DESCRIPTION
MEDICAL EXPERIMENT/SCIENTIFIC RESEARCH

1. **Study title: The Impact of Basal Stimulation Therapy in Adult Patients with Schizophrenia Requiring Permanent Institutional Care**
2. **Date: 01/September/2025**
3. **Institution/Place:**
   1. Clinical Psychiatric Hospital SPZOZ in Rybnik, Rybnik, Gliwicka Street 33, 44-200 Rybnik
   2. Institute of Physiotherapy and Health Sciences, Jerzy Kukuczka Academy of Physical Education in Katowice, Mikolowska 72B Street, 40-065 Katowice.
4. **Duration:** until July 31, 2027.
5. **Purpose of the study:** obtaining knowledge about the impact of basal therapy on the health of adults suffering from schizophrenia and requiring permanent institutional care (profoundly disabled).
6. **Study participants**

The study will include 12 patients staying in and receiving permanent institutional care within the SPZOZ Clinical Psychiatric Hospital in Rybnik.

Study inclusion criteria:

- women and men aged ≥ 55 years,
- consent of the legal guardian to participate in the study,
- schizophrenia clinically confirmed for at least 5 years, with predominance of negative symptoms,
- stable drug therapy (treatment unchanged for at least 3 months)
- functional ability of everyday life on the Barthel scale below 40 points.

Exclusions criteria from the study:

- lack of consent to participate in the study;
- pregnancy
- general contraindications (acute inflammatory and febrile diseases, venous thrombosis, unstable arterial hypertension, early condition after contrast-enhanced computed tomography, early condition after lumbar puncture, general serious condition of the patient)
- exacerbation of the main disease (acute psychosis, severe anxiety, tendency to active aggression, visual seizures)
- active disease notovtorowa ;
- diseases of the nervous system (neuropathy, stroke, damage to the cerebellum, labyrinth) causing altered sensitivity to stimuli;

- diseases and illnesses of the musculoskeletal system that significantly disturb the body's balance and the mobility of the limbs;
- pressure ulcers grade IV and V on the Torrance scale.

7. Indication of the research methods adopted [1]:
Randomized Control Study (RCT - Randomized Controlled Trial).

Acquisition methods data:
a. Medical qualification, clinical observation
b. Surveys/questionnaires
c. Laboratory tests, EEG

8. Summary of the medical therapeutic experiment project

A detailed description can be found in: Appendix.

9. Description of expected therapeutic and cognitive benefits

Expected therapeutic and cognitive benefits

Basal therapy is used in neonatal wards, kindergartens, schools, as well as in intensive care and geriatrics, in Germany, Scandinavia, Croatia, the Czech Republic, and Slovakia, and increasingly in Poland (Svennigsen 2008, Rudomska 2016, Bednova et al. 2016, Mielke-Reusch et al. 2000, Trnčević et al. 2022). However, scientific reports (outside Germany) are scarce (Egerod et al. 2009). However, limited scientific evidence indicates a significant reduction in anxiety levels in people using the therapy (Potmesilova et al. 2023) and an improvement in their quality of life (Krug et al. 2008).

To date, no studies have been conducted using basal therapy in individuals with profound disabilities resulting from schizophrenia. The lack of scientific evidence regarding the potential impact of this therapy on improving outcomes for patients in psychiatric wards prompted this study.

The results obtained in the study will be innovative and will allow us to answer the question whether basal therapy in people suffering from schizophrenia will have a positive impact on the health of adults suffering from schizophrenia who require institutional care (profoundly disabled).

Effects of possible side effects

Therapy will be conducted and supervised by a certified occupational therapist and physiotherapist.

[1] If the examination involves exposure to ionizing radiation, Article 33z of the Atomic Law will apply.

The methodology of therapeutic activities was developed based on scientific works in which basal therapy was safely used in the therapeutic process.

