


BMJ Open Effects of flexi-bar training on muscle strength and physical performance in older people with dynapenia: the protocol of a randomised controlled trial

Ning Wei , Xinxin Wang, Ling Chen, Mengyu Lyu

To cite: Wei N, Wang X, Chen L, *et al.* Effects of flexi-bar training on muscle strength and physical performance in older people with dynapenia: the protocol of a randomised controlled trial. *BMJ Open* 2021;**11**:e048629. doi:10.1136/bmjopen-2021-048629

► Prepublication history for this paper is available online. To view these files, please visit the journal online (<http://dx.doi.org/10.1136/bmjopen-2021-048629>).

Received 02 January 2021
Accepted 23 July 2021

ABSTRACT

Introduction Dynapenia is a new term that is used to describe the age-related loss of muscle strength. Flexi-bar training is a safe and feasible device for older people with dynapenia. This study will investigate the effects of a 12-week flexi-bar training programme on muscle strength and physical function in older people with dynapenia.

Methods and analysis A total of 114 participants (aged more than 65 years) with age-related muscle loss will participate in a 12-week flexi-bar training programme. The participants will be randomly divided into three groups, namely, flexi-bar, placebo and control, with equal number of participants in each group. The assessments will be conducted at preintervention, postintervention and 12 weeks after training completion. The primary outcome is timed-up-and-go test. The secondary outcomes are five-repetition sit-to-stand test, 10-metre walking test, handgrip strength, as well as the serum albumin and haemoglobin levels.

Ethics and dissemination The procedures of this study were reviewed and approved by the Human Ethics Review Board of Wuhan Brain Hospital (General Hospital of the Yangtze River Shipping) on 29 September 2020 (#L20200013). The findings of this study will be published in peer-reviewed journals and presented at conferences. The trial was registered on 6 November 2020.

Trial registration number ISRCTN14316668.

INTRODUCTION

Dynapenia is the age-related loss of muscle strength and was defined by Clark and Manini¹. The prevalence of dynapenia is more than 20% in some countries.^{2 3} The mechanisms of dynapenia remain unclear; however, age-related biological factors, unhealthy lifestyle and mental-health variables have been identified as the possible factors contributing to dynapenia.^{4 5} Age-related loss of muscle strength is strongly associated with a high risk of falls,⁶ poor physical performance,^{7 8} disability⁹ and mortality.¹⁰ Moreover, a few studies have reported that low muscle strength is related to a low level of serum albumin and haemoglobin.^{11 12} Long-term exercise training programme has

Strengths and limitations of this study

- This study is the first parallel randomised controlled trial on the effects of a 12-week flexi-bar training programme on muscle strength and physical function in older people with dynapenia, and the study design involves a placebo group.
- This study, comprising 12-week flexi-bar training and 12-week follow-up, can accurately examine the effects of flexi-bar on older people with dynapenia.
- The first limitation of this study is that the muscle loading of each participant will not be uniform.
- The second limitation is that the sample size may be insufficient for the secondary outcome variables.
- The third limitation is the single-blinded design.

been proved to be an effective approach to improve both muscle and functional performance in older people with dynapenia.^{13–16}

Flexi-bar is a type of vibration device, and it consists of a bar, with two weighty rubbers at each end of the bar.¹⁷ Some studies have reported that long-term flexi-bar training has positive effects on the muscle mass,^{18 19} muscle strength²⁰ and physical performance.^{21 22} A study reported that the thickness of the transversus abdominis muscle of young university adults increases to 2.4mm after a 6-month (48 times) flexi-bar training programme.¹⁸ In another study, the overweight adults with a 12-week flexi-bar training programme exhibited a significant increase in handgrip strength, which was significantly different from that of the control group.²⁰ In a study on the physical performance by Lee and Han, older people with chronic stroke exhibited significant improvement in the score of Berg Balance Scale, the duration of completion of timed-up-and-go test (TUG) and 10-metre walking test (10MWT) after 4 weeks of flexi-bar training (20 times).²¹ Moreover, the flexi-bar training could induce a strong stimulus on the muscle during submaximal exercise,^{17 23}



© Author(s) (or their employer(s)) 2021. Re-use permitted under CC BY-NC. No commercial re-use. See rights and permissions. Published by BMJ.

