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Effect of vibration training on fall risk factors and quality of life in older people

Submission date
29/10/2022

Recruitment status
No longer recruiting

Registration date
30/11/2022

Overall study status
Completed

Last Edited
14/02/2023

Condition category
Other

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

Plain English summary of protocol

Background and study aims
According to US Department of Health statistics, falls are the leading cause of injury to older people and the second leading cause of death from unintentional injuries in this age group. The main endogenous (having an internal cause or origin) risk factors for falls in seniors include: low physical activity, range of motion (ROM) and functional independence limitations, previous fall and fear of falling, impaired vision, depressed mood, multi-drug therapy, muscle weakness, gait and balance disorders, bone mass loss and chronic inflammation. The risk of falling is also influenced by the deterioration of cognitive functions, which is responsible for the correct interpretation of stimuli coming from the environment. So far, it has not been clearly demonstrated which of the endogenous risk factors has the greatest impact on the very risk of falling in seniors.
As research shows, medical and physiotherapeutic activities bring the greatest benefits in preventing falls and fractures. It is recommended to introduce appropriate physical exercises such as strength, endurance, proprioception, balance and bone strengthening exercises. Vibration training, which involves subjecting the whole body to vibrations generated by a vibration platform, may also reduce the fall risk. Vibration has a positive effect on bones, joints and muscles but the current state of knowledge regarding vibration training in the older age group is still insufficient. Therefore, the aim of the research is to verify whether vibration training has an effect on endogenous fall risk factors, biological factors, daily living activities, mood and quality of life in people aged 60 years and older.

Who can participate?
Women and men over 60 years of age.

What does the study involve?
83 seniors, who will be assigned to one of the 2 following groups:
1. The experimental group (EG), in which vibration training will be administered 2 days a week for 10 minutes a day for 12 weeks. Whole body vibrations with a frequency of 20 Hz and an amplitude of 2 mm will be applied. Exercises will be conducted in five series, each lasting 1 minute with 1-minute breaks between each series. Exercises will be held in a standing, semi-squat position. Seniors will be also informed to maintain their regular physical activity for a peroid of 12 weeks.

2. The control group (CG), subjects will be informed to maintain their regular physical activity for a peroid of 12 weeks.

The aim of the exercises will be to improve endogenous fall risk factors, biological factors, daily living activities, mood and quality of life.

What are the possible benefits and risks of participating?
It is presumed that the treatment will contribute to the improvement of fall risk and biological factors, activities of daily living, mood and quality of life in people aged 60 years and older. 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 individual exercises will be planned on the basis of scientific publications. Therefore, no adverse events except fatigue is expected in patients. 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?
1. Jerzy Kukuczka Academy of Physical Education in Katowice (Poland)
2. Saint Elizabeth Nursing Home in Ruda Slaska (Poland)

When is the study starting and how long is it expected to run for?
November 2018 to July 2022

Who is funding the study?
1. Jerzy Kukuczka Academy of Physical Education in Katowice (Poland)
2. The "Regional Excellence Initiative" Ministry of Education and Science grant for 2019-2022. Project no. 019/RID/2018/19.

Who is the main contact?
Laura Piejko
l.piejko@awf.katowice.pl

Contact information

Type(s)
Scientific

Contact name
Dr Laura Piejko

ORCID ID
http://orcid.org/0000-0002-5338-1842

Contact details
Jerzy Kukuczka Academy of Physical Education in Katowice
72a Mikolowska Street
Katowice
Poland
40-065
+48 (0)32 207 53 01
l.piejko@awf.katowice.pl

Type(s)
Scientific

Contact name
Dr Agnieszka Nawrat-Szoltysik

ORCID ID
http://orcid.org/0000-0002-9193-3724

Contact details
Jerzy Kukuczka Academy of Physical Education in Katowice
72a Mikolowska Street
Katowice
Poland
40-065
+ 48 (0)32 207 53 02
a.nawrat-szoltysik@awf.katowice.pl

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Effect of vibration training on endogenous fall risk factors, biological factors, daily living activities, mood and quality of life in people aged 60 years and older

Study objectives
1. Vibration training will improve endogenous fall risk factors in people aged 60 years and older.
2. Vibration training will improve biological factors (bone markers and pro-inflammatory cytokines) in people aged 60 years and older.
3. Vibration training will improve daily living activities in people aged 60 years and older.
4. Vibration training will improve quality of life in people aged 60 years and older.
5. Vibration training will improve mood in people aged 60 years and older.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 15/11/2018, Bioethics Commission for Scientific Research at The Jerzy Kukuczka Academy of Physical Education in Katowice (Mikolowska 72a Street, 40-065 Katowice, Poland; +48 032 2075152; komisjabioetyczna@awf.katowice.pl), ref: 1/2018

Study design
Single-center interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Care home

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Vibration training in older people

Interventions
Community dwelling and independently living 100 elderly people aged 60 years and older living in Ruda Slaska (Poland) will participate in the study.

