RESOLUTION No. 2-IX/2025

University Bioethics Committee for Scientific Research

Jerzy Kukuczka Academy of Physical Education in Katowice

September 2025

The Committee reviewed the application submitted by MD Alicja Kosmalska and Laura Piejko, PT, PhD entitled "**The Impact of Snoezelen Therapy in Adults with Alcohol Dependence and Adults with Schizophrenia**" and adopted a resolution issuing a **positive opinion**.

JUSTIFICATION

The purpose of the study is to assess the influence of Snoezelen therapy on adults with schizophrenia requiring institutional care, adults with schizophrenia, and adult women with alcohol dependence.

The applicants expect innovative findings and beneficial effects on participants, including improved cognitive functioning, better organisation of daily activities, reduction of negative symptoms of schizophrenia, improved mood, reduced anxiety and sadness, enhanced quality of life and emotional intelligence.

The application presents a clear rationale and innovative elements. Risks were assessed as minimal and no significant adverse events are expected. 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

DESCRIPTION

MEDICAL EXPERIMENT/SCIENTIFIC RESEARCH

1. **Study title: Impact of Snoezelen® therapy in adults with alcohol dependence and in adults with schizophrenia.**
2. **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.
3. **Duration:** until July 31, 2027.
4. **Purpose of the study:** obtaining knowledge about the impact of Snoezelen® therapy on the health of adults suffering from schizophrenia and requiring permanent institutional care, adults suffering from schizophrenia and adults (women) addicted to alcohol**.**
5. **Study participants** The study will include:

1) adults suffering from schizophrenia requiring permanent institutional care, N=40

Criteria inclusion in the study :

- women and men aged ≥ 18 years,
- consent of the patient or 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)
- ability to understand and follow the therapist's instructions,
- functional ability of everyday life on the Barthel scale below 40 points,

The exclusion criteria from the study will be:

- 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 computed tomography, early condition after lumbar puncture, general serious condition of the patient);
- unstable or untreated epilepsy, based on EEG;
- exacerbation of the main disease (acute psychosis, severe anxiety, tendency to active aggression, etc.);
- active cancer disease;
- diseases of the nervous system (neuropathies, stroke, damage to the cerebellum, labyrinth, Parkinson's disease) causing altered sensitivity to stimuli;
- diseases and illnesses of the musculoskeletal system that disturb the body's balance and the mobility of the limbs.

2) adults suffering from schizophrenia, N=40

Criteria inclusion in the study:

- men aged ≥ 18 years,
- consent of the patient or legal guardian to participate in the study,
- clinically confirmed schizophrenia with predominance of negative symptoms,
- stable drug therapy (treatment unchanged for at least 1 month),
- ability to understand and follow the therapist's instructions,
- functional ability of everyday life on the Barthel scale above 40 points,

The exclusion criteria from the study will be:

- lack of consent to participate in the study;
- general contraindications (acute inflammatory and febrile diseases, venous thrombosis, unstable arterial hypertension, early condition after contrast computed tomography, early condition after lumbar puncture, general serious condition of the patient);
- unstable or untreated epilepsy, based on EEG;
- exacerbation of the main disease (acute psychosis, severe anxiety, tendency to active aggression, etc.);
- active cancer disease;
- diseases of the nervous system (neuropathies, stroke, damage to the cerebellum, labyrinth, Parkinson's disease) causing altered sensitivity to stimuli; diseases and illnesses of the musculoskeletal system disturbing body balance and limb mobility.

3) adults (women) addicted to alcohol, N= 60

Criteria inclusion in the study:

- female gender;
- age ≥ 18 years;
- consent of the patient or legal guardian to participate in the study;
- alcohol dependence syndrome (F10.2 according to ICD-10);
- history of depressive and anxiety symptoms;
- ability to understand and follow the therapist's instructions;
- functional ability of everyday life on the Barthel scale above 40 points.

