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Virtual reality-based exercise in elderly people, people with Alzheimer's disease and people with schizophrenia

Submission date
25/02/2023

Recruitment status
No longer recruiting

Registration date
14/03/2023

Overall study status
Completed

Last Edited
15/11/2024

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
The Kinect device uses a combination of sensors and software to interpret motion, gestures, voice commands and facial features and transports a digitised representation of movements into the virtual reality (VR). Virtual reality-based exercise have been used in studies involving i.e. the elderly, patients with neurological diseases and in people with minor depressive disorder. There have been only few studies using the VR-based exercise in the treatment of Alzheimer's disease or schizophrenia.

The study will assess the impact of virtual reality-based exercise with the use of the Kinect device on cognition, functional performance, activities of daily living, mood, quality of life and on biological factors in people aged 60+ without neurodegenerative diseases and mental disorders, in elderly people with Alzheimer's disease and in people with schizophrenia.

The VR exercises will be carried out in 3 independent clinical trials.
- Clinical trial no. 1 will include people aged 60+ without neurodegenerative and mental disorders (people with only age-related diseases);
- Clinical trial no. 2 will include people aged 60+ with Alzheimer's disease in stage I-II;
- Clinical trial no. 3 will include people of different ages with schizophrenia.

The aim of the study is to obtain knowledge on the effectiveness of the virtual reality-based exercise with the Kinect device in the rehabilitation of people aged 60+ without neurodegenerative and mental disorders, in people aged 60+ with Alzheimer's disease and people with schizophrenia.

Who can participate?
Women and men aged 60+ in the first and second clinical trials.
Women and men over 18 years of age in the third clinical trial.

What does the study involve?
The study will include women and men aged 60+ without neurodegenerative diseases and

mental disorders in the 1st clinical trial, people aged 60+ with Alzheimer's disease in the 2nd clinical trial and people of different ages with schizophrenia in the 3rd clinical trial.
After the medical examination and meeting the inclusion criteria, all participants will be randomly assigned to the experimental or control group. Patients will be randomly assigned by the main investigator to the experimental group and to the control group. Patients will be randomly assigned to groups based on the group symbol with the block randomization method

The VR exercises will be carried out in 3 independent clinical trials.
Clinical trial no. 1
The first clinical trial will include people aged 60+ without neurodegenerative and mental disorders (people with only age-related diseases) - one experimental and one control group.
Participants in the experimental group will receive Kinect VR exercise for 10-30 minutes a day, 3 times a week, for 15 weeks depending on the condition of the patient.
Participants in control and experimental group will attend to occupational therapy for 30 minutes a day, 3 times a week (with a one-day break), for 15 weeks, based on the principles of best clinical practices.

Clinical trial no. 2
The second clinical trial will include people aged 60+ with Alzheimer's disease in stage I-II - one experimental and one control group. Participants in the experimental group will receive Kinect VR exercise for 10-30 minutes a day, 3 times a week, for 15 weeks depending on the condition of the patient.
Participants in control and experimental group will attend to occupational therapy for 30 minutes a day, 3 times a week (with a one-day break), for 15 weeks, based on the principles of best clinical practices.

Clinical trial no. 3
The third clinical trial will include people of different ages with schizophrenia - one experimental and one control group.
Participants in the experimental group will receive Kinect VR exercise for 10-30 minutes a day, 3 times a week, for 15 weeks, depending on the condition of the patient.
Patients in control and experimental group will attend to psychological therapies and occupational therapy for 30 minutes a day, 3 times a week (with a one-day break), for 15 weeks, based on the principles of best clinical practices.

What are the possible benefits and risks of participating?
The VR treatment may contribute to the participants' improvement of cognitive functions, functional efficiency, activities of daily living, emotional state and quality of life.
The exercises will be conducted and supervised by physiotherapists. During the exercises, patients will be provided with protection against falls and injuries. The methodology of the exercises will be planned on the basis of scientific publications in which modern VR technologies were used safely in rehabilitation process. Therefore, no adverse events except fatigue and slight dizziness are expected to occur. Possible side effects will be noted and, if necessary, the studies will be modified or discontinued, with appropriate notification to the Bioethics Committee.