After the medical examination and meeting the inclusion criteria, 100 seniors will be assigned to the experimental (50 patients) and control (50 patients) groups. The size of the study group was estimated from pilot study. The method of randomisation: sequentially numbered, opaque sealed envelopes.

Vibration training (FitVibe®, Uniphy Elektromedizin GmbH & Co., Germany.) will be administered to patients in the experimental group (EG). Vibration training will be performed 2 days a week for 10 minutes a day for 12 weeks. Whole body vibrations with a frequency of 20 Hz and an amplitude of 2 mm will be applied. Exercises will be conducted in five series, each lasting 1 minute with 1-minute breaks between each series. Exercises will be held in a standing, semi-squat position. Seniors will be also informed to maintain their regular physical activity for a peroid of 12 weeks.

Subjects in the control group (CG) will be informed to maintain their regular physical activity for a peroid of 12 weeks.

The aim of the exercises will be to improve endogenous fall risk factors, biological factors, daily living activities, mood and quality of life.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
FitVibe® vibration platform, Uniphy Elektromedizin GmbH & Co., Germany.

Primary outcome measure
1. Endogenous fall risk factors assessed by Time Up and Go Test (TUG), at baseline and after the 12-week rehabilitation period.
2. Endogenous fall risk factors assessed by 6 Metre Walk Test (6MWT), at baseline and after the 12-week rehabilitation period.
3. Endogenous fall risk factors assessed by 4,572 Metre Walk Test, at baseline and after the 12-week rehabilitation period.
4. Endogenous fall risk factors assessed by 30 Seconds Sit To Stand Test, at baseline and after the 12-week rehabilitation period.
5. Endogenous fall risk factors assessed by hand dynamometer at baseline and after the 12-week rehabilitation period.
6. Endogenous fall risk factors assessed by Falls Efficacy Scale (FES-I). at baseline and after the 12-week rehabilitation period.
7. Biological factors assessed (proccolagene, CTX-1) by blood tests, at baseline and after the 12-week rehabilitation period.
8. Daily living activities assessed by Barthel Scale, at baseline and after the 12-week rehabilitation period.
9. Daily living activities assessed by Katz Index of Independence Scale, at baseline and after the 12-week rehabilitation period.
10. Quality of life assessed by WHO Quality of Life-BREF (WHOQOL-BREF), at baseline and after the 12-week rehabilitation period.
11. Mood assessed by Center for Epidemiologic Studies Depression Scale (CES-D), at baseline and after the 12-week rehabilitation period.

Secondary outcome measures
1. Endogenous fall risk factors assessed by Mini–Mental State Examination (MMSE), at baseline and after the 12-week rehabilitation period.
2. Endogenous fall risk factors assessed by Fracture Risk Assessment Tool (FRAX), at baseline and after the 12-week rehabilitation period.
3. Biological factors assessed (IL-6) by blood tests, at baseline and after the 12-week rehabilitation period.

Overall study start date
15/11/2018

Completion date
01/07/2022

Eligibility

Key inclusion criteria
1. Women and men over 60 years of age;
2. Ability to walk independently;
3. Logical verbal contact above 24 points according to Mini–Mental State Examination (MMSE);

4. Functional independence above 20 points according to Barthel Scale;
5. Lack of any medical contraindications to vibration training;
6. Written consent to participate in the study.

Participant type(s)
Other

Age group
Senior

Sex
Both

Target number of participants
100

Total final enrolment
83

Key exclusion criteria
1. Women and men under 60 years of age;
2. Lack of ability to walk independently;
3. Lack of logical verbal contact;
4. Functional independence below 20 points according to Barthel Scale;
5. Medical contraindications to vibration training including: diseases of the nervous system (stroke, neuropathies, diseases of the cerebellum and labyrinth); diseases of the cardiovascular system (orthostatic hypotension, arrhythmia, carotid artery stenosis); gastrointestinal diseases (gastrointestinal bleeding; diarrhea) and emerging imbalances resulting from diseases of the ears, eyes, and blood vessels of the head and neck.
6. Lack of written consent to participate in the study.

Date of first enrolment
01/01/2019

Date of final enrolment
15/04/2022

Locations

Countries of recruitment
Poland

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

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

Sponsor information

Organisation
Akademii Wychowania Fizycznego im. Jerzego Kukuczki w Katowicach

Sponsor details
72a Mikolowska Street
Katowice
Poland
40-065
+48 (0)32 207 53 10
j.srubarczyk@awf.katowice.pl

Sponsor type
University/education

Website
http://awf.katowice.pl/en

ROR
https://ror.org/05wtrdx73

Funder(s)

Funder type
Government

Funder Name
"Regional Excellence Initiative" Ministry of Education and Science grant for 2019-2022. Project no. 019/RID/2018/19.

Results and Publications

Publication and dissemination plan
Publication in a scientific journal.

Intention to publish date
01/11/2022

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date