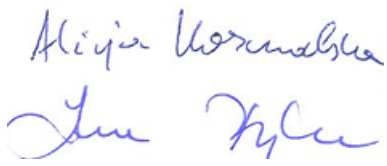
In both groups, standard therapy will be conducted based on the principles of best clinical practices, therefore patients undergoing physiotherapy should not experience any adverse reactions other than: muscle and joint pain, dizziness, headaches, skin abrasions, and fainting.

Patients using basal therapy may experience side effects such as muscle and joint pain and sleep problems.

Any adverse effects will be recorded and, if necessary, the study will be modified or discontinued, with appropriate notification to the Bioethics Committee.

10. Description of how the research results will be used, including the persons who have access to the research results, the method of securing them and the location of their storage

All information collected during the study, including personal data, medical history, and treatment history, will be available only to the attending physicians and study directors. This data will not be identifiable in any publication of study results. Storage location: locked cabinet to prevent unauthorized access.

Principal investigator	Name and surname: Dr. Alicja Kosmalska Dr. Laura Piejko	Signature and date: **01/September/2025** 

INFORMATION FOR THE PARTICIPANT – patients suffering from schizophrenia requiring institutional care

1. **Study title: The Impact of Basal Stimulation Therapy in Adult Patients with Schizophrenia Requiring Permanent Institutional Care**
2. **Date: 01/September/2025**

3. **Place of examination:** Clinical Psychiatric Hospital in Rybnik, Rybnik, Gliwicka 33 Street, 44-200 Rybnik

Duration: 12 weeks

Name and surname of the study director/ principal investigator (name, professional title, email, telephone number):

Alicja Kosmalska, MD (physician, specialist in psychiatry); General Psychiatric Ward XVIIIA, Clinical Psychiatric Hospital, Rybnik, Gliwicka 33 Street, 44-200 Rybnik; Department of Clinical Physiotherapy, J. Kukuczka Academy of Physical Education, Mikolowska 72B Street, 40-065 Katowice; alicja.kosmalska@psychiatria.com ; tel.no. 032 43 28 217.

Head of the non-medical part of the research experiment (name and surname, professional title, email, telephone number):

Laura Piejko, PhD (physiotherapist), Department of Clinical Physiotherapy, J. Kukuczka Academy of Physical Education, Mikolowska 72B Street, 40-065 Katowice; Clinical Psychiatric Hospital in Rybnik, Rybnik, Gliwicka 33 Street, 44-200 Rybnik; laura.piejko@psychiatria.com ; tel. no. 032 43 28 185.

11. Content of information for the participant[2]

Dear Madam / Dear Sir,

[2]Information about a planned medical experiment (pursuant to Article 24, paragraphs 1-3 of the Act on the Professions of Physicians and Dentists) should include:

Before expressing consent referred to in Art. 25, the participant or his or her legal representative shall receive oral and written information, presented in an understandable manner . The provision of information is recorded in the experiment documentation.
2. The information referred to in paragraph 1 includes:
1) the purpose , complete plan of the medical experiment and the risks and benefits associated with the experiment;
2) the scope and duration of the procedures to be used, in particular any nuisances and risks to the participant's health related to his or her participation in the experiment ;
3) arrangements for responding to adverse events and participant questions and concerns;
4) measures taken to ensure respect for the participant's private life and the confidentiality of his or her personal data;
5) rules for access to information relevant to the participant, obtained during the implementation of this experiment and to its general results ;
6) rules for the payment of compensation in the event of damage;
7) any anticipated further use of the results of the medical experiment, data and biological material collected during it, including its use for commercial purposes ;
8) sources of financing for the medical experiment;
The above requirements apply accordingly to scientific research that is not a medical experiment.

Dear caregiver or legal guardian of the participant,

We would like to ask you to consent to your ward's participation in the study entitled: **"The impact of basal therapy in adults with schizophrenia requiring permanent institutional care".** The study has been approved by the Bioethics Committee for Scientific Research at the J. Kukuczka Academy of Physical Education in Katowice.

Participation in the study is voluntary, and you may withdraw your consent at any time. We assure you that refusing to participate will in no way affect your patient's subsequent treatment at the hospital.

