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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

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

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. 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?
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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file			01/06/2021	No	No