Clinical Interventions in Aging
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CLINICAL TRIAL REPORT

Graded Progressive Home-Based Resistance Combined with Aerobic Exercise in Community-Dwelling Older Adults with Sarcopenia: A Randomized Controlled Trial

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Purpose: This randomized parallel controlled trial aimed to determine the effectiveness of graded progressive home-based resistance combined with aerobic exercise in improving physical fitness in community-dwelling older adults with sarcopenia.
Patients and Methods: Community-dwelling older adults (≥60 years) with sarcopenia were randomly assigned to the intervention group (IG), receiving 12 weeks of graded progressive home-based resistance and aerobic exercise training, and the control group (CG), maintaining lifestyle unchanged. The primary outcomes were knee extensor muscle strength and the six-minute walk distance (6MWD). Intention-to-treat analysis was applied to the data from all participants in the CG and IG. Post-intervention differences between the intervention and control groups were determined using a generalized estimated equation model with pre-values adjusted.
Results: Data from all the participants in the IG (n=41) and CG (n=45) were analyzed. After the intervention, knee extensor muscle strength (95% CI: 0.140–3.460, *P*=0.036), 6MWD (95% CI: 35.350–80.010, *P*<0.001), flexor muscle strength and the results of 30s bicep curls, 30s chair stand, the chair sit and reach test and back stretch test in the IG were larger and value of the timed up-and-go test was smaller than those in the CG (*P*<0.05). The body composition, quality of life and their changes showed no group differences. The attendance rates were 82.9% and 85.4% for resistance and aerobic exercise, respectively.
Conclusion: The 12-week graded progressive home-based resistance and aerobic exercise intervention improved muscle strength, balance, flexibility, and cardiorespiratory fitness in community-dwelling older adults with sarcopenia, whereas body composition and quality of life remained unchanged. The research was approved by the Ethics Committee of Soochow University (ECSU-2019000161) and registered at the Chinese Clinical Trial Registry (ChiCTR1900027960, http://www.chictr.org.cn/showproj.aspx?proj=45968).
Keywords: physical function, muscle strength, multicomponent exercise, walking, skeletal muscle disease

Introduction

Sarcopenia is a disease characterized by age-related progressive loss of skeletal muscle mass plus loss of muscle strength and/or reduced physical performance.[1] Due to reduced muscle strength and physical function, sarcopenia is associated with various adverse health outcomes including increased mortality rate, cognitive impairment, osteoporosis, falls, fractures, functional decline, hospitalization, metabolic syndrome, depression, frailty, etc.[2] Apart from age, many risk factors, including lifestyle factors of physical inactivity, malnutrition, smoking, extreme sleep duration, chronic disease

Received: 25 April 2024
Accepted: 6 September 2024
Published: 26 September 2024

factors of diabetes and osteoporosis, and other health status including inflammation,[3] oxidative stress, and mitochondrial dysfunction[4] etc. are found to be associated with increased risk of sarcopenia.[2]

Evidence-based clinical practice guidelines provide strong recommendations for physical activity and exercise as the primary treatment for sarcopenia.[5] Being a well-established countermeasure against sarcopenia, exercise has been shown to attenuate age-related decreases in muscle health, and improve quality of life in patients with sarcopenia.[6,7] Additionally, exercise can influence most of the risk factors and consequences related to sarcopenia.[8–10] Thereby, exercise should be emphasized as part of a lifestyle essential to healthy aging and sarcopenia prevention and rehabilitation.

Currently, resistance exercise is recommended as the first-line treatment for sarcopenia in older adults because of its favorable effects on muscle mass, strength and function.[5] Aerobic (or endurance) exercise, apart from increasing aerobic capacity and elevating muscle endurance, can significantly promote muscle mitochondrial biogenesis,[8] attenuated oxidative stress[9] and inflammation,[10] which may indirectly benefit muscle hypertrophy in patients with sarcopenia. It is recommended to consider multicomponent interventions or combined resistance and aerobic exercise to impact different aspects of physical function in the elderly.[11,12]

The evidence-based clinical practice guidelines for sarcopenia were published in 2018. However, only resistance exercise was referred within physical activity or exercise intervention strategy without aerobic exercise to be mentioned.[5] Currently, the optimal exercise pattern, intensity, duration, and frequency for older adults with sarcopenia are not known. More research is needed to explore the effect of exercise therapy regimens in sarcopenia.[13] Additionally, due to the differences in lifestyle and exercise habits among populations in different regions, it remains to be explored whether some exercise programs that have achieved good intervention effects in some populations are actually feasible and effective in Chinese patients with sarcopenia. Furthermore, adherence to the exercise protocols was mostly not reported in previous studies, which impacts the assessment of the real effect of exercise on muscle features.[7] The best physical exercise is the one that is actually carried out. However, exercise adherence is often poor in community-dwelling older adults, especially those who have low levels of physical fitness. One study of a 12-week exercise intervention in community-dwelling older adults showed that only approximately 50% of the participants completed 70% of the exercise.[14] In another study of older adults in frail and prefrail status, the exercise attendance rate was only 68.75% in a multicomponent exercise intervention that lasted 6 weeks.[15] With the poor adherence rate, many studies included only the participants with good compliance in statistical analyses, which may exaggerate the effect of the intervention program.[16–18]