Where is the study run from?
1. Academy of Physical Education in Katowice (Poland)
2. St. Elizabeth Nursing Home in Ruda Slaska (Poland)
3. Saint Antoni Social Welfare House in Swietochlowice (Poland)
4. Independent Public Mental Health Hospital in Rybnik (Poland)

When is the study starting and how long is it expected to run for?
May 2022 to December 2025

Who is funding the study?
1. Academy of Physical Education in Katowice (Poland)
2. Independent Public Mental Health Hospital in Rybnik (Poland)

Who is the main contact?
Laura Piejko
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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
Nil known

Study information

Scientific Title
The impact of virtual reality-based exercise in the rehabilitation of people aged 60+ without neurodegenerative and mental disorders, in people aged 60+with Alzheimer's disease and in people of different ages suffering from schizophrenia.

Study objectives

Clinical trial no. 1 (people aged 60+ without neurodegenerative and mental disorders).
1. VR Kinect exercise performed 3 times a week for 15 weeks will improve cognitive functions in people aged 60+ without neurodegenerative and mental disorders.
2. VR Kinect exercise performed 3 times a week for 15 weeks will improve everyday activities in people aged 60+ without neurodegenerative and mental disorders.
3. VR Kinect exercise performed 3 times a week for 15 weeks will improve functional efficiency in people aged 60+ without neurodegenerative and mental disorders.
4. VR Kinect exercise performed 3 times a week for 15 weeks will improve posture control in people aged 60+ without neurodegenerative and mental disorders.
5. VR Kinect exercise performed 3 times a week for 15 weeks will improve emotional state in people aged 60+ without neurodegenerative and mental disorders.
6. VR Kinect exercise performed 3 times a week for 15 weeks will improve quality of life in people aged 60+ without neurodegenerative and mental disorders.
7. VR Kinect exercise performed 3 times a week for 15 weeks will affect the concentration of selected biological factors in the blood, including: anti and pro-inflammatory cytokines, cortisol, creatine kinase, fibrinogen, lactate dehydrogenase, C-reactive protein in people aged 60+ without neurodegenerative and mental disorders.

Clinical trial no. 2 (people aged 60+ with Alzheimer's disease):
1. VR Kinect exercise performed 3 times s a week for 15 weeks will improve cognitive functions in people with Alzheimer's disease (stage I - II).
2. VR Kinect exercise performed 3 times a week for 15 weeks will improve everyday activities in people with Alzheimer's disease (stage I - II).
3. VR Kinect exercise performed 3 times a week for 15 weeks will improve functional efficiency in people with Alzheimer's disease (stage I - II).
4. VR Kinect exercise performed 3 times a week for 15 weeks will improve posture control in people with Alzheimer's disease (stage I - II).
5. VR Kinect exercise performed 3 times a week for 15 weeks will improve emotional state in people with Alzheimer's disease (stage I - II).
6. VR Kinect exercise performed 3 times a week for 15 weeks will improve quality of life in people with Alzheimer's disease (stage I - II).
7. VR Kinect exercise performed 3 times a week for 15 weeks will affect the concentration of selected biological factors in the blood, including: including: anti and pro-inflammatory cytokines, cortisol, creatine kinase, fibrinogen, lactate dehydrogenase, C-reactive protein in people with Alzheimer's disease (stage I - II).

Clinical trial no. 3 (people of different ages with schizophrenia).
1. VR Kinect exercise performed 3 times a week for 15 weeks will improve cognitive functions in people with schizophrenia.
2. VR Kinect exercise performed 3 times a week for 15 weeks will improve everyday activities in people with schizophrenia.
3. VR Kinect exercise performed 3 times a week for 15 weeks will improve functional efficiency in people with schizophrenia.
4. VR Kinect exercise performed 3 times a week for 15 weeks will affect schizophrenia in people with schizophrenia.
5. VR Kinect exercise performed 3 times a week for 15 weeks will improve emotional state in people with schizophrenia.
6. VR Kinect exercise performed 3 times a week for 15 weeks will improve quality of life in people with schizophrenia.
7. VR Kinect exercise performed 3 times a week for 15 weeks will affect the concentration of

selected biological factors in the blood, including basic biochemistry blood tests and anti and pro-inflammatory cytokines, adhesion proteins, neurotrophins, brain-derived growth factor (BDNF), creatine kinase, fibrinogen, lactate dehydrogenase, CRP in people with schizophrenia.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved on 23/06/2022, Bioethics Commission for Scientific Research at The Jerzy Kukuczka Academy of Physical Education in Katowice (Mikolowska 72a Street, 40-065 Katowice, Poland; +48 (0)32 2075152; komisjabioetyczna@awf.katowice.pl), Resolution No. 2/2022.