The exclusion criteria from the study will be:

- lack of consent to participate in the study;
- pregnancy;
- psychoactive substances other than alcohol;
- exacerbation of the main disease (acute psychosis, severe anxiety, tendency to active aggression, etc.);
- mental illnesses other than depression and anxiety disorders;
- psychotic diseases (F20- schizophrenia and other schizophrenic disorders);
- general contraindications (acute inflammatory and febrile diseases, venous thrombosis, unstable arterial hypertension, early condition after contrast computed tomography, early condition after lumbar puncture, general serious condition of the patient);
- unstable or untreated epilepsy, based on EEG;
- active cancer disease;
- diseases of the nervous system (neuropathies, stroke, damage to the cerebellum, labyrinth, Parkinson's disease) causing altered sensitivity to stimuli;
- severe cognitive impairment;

- diagnosis of autism and ADHD;
- PTSD;
- intellectual disability (diagnosis F70 – F79);
- diseases and illnesses of the musculoskeletal system that disturb the body's balance and the mobility of the limbs.

6. 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, patient interviews
c. Laboratory tests

7. Summary of the medical therapeutic experiment project

A detailed description can be found in: Appendix.

8. Description of risks, inconveniences and possible threats to the health or life of the study participants:

Therapy will be conducted and supervised by a psychologist, occupational therapists, and/or addiction therapists (two caregivers per group of four). Patients will be provided with uninterrupted care during therapy and on the way to therapy.

The methodology of therapeutic activities was developed based on scientific publications in which the therapy Snoezelen ® Snoezellen ® has been used safely in the therapeutic process.

Therefore patients should not experience any adverse reactions other than those related to overstimulation , such as: dizziness, headaches, photophobia, sleep problems, difficulty concentrating and focusing, severe stress and anxiety, panic attacks, feelings of impatience, excessive irritability and irritation, anger attacks, excessive excitement and hyperactivity, and previously undiagnosed epileptic seizures.

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

9. Description of benefits for study participants:

Snoezelen® room, as a multisensory interaction environment, has been widely used in studies involving older adults, people with neurological conditions (including children and adults with disabilities), neurodegenerative conditions, and people struggling with depressive and anxiety disorders. Scientific evidence indicates a significant reduction in depression and anxiety levels in people using Snoezelen® therapy (Solé et al., 2022), as well as an improvement in the quality of life of people with intellectual disabilities (Masuri et al., 2024). In a recent case study, Snoezelen® therapy improved emotion recognition

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

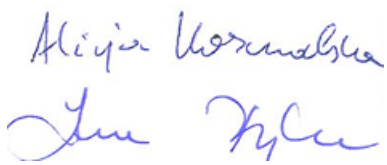
and the development of emotional functions in a patient with alexithymia, highlighting the potential of this therapy in psychiatric rehabilitation (Taranto et al., 2022).

To date, few scientific studies of Snoezelen® therapy have been conducted with psychiatric patients, as confirmed by a recent review (Hudon et al. 2023). There have also been no studies of Snoezelen® therapy specifically targeting groups of patients struggling with addiction or schizophrenia. The lack of scientific evidence regarding the potential impact of Snoezelen® therapy on improving outcomes in psychiatric patients prompted the development of this study to better understand the effectiveness of the therapy in this patient group.

The results obtained in the study will be innovative and will allow us to answer the question whether therapy in the Snoezelen ® room in people suffering from schizophrenia and adults with alcohol addiction will result in improved cognitive functioning, organization of daily activities, improvement in the negative symptoms of schizophrenia, improvement in mood, including a reduction in emotions such as anxiety and sadness, as well as an increase in the patient's overall quality of life and emotional intelligence.

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: 

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

11. **Study title: Impact of Snoezelen® therapy in adults with alcohol dependence and in adults with schizophrenia.**
2. **Place of examination:** Clinical Psychiatric Hospital in Rybnik, Rybnik, Gliwicka 33 Street, 44-200 Rybnik
3. **Test duration:** 12 weeks
4. **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.