To address the above issues, the following aspects were paid attention to when we were designing the exercise intervention in this study. Firstly, the exercise should be multicomponent to maximize beneficial effects on physical fitness in patients with sarcopenia. Secondly, the exercise should be individualized and gradually progressed, in which each participant can choose a suitable level of exercise based on his/her physical fitness capacity. Finally, the choice of exercise time and location needs to be highly flexible, and the exercise should be easy to perform without special equipment required. Based on these considerations, we aimed to study the effect of a graded home-based multicomponent exercise program in Chinese community-dwelling patients with sarcopenia and used intention-to-treat analysis for data statistic to evaluate whether the exercise program could improve physical fitness, body composition, and quality of life.

Material and Methods

Study Design

This is a randomized parallel controlled trial. Older adults with sarcopenia in the community were randomly allocated to the control group (CG) and the intervention group (IG) at a ratio of 1:1. The IG received one-on-one exercise coaching over 12 weeks. For assessment of the intervention effect, data at baseline and 12 weeks post-intervention were collected. This study was conducted in compliance with the guidelines stated in the World Medical Association (WMA) Declaration of Helsinki. The research was approved by the Ethics Committee of Soochow University approved (ECSU-2019000161) and registered at the Chinese Clinical Trial Registry (ChiCTR1900027960, http://www.chictr.org.cn/showproj.aspx?proj=45968). Reporting abides by the CONSORT reporting guidelines.[19]

Participants

The participants were recruited from communities in Suzhou between July 2020 and October 2020. The inclusion criteria were as follows: (1) 60 years of age or older; (2) meeting the diagnostic criteria for sarcopenia from the Asian Sarcopenia Working Group (ASWG):[1] ① grip strength in males <28 kg, in females <18 kg and/or usual gait speed (six-meter gait speed, 6MGS) ≤1.0 m/s; ② skeletal muscle mass index (SMI) in males <7.0 kg/m^2 and in females <5.7 kg/m^2. Individuals were excluded if they (1) were unable to perform body composition measurements, (2) had regular exercise habits (resistance exercise ≥2 times a week and moderate-intensity aerobic exercise ≥3 times a week);[20] (3) had exercise contraindications, or (4) were incapable of understanding or speaking Mandarin (some older adults only speak the local dialect of Suzhou, which makes communication difficult with researchers). The withdrawal criteria were incapability, unsuitability, or unwillingness to continue the study for subjective or objective reasons. All the participants were fully informed of the research purpose, content, and risks before signing a consent form.

Sample Size

The sample size was estimated using the PASS 11 with the method of [Tests for Two Means (Two-Sample *T* Test) Differences] with the primary outcome of knee extensor muscle strength. The mean value and standard deviation (SD) of the knee extensor muscle strength were 16.45 and 5.82 at baseline and 19.73 and 5.07 after intervention based on the results of the previous preliminary experiment (unpublished). The bilateral test was adopted with α=0.05, and 1-β=0.08. The calculated result was n1=n2≈44. Assuming an attrition rate of 15%, a total number of 52 participants were required per group, resulting in 104 participants in this study.

Randomization Procedure and Blinding

A simple randomization method was used for grouping. A set of random numbers was generated using IBM SPSS 23.0 statistical software. The random sequence was maintained by a third party who was not involved in the intervention. Odd numbers were assigned to the CG and even numbers to the IG. The random sequence was placed in opaque and sealed envelopes that were opened after the baseline measurements. The researchers who were responsible for assessing outcomes and performing statistical analysis were blinded to the grouping and intervention.

Intervention

Participants in the CG were asked to maintain their usual lifestyles. Researchers telephoned them monthly throughout the intervention period to learn about and record any change in their lifestyle.

Participants in IG accepted the combined home-based progressive resistance training and aerobic walking exercise intervention for 12 weeks. The exercise was originally adopted from a previously published program applied to patients aged ≥70 years scheduled to receive first-line chemotherapy for newly diagnosed, advanced pancreatic, or non-small-cell lung cancer[21] and modified through expert consultation and pre-trial (more details are provided in the supplementary materials). The main modifications based on expert consultation and pre-trial included adding upper limb movements in resistance exercise, elevated resistance exercise loads, decreased required exercise frequency, and redefining the aerobic walking exercise as at least 10 minutes of continuous walking (the walking steps within these continuous walking instead of any discrete steps was defined as effective walking steps). See eDocument 1 for the program formation and the QR code link of the exercise intervention atlases and videos (eFigure 1).

The individualized resistance exercise program consisted of three to seven of the following exercise components: ①standing hip flexion, ②straight arm lift, ③sit-to-stand, ④chest expansion, ⑤knee extension, ⑥side leg raise, and ⑦calf raise. Four levels were prepared as follows:

Level 1: ① ② ③.
Level 2: ① ② ③ ④ ⑤.
Level 3: ① ② ③ ④ ⑤ ⑥ ⑦.