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Neurodegenerative and mental disorders, Alzheimer's disease, schizophrenia

Interventions
Clinical trial no. 1
The first clinical trial will include people aged 60+ (with only age-related diseases and without neurodegenerative and mental disorders) - one control group and one experimental group.

After the medical examination and meeting the inclusion criteria, all participants will be randomly assigned by the main investigator to the experimental group and to the control group. Patients will be randomly assigned to groups based on the group symbol with the block randomization method. Randomization will take place after the medical examination and meeting the inclusion criteria.

Participants in the experimental group will receive VR Kinect exercise for 10-30 minutes a day, 3 times a week, for 15 weeks, depending on the condition of the patient.

The VR therapy station will consist of an external motion controller (Microsoft Kinect®), a computer and a monitor. The exercise room will be well ventilated. There will be free space in the patient's movement area with no obstructions restricting the patient's movement. Only the patient will be in the front view of the Kinect camera. The therapist supervising the patient's exercises will be outside of the area of Kinect camera, but close enough to ensure the patient's safety during the exercises. The background behind the patient will be in a solid color. The patient will be standing 2 meters from the Kinect camera and will perform the exercises in a standing position. The patient will be dressed in a comfortable outfit that does not restrict movement during exercise. The footwear will be well-adhering to the floor, protecting the patient from slipping and falling.

A single VR session will last from 10 to 30 minutes and the exercise time will be increased gradually according to the following scheme:

[Week]: exercise time - rest time - exercise time - rest time - exercise time:
[1-3 week]: 10 min - 0 min - 0 min - 0 min - 0 min
[4-6 week]: 10 min - 3 min- 5 min - 0 min - 0 min
[7-9 week]: 10min - 3 min - 10min - 0 min - 0 min
[10-12 week]: 10 min - 3 min - 10min - 3 min - 5 min
[13-15 week]: 10 min - 3 min - 10 min- 3 min- 10 min

Upper and lower limbs and trunk exercises will be introduced in the VR exercises.
The aim of the VR exercises will be to improve motor coordination and increase range of motion. Exercises to improve body balance and reaction speed, as well as exercises of cognitive functions will also be implemented.

Participants in control and experimental group will also attend to occupational therapy for 30 minutes a day, 3 times a week (with a one-day break), for 15 weeks, based on the principles of best clinical practices.

Clinical trial no. 2
The second clinical trial will include people aged 60+ with Alzheimer's disease - one control group and one experimental group.

After the medical examination and meeting the inclusion criteria, all participants will be randomly assigned by the main investigator to the experimental group and to the control group. Patients will be randomly assigned to groups based on the group symbol with the block randomization method. Randomization will take place after the medical examination and meeting the inclusion criteria.

Participants in the experimental groups will receive VR Kinect exercise for 10-30 minutes a day, 3 times a week, for 15 weeks, depending on the condition of the patient.

The VR therapy station will consist of an external motion controller (Microsoft Kinect®), a computer and a monitor. The exercise room will be well ventilated. There will be free space in the patient's movement area with no obstructions restricting the patient's movement. Only the patient will be in the front view of the Kinect camera. The therapist supervising the patient's exercises will be outside of the area of Kinect camera, but close enough to ensure the patient's safety during the exercises. The background behind the patient will be in a solid color. The patient will be standing 2 meters from the Kinect camera and will perform the exercises in a standing position. The patient will be dressed in a comfortable outfit that does not restrict movement during exercise. The footwear will be well-adhering to the floor, protecting the patient from slipping and falling.

A single VR session will last from 10 to 30 minutes and the exercise time will be increased gradually according to the following scheme:
[Week]: exercise time - rest time - exercise time - rest time - exercise time:
[1-3 week]: 10 min - 0 min - 0 min - 0 min - 0 min
[4-6 week]: 10 min - 3 min- 5 min - 0 min - 0 min
[7-9 week]: 10min - 3 min - 10min - 0 min - 0 min
[10-12 week]: 10 min - 3 min - 10min - 3 min - 5 min
[13-15 week]: 10 min - 3 min - 10 min- 3 min- 10 min

Upper and lower limbs and trunk exercises will be introduced in the VR exercises.
The aim of the VR exercises will be to improve motor coordination and increase range of motion. Exercises to improve body balance and reaction speed, as well as exercises of cognitive functions will also be implemented.