5. **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.

6. **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.

We invite you to participate in a study entitled: **"Impact of Snoezelen® therapy in adults addicted to alcohol and in adults suffering from schizophrenia".** 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 at any time. We assure you that refusing to participate will in no way affect your subsequent treatment at the hospital.

Please review the study information below. We are happy to provide additional information if needed. Questions can be directed to the person providing this information and the study directors.

Treatment for schizophrenia is primarily based on pharmacotherapy. Community-based treatment, including rehabilitation and psychotherapy, also plays a significant role. Psychiatric rehabilitation aims to help patients maintain interpersonal relationships, better cope with daily activities, and address deteriorating cognitive functions. Following pharmacotherapy, persistent negative and cognitive symptoms predominate, including: blunted emotional expression, anxiety, indifference, involuntary withdrawal from all purposeful activity, degradation of interpersonal and social skills, a desire for isolation, and impairments in executive function, memory, and concentration.

Snoezelen® Therapy helps alleviate difficulties in all of the above areas. Snoezelen ® develops the ability to enter a state of relaxation, reducing the level of anxiety and tension experienced by patients. It also allows for the free adjustment of stimulation to suit the patient's needs at a given moment, allowing for a gradual increase in activity and a sense of empowerment, which should translate into better functioning in everyday life. Research to date indicates a positive impact of Snoezelen ® therapy on cognitive functioning, which is crucial in improving the condition of patients suffering from schizophrenia and improving the quality of life after the symptoms disappear.

The aim of the study is to obtain knowledge about the impact of Snoezelen® therapy on the health of adults suffering from schizophrenia requiring permanent institutional care.

Criteria inclusion in the study :

- women and men aged ≥ 18 years,
- consent of the patient or 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)
- ability to understand and follow the therapist's instructions,
- functional ability of everyday life on the Barthel scale below 40 points,

Criteria exclusions 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 computed tomography, early condition after lumbar puncture, general serious condition of the patient);
- unstable or untreated epilepsy, based on EEG;
- exacerbation of the main disease (acute psychosis, severe anxiety, tendency to active aggression, etc.);
- active cancer disease;
- diseases of the nervous system (neuropathies, stroke, damage to the cerebellum, labyrinth, Parkinson's disease) causing altered sensitivity to stimuli;
- diseases and illnesses of the musculoskeletal system that disturb the body's balance and the mobility of the limbs.

Study groups and therapy

The health status of patients will be assessed by a doctor, a clinical psychologist and a psychotherapist before the study begins.

After consenting to participate in the study, patients will be randomly assigned to two groups: an experimental group (20 individuals) and a control group (20 individuals). The allocation method will be confidential to the physician enrolling in the study, medical staff, and patients. The study director will assign patients to the groups, who will have no direct contact with them before assigning them to the groups.

In both groups, for ethical reasons, standard therapy based on the principles of best clinical practice will be conducted for 12 weeks.

Snoezelen® therapy twice a week (for 30 minutes) for 12 weeks. The goal of the therapy will be to improve cognitive functioning, organization in daily activities, mood, including reducing emotions such as anxiety and sadness, and to increase the patient's overall quality of life.

Course classes therapy Snoezelen® :

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) experiencing therapeutic activities together with the patient,
e) recording the therapist's presence and comments on the therapy card.

The following tests will be performed twice, immediately before and after the completion of the study in both groups:

1. Cognitive function testing using the MOCA or ACE-III diagnostic tools
2. Emotional state examination, which will be carried out by determining the degree of:
    a. Severity of depressive symptoms using the BDI or GDS scale.
    b. Anxiety levels using the Burns Anxiety Inventory
    c. Life satisfaction using the SWLS scale
3. Examination of activities of daily living using the Barthel scale .
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.