Level 4: ① ② ③ ④ ⑤ ⑥ ⑦ plus 0.5 kg and 1.0 kg external loads with sandbag for each side of the upper and lower limbs, respectively. The loads could be gradually increased by every 0.5 kg on each side of the limbs when necessary. Before being assigned to the participants, the sandbags were checked in the lab to ensure the correct weight.

On the first day of the week before the intervention, the researcher visited and instructed the participants to learn resistance exercise movements and provided them with a training atlas and video. After one week, the instructor checked whether the movements could be performed correctly during the second visit. When the movements were completed correctly, the participants were instructed to complete Level 2 exercises. Rating of perceived exertion (RPE) was assessed immediately after exercise. When RPE was within 12–14, the current exercise would be maintained, when RPE > 14, it was reduced by one level, and when RPE < 12, it was increased by one level. RPE evaluation and exercise level adjustment were performed once every four weeks.

The aerobic exercise program was divided into three levels in which the target walking steps were increased from level 1 to 3. The prescribed level for each participant was based on his/her baseline daily steps. When counting the target walking steps and baseline daily steps, only effective walking steps (defined as walking steps that continuously lasted for more than 10 minutes) were included. Three levels of walking were prepared as follows:

Level 1: The target walking steps per day were 2000 steps, and used for individuals with baseline daily steps of ≤2000.

Level 2: The target walking steps per day were set to be the baseline steps plus 1000 steps with a maximum of 8000 steps and used for individuals with the baseline daily steps of 2001 to 7999.

Level 3: The target walking steps were the same as the baseline level, for those individuals with baseline daily steps ≥8000 steps.

The researcher visited the participant in the week before the intervention for the first time, provided the pedometer (Omron HJ-208) and taught them how to use it. The participants were required to wear the pedometer for at least 5 hours per day. At the second visit, after one week, the researcher checked the daily effective walking steps of the previous week to learn the baseline daily steps, and the aerobic walking level was determined accordingly. The participants were required to reach the target steps for at least three days every week. Reassessment and adjustment were performed once every four weeks. See the eDocument 1 for additional information about the intervention.

Each individual was provided with one level of resistance exercise and one level of aerobic exercise based on their current exercise habits and physical fitness levels. The choice of resistance exercise levels was adjusted based on the participants' RPE score, and aerobic exercise was adjusted by RPE scores and heart rate (HR), which were evaluated every four weeks. For those who could not accurately record these parameters, researchers would come to their homes weekly to assist with measurements and recordings.

Weekly telephone follow-up was conducted to inquire about exercise execution, and monthly on-site follow-up was implemented to reassess physical fitness and the suitability of the selected exercise level and ensure accurate recording of the exercise diary.

Outcome Measurements

A self-designed questionnaire containing sociodemographic data, health-related data (including comorbid chronic diseases, history of trauma, weight loss and so on), and lifestyle information (Table 1) was filled out during a face-to-face interview. Among the questions investigated, weight loss referred to weight loss of at least 5% in one year or less,[22] smoking habit referred to smoking ≥1 time per week for 6 months or more in a year,[23] alcohol drinking was defined as drinking ≥1 time per week over the past year,[24] and exercise habit was defined as exercising >1 time per week for 30 minutes or more each time (Previous research has pointed out that regular exercise refers to 20 minutes or more at least 3 times/week).[25] The participants were asked to choose the appropriate option according to their actual situation. The willingness to exercise was scored by the participants within the range of 0–100, with a higher score representing a higher willingness.

Physical Fitness

Physical fitness measurements included tests of knee extensor and flexor muscle strength, six-minute walk distance (6MWD), 30s bicep curl, 30s chair stand, timed up-and-go, time of one-leg stand with eyes closed, back scratch, chair sit, and reach test. Among them, knee extensor muscle strength and the 6MWD were considered the primary outcomes.

Table 1 Basic Characteristics of Participants, Mean±SD or n (%)