Please review the study information below. We will also provide additional information as needed. Questions can be directed to the person providing this information and to the study directors.

Basal stimulation (also referred to as basal therapy) was developed by Prof. Andreas Fröhlich in the 1970s in Germany, at the Special Care Center (Landstuhl).

Basal stimulation defines the approach and work with individuals with profound disabilities. The world of individuals with profound disabilities is very limited and focused primarily on close physical contact, which provides them with (usually minimal) opportunities to explore their surroundings. Therapy allows the patient to interact with their surroundings and experience a variety of stimuli, and is based primarily on nonverbal communication while simultaneously ensuring the patient's physical activity.

Multisensory stimulation, is primarily to provide individuals with profound disabilities with physical activity (even minimal) while simultaneously stimulating the cerebral motor cortex. As a result, the profoundly disabled person is helped to connect with their own body and the outside world. This, in turn, facilitates the therapeutic process between the patient and the outside world.

Basal stimulation focuses on creating an appropriate, harmonious environment in daily life. This is achieved through appropriate stimulation or relaxation. The patient responds to the stimuli, allowing them to not only decide about the basal therapy process but also experience themselves, feel the boundaries of their body, and perceive the outside world. Basal stimulation also helps reduce stress and aggression. Each intervention aims to meet the real needs of a person with profound disabilities (Gsodam et al . 2000).

The study will assess the impact of basal therapy on the health of adults suffering from schizophrenia who require institutional care (profoundly disabled).

Study inclusion criteria:

- women and men aged ≥ 55 years,
- consent of the legal guardian to participate in the study,
- schizophrenia clinically confirmed for at least 5 years, with predominance of negative symptoms,
- stable drug therapy (treatment unchanged for at least 3 months)
- functional ability of everyday life on the Barthel scale below 40 points.

Exclusions criteria from the study:

- lack of consent to participate in the study;
- pregnancy
- general contraindications (acute inflammatory and febrile diseases, venous thrombosis, unstable arterial hypertension, early condition after contrast-enhanced computed tomography, early condition after lumbar puncture, general serious condition of the patient)
- exacerbation of the main disease (acute psychosis, severe anxiety, tendency to active aggression, visual seizures)
- active disease notovtorowa ;
- diseases of the nervous system (neuropathy, stroke, damage to the cerebellum, labyrinth) causing altered sensitivity to stimuli;
- diseases and illnesses of the musculoskeletal system that significantly disturb the body's balance and the mobility of the limbs;
- pressure ulcers grade IV and V on the Torrance scale.

Study groups and therapy in individual groups

The health condition of patients will be assessed by a doctor and a nurse before the study begins.

After you agree to participate in the study, patients will be divided into two experimental groups of six participants (groups 1 and 2). An AB/ BA crossover experimental design will be used, where:

A – means standard therapy + physiotherapy, 2 x a week for 6 weeks.

B – means standard therapy + basal therapy , 2 x a week for 6 weeks.

Patients in group 1 will receive AB therapy,

Patients in group 2 will receive BA therapy.

The total duration of the study will be 12 weeks and include 12 patients.

Group assignment will be random, and the allocation method will be confidential to the physician qualifying patients for the study, medical staff, and patients. The study director will assign patients to groups, but will not have direct contact with them before assigning them to groups.

Each basal therapy session will consist of:

a) preparation and adjustment of stimuli based on information regarding the assessment of the patient's condition and problems,
b) careful observation and appropriate care of the patient,
c) grading of stimuli and their appropriate stimulation,
d) recording the therapist's comments on the therapy card.

Both groups will receive standard therapy based on best clinical practice principles for 12 weeks of follow-up. Additionally, the experimental groups will receive basal therapy (for 6 weeks) and physiotherapy (for the next 6 weeks) twice a week (for 30 minutes).

Basal therapy will be conducted to help patients with schizophrenia with profound disabilities compensate for the lack of their own life experiences, including independent movement and interaction with the environment, strengthening the meaning and purpose of individual movements, stimulating movements, even minimal ones, and entering into contact with the external environment through various types of stimulation, offering numerous environmental stimuli and multi-sensory experiences that will facilitate awareness of one's own existence.

