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Effect of lower limb muscle focused vibration, balance platform exercises and treadmill exercises on selected fall risk factors in people aged 65+

Submission date 17/11/2024	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 30/12/2024	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 30/12/2024	**Condition category** Other	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
In recent years, the number of people aged over 60 years has been growing rapidly worldwide, and this increase is incomparable to any other age group. The life expectancy of seniors is increasing due to the development of pro-health prevention, advances in medicine and rehabilitation, greater access to medical services and improved personal hygiene of the elderly. However, longer life is not always associated with good health and good quality of life for seniors. It is believed that in the coming years, the incidence of infectious diseases will significantly decrease worldwide, but the number of neuropsychiatric diseases and non-communicable chronic diseases will increase. Degenerative changes that occur with age in the nervous system, sense organs, and the motor apparatus result in impairment of functions responsible for postural control and motor coordination, which increases the risk of falls and injuries in the elderly. In the elderly, falls often result in injuries that become the cause of disability or even death. Most falls by the elderly are multi-causal and are the result of the co-occurrence of involutional changes in the body, pathologies accompanying diseases, multi-drug therapy and environmental factors related to lifestyle and living conditions. The results of the clinical studies confirm that physical exercises reduce the risk of falls in seniors. In randomly allocated medical trials the improvement of body balance and gait quality, as well as the reduction of the risk of falls in seniors were achieved using various types of physical exercises, including strength and endurance exercises, resistance exercises using elastic bands and multidirectional physical training (moderate intensity) including aerobic, strength, flexibility and balance exercises. Studies should take into account and compare different forms of therapy to develop diversified and attractive exercise programs for seniors at fall risk.

Who can participate?
Patients aged 65 to 89 years old undergoing a 2-week rehabilitation stay

What does the study involve?
Participants will be randomly assigned to one of the four groups: experimental groups involving

1. gait training using a treadmill and physical therapy agents; 2. gait training using the treadmill and balance training using a balance system and physical therapy agents; 3. gait training using the treadmill, lower limb muscle-focused vibration with Vibramoov and physical therapy agents; and, 4. a control group will receive physical therapy agents (massage therapy, thermotherapy) as the only form of therapy.

What are the possible benefits and risks of participating?
It is presumed that the treatment will contribute to reducing selected risk factors of falls in people aged 65+.

The selection and methodology of diagnostics and exercises planned in the study were developed based on the analysis of scientific literature and the knowledge and practical experience of the research team members. No invasive diagnostics were used in the study, and the proposed surveys and functional diagnostics are well-known in clinical practice and commonly used in the elderly. Therefore, the occurrence of potential adverse effects during the study is low. Nevertheless, as a result of the exercises, seniors may experience symptoms of fatigue and intensification of pain symptoms associated with degenerative joint disease. There is also a small risk of injuries or falls, especially during exercises on a mechanical treadmill and a balance platform. However, this risk will be minimal because the study will include seniors who move independently, the treadmill and platform will be equipped with side and front handrails for self-protection, and all exercises will be performed under the supervision of a physiotherapist.

Vibration training carries the risk of exacerbating blood vessel and heart diseases, but this applies primarily to whole-body vibration training performed on vibration platforms. In the case of focused vibration of individual muscle groups, which is planned in the study, this risk is small, and in addition, heart and blood vessel diseases, which are a contraindication to vibration therapy, will be a criterion for exclusion from the study. Some people may experience dizziness, headaches, or nausea during exercises using virtual reality. However, this applies in particular to immersive virtual reality, and the study will use virtual reality without immersion, so the risk of the above symptoms is small.

Possible side effects will be noted and, if necessary, the studies will be modified and discontinued, with appropriate notification to the Bioethics Committee.

Where is the study run from?
Rehabilitation Center ''Marzenie'' in Zakopane (Poland).

When is the study starting and how long is it expected to run for?
May 2024 to March 2025

Who is funding the study?
Rehabilitation Center ''Marzenie'' in Zakopane (Poland).
The study was co-financed by the European Regional Development Fund for the Lesser Poland Voivodeship

Who is the main contact?
Anna Polak, a.polak@awf.katowice.pl

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Prof Anna Polak

ORCID ID
https://orcid.org/0000-0001-6932-5047

Contact details
72a Mikolowska Street
Katowice
Poland
40-065
+48 (0)32 2075129
a.polak@awf.katowice.pl

Additional identifiers

Protocol serial number
European Regional Development Fund for the Lesser Poland Voivodeship Poland no. RPMP. 01.02.02-12-0144/19-00

Study information

Scientific Title
The impact of focused vibration of lower limb muscles, balance platform exercises and virtual reality- based treadmill exercises on selected fall risk factors in people aged 65+. Randomized clinical trial

Study objectives
Focused vibration of lower limb muscles, virtual reality-based treadmill exercises, exercises on a balance platform with a stable surface will reduce fear of falling, improve body balance and gait quality in people aged 65+.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 27/06/2024, Bioethics Commission for Scientific Research at The Jerzy Kukuczka Academy of Physical Education in Katowice (72a Mikolowska Street, Katowcie, 40-065, Poland; +48 (032) 2075352; komisjabioetyczna@awf.katowice.pl), ref: 4-VI/2024

Primary study design
Interventional

Study design
Single-center interventional randomized controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied
Exercises for reducing selected risk factors of falls in people aged 65+

Interventions
The method of randomisation is sequentially numbered, opaque sealed envelopes. Participants are randomly assigned to groups based on the group symbol in an opaque and sealed envelope.