Item	Total	CG	IG	*P*
Number	86	45	41	
Sex				0.297
Men	30 (34.9)	18 (40.0)	12 (29.3)	
Women	56 (65.1)	27 (0.0)	29 (70.7)	
Age (years)	74.2±5.88	75.6±6.35	74.2±4.67	0.055
Height (m)	1.57±0.08	1.56±0.08	1.58±0.08	0.422
Weight (kg)	50.8±7.20	50.8±6.46	50.9±8.01	0.925
BMI (kg/m^2)	20.6±2.16	20.7±1.89	20.4±2.43	0.515
Educational level				0.678
Primary and below	28 (32.6)	15 (33.3)	13 (31.7)	
Secondary school	50 (58.1)	27 (60.0)	23 (56.1)	
College and above	8 (9.3)	3 (6.7)	5 (12.2)	
Marital status				0.055
Married	51 (70.8)	19 (55.9)	32 (84.2)	
Other	21 (29.2)	15 (44.1)	6 (15.8)	
Residence				0.101
Solitary	22 (25.6)	16 (35.6)	6 (14.6)	
Residence with spouse	54 (62.8)	23 (51.1)	31 (75.6)	
Residence with spouse and children	10 (5.4)	6 (13.3)	4 (9.8)	
Comorbidities				0.797
Yes	47 (54.7)	24 (53.3)	23 (56.1)	
No	39 (45.3)	21 (46.7)	18 (43.9)	
Hypertension				0.370
Yes	40 (46.5)	23 (51.1)	17 (41.5)	
No	46 (53.5)	22 (48.9)	24 (58.5)	
Diabetes				0.126
Yes	19 (22.1)	7 (15.6)	12 (29.3)	
No	67 (77.9)	38 (84.4)	29 (70.7)	
Hyperlipidemia				0.401
Yes	18 (20.9)	11 (24.4)	7 (17.1)	
No	68 (79.1)	34 (75.6)	34 (82.9)	
History of trauma				0.053
Yes	23 (26.7)	16 (35.6)	7 (17.1)	
No	63 (73.3)	29 (64.4%)	34 (82.9)	
Weight loss				0.776
Yes	26 (30.2)	13 (28.9)	13 (31.7)	
No	60 (69.8)	32 (71.1)	28 (68.3)	
Sleep status				0.883
Good	40 (46.5)	20 (48.8)	20 (44.4)	
General	23 (26.7)	11 (26.8)	12 (26.7)	
Poor	23 (26.7)	10 (24.4)	13 (28.9)	
Emotional status				0.420
Good	51 (59.3)	23 (56.1)	28 (62.2)	
General	28 (32.6)	13 (31.7)	15 (33.3)	
Poor	7 (8.1)	5 (12.2)	2 (4.4)	
Walking aids				0.344
Required	4 (4.7)	3 (6.7)	1 (2.4)	
Not required	82 (95.3)	42 (93.3)	40 (97.6)	
Smoking				0.625
Yes	11 (12.8)	6 (14.6)	5 (11.1)	
No	75 (87.2)	35 (85.4)	40 (88.9)	

(*Continued*)

Table 1 (Continued).

Item	Total	CG	IG	*P*
Alcohol drinking				0.298
Yes	13 (15.1)	8 (19.5)	5 (11.1)	
No	73 (84.9)	33 (80.5)	40 (88.9)	
Tea drinking				0.314
Yes	33 (38.4)	18 (43.9)	15 (33.3)	
No	53 (61.6)	23 (56.1)	30 (66.7)	
Coffee drinking				0.378
Yes	8 (9.3)	3 (6.7)	5 (12.2)	
No	78 (90.7)	42 (93.3)	36 (87.8)	
Exercise habits				0.146
Yes	54 (62.8)	29 (70.7)	25 (55.6)	
No	32 (37.2)	12 (29.3)	20 (44.4)	
Sedentary time (h)	3.88±1.93	4.08±2.12	3.65±1.70	0.311
Score of willingness to exercise	57.5±25.1	56.3±25.9	58.8±24.5	0.687

Note: IG= intervention group; CG= control group; BMI= body mass index.

The strength of knee extensor and flexor muscles was measured by MicroFET3™ Muscle Test Dynamometer and Inclinometer (Hoggan, 120382, USA). The participants sat and kept their hips and knees flexed at 90°. Verbal instructions specified in the standardized protocol[26] was provided. A submaximal practice trial was firstly performed to ensure correct movement. Thereafter, two trials were tested for each muscle group in the right limb with 1min interval time, and the higher value was recorded.

The 6MWD was used to assess cardiorespiratory fitness. Prior to the test, participants were asked to sit and rest for 10 minutes, thereafter blood pressure, HR, and RPE were measured. Participants were instructed to walk as fast as possible for six minutes without running or jogging in a 30-meter corridor. The distance walked per minute was also recorded. Testing was interrupted if threatening symptoms appeared, and the walking distance and time could be recorded. The blood pressure, HR, and RPE were retested immediately after the test. Standardized encouragement was provided in accordance with the recommendations of the American Thoracic Society.[27]

The 30s bicep curl times was used to assess the upper extremity functioning. Men used 8-pound dumbbells and women used 5-pound dumbbells, and the number of bicep curls completed within 30s was recorded.[28]

The 30s chair stand times was tested to evaluate lower extremity strength and function. Participants were asked to complete as many sit-to-stand movements as possible within 30 seconds on a 43 cm chair, and the number of times was recorded.[29]

The timed up-and-go (TUGT) was used to evaluate the dynamic balance. The participants were asked to stand up from a chair, walk 8 feet to and around the cone as fast as possible, and then return to the chair. After each trial, participants were measured twice and the time spent was averaged.[30]

One-leg stand with eyes closed was used to measure the static balance. The time the participants stood on one foot with their eyes closed without support was recorded. After each trial, the participants were measured twice, and the average value was used.