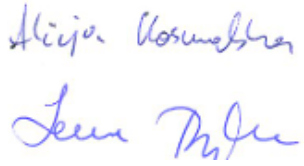
7. Contact details for additional information:

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

8. Confirmation of information provided/received with signatures :

Study participant	Name and surname:	Signature and date:

Confirmation

Principal investigator	Name and surname: Alicja Kosmalska Laura Piejko	Signature and date: 

INFORMATION FOR THE PARTICIPANT– patients suffering from schizophrenia

1. **Study title: Impact of Snoezelen ® therapy in adults with alcohol dependence and in adults with schizophrenia.**

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

2. **Test duration:** 12 weeks

3. **Name and surname of the study director (name, professional title, email, telephone number):**

Alicja Kosmalska, MD (physician, psychiatrist); 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.

4. **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, Rybnik, Gliwicka 33 Street, 44-200 Rybnik; laura.piejko@psychiatria.com ; tel. no. 032 43 28 185.

5. **Content of information for the participant**[3]

Dear Madam / Dear Sir,

[3]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.

We invite you to participate in a study entitled: **"Impact of Snoezelen ® therapy in adults addicted to alcohol and in adults suffering from schizophrenia".** 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 at any time. We assure you that refusing to participate will in no way affect your 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.
Treatment for schizophrenia is primarily based on pharmacotherapy. Community-based treatment, including rehabilitation and psychotherapy, also plays a significant role. Psychiatric rehabilitation aims to help patients maintain interpersonal relationships, better cope with daily activities, and address deteriorating cognitive functions. Following pharmacotherapy, persistent negative and cognitive symptoms predominate, including: blunted emotional expression, anxiety, indifference, involuntary withdrawal from all purposeful activity, degradation of interpersonal and social skills, a desire for isolation, and impairments in executive function, memory, and concentration .
Snoezelen® therapy helps alleviate difficulties in all of the above areas. Snoezelen® develops the ability to enter a state of relaxation , reducing the level of anxiety and tension experienced by patients. It also allows for the free adjustment of stimulation to suit the patient's needs at a given moment, allowing for a gradual increase in activity and a sense of agency, which should translate into better functioning in everyday life. Research to date indicates a positive impact of Snoezelen ® therapy on cognitive functioning, which is crucial in improving the condition of patients suffering from schizophrenia and improving the quality of life after the symptoms disappear.
The aim of the study is to obtain knowledge about the impact of Snoezelen ® therapy on the health of adults suffering from schizophrenia.

Criteria inclusion in the study :

- men aged ≥ 18 years,
- consent of the patient or legal guardian to participate in the study,
- clinically confirmed schizophrenia with predominance of negative symptoms,
- stable drug therapy (treatment unchanged for at least 1 month)
- ability to understand and follow the therapist's instructions,
- functional ability of everyday life on the Barthel scale above 40 points,

Criteria exclusions from the study :

- lack of consent to participate in the study;
- general contraindications (acute inflammatory and febrile diseases, venous thrombosis , unstable arterial hypertension , early condition after contrast computed tomography , early condition after lumbar puncture, general serious condition of the patient);

- unstable or untreated epilepsy, based on EEG;
- exacerbation of the main disease (acute psychosis, severe anxiety, tendency to active aggression, etc.);
- active cancer disease;
- diseases of the nervous system (neuropathies, stroke, damage to the cerebellum, labyrinth, Parkinson's disease) causing altered sensitivity to stimuli;
- diseases and illnesses of the musculoskeletal system that disturb the body's balance and the mobility of the limbs.

Study groups and therapy

The health status of patients will be assessed by a doctor, a clinical psychologist and a psychotherapist before the study begins.

After agreeing to participate in the study, patients will be divided into two groups, including an experimental group (20 people) and a control group (20 people).

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

In both groups, for ethical reasons, standard therapy based on the principles of best clinical practice will be conducted for 12 weeks.

Snoezelen ® therapy will be used twice a week (for 30 minutes) for 12 weeks.

The goal of the therapy will be to improve cognitive functioning, organization of daily activities, mood improvement, including reducing emotions such as anxiety and sadness, as well as increasing the patient's overall quality of life and emotional intelligence .