Department of Rehabilitation Sciences, Wuhan Polytechnic University, Wuhan, China

Correspondence to

Dr Ning Wei;
nicole.weining@whpu.edu.cn

which could be the indirect evidence for supporting the positive effect of flexi-bar training on muscle strength. These findings suggest that flexi-bar training might be an effective approach to enhance muscle strength and physical performance at the submaximal level.

According to the findings of the previous studies, flexi-bar might be an effective and safe training device for older people with dynapenia. Considering the inadequacy of the number of studies conducted in the population with dynapenia, examining the effects of flexi-bar training on the muscle and physical performance in older people with dynapenia seems meaningful. The present study aims to investigate the effects of a 12-week flexi-bar training programme on muscle strength and physical function in older people with dynapenia.

METHODS AND ANALYSIS

Participants

The advertisement will be put on the notice board in the Health Service Centres in General Hospital of the Yangtze River Shipping, Wuhan. Participants aged 65 years or more attending the Health Centre will be invited to a screening test of handgrip strength measurement. Men and women with muscle strength less than 26 kg and 18 kg, respectively, and diagnosed as having dynapenia will be included.²⁴ Participants with severe heart diseases, neurodegenerative diseases, vestibular disorders, cognitive impairment, severe osteoporosis, visual impairment or mental diseases will be excluded from this study. All participants will provide their written consent to the principal investigator (NW) before participating in the study. Only the principal investigator (NW) will be able to access the personal information of the study participants, and the information will be kept confidential during and after the study. The procedures have been reviewed and approved by the Human Ethics Review Board of Wuhan Brain Hospital (General Hospital of the Yangtze River Shipping; #L20200013). The trial was registered on 6 November 2020.

Randomisation and blinding

This protocol was designed as a single-blinded randomised controlled trial in accordance with the Standard Protocol Items: Recommendations for Interventional Trials guidelines. The participants will be randomised into flexi-bar, placebo and control groups (no training). Each participant will be provided an identification number by the main investigator (NW), who will perform the randomisation using a computer programme (Research Randomizer Form; www.randomizer.org/). All training sessions will be conducted under the supervision of a physical therapist, who will be blinded to the randomisation. The assessments and data analysis will be performed by a researcher (XW). Two research assistants (LC and ML) will be responsible for data entry (double data entry), and both of them will be blinded to randomisation and intervention.

Interventions

A total of 36 training sessions (3 times/week, 12 weeks) will be conducted at Health Service Centres. Each training session will include 10 sets of 30-second vibration or sham exercises. One minute of rest period will be given between training sets to avoid overexertion of the participants. During training, the flexi-bar group will hold a flexi-bar (FLEXI-BAR; Flexi-Sports, Germany), with the shoulder flexed at 90°, to perform an up-and-down vibration exercise. The participants will be instructed to activate the flexi-bar at the highest individual frequency. The placebo group will hold the same flexi-bar with no active vibration workout. During the training sessions, the participants will be asked to stand with a knee angle of 120°. ²⁵ To cater for missing appointments, extra sessions will be arranged to ensure that all the participants complete the equal number of training sessions. The training sessions will be supervised by a physical therapist, who will be blinded to the randomisation. Any adverse event will be reported to the Human Ethics Review Board of Wuhan Brain Hospital (General Hospital of the Yangtze River Shipping), and the intervention will be discontinued for the participant reporting adverse events. The control group will receive no additional exercise training during the study period. All the participants will be asked to maintain their normal lifestyle during the training and follow-up period.

Outcome variables

The primary outcome is TUG, whereas the secondary outcomes are handgrip muscle strength, five-repetition sit-to-stand test (5STS), 10MWT, as well as the serum albumin and haemoglobin levels. Both primary and secondary outcomes will be measured at baseline, post-intervention (1 day after training completion) and 12 weeks after training completion. To promote the retention, all the assessments will be provided free of cost, and transportation fee will be reimbursed. The study plan for recruitment, interventions and assessment for participants is summarised in [table 1](#).