Back scratch and chair sit-and-reach tests were used as parameters for upper and lower body flexibility. Back scratch involves reaching behind the head with one hand and behind the back with the other, and trying to touch the middle fingers of both hands together behind the back. In the chair sit-and-reach test, the participants sat on the front edge of a chair and extended one leg straight out in front of the hip, with the foot flexed and heel resting on the floor (the other leg was bent, foot flat on the floor), to reach as far forward as possible toward (or past) the toes.[31]

Sarcopenia Diagnosis

According to the diagnostic criteria for sarcopenia defined by the AWGS, diagnostic indicators include SMI, grip strength, and 6MGS.[30]

The SMI was calculated as appendicular skeletal muscle mass (ASM)/height^2. ASM was assessed by bioelectrical impedance analysis (BIA) with a TANITA MC-180 device (Tokyo, Japan). Participants were instructed to avoid vigorous exercise and keep fast for three hours before the test, and shoes, socks, heavy clothing, and any magnetic object, such as cell phone, were removed immediately before the test. During the test, participants were asked to avoid chatting, keep hands and feet in close contact with the eight-electrode points, arms straight, and dropped maintaining a 15° angle with the trunk.[32] The tests before and after the intervention in each individual were performed under the same conditions to minimize the error caused by other factors.

Grip strength was assessed using a handgrip dynamometer (Jamar, 563213, USA).[33] Participants sat in a chair in a neutral position and the shoulder joint in a neutral position at 90° with the elbow joint. During testing, the participants maintained their dominant hand for as much as possible for three seconds. The participants were measured three times and the maximum value was used. The 6MGS was tested by asking participants to walk 10 meters at a normal speed, and the walking time (seconds) in the middle 6 meters was recorded for the calculation of 6MGS (m/s).

Body Composition

Body composition included muscle mass indicators (fat-free mass, muscle mass, trunk muscle mass, ASM, upper and lower limb muscle mass) and fat indicators (adiposity, body fat percentage, visceral fat content, subcutaneous fat content, trunk fat content, and extremity fat content) assessed by BIA with a TANITA MC-180 device (Japan). The test method was the same as that used for the ASM assessment.

Quality of Life

Health-related quality of life was measured using the Chinese version of the 36-item Short-Form Health Survey (SF-36).[34] The participants completed the questionnaire.

Adherence

Adherence comprises attendance and compliance. Attendance was measured based on the number of participants participating in the exercise program and the number of exercise diary fill-in days for both resistance and aerobic exercises. Resistance exercise compliance was measured by percent complete of resistance exercise movements (%) and the percentage of actual completed days (%). The resistance exercise movements percent complete (%) = (actual exercise groups per day ×actual repetitions per group ×actual exercise days)/ [prescribed exercise groups per day (3 groups) ×prescribed repetitions per group (10 repetitions) ×prescribed completed days]. Percentage of actual completed days (%) = actual completed days/prescribed days. Compliance of walking exercise was measured by the number of participants who reached the target steps and the percent complete of target steps. The percent complete of the target steps (%) = actual days that met the target steps per week/prescribed days that met the target steps per week.

Exercise Volume

Exercise volume in the three months before the experiment was measured using a modified amateur exercise volume questionnaire (see eTable 1 for details). The questionnaire was modified[35] based on the study results by Liao BG et al,[36] the exercise characteristics of the middle-aged and older adult populations, and the exercise habits of older adults. The participants selected the exercise program that they had done >2 times in the past 3 months and filled in the average number of exercises per month and the average time spent per exercise for each program. Exercise volume was calculated based on metabolic equivalents (METs) for each exercise program as defined by the American College of Sports Medicine (ACSM). Exercise volume (METs-h/week) = months × average number of exercises per month (times/ month) × average time spent exercising per month (minutes/time) × METs ÷ 60 min/h ÷ 13 weeks/quarter.

Data Collection and Statistical Analysis

All data were collected at the Hengjie Community Health Service Center in the Gusu District, Suzhou. Data analysis was performed using SPSS (version 23.0 (IBM, Armonk, NY, USA). Intention-to-treat analysis was applied to the data from 45 to 41 participants in the CG and IG groups, respectively. The Shapiro–Wilk test was used to test whether the numerical variable data were normally distributed. Data of numerical variables conforming to a normal distribution were expressed as mean±standard deviation (SD); otherwise, they were expressed as M (P_{25}, P_{75}). Categorical variable data were expressed as frequencies and percentages, n (%). Independent sample *t* and χ^2 tests were used for group comparisons of basic characteristics. A generalized estimated equation (GEE) model was applied to determine the differences between the intervention and control groups at post with adjusted pre values. $P < 0.05$ was set as statistically significant.

Results

Eighty-six participants (45 in the CG, 41 in the IG) aged 74.2±5.88 years old completed the study (Figure 1). Among the participants, 65.1% were women and 54.7% had one or more chronic diseases, including hypertension, diabetes, and hyperlipidemia. A total of 12.8% and 15.1% of participants had the habits of smoking and alcohol drinking respectively. The participants in the two groups showed no differences in their basic characteristics (Table 1). Two participants in the IG became non-sarcopenic after intervention.