Course classes therapy Snoezelen® :

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) experiencing therapeutic activities together with the patient ,
e) recording the therapist's presence and comments on the therapy card.

The following tests will be performed twice, immediately before and after the completion of the study in both groups:

1. Cognitive function testing using the MOCA or ACE-III diagnostic tools or the CSSS Cognitive Screening Scale for Schizophrenia.
2. The intensity of positive or negative symptoms is assessed using the PSYRATS Psychotic Symptom Rating Scale and the BNSS (Brief Negative Syndrome Scale).
3. Emotional state examination, which will be carried out by determining the degree of:
    a. Severity of depressive symptoms using the BDI or GDS or CES-D scale (The Center for Epidemiologic Studies Depression Scale) .
    b. Anxiety level using the Burns Anxiety Inventory or the STAI State-Trait Anxiety Inventory.
    c. Satisfaction with life using the SWLS scale.
4. Emotional intelligence testing with the INTE Emotional Intelligence Questionnaire.
5. 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.

6. Contact details for additional information:

MD Alicja Kosmalska (physician, specialist in psychiatry) alicja.kosmalska@psychiatria.com ; tel. 032 43 28 217.

PhD Laura Piejko (physiotherapist) laura.piejko@psychiatria.com ; tel. 032 43 28 185

7. Confirmation of information provided/received with signatures :

Study participant	Name and surname:	Signature and date:

Principal investigator	Name and surname:	Signature and date:
	Alicja Kosmalska Laura Piejko	 

INFORMATION FOR THE PARTICIPANT – patients addicted to alcohol

1. **Study title: Impact of Snoezelen® therapy in adults with alcohol dependence and in adults with schizophrenia.**
2. **Place of examination:** Clinical Psychiatric Hospital in Rybnik, Rybnik, Gliwicka 33 Street, 44-200 Rybnik
3. **Study duration:** 10 weeks, including: 6 weeks of study duration and a telephone interview 4 weeks after the end of the study.
4. **Name and surname of the study director (name, professional title, email, telephone number):**

Alicja Kosmalska, MD (physician, psychiatrist); 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.

5. **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, ul. Mikołowska 72B, 40-065 Katowice ; Clinical Psychiatric Hospital, Rybnik, Gliwicka 33 Street, 44-200 Rybnik; laura.piejko@psychiatria.com ; tel. no. 032 43 28 185.

6. **Content of information for the participant**[4]

[4]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.

Madam,

We invite you to participate in a study entitled: **"Impact of Snoezelen® therapy in adults addicted to alcohol and in adults suffering from schizophrenia".** 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 at any time. We assure you that refusing to participate will in no way affect your 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.

The aim of the study is to obtain knowledge about the impact of Snoezelen® therapy on the health of women addicted to alcohol.

Criteria inclusion in the study:

- female gender;
- age ≥ 18 years;
- consent of the patient or legal guardian to participate in the study;
- diagnosis of alcohol dependence syndrome (F10.2 according to ICD-10);
- history of depressive and anxiety symptoms;
- ability to understand and follow the therapist's instructions;
- functional ability of everyday life on the Barthel scale above 40 points.

Criteria exclusions from the study :

- lack of consent to participate in the study;
- pregnancy;
- psychoactive substances other than alcohol;
- exacerbation of the main disease (acute psychosis, severe anxiety, tendency to active aggression, etc.);
- mental illnesses other than depression and anxiety disorders;
- psychotic diseases (F20- schizophrenia and other schizophrenic disorders);
- general contraindications (acute inflammatory and febrile diseases, venous thrombosis, unstable arterial hypertension, early condition after contrast computed tomography, early condition after lumbar puncture, general serious condition of the patient);
- unstable or untreated epilepsy, based on EEG;
- active cancer disease;
- diseases of the nervous system (neuropathies, stroke, damage to the cerebellum, labyrinth, Parkinson's disease) causing altered sensitivity to stimuli;
- severe cognitive impairment;

- autism and ADHD diagnosis;
- PTSD;
- intellectual disability (diagnosis F70 – F79);
- diseases and illnesses of the musculoskeletal system that disturb the body's balance and the mobility of the limbs.

