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Is the Flexi-bar exercise tool useful for combating loss of muscular strength?

Submission date
02/10/2020

Recruitment status
No longer recruiting

Registration date
10/11/2020

Overall study status
Completed

Last Edited
17/06/2021

Condition category
Musculoskeletal Diseases

[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
Dynapenia is defined as age-related loss of muscle strength and power. It is strongly associated with a high risk of falls, poor physical performance, disability and death. Flexi-bar is a type of vibration training. It has bee used as a strength training device in recent years. The objective of this study is to investigate the effects and mechanisms of 12-week Flexi-bar training program on muscle strength and physical function in the older people with dynapenia.

Who can participate?
People aged over 65 yrs with dynapenia (age-related muscle loss) can participate in this study.

What does the study involve?
Community-dwelling seniors with dynapenia will be randomly divided into 3 equal groups, namely, Flexi-bar group, sham group and control group (no training) for 12-week Flexi-bar training. Assessments will be done before and after the intervention and 12-week follow-up.

What are the possible benefits and risks of participating?
Long-term Flexi-bar use has positive effects on muscle strength and physical function in old people. The older people with dynapenia might gain muscle strength after a 12-week Flexi-bar training. Flexi-bar is a convenient and safe training device for older people.

Where is the study run from?
This study will run in Health Service Centers in General Hospital of the Yangtze River Shipping, Wuhan (China)

When is the study starting and how long is it expected to run for?
September 2020 to December 2023

Who is funding the study?
Natural Science Foundation of Hubei Province (Project #2019CFB349)

Who is the main contact?
Dr Ning Wei (Nicole), nicole.weining@whpu.edu.cn

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil Known

IRAS number

ClinicalTrials.gov number
Nil Known

Secondary identifying numbers
NSFHB2019

Study information

Scientific Title
The effect and mechanisms of Flexi-bar on muscle strength and physical performance in the older people with dynapenia

Study objectives
Flexi-bar can improve muscle strength and physical performance in the older people with dynapenia

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 29/09/2020, Yangtze river shipping general hospital, Wuhan brain hospital, Ethical review board (5 Huiji Road, Jiangan District, Wuhan, China; +862782451304; chzyykjc@163.com), ref: L20200013

Study design
Interventional single-blinded randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Dynapenia

Interventions
Current interventions as of 25/03/2021:
The participants will be randomized to flexi-bar group, sham group and control group (no training). Training sessions (3 days/week, for 12 weeks) will be conducted at the General Hospital of Yangtze River Shipping, Wuhan. Each training session will include 10 sets of 30-second vibration. One minute of rest period will be given between training set to avoid over exertion of the participants. During training, the flexi-bar group will hold a Flexi-Bar (FLEXI-BAR®; Flexi-Sports, Germany) with shoulder flexed 90° to perform an up-and-down vibration exercise. The sham group will hold the same flexi-bar with no active vibration workout to performa same up-and-down exercise. During the training sessions, the participants will be asked to stand with knee angle of 120°. All participants will be asked to keep their lifestyle as usual.

Randomization:
Each recruited participant will be given an identification number by a research assistant (CL), who performed the randomization with a computer program (Research Randomizer Form www.randomizer.org/).

Previous interventions:
The participants will be randomized to flexi-bar group, sham group and control group (no training). A total of 20 training sessions (5 days/week, 4 weeks) will be conducted in Department of Rehabilitation of Health Service Centers. Each training session will include 10 sets of 30-second vibration. One minute of rest period will be given between training set to avoid over exertion of the participants. During training, the flexi-bar group will hold a Flexi-Bar (FLEXI-BAR®; Flexi-Sports, Germany) with shoulder flexed 90° to perform an up-and-down vibration exercise. The sham group will hold the same flexi-bar with no active vibration workout to performa same up-and-down exercise. During the training sessions, the participants will be asked to stand with knee angle of 120°. All participants will be asked to keep their lifestyle as usual.

Randomization:
Each recruited participant will be given an identification number by a research assistant (CL), who performed the randomization with a computer program (Research Randomizer Form www.randomizer.org/).

Intervention Type
Device

Phase
Phase III/IV

Drug/device/biological/vaccine name(s)
FLEXI-BAR®; Flexi-Sports, Germany

Primary outcome measure
Current primary outcome measure as of 16/06/2021:
Fitness measured using the timed-up-and-go test (TUG) at baseline, 1 day after training completion, and 12 weeks after training completion

Previous primary outcome measure:
Handgrip muscle strength will be measured using a hand dynamometer at baseline, after intervention and follow-up

Secondary outcome measures
Current secondary outcome measures as of 16/06/2021:
1. Handgrip muscle strength measured using a hand dynamometer at baseline, 1 day after training completion, and 12 weeks after training completion
2. Fitness measured using five-repetition sit-to-stand test and 10-meter walking test at baseline, 1 day after training completion, and 12 weeks after training completion
3. Levels of serum albumin and hemoglobin measured by blood test at baseline, 1 day after training completion, and 12 weeks after training completion

Previous secondary outcome measures:
1. Fitness measured using timed-up-and-go test, five-repetition sit-to-stand, 10-meter walking test at baseline, after intervention and follow-up.
2. Clinical parameters (C-reactive protein, Hemoglobin, Serum albumin, Serum creatinine, Serum creatinine and Glucose) will be measured by blood test at pre and post-intervention.

Overall study start date
29/09/2020

Completion date
31/12/2023

Eligibility

Key inclusion criteria
1. Participants aged 65 years or above attending the Health Service Centers in General Hospital of the Yangtze River Shipping, Wuhan
2. Men and women with muscle strength less than 26kg and 18kg, respectively

Participant type(s)
Other

Age group
Senior

Sex
Both

Target number of participants
114

Key exclusion criteria
1. Severe heart problem
2. Neuro-degenerative diseases
3. Vestibular disorders
4. Cognitive impairment
5. Severe osteoporosis
6. Visual impairment
7. Mental diseases

Date of first enrolment
06/09/2021

Date of final enrolment
01/03/2022

Locations

Countries of recruitment
China

Study participating centre
General Hospital of the Yangtze River Shipping
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Sponsor information

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University/education

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ROR
https://ror.org/05w0e5j23

Funder(s)

Funder type
Government

Funder Name
Natural Science Foundation of Hubei Province (Project #2019CFB349)

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
31/12/2024

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