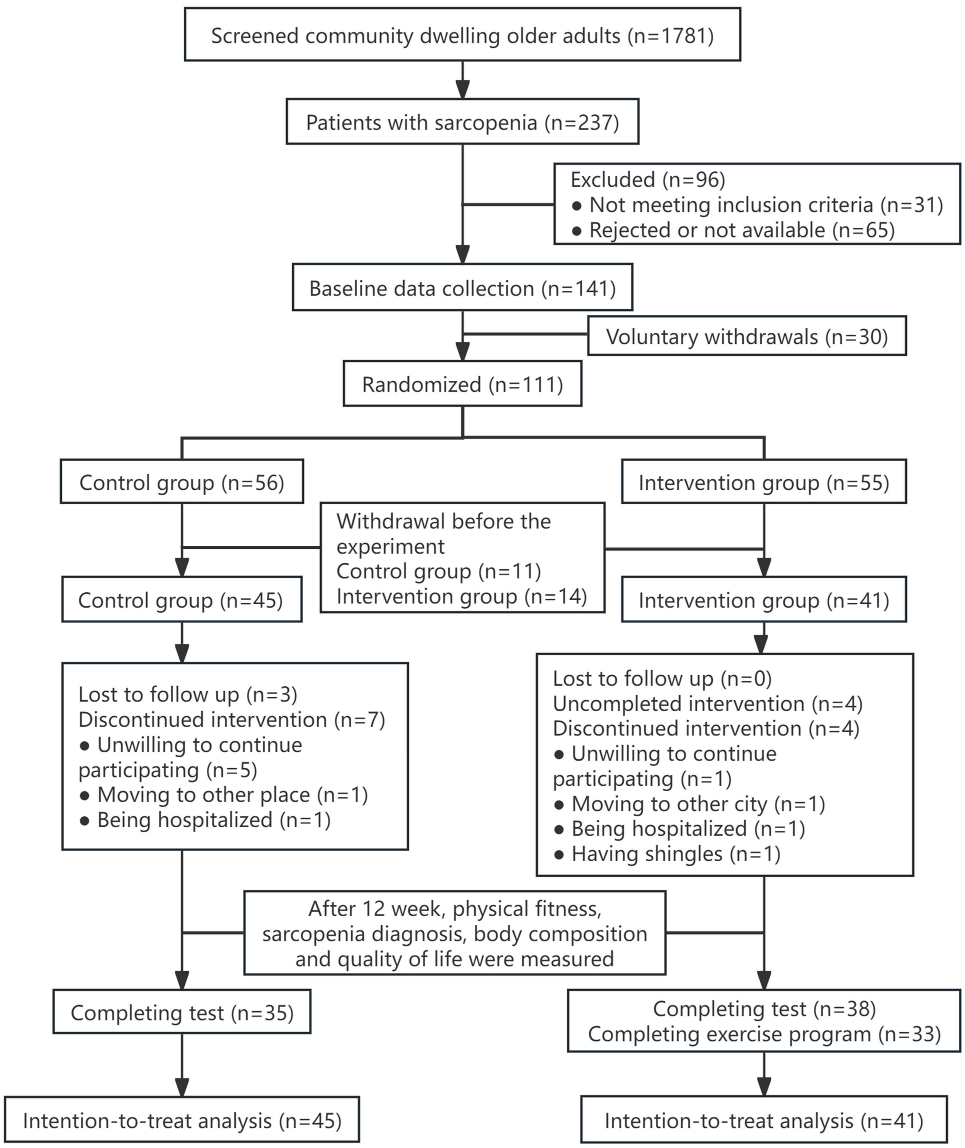

Figure 1 Flow chart of the study.

Physical Fitness

Analysis using the GEE model showed significant differences between the IG and CG with eight physical fitness parameters (knee extensors muscle strength, knee flexors muscle strength, 30s bicep curls, 30s chair stand test, 6MWD, TUGT, back scratch test and chair sit and reach test) among the total 11 tested (Table 2).

The knee extensor and flexor muscle strength, 30s bicep curl times, 6MWD, 30s chair stand times, back stretch, and chair sit and reach test results in the IG were larger, and the value of TUGT was smaller than those in the CG (P<0.05) (Table 2).

Handgrip strength, 6MGS, and one-leg standing time with eyes closed were not significantly different between the IG and CG (P>0.05). However, these parameters showed an improved trend in the intervention group after intervention (P = 0.059 for the one-leg standing test with eyes closed) (Table 2).

Apart from the above, we did additional subgroup and covariant analyses for the primary outcomes of knee extensor muscle strength and 6MWD with regard to the three parameters in baseline data including age, marital status and trauma history, which were close to be significantly different between the intervention and control groups (P = 0.055, 0.055 and 0.053) to examine their potential impact on the results. Firstly, subgroup analyses were performed and no statistical difference between the subgroups based on these parameters was found for the two primary outcomes (eTable 2). Secondly, with the three parameters as covariates, the primary outcome measures were compared between the intervention and control groups, and no statistical difference was found either (eTable 3).

Body Composition

Analysis using the GEE model showed no significant differences between the IG and CG in any of the body composition parameters. In IG, muscle-related indexes (fat-free mass, muscle mass, SMI, trunk muscle mass, upper limbs muscle mass and lower limbs muscle mass) showed an upward trend, while fat-related indexes (adiposity, body fat percentage, visceral fat content, subcutaneous fat content, trunk fat content and extremity fat content) showed a downward trend (Table 3).