Study groups and therapy

The health status of patients will be assessed by a doctor, a clinical psychologist and a psychotherapist before the study begins.

After agreeing to participate in the study, patients will be divided into two groups: an experimental group (30 people) and a control group (30 people).

Group allocation will be random, and the allocation method will be kept confidential to the physician qualifying patients for the study, medical staff, and patients. Group allocation will be performed by the study director, who will not have direct contact with patients before group allocation. Group allocation will be performed using block randomization.

In both groups, for ethical reasons, standard therapy based on the principles of best clinical practices will be conducted for 6 weeks.

Snoezelen ® therapy will be used twice a week (for 30 minutes) for 6 weeks.

Then, 4 weeks after the end of therapy (so-called follow-up), a telephone interview will be conducted to assess mood and the short Penn Alcohol Craving Scale.
The goal of the therapy will be to improve cognitive functioning, organization of daily activities, mood improvement, including reducing emotions such as anxiety and sadness, as well as increasing the patient's overall quality of life and emotional intelligence.

Course classes therapy Snoezelen® :

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) experiencing therapeutic activities together with the patient,
e) recording the therapist's presence and comments on the therapy card.

The following tests will be performed twice, immediately before and after the completion of the study in both groups:

1. Cognitive function testing using the MOCA or ACE-III diagnostic tools
2. Emotional state examination, which will be carried out by determining the degree of:
    a. Severity of depressive symptoms using the BDI or GDS or CES-D scale (The Center for Epidemiologic Studies Depression Scale).
    b. Anxiety levels using the Burns Anxiety Inventory or STAI State-Trait Anxiety Inventory.
    c. CISS (Coping Inventory for Stressful Situations).
    d. Satisfaction with life using the SWLS scale.
3. Emotional intelligence testing with the INTE Emotional Intelligence Questionnaire.
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

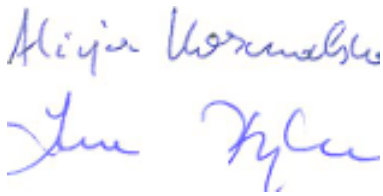
All information collected during the study, including your personal data, medical history, and treatment history, will be available only to the attending physicians and study directors. This data will not be identifiable in any publication of study results.

7. Contact details for additional information:

Alicja Kosmalska, MD (physician, specialist in psychiatry) alicja.kosmalska@psychiatria.com ; tel. 032 43 28 217.
Laura Piejko, PhD (physiotherapist) laura.piejko@psychiatria.com ; tel. 032 43 28 185

8. Confirmation of information provided/received with signatures :

Study participant	Name and surname:	Signature and date:

Principal investigator	Name and surname: Alicja Kosmalska Laura Piejko	Signature and date: 

STATEMENT OF THE PARTICIPANT AND

PARTICIPANT INFORMED CONSENT

Participant's [5] name and surname:

……

Address: …… …….

…….

Age: …… ……. …. …….

Name and surname of legal guardian/caregiver [6]:

……

** 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 Snoezelen ® therapy in adults with alcohol dependence and in adults with schizophrenia.

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.**

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

[5]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)

[6]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.

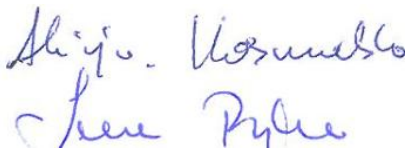
In the case of fully or partially incapacitated persons, persons who are not incapacitated but who are unable to properly understand the content of the consent, etc. , the provisions of Article 25, paragraphs 3-11 and 25 a of the Act on the Professions of Physician and Dentist will apply .

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: 

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 Snoezelen® therapy in adults with alcohol dependence and in adults with schizophrenia.

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: