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# The effect of biofeedback therapy in psychiatric rehabilitation

| Submission date | Recruitment status | [_] Prospectively registered |
|---|---|---|
| 06/04/2021 | No longer recruiting | [X] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 18/05/2021 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 07/07/2025 | Mental and Behavioural Disorders | |

**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

### Primary study design
Interventional

### Study design
Interventional single-center randomized study

### 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. Racławickie 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 |