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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
14/06/2023	Mental and Behavioural Disorders	

Plain English Summary
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

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 hypothesis
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)

Condition
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

Overall study end date
11/01/2021

Eligibility

Participant 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

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Male

Target number of participants
63

Total final enrolment
62

Participant exclusion criteria

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

Recruitment start date
25/09/2016

Recruitment end date
23/12/2019

Locations

Countries of recruitment
Poland

Study participating centre
Medical University of Lublin
Al. Racławickie 1
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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?
Protocol file			01/06/2021	No	No
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