The following tests will be performed in both groups:

1. Examination of the patient using the Barthel scale.
2. Cognitive function testing using the Glasgow Coma Scale (GCS) and the CRS -R scale.
3. EEG test (the test is painless and assesses changes in the bioelectrical activity of the brain).
3. Recording the emotional state (movements of limbs, opening of eyes, eyelids).
4. Blood concentration testing for selected biological factors. Patients will have 5 ml of venous blood drawn twice (before and after completing the exercise) to perform the blood test.

Final information

All information collected during the study, including your personal details, medical history, and treatment history, will be available only to the physicians and study directors. This data will not be identifiable in any publication of study results.

12. Contact details for additional information:

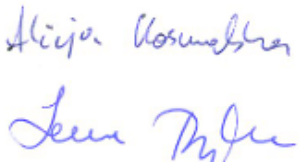
MD. Alicja Kosmalska (physician, specialist in psychiatry) alicja.kosmalska@psychiatria.com ; phone no. 032 43 28 217.
PhD Laura Piejko (physiotherapist) laura.piejko@psychiatria.com ; phone no. 032 43 28 185

13. Confirmation of information provided/received with signatures:

Study participant	Name and surname:	Signature and date:

Confirmation

Principal investigator	Name and surname:	Signature and date:

	Alicja Kosmalska Laura Piejko	**01/September/2025** 

STATEMENT OF THE PARTICIPANT AND

PARTICIPANT INFORMED CONSENT

Participant's [3] name and surname:

……

Address: …… …….

…….

Age: …… ……. …. …….

Name and surname of legal guardian/caregiver [4]:

……

** if applicable*

Name and surname of the principal investigator and the person supervising the non-medical part: Alicja Kosmalska, MD; Laura Piejko, PT, PhD

Contact telephone number for the participant : MD Alicja Kosmalska – tel. no. 032 43 28 217; Laura Piejko - tel.no. 032 43 28 185.

Study title: Impact of Basal Stimulation Therapy in Adult Patients with Schizophrenia Requiring Permanent Institutional Care

Date: 01/September/2025

Hereby declare that I have been informed by: …….

1. about the purpose of the intended research and the manner of its conduct, and that I had the opportunity to ask questions to the person conducting the medical experiment/research study not constituting a medical experiment. I have received answers to these questions, I understand what the research will involve , and why my consent is required. I have become familiar with the content of the " Information for the Subject," of which I have received one copy. I have been informed of the potential risks associated with the research program. Therefore I **voluntarily consent to undergo a medical experiment/research study.**

[3]A medical experiment/scientific study that is not a medical experiment may be carried out, in principle, after obtaining the consent of the participant or the person who may be directly affected by the effects of the experiment/scientific study (Article 25 et seq. of the Act on the Professions of Physicians and Dentists)

[4]In the case of a minor participant under the age of 13, consent is provided by their legal representative. In the case of a minor participant over the age of 13, the consent of that minor and their legal representative is required.

In the case of fully or partially incapacitated persons, persons who are not incapacitated but who are unable to properly understand the content of the consent, etc. , the provisions of Article 25, paragraphs 3-11 and 25 a of the Act on the Professions of Physician and Dentist will apply .

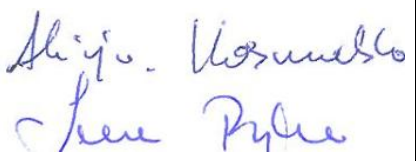
2. about the possibility of refusing consent to participate in research or withdrawing it at any time – including during its performance.

Comments from a participant in a therapeutic medical experiment:

…… ...

Study participant	Name and surname:	Signature and date:

Confirmation

Principal investigator	Name and surname: Alicja Kosmalska Laura Piejko	Signature and date: **01/September/2025** 

OBLIGATORY INFORMATION FOR PARTICIPANTS

PROTECTION OF PERSONAL DATA

Name and surname : ……

Address: …… …….