The TUG was recommended as a suitable assessment for balance and physical function in older people with low muscle function.²⁵ The participants will perform this test with their regular footwear. They will stand up from an armchair, walk a distance of 3 m, turn and walk back to the chair and sit down with their normal pace without taking help from another person. The average time of the two trials will be used for data analysis.

The 5STS is a reliable and valid assessment for physical function in older people.²⁵ The participant will sit on a chair of 43–47-centimetre height, with back against the chair, arms crossed on the chest and feet comfortably placed on the floor. When the tester will say ‘start’, the participant will rise from the chair to assume a full standing position and return to a sitting position, and this action will be repeated five times without rest in between. The time taken to complete

Table 1 Timetable of activities planned during the study

Timepoint	Study period				
	Enrolment	Allocation	Post-allocation		Close-out
	Day 0	Week 0	Week 12	Week 24	After week 24
Enrolment					
Eligibility screen	X				
Informed consent	X				
Randomisation	X				
Allocation	X				
Interventions					
Flexi-bar group		←————→			
Sham group		←————→			
Control group		←————→			
Assessments					
Timed-up-and-go test		X	X	X	
10-metre walking test		X	X	X	
Five-repetition sit-to-stand test		X	X	X	
Handgrip strength		X	X	X	
Serum albumin		X	X	X	
Haemoglobin		X	X	X	

the test will be recorded, and the average time of the two tests will be calculated.

The 10MWT will be assessed at a self-preferred and maximum walking speed. It is used as a golden tool to evaluate the mobility in the older people.²⁵ The time will be measured only for the middle 6 m. Walking aid is allowed in this test. The average walking speed of three trials will be for the data analysis.

The handgrip strength of the dominant side will be measured using a hand-held dynamometer (kg; CAMRY Model EH101). Participants will be instructed to stand straight, with arms close to the body and the elbow flexed at 90°. The participants will then be asked to squeeze the dynamometer as hard as possible. The maximum value of the three trials will be used for analyses.

The serum albumin and haemoglobin levels will be measured. Blood will be collected from the antecubital vein, with participants seated after a 12-hour fasting period. After collection, the tubes containing ethylenediamine tetraacetic acid and samples will be centrifuged at 3000g for 15 min, and plasma aliquots will be stored at -70°C until analysis.

Sample size calculation

To date, no study has examined the long-term effects of flexi-bar training in older people with dynapenia. Thus, this study adopted an effect size of 0.27 to estimate the sample size, as reported in a previous study investigating the effects of 12-week power training programme on TUG in older people with dynapenia.¹⁴ Since this study involved two factors (two groups and three times of

assessments), the sample size calculated using a software (GPower V.3.1) was 30 for each group, with a power of 0.8 and an α value of 0.05. Considering a 20% dropout rate, the total sample size will be 114.

Patient and public involvement

Patients or members of the public will not be involved in this study. The research design, enrolment, allocation, interventions and assessments will be conducted by trained researchers.

Data analysis

To compare the baseline characteristics of the three groups, one-way analysis of variance (ANOVA) (for data with normal distribution) or Kruskal-Wallis test (for data with non-normal distribution) will be conducted. Two-way repeated-measures ANOVA (time \times group) or Friedman test will be used to explore the effect of flexi-bar training. The last observation carried forward (LOCF) of an intention-to-treat (ITT) analysis, will be used for data analysis. Descriptive analyses will be reported as means \pm SD. SPSS V.20.0 will be used for statistical analyses. The significance level will be set at $p < 0.05$, unless stated otherwise.

Ethics and dissemination

The procedures of this study were reviewed and approved by the Human Ethics Review Board of Wuhan Brain Hospital (General Hospital of the Yangtze River Shipping) on 29 September 2020 (#L20200013). The findings of this study will be published in peer-reviewed



journals and presented at conferences. Meanwhile, the results will be disseminated to the study participants.

DISCUSSION

To the best of our knowledge, this study is the first to investigate the effects of flexi-bar training on muscle strength and physical performance in older people with dynapenia. Two studies have investigated the effects of flexi-bar training on the physical performance in the older population.^{21 22} The authors reported that the performance in TUG and 10MWT was improved after long-term flexi-bar training.²¹ However, these studies had no placebo group. Thus, drawing a conclusion from these two studies is inappropriate.

Some studies have indicated that older people with low muscles strength exhibit low levels of albumin and haemoglobin.^{26–28} One population-based cross-sectional study reported that serum albumin and haemoglobin levels are associated positively with muscle strength and balance but negatively with instrumental activities of daily living in the community-dwelling population aged 55 years and more.²⁶

This study has some strengths. First, this study is the first to investigate the effects of flexi-bar training on muscle strength and physical performance in older population with dynapenia. In this study, we will attempt to determine whether a 12-week flexi-bar training programme would influence the levels of albumin and haemoglobin, which might explain the effect of flexi-bar training on the muscle strength in older people with dynapenia. Second, this study will involve a placebo group, which can rule out the effect of static squatting.

The study will have some limitations. First, the muscle loading might not be unified since the flexi-bar is an individual-activ-induced training device. However, the physical therapist will ask the participants to try their best to activate the flexi-bar during training. If participants do not try their best, the flexi-bar will stop vibrating. In this case, the therapist will remind the participants to activate the flexi-bar more intensively. Considering that the participants in our study might be at a different level of health condition, training them with individual efforts is an effective and safe approach. Thus, uniform muscle loading might not be suitable for our participants. Second, the sample size might be insufficient for assessing the secondary outcomes. In this protocol, the sample size will be calculated according to the effect size of the primary outcome. However, whether the sample size is adequate for each secondary outcome remains uncertain. Third, due to practical consideration, this study is designed as a single-blinded randomised controlled trial and not as a double-blinded trial.

Acknowledgements We thank doctors, nurses and physical therapists of the Department of Rehabilitation of Wuhan Brain Hospital (General Hospital of the Yangtze River Shipping) for their support in planning this study.

Contributors NW made substantial contributions to conception and design, and drafted the manuscript. XW, ML and LC will collect and analyse data.

Funding This work was supported by the Natural Science Foundation of Hubei Province (project number: #2019CFB349).

Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not required.

Provenance and peer review Not commissioned; externally peer reviewed.

Open access This is an open access article distributed in accordance with the Creative Commons Attribution Non Commercial (CC BY-NC 4.0) license, which permits others to distribute, remix, adapt, build upon this work non-commercially, and license their derivative works on different terms, provided the original work is properly cited, appropriate credit is given, any changes made indicated, and the use is non-commercial. See: <http://creativecommons.org/licenses/by-nc/4.0/>.