Participants in control and experimental group will also attend to occupational therapy for 30 minutes a day, 3 times a week (with a one-day break), for 15 weeks, based on the principles of best clinical practices.

Clinical trial no. 3
The third clinical trial will include people of different ages with schizophrenia - one control group and one experimental group.

After the medical examination and meeting the inclusion criteria, all participants will be randomly assigned by the main investigator to the experimental group and to the control group. Patients will be randomly assigned to groups based on the group symbol with the block randomization method. Randomization will take place after the medical examination and meeting the inclusion criteria.

Participants in the experimental groups will receive VR Kinect exercise for 10-30 minutes a day, 3 times a week, for 15 weeks, depending on the condition of the patient.

The VR therapy station will consist of an external motion controller (Microsoft Kinect®), a computer and a monitor. The exercise room will be well-ventilated. There will be free space in the patient's movement area with no obstructions restricting the patient's movement. Only the patient will be in the front view of the Kinect camera. The therapist supervising the patient's exercises will be outside of the area of Kinect camera, but close enough to ensure the patient's safety during the exercises. The background behind the patient will be in a solid color. The patient will be standing 2 meters from the Kinect camera and will perform the exercises in a standing position. The patient will be dressed in a comfortable outfit that does not restrict movement during exercise. The footwear will be well-adhering to the floor, protecting the patient from slipping and falling.

A single VR session will last from 10 to 30 minutes and the exercise time will be increased gradually according to the following scheme:
[Week]: exercise time - rest time - exercise time - rest time - exercise time:
[1-3 week]: 10 min - 0 min - 0 min - 0 min - 0 min
[4-6 week]: 10 min - 3 min- 5 min - 0 min - 0 min
[7-9 week]: 10min - 3 min - 10min - 0 min - 0 min
[10-12 week]: 10 min - 3 min - 10min - 3 min - 5 min
[13-15 week]: 10 min - 3 min - 10 min- 3 min- 10 min

Upper and lower limbs and trunk exercises will be introduced in the VR exercises.
The aim of the VR exercises will be to improve motor coordination, increase range of motion, and improve general strength. Exercises to improve body balance and reaction speed, as well as exercises of cognitive functions will also be implemented.

Participants in control and experimental groups will also attend psychological therapies and occupational therapy for 30 minutes a day, 3 times a week (with a one-day break), for 15 weeks, based on the principles of best clinical practices.

Intervention Type

Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Microsoft Kinect®

Primary outcome(s)
Clinical trial no. 1
(people aged 60+ with only age-related diseases and without neurodegenerative and mental disorders)
1. Cognitive functions assessed by Mini-Mental State Examination Test (MMSE), at baseline and after the 15-week rehabilitation period.
2. Cognitive functions assessed by verbal fluency test at baseline and after the 15-week rehabilitation period.
3. Cognitive functions assessed by Digit Symbol Substitution Test (DSST), at baseline and after the 15-week rehabilitation period.
4. Cognitive functions assessed by reverse number memorization test, at baseline and after the 15-week rehabilitation period.
5. Cognitive functions assessed by Stroop test, at baseline and after the 15-week rehabilitation period.
6. Cognitive functions assessed by Reven's test, at baseline and after the 15-week rehabilitation period.
7. Cognitive functions assessed by Rey's 15 words test, at baseline and after the 15-week rehabilitation period.
8. Activities of daily living assessed by Barthel Index, at baseline and after the 15-week rehabilitation period.
9. Functional fitness assessed by Fullerton Test (Functional Fitness Test), at baseline and after the 15-week rehabilitation period.
10. Static and dynamic body balance assessed by stabilometric platform (Zebris FDM-S; Rehawalk, MaxxusDaum h/p Cosmos Force), at baseline and after the 15-week rehabilitation period.
11. Emotional state assessed by Center for Epidemiologic Studies Depression Scale (CES-D), at baseline and after the 15-week rehabilitation period.
12. Quality of life assessed with WHOQOL-BREF questionnaire, at baseline and after the 15-week rehabilitation period.