120 participants will be randomly assigned to one of the 4 following groups:
1. The first experimental group of patients will receive gait training with the use of Zebris FDM treadmill (Medical GmbH, Germany) and physical therapy agents.
2. The second experimental group of patients will receive gait training with the use of Zebris FDM treadmill (Medical GmbH, Germany) and balance training with the use of Biodex Balance System SD (Biodex Medical Systems Inc., Shirley, NY, USA) and physical therapy agents.
3. The third experimental group of patients will receive gait training with the use of Zebris FDM treadmill (Medical GmbH, Germany) and lower limb muscle-focused vibration with Vibramoov (TechnoConcept, France) and physical therapy agents.
4. The control group will receive physical therapy agents (massage therapy, thermotherapy) as the only form of therapy.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Zebris FDM treadmill (Medical GmbH, Germany), Balance platform Biodex Balance System SD (Biodex Medical Systems Inc., Shirley, NY, USA), Focused vibration Vibramoov (TechnoConcept, France)

Primary outcome(s)
1. Dynamic body balance measured using the Time Up and Go Test (TUG), at baseline and after the 2-week rehabilitation period

Key secondary outcome(s)
The following secondary outcome measures are assessed at baseline and after the 2-week rehabilitation period:
1. Fear of fall measured using the Falls Efficacy Scale – International (FES-I)
2. Lower body muscle strength measured using the 30-second Sit-to-Stand Test
3. Static body balance measured using the treadmill walking test (Zebris FDM; Medical GmbH, Germany)
4. Gait measured using the treadmill walking test (Zebris FDM;Medical GmbH, Germany)

Completion date
31/03/2025

Eligibility

Key inclusion criteria
1. Aged 65 to 89 years old
2. Who provides informed consent to participate in the study
3. Able to move independently
4. Staying on a 2-week rehabilitation stay to treat chronic pain caused by degenerative changes in the lower spine and lower limbs, but who do not have symptoms of acute inflammation accompanying the degenerative disease and whose joint pain intensity does not exceed level 5 on the 10-point vas pain assessment scale
5. Whose score for the assessment of independence in daily activities on the 100-point Barthel scale will be above 20 points
6. Whose score for the assessment of cognitive functions in the mini-mental state examination (MMSE) will be above 23 points
7. Who has a clinical history of at least one fall in the past year
8. Who have an increased fear of falling and a fall anxiety score of at least 17 on the 16-item falls efficacy scale – international (FES-I)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Lower age limit
65 Years

Upper age limit
89 Years

Sex
All

Key exclusion criteria
1. Contraindications to the exercises included in the study, including acute inflammation, osteoporosis, bone fractures and other injuries to the lower limbs and spine in the period less than 1 year before the start of the study
2. Malignant neoplastic diseases during treatment, uncontrolled diabetes, diseases of the blood vessels; and lymphatic vessels, and risk of internal and external bleeding
3. Pain intensity due to degenerative spine and limbs exceeding 5 points on a 10-point VAS scale
4. Body balance and movement disorders resulting from diseases of the nervous system, sense organs and cardiovascular system

Date of first enrolment
01/07/2024

Date of final enrolment
31/03/2025

Locations

Countries of recruitment
Poland

Study participating centre
Rehabilitation Center "Marzenie" in Zakopane, Poland
1 Stara Pardalowka Street
Zakopane
Poland
34-500

Sponsor information

Organisation
Rehabilitation Center "Marzenie" in Zakopane, Poland

Funder(s)

Funder type
Government

Funder Name
European Regional Development Fund

Alternative Name(s)
Fondo Europeo de Desarrollo Regional, Europäischer Fonds für regionale Entwicklung, Европейски фонд за регионално развитие, Evropský fond pro regionální rozvoj, Fundo Europeu de Desenvolvimento Regional, ERDF, FEDER, EFRE, ЕФРР, EFRR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Funder Name
Rehabilitation Center "Marzenie" in Zakopane, Poland

Results and Publications

Individual participant data (IPD) sharing plan

The study protocol, the statistical analysis plan and the trial database will be made available at a later date upon request from a.polak@awf.katowice.pl.

- Participant-level data will be available upon request at a later date.
- Written consent to participate in the study is obtained from each participant.
- All participants' data are stored in a form that protects personal health information and prevents personal identification.
- Coded data are collected in paper form and electronic documentation.
- There are no ethical or legal restrictions to the study. The study was approved on 27/06/2024 by the Bioethics Commission for Scientific Research at The Jerzy Kukuczka Academy of Physical Education in Katowice (ref no.: 4-VI/2024).

IPD sharing plan summary

Available on request