Quality of Life

Similar to body composition, no significant differences between IG and CG were found in all the parameter of quality of life (the P value for the score of vitality was 0.074). However, in IG, physical functioning, role physical, bodily pain, role-emotional, mental health, vitality, social functioning and general health all showed an upward trend (Table 3).

Table 2 Physical Fitness Levels and Their Change in Two Groups, M(P25, P75)/Mean±SD

Group	*Pre*		*Post*		Mean Difference* (95% CI)	$P^{\#}$
	CG	IG	CG	IG		
Knee extensors muscle strength (kg)	16.0 (13.8,20.9)	16.3 (13.6,21.3)	15.1 (12.3,21.1)	18.9 (15.9,22.4)	1.800 (0.140–3.460)	**0.036**
Knee flexors muscle strength (kg)	11.3±3.15	11.1±3.08	11.4±3.53	12.5±3.67	1.250 (0.170–2.330)	**0.023**
30s bicep curls (reps.)	16.0 (14.0,18.0)	17.0 (15.0,19.0)	16.0 (14.0,19.0)	18.0 (16.8,19.3)	1.540 (0.500–2.58)	**0.004**
Handgrip strength (kg)	20.7 (16.2,27.3)	19.2 (16.9,26.6)	20.7 (15.3,30.1)	21.7 (19.0,28.0)	0.460 (−1.730–2.650)	0.680
30s chair stand test (reps.)	13.0 (11.0,16.0)	15.0 (13.0,17.0)	14.0 (12.0,17.3)	16.5 (14.0,19.0)	1.500 (0.240–2.760)	**0.019**
6MWD (m)	412.3±76.7	467.3±55.9	417.8±86.0	478.2±50.5	57.680 (35.350–80.010)	**<0.001**
6MGS (m/s)	0.93±0.13	0.93±0.13	0.96±0.15	1.04±0.13	0.039 (−0.010–0.087)	0.177
One leg standing test with eye closed (s)	1.86 (1.19,3.04)	2.55 (1.73,5.00)	1.69 (1.07,3.29)	2.38 (1.53,3.51)	0.820 (−0.030–1.680)	0.059
TUGT (s)	7.62 (6.59,9.11)	7.25 (6.37,7.91)	7.25 (6.48,8.69)	6.23 (5.80,7.05)	−1.220 (−1.770–0.66)	**<0.001**
Back scratch test (cm)	−7.94±9.09	−5.76±7.54	−9.79±9.90	−4.33±9.07	3.810 (0.910–6.700)	**0.010**
Chair sit and reach test (cm)	−6.36±7.31	−2.03±6.93	−7.81±9.88	0.24±7.18	6.190 (3.650–8.730)	**<0.001**

Notes: IG= intervention group; CG= control group; reps= repetitions; 6MWD= six-minute walk distance; 6MGS= six-meter gait speed; TUGT= timed up-and-go test. *: Mean difference between the intervention and control groups at post-with adjusted pre-values. #: Significance of the mean difference, and all the P values displayed in bold are smaller than 0.05.

https://doi.org/10.2147/CIA.S473081

Table 3 Body Composition and Health-Related Quality of Life in the Two Groups, M (P25, P75)/Mean±SD