Clinical trial no. 2
(people aged 60+ with Alzheimer's disease)
1. Cognitive functions assessed by Mini-Mental State Examination Test (MMSE), at baseline and after the 15-week rehabilitation period.
2. Cognitive functions assessed by verbal fluency test at baseline and after the 15-week rehabilitation period.
3. Cognitive functions assessed by Digit Symbol Substitution Test (DSST), at baseline and after the 15-week rehabilitation period.
4. Cognitive functions assessed by reverse number memorization test, at baseline and after the 15-week rehabilitation period.
5. Cognitive functions assessed by Stroop test, at baseline and after the 15-week rehabilitation period.
6. Cognitive functions assessed by Reven's test, at baseline and after the 15-week rehabilitation

period.
7. Cognitive functions assessed by Rey's 15 words test, at baseline and after the 15-week rehabilitation period.
8. Activities of daily living assessed by Barthel Index, at baseline and after the 15-week rehabilitation period.
9. Functional fitness assessed by Fullerton Test (Functional Fitness Test), at baseline and after the 15-week rehabilitation period.
10. Static and dynamic body balance assessed by stabilometric platform (Zebris FDM-S; Rehawalk, MaxxusDaum h/p Cosmos Force), at baseline and after the 15-week rehabilitation period.
11. Emotional state assessed by Center for Epidemiologic Studies Depression Scale (CES-D), at baseline and after the 15-week rehabilitation period.
12. Quality of life assessed with WHOQOL-BREF questionnaire, at baseline and after the 15-week rehabilitation period.

Clinical trial no. 3
(people of different ages with schizophrenia)
1. Cognitive functions assessed by Mini-Mental State Examination Test (MMSE), at baseline and after the 15-week rehabilitation period.
2. Cognitive functions assessed by verbal fluency test at baseline and after the 15-week rehabilitation period.
3. Cognitive functions assessed by Digit Symbol Substitution Test (DSST), at baseline and after the 15-week rehabilitation period.
4. Cognitive functions assessed by reverse number memorization test, at baseline and after the 15-week rehabilitation period.
5. Cognitive functions assessed by Stroop test, at baseline and after the 15-week rehabilitation period.
6. Cognitive functions assessed by Reven's test, at baseline and after the 15-week rehabilitation period.
7. Cognitive functions assessed by Rey's 15 words test, at baseline and after the 15-week rehabilitation period.
8. Activities of daily living assessed by Barthel Index, at baseline and after the 15-week rehabilitation period.
9. Functional fitness assessed by Fullerton Test (Functional Fitness Test), at baseline and after the 15-week rehabilitation period.
10. Symptom severity of patients with schizophrenia assessed by The Positive and Negative Syndrome Scale (PANSS), at baseline and after the 15-week rehabilitation period
11. Emotional state assessed by Calgary Depression Scale for Schizophrenia (CDSS), at baseline and after the 15-week rehabilitation period.
12. Quality of life assessed by WHOQOL-BREF questionnaire, at baseline and after the 15-week rehabilitation period.

Key secondary outcome(s))

Clinical trial no. 1
Laboratory indicators (anti and pro-inflammatory cytokines, cortisol, creatine kinase, fibrinogen, lactate dehydrogenase, C-reactive protein) measured by laboratory blood tests at baseline and after the 15-week rehabilitation period.

Clinical trial no. 2
Laboratory indicators (anti and pro-inflammatory cytokines, cortisol, creatine kinase, fibrinogen, lactate dehydrogenase, C-reactive protein) measured by laboratory blood tests at baseline and after the 15-week rehabilitation period.

Clinical trial no. 3
Laboratory indicators (basic biochemistry blood tests and anti and pro-inflammatory cytokines, adhesion proteins, neurotrophins, brain-derived growth factor (BDNF), creatine kinase, fibrinogen, lactate dehydrogenase, CRP) measured by laboratory blood tests at baseline and after the 15-week rehabilitation period.

Completion date
31/12/2025

Eligibility

Key inclusion criteria
Current inclusion criteria as of 15/11/2024:

Clinical trial no. 1
1.1. Women and men aged ≥ 60,
1.2. Written consent to participate in the study,
1.3. The ability to understand and follow the therapist's instructions,
1.4. Everyday functional efficiency assessed on the Barthel index above 20 points,
1.5. Cognitive efficiency assessed using the mini-mental state examination test, at the level of 26 - 30 points.

Clinical trial no. 2
2.1. Women and men aged ≥ 60,
2.2. I or II stage of Alzheimer's disease,
2.3. Written consent from the participant or his legal health care provider to participate in the study,
2.4. The ability to understand and follow the therapist's instructions,
2.5. Everyday functional efficiency assessed on the Barthel index above 20 points,
2.6. Cognitive efficiency assessed using the mini-mental state examination test at the level of 11 - 24 points.

Clinical trial no. 3
3.1. Women and men aged ≥ 18,
3.2. Clinically confirmed schizophrenia for at least 5 years, with predominance of negative symptoms,
3.3. Unchanged pharmacotherapy for at least 3 months,
3.4. Written consent from the patient or his legal medical provider to participate in the study,
3.5. The ability to understand and follow the therapist's instructions,
3.6. Everyday functional efficiency assessed on the Barthel index above 20 points,
3.7. Cognitive efficiency assessed using the mini-mental state examination test at the level of above 19 points.

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Previous inclusion criteria:

Clinical trial no. 1
1.1. Women and men aged ≥ 60,
1.2. Written consent to participate in the study,

1.3. The ability to understand and follow the therapist's instructions,
1.4. Everyday functional efficiency assessed on the Barthel index above 20 points,
1.5. Cognitive efficiency assessed using the mini-mental state examination test, at the level of 26 - 30 points.

Clinical trial no. 2
2.1. Women and men aged ≥ 60,
2.2. I or II stage of Alzheimer's disease,
2.3. Written consent from the participant or his legal health care provider to participate in the study,
2.4. The ability to understand and follow the therapist's instructions,
2.5. Everyday functional efficiency assessed on the Barthel index above 20 points,
2.6. Cognitive efficiency assessed using the mini-mental state examination test at the level of 11 - 24 points.

Clinical trial no. 3
3.1. Women and men aged ≥ 18,
3.2. Clinically confirmed schizophrenia for at least 5 years, with predominance of negative symptoms,
3.3. Unchanged pharmacotherapy for at least 3 months,
3.4. Written consent from the patient or his legal medical provider to participate in the study,
3.5. The ability to understand and follow the therapist's instructions,
3.6. Everyday functional efficiency assessed on the Barthel index above 20 points,
3.7. Cognitive efficiency assessed using the mini-mental state examination test at the level of 19 - 24 points.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
Clinical trial no. 1
1.1. Contraindications to the exercises applied in the study,
1.2. Neurodegenerative and mental diseases,
1.3. Diseases of the nervous system (neuropathy, stroke, damage to the cerebellum, inner ear and labyrinth of the ear, Parkinson's disease),
1.4. Illnesses and diseases of the musculoskeletal system that disturb the balance of the body and the mobility of the limbs.

Clinical trial no. 2
2.1. Contraindications to the exercises applied in the study,
2.2. III stage of Alzheimer's disease;
2.3. Diseases of the nervous system (neuropathy, stroke, damage to the cerebellum, inner ear and labyrinth of the ear, parkinson's disease and others affecting functional efficiency and posture control),
2.4. Illnesses and diseases of the musculoskeletal system that disturb the balance of the body and the mobility of the limbs.

Clinical trial no. 3
3.1. Contraindications to the exercises applied in the study,
3.2. Diseases of the nervous system and sense organs (neuropathy, stroke, damage to the cerebellum, inner ear and labyrinth of the ear, parkinson's disease and others affecting functional efficiency),
3.3. Illnesses and diseases of the musculoskeletal system that impair functional efficiency.

Date of first enrolment
27/03/2023

Date of final enrolment
15/09/2025

Locations

Countries of recruitment
Poland

Study participating centre
The Jerzy Kukuczka Academy of Physical Education in Katowice
Mikolowska 72a Street
Katowice
Poland
40-065

Study participating centre
St. Elizabeth Nursing Home
Wolnosci 30 Street
Ruda Slaska
Poland
41-700

Study participating centre
Saint Antoni Social Welfare House
Bishop Kubina 11 Street
Swietochlowice

Poland
41-600

Study participating centre
Independent Public Mental Health Hospital in Rybnik
Gliwicka 33 Street
Rybnik
Poland
44-201

Sponsor information

Organisation
Akademii Wychowania Fizycznego im. Jerzego Kukuczki w Katowicach

ROR
https://ror.org/05wtrdx73

Funder(s)

Funder type
University/education

Funder Name
Akademia Wychowania Fizycznego im. Jerzego Kukuczki w Katowicach

Alternative Name(s)
The Jerzy Kukuczka Academy of Physical Education in Katowice, AWF Katowice

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Poland

Funder Name
Independent Public Mental Health Hospital in Rybnik

Results and Publications

Individual participant data (IPD) sharing plan

The study protocol, the statistical analysis plan and the trial database will be available upon request form at l.piejko@awf.katowice.pl.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes