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Effect of Nordic walking with weighted vest training on fall risk factors and quality of life in older people

Submission date
17/12/2022

Recruitment status
No longer recruiting

Registration date
03/02/2023

Overall study status
Completed

Last Edited
03/02/2023

Condition category
Other

[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
According to the 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. Nordic walking (NW) with weighted vest training may also reduce fall risk factors. NW and weight and strengthening exercises have a positive effect on bones, joints and muscles. Although the current state of knowledge on NW with weighted vest training alone in the older age group is still insufficient. Therefore, the aim of the study is to verify whether NW with weighted vest 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 aged 60 years and over

What does the study involve?
Participants will be assigned to one of the 2 following groups:
1. The experimental group (EG), in which NW with weighted vest training will be conducted on a flat area, 3 days a week for 12 weeks. The walking speed will be approx. 2-3 km/h. Each training session will consist of a 5-10 min warm-up with stretching and breathing exercises, 30 min of the NW weighted vest training (the time of NW weighted vest training will be increased every 3 weeks by 5 min) and a 5-10 min cool-down - mainly with breathing exercises. During the NW

weighted vest training, the subjects will be wearing 5-8 kg vests. Seniors will be also informed to maintain their regular physical activity for a period of 12 weeks.
2. The control group (CG), in which subjects will be informed to maintain their regular physical activity for a period of 12 weeks.

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 are 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 November 2023

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

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Effect of Nordic walking with weighted vest 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. Nordic walking with weighted vest training will improve endogenous fall risk factors in people aged 60 years and older

2. Nordic walking with weighted vest training will improve biological factors (bone markers and pro-inflammatory cytokines) in people aged 60 years and older
3. Nordic walking with weighted vest training will improve daily living activities in people aged 60 years and older
4. Nordic walking with weighted vest training will improve the quality of life in people aged 60 years and older
5. Nordic walking with weighted vest 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

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Nordic walking with weighted vest training in older people

Interventions
Community-dwelling and independently living 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, seniors will be assigned to the experimental (approx. 30 patients) and control (approx. 30 patients) groups. The method of randomisation: sequentially numbered, opaque sealed envelopes.

Nordic walking (NW) with weighted vest training methodology: NW training will be conducted on a flat area, 3 days a week for 12 weeks. The walking speed will be approx. 2-3 km/h. Each training session will consist of 3 parts:
1. 5-10 min warm-up with stretching and breathing exercises
2. 30 min of the NW weighted vest training (the time of NW weighted vest training will be increased every 3 weeks by 5 min)
3. 5-10 min cool-down - mainly with breathing exercises
During the NW weighted vest training, the subjects will be wearing 5-8 kg vests.

Seniors in both groups will be informed to maintain their regular physical activity for a period 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)
HMS WHO05 training vest with a 5 kg weight, HMS WHO08 training vest with a 8 kg weight

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

Key secondary outcome(s))
All outcomes will be assessed at baseline and after the 12-week training period:
1. Endogenous fall risk factors measured using the Mini–Mental State Examination (MMSE)
2. Endogenous fall risk factors measured using the Fracture Risk Assessment Tool (FRAX)

Completion date
30/11/2023

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 NW with weighted vest training
6. Written consent to participate in the study

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
60 years

Sex
All

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 NW with weighted vest 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
13/02/2023

Date of final enrolment
28/07/2023

Locations

Countries of recruitment
Poland

Study participating centre
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Sponsor information

Organisation
Akademii Wychowania Fizycznego im. Jerzego Kukuczki w Katowicach

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

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