvement in cognitive and psychosocial performance (scales: BCIS, CTT-1, CTT-2, d2, AIS and GSES)

which all correspond to biochemical and electrophysiological effects:

3. Biochemical markers e.g. BDNF (brain-derived neurotrophic factor) serum level
4. Event-related potentials (ERP) and quantitative electroencephalography – neurofeedback-dependent (QEEG-NF)

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 25/02/2016, Bioethics Committee of the Medical University of Lublin (Al. Racławickie 1, 20-059 Lublin; room 132, Poland; +48 (0)81448 5213; komisja.bioetyczna@umlub.pl), ref: KE-0254/35/2016

Study design

Interventional single-center randomized study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Schizophrenia

Interventions

Patients are randomly assigned to three groups:

Group 1 receive standard rehabilitation interventions (n = 18)

Group 2 receive a standard rehabilitation program according to an established schedule (n = 26)

Group 3 undergo galvanic skin response neurofeedback (GSR-NF) training (n = 19)

The rehabilitation measures are carried out over a period of 3 months. The initial and final measurements are compared in each group based on the adopted research tools (according to the research protocol).

Intervention Type

Behavioural

Primary outcome(s)

Measured at the beginning of the study and after 3 months:

1. Psychopathological symptoms measured using the Positive and Negative Syndrome Scale (PANSS)
2. Cognitive and psychosocial performance measured using the Beck Cognitive Insight Scale (BCIS), Color Trails Test (CTT)-1, CTT-2, d2, Acceptance of Illness Scale (AIS) and General Self-efficacy Scale (GSES)
3. Biochemical markers e.g. serum level of brain-derived neurotrophic factor (BDNF)
4. Event-related potentials (ERP) and quantitative electroencephalography – neurofeedback-dependent (QEEG-NF)

Key secondary outcome(s)

There are no secondary outcome measures

Completion date

11/01/2021

Eligibility

Key inclusion criteria

1. Patients diagnosed with schizophrenia (DSM-5), residual, in partial remission for ≥ 1.5 years
2. Patient's consent
3. Aged 18-65 years
4. Right-handedness

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

65 years

Sex

Male

Total final enrolment

62

Key exclusion criteria

1. Current neurological diseases
2. Mental disability
3. Alcohol or psychoactive substances addiction

Date of first enrolment

25/09/2016

Date of final enrolment

23/12/2019

Locations**Countries of recruitment**

Poland

Study participating centre

Medical University of Lublin

Al. Raławickie 1

Lublin

Poland

20-059

Sponsor information

Organisation

Medical University of Lublin

ROR

<https://ror.org/016f61126>

Funder(s)

Funder type

Government

Funder Name

Ministerstwo Nauki i Szkolnictwa Wyższego

Alternative Name(s)

Ministerstwo Nauki i Szkolnictwa Wyższego, Ministry of Science and Higher Education, Ministry of Science and Higher Education, Republic of Poland, MNiSW

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Poland

Results and Publications

Individual participant data (IPD) sharing plan

The database and documentation of the study are held by the principal investigator Renata Markiewicz (under copyright), and can be made available upon request from renata.markiewicz@umlub.pl.

IPD sharing plan summary

Available on request

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|-------------|---------|--------------|------------|----------------|-----------------|
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|---------------------------------|--|------------|------------|-----|----|
| Results article | | 12/08/2021 | 12/04/2022 | Yes | No |
| Results article | | 11/06/2022 | 14/06/2023 | Yes | No |
| Results article | | 06/09/2022 | 14/06/2023 | Yes | No |
| Results article | Pre- and posttherapy primary outcomes | 12/08/2021 | 07/07/2025 | Yes | No |
| Results article | associations of the reelin blood level with clinical and neurocognitive parameters | 10/07/2024 | 07/07/2025 | Yes | No |
| Protocol file | | | 01/06/2021 | No | No |