ORCID iD

Ning Wei <http://orcid.org/0000-0002-7827-375X>

REFERENCES

- Clark BC, Manini TM. Sarcopenia =/≠ dynapenia. *J Gerontol A Biol Sci Med Sci* 2008;63:829–34.
- Borges VS, Lima-Costa MFF, Andrade FBde. A nationwide study on prevalence and factors associated with dynapenia in older adults: ELSI-Brazil. *Cad Saude Publica* 2020;36:e00107319.
- Tessier A-J, Wing SS, Rahme E, et al. Physical function-derived cut-points for the diagnosis of sarcopenia and dynapenia from the Canadian longitudinal study on aging. *J Cachexia Sarcopenia Muscle* 2019;10:985–99.
- Clark BC, Manini TM. What is dynapenia? *Nutrition* 2012;28:495–503.
- da Cunha Leme DE. Dynapenia in middle-aged and older persons with and without abdominal obesity and the complex relationship with behavioral, physical-health and mental-health variables: learning Bayesian network structures. *Clin Nutr ESPEN* 2021;42:366–72.
- Gadelha AB, Neri SGR, Vainshelboim B, et al. Dynapenic abdominal obesity and the incidence of falls in older women: a prospective study. *Aging Clin Exp Res* 2020;32:1263–70.
- Hasselgren L, Olsson LL, Nyberg L. Is leg muscle strength correlated with functional balance and mobility among inpatients in geriatric rehabilitation? *Arch Gerontol Geriatr* 2011;52:e220–5.
- Manini TM, Visser M, Won-Park S, et al. Knee extension strength cutpoints for maintaining mobility. *J Am Geriatr Soc* 2007;55:451–7.
- Xue Q-L, Walston JD, Fried LP, et al. Prediction of risk of falling, physical disability, and frailty by rate of decline in grip strength: the women's health and aging study. *Arch Intern Med* 2011;171:1119–21.
- Newman AB, Kupelian V, Visser M, et al. Strength, but not muscle mass, is associated with mortality in the health, aging and body composition study cohort. *J Gerontol A Biol Sci Med Sci* 2006;61:72–7.
- Penninx BWJH, Pahor M, Cesari M, et al. Anemia is associated with disability and decreased physical performance and muscle strength in the elderly. *J Am Geriatr Soc* 2004;52:719–24.
- Schalk BWM, Deeg DJH, Penninx BWJH, et al. Serum albumin and muscle strength: a longitudinal study in older men and women. *J Am Geriatr Soc* 2005;53:1331–8.
- Barbat-Artigas S, Filion M-E, Dupontgand S, et al. Effects of tai chi training in dynapenic and nondynapenic postmenopausal women. *Menopause* 2011;18:974–9.
- Carvalho LP, Pion CH, El Hajj Boutros G, et al. Effect of a 12-week mixed power training on physical function in dynapenic-obese older men: does severity of dynapenia matter? *Aging Clin Exp Res* 2019;31:977–84.
- Correa CS, Cunha G, Marques N, et al. Effects of strength training, detraining and retraining in muscle strength, hypertrophy and functional tasks in older female adults. *Clin Physiol Funct Imaging* 2016;36:306–10.
- Yamada M, Kimura Y, Ishiyama D, et al. Synergistic effect of bodyweight resistance exercise and protein supplementation on skeletal muscle in sarcopenic or dynapenic older adults. *Geriatr Gerontol Int* 2019;19:429–37.
- Mileva KN, Kadr M, Amin N, et al. Acute effects of Flexi-bar vs. Sham-bar exercise on muscle electromyography activity and performance. *J Strength Cond Res* 2010;24:737–48.
- Lee S-J, Kim Y-N, Lee D-K. The effect of flexi-bar exercise with vibration on trunk muscle thickness and balance in university students in their twenties. *J Phys Ther Sci* 2016;28:1298–302.

- 19 Chung SH, You YY, Lee HJ, *et al.* Effects of stabilization exercise using flexi-bar on functional disability and transverse abdominis thickness in patients with chronic low back pain. *J Phys Ther Sci* 2018;30:400–4.
- 20 Phanpheng Y, Hiruntrakul A, Phanpheng Y. Effects of flexi bar training model to health-related physical fitness in overweight adults. *J Phys Ther Sci* 2020;32:489–95.
- 21 Lee D-K, Han J-W. Effects of active vibration exercise using a Flexi-Bar on balance and gait in patients with chronic stroke. *J Phys Ther Sci* 2018;30:832–4.
- 22 Lee D-K, Kim Y-N, Park C-B, *et al.* The effect of actively induced vibration using shoulder joint on pain and dysfunction in patients with low back pain. *J Phys Ther Sci* 2018;30:23–6.
- 23 Kim J-H, So K-H, Bae Y-R, *et al.* A comparison of Flexi-bar and general lumbar stabilizing exercise effects on muscle activity and fatigue. *J Phys Ther Sci* 2014;26:229–33.
- 24 Chen L-K, Liu L-K, Woo J, *et al.* Sarcopenia in Asia: consensus report of the Asian Working group for sarcopenia. *J Am Med Dir Assoc* 2014;15:95–101.
- 25 Wei N, Pang MY, Ng SS, *et al.* Optimal frequency/time combination of whole body vibration training for developing physical performance of people with sarcopenia: a randomized controlled trial. *Clin Rehabil* 2017;31:1313–21.
- 26 Aung KCY, Feng L, Yap KB, *et al.* Serum albumin and hemoglobin are associated with physical function in community-living older persons in Singapore. *J Nutr Health Aging* 2011;15:877–82.
- 27 Lee HN, Chang YS, Wu YH, *et al.* Sarcopenia in female patients with Alzheimer's disease are more likely to have lower levels of haemoglobin and 25-hydroxyvitamin D. *Psychogeriatrics* 2020;20:858–64.
- 28 Can B, Kara O, Kizilarlanoglu MC, *et al.* Serum markers of inflammation and oxidative stress in sarcopenia. *Aging Clin Exp Res* 2017;29:745–52.