…….

Age: …… ……. .

Name and surname of legal guardian/caregiver:

……

** if applicable*

Name and surname of the research director (medical part/person supervising the non-medical part): Alicja Kosmalska, MD, Laura Piejko PT, PhD

Study title: Impact of Basal Stimulation Therapy in Adult Patients with Schizophrenia Requiring Permanent Institutional Care

Date: 01/September/2025

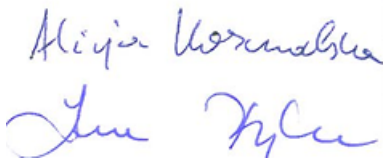
Based on Article 13 of Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC, I hereby inform you that:

1. The controller of your personal data is the Clinical Psychiatric Hospital in Rybnik, Gliwicka 33 Street, 44-200 Rybnik.
2. Contact with the Data Protection Officer is possible via the following e-mail address: iodo@psychiatria.com or by phone: 32 43-28-171.
3. Your data is processed in particular for the purposes of conducting proceedings constituting a medical experiment or scientific research within the meaning of the provisions of the Act on the professions of physician and dentist or others.
4. The basis for the processing of your personal data is your voluntary consent granted pursuant to Article 6(a) of the GDPR.
5. The recipients of your personal data are entities authorized to obtain such data under the provisions of law and entities carrying out proceedings as part of a medical experiment or scientific research, with whom personal data processing agreements have been concluded - guaranteeing appropriate measures for the protection of the personal data being processed.
6. Your personal data will be stored for the duration of the consent granted.

7. You have the right to access the content of your data, rectify it, delete it (only to the extent that the obligation to process it does not result from legal provisions), limit the processing of data, as well as the right to object to the processing of personal data and the right to transfer data.
8. You have the right to lodge a complaint with the supervisory authority if you believe that the Clinical Psychiatric Hospital, Rybnik, Gliwicka 33 Street, 44-200 Rybnik, processes your personal data in a manner inconsistent with the provisions. General Data Protection Regulation .
9. If the Clinical Psychiatric Hospital in Rybnik processes your personal data on the basis of your consent, you have the right to withdraw it at any time, without affecting the lawfulness of processing based on consent before its withdrawal.
10. Providing personal data is voluntary, but necessary to initiate cooperation. Failure to provide personal data will mean that we will not be able to conduct a medical experiment or scientific study involving you.
11. The Administrator does not transfer personal data outside the European Area.
12. There is no automated decision-making or profiling in the activities related to this Agreement.

Study participant	Name and surname:	Signature and date:

Confirmation

Principal investigator	Name and surname: Alicja Kosmalska Laura Piejko	Signature and date: **01/September/2025** 

RESOLUTION No. 1-IX/2025

University Bioethics Committee for Scientific Research

Jerzy Kukuczka Academy of Physical Education in Katowice

12 September 2025

The University Bioethics Committee, after reviewing the application submitted by MD Alicja Kosmalska and Dr. Laura Piejko entitled "**The Impact of Basal Stimulation Therapy in Adult Patients with Schizophrenia Requiring Permanent Institutional Care**", and after hearing additional information, discussion and voting, adopted a resolution issuing a **positive** opinion on the application.

JUSTIFICATION

The aim of the study is to obtain knowledge regarding the impact of basal stimulation therapy on the health status of adults suffering from schizophrenia and requiring permanent institutional care.

The use of basal stimulation therapy in many European centres for several decades, combined with the limited amount of scientific evidence, justifies undertaking the proposed research. Available evidence indicates reduced anxiety and improved quality of life. No such studies have previously been conducted in institutionalised patients with schizophrenia.

The application clearly presents the aim, rationale and innovative aspects of the project. The project is justified and feasible.

The Committee expects a final report upon completion of the project.

Podpisano przez/ Signed by:
Krzysztof
Ficek
Data/ Date: 12.09.2025 13:13
mSzafir