

# The effect of biofeedback therapy in psychiatric rehabilitation

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

Dr Renata Markiewicz

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# Additional identifiers

## EudraCT/CTIS number

Nil known

## IRAS number

## ClinicalTrials.gov number

Nil known

## Secondary identifying numbers

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

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

Hospital

### **Study type(s)**

Treatment

### **Participant information sheet**

Not available in web format, the study information sheets and consent of all participants in the experiment are available from the author of the research project (Renata Markiewicz)

### **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 measure**

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)

### **Secondary outcome measures**

There are no secondary outcome measures

### **Overall study start date**

25/02/2016

### **Completion date**

11/01/2021

## **Eligibility**

### **Key inclusion criteria**

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

### **Participant type(s)**

Patient

### **Age group**

Adult

### **Lower age limit**

18 Years

### **Upper age limit**

65 Years

### **Sex**

Male

### **Target number of participants**

63

### **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

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20-059

## **Sponsor information**

**Organisation**

Medical University of Lublin

**Sponsor details**

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**Sponsor type**

University/education

**Website**

<http://www.umlub.pl/en/>

**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

## Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

## Intention to publish date

11/01/2023

## 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?
<a href="#">Protocol file</a>			01/06/2021	No	No
<a href="#">Results article</a>		12/08/2021	12/04/2022	Yes	No
<a href="#">Results article</a>		11/06/2022	14/06/2023	Yes	No
<a href="#">Results article</a>		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