Group	*Pre*		*Post*		Mean Difference (95% CI)	*P*
	CG	IG	CG	IG		
Body composition						
Fat-free mass (kg)	38.1 (32.0,44.9)	37.7±5.8	39.4 (36.5,43.7)	40.2±7.32	−0.590 (−3.440–2.250)	0.682
Muscle mass (kg)	35.6 (30.4,42.2)	34.3 (32.0,37.7)	37.1 (34.5,41.1)	36.3 (32.4,42.2)	−0.580 (−3.270–2.210)	0.673
Appendicular skeletal muscle mass (kg)	13.8 (11.8,16.8)	13.6 (12.4,16.0)	14.3 (12.7,17.0)	13.1 (12.3,15.3)	−0.250 (−1.490–0.990)	0.690
SMI (kg/m^2)	5.59 (5.41,6.04)	5.66 (5.42,6.37)	5.54 (5.30,5.84)	5.73 (5.56,6.22)	−0.245 (−0.542–0.052)	0.106
Trunk muscle mass (kg)	22.6 (18.4,25.3)	20.5 (19.7,23.6)	23.0 (21.1,25.7)	23.6 (20.1,25.7)	−0.330 (−1.940–1.280)	0.687
Upper limbs muscle mass (kg)	3.60 (2.95,4.15)	3.30 (2.90,3.65)	3.70 (3.30,4.20)	3.40 (2.92,3.80)	−0.170 (−0.510–0.180)	0.338
Lower limbs muscle mass (kg)	10.2 (9.00,12.6)	10.30 (9.40,11.67)	9.90 (9.33, 11.5)	10.4 (9.3,12.6)	−0.080 (−1.000–0.840)	0.859
Adiposity (kg)	11.6±5.44	13.0±4.74	12.1±3.96	11.2±4.70	0.240 (−1.590–2.080)	0.794
Body fat percentage (%)	22.8±10.1	25.2±7.73	23.0±6.79	22.0±7.73	0.500 (−2.570–3.570)	0.750
Visceral fat content (kg)	1.81±1.02	1.99±1.14	1.98±0.92	1.65±1.04	−0.080 (−0.470–0.310)	0.695
Subcutaneous fat content (kg)	9.76±4.48	11.0±3.73	10.1±3.17	9.49±3.73	0.330 (−1.160–1.820)	0.664
Trunk fat content (kg)	6.78±3.48	7.52±3.17	7.25±2.72	6.50±3.21	−0.007 (−1.229–1.215)	0.991
Extremity fat content (kg)	5.10 (3.10,6.50)	5.75 (4.18,6.43)	5.00 (4.40,5.70)	4.50 (3.65,5.80)	0.270 (−0.400–0.940)	0.431
Health-related quality of life						
Physical functioning	85.0 (75.0,90.0)	82.5 (70.0,90.0)	85.0 (75.0,90.0)	90.0 (80.0,95.0)	1.330 (−4.740–7.410)	0.667
Role physical	100.0 (25.0,100.0)	100.0 (43.8,100.0)	100.0 (50.0,100.0)	100.0 (50.0,100.0)	−1.530 (−14.580–11.510)	0.818
Bodily pain	84.0 (74.0,100.0)	79.0 (62.0,100.0)	84.0 (72.0,100.0)	84.0 (72.0,100.0)	−1.560 (−9.390–6.270)	0.695
Role-emotional	100.0 (66.7,100.0)	100.0 (100.0,100.0)	100.00 (66.7,100.0)	100.00 (66.7,100.0)	0.110 (−12.380–12.600)	0.986
Mental health	74.7±12.9	71.6±17.0	78.6±13.6	75.1±17.2	−3.370 (−9.530–2.790)	0.284
Vitality	75.0 (70.0,85.0)	75.0 (60.0,85.0)	80.0 (70.0,90.0)	77.5 (60.0,85.0)	−5.820 (−12.210–0.570)	0.074
Social functioning	112.5 (100.0,125.0)	118.8 (84.4,125.0)	125.0 (112.5,125.0)	125.0 (109.4,125.0)	−5.580 (−14.790–3.640)	0.236
General health	58.1±14.9	54.1±19.0	59.7±15.9	61.4±19.8	−1.120 (−8.550–6.300)	0.767

Notes: IG= intervention group; CG= control group; SMI= skeletal muscle mass.

Adherence to the Exercise Intervention

At baseline, 41 participants were enrolled, one dropped out after the screening examination because of moving away, and 40 (97.5%) participants attended the exercise intervention program. In the resistance exercise, six participants dropped out at different periods, and among them, one resumed later. A total of 34 participants attended 12 weeks of resistance training with an attendance rate of 82.9% (34/41). The resistance exercise diary fill-in days was (34.7±14.2) days, accounting for 82.9% of the prescribed 36 days (3 days/week × 12 weeks). During aerobic exercise, five participants dropped out during different periods and one of them returned later. A total of 35 participants attended 12 weeks of aerobic walking exercise with an adherence rate of 85.4% (35/41) (see eTable 4 for details). The number of aerobic walking exercise dairy fill-in days was (76.6 ±20.3) days, accounting for 85.4% of the prescribed 84 days (7 days/week × 12 weeks) (Table 4).

The percent complete for resistance exercise movements was 76.9%, and the actual completed days accounted for 95.9% of the prescribed days (Table 4).

In aerobic walking exercise, 13 participants met the target steps. The days reaching the target steps accounted for 83.3% of the prescribed days. Records showed an increasing trend in effective walking steps, time, and physical activity steps and times during the intervention period. However, no significant differences were observed (P >0.05) (Table 4).

Exercise Volume

Exercise volume was similar in the two groups before the intervention [CG: 9.35±9.73 (METs-h/week), IG: 7.65±7.17 (METs-h/week), P>0.05)], and was significantly larger in the IG [18.46±12.83 (METs-h/week)] than in the CG [7.65±7.17 (METs-h/week)] after the intervention (P < 0.01).

Adverse Events

During the intervention period, muscle soreness was reported in six participants after the exercise. Soreness gradually disappeared with a reduction in exercise volume in the sore muscles and did not have an impact on health status (see eTable 5 for details).

Table 4 Adherence to the Exercise Intervention, Mean±SD or n (%)

Item	1st ~4th week	5th ~ 8th week	9th ~12th week	1st ~ 12th week
Resistance training				
Participants [n (%)]	40 (97.6)	36 (87.8)	35 (85.4)	34 (82.9)
Exercise diary fill-in days[a] (d)	12.0±4.24	11.5±5.01	11.2±5.56	34.7±14.2
Percent complete of exercise movements[b] (%)	91.7 (62.5,100)	84.7 (43.7,100)	74.9 (30.0,100)	76.9 (48.3,100)
Actual completed days/prescribed days[c] (%)	437/480 (91.0)	381/432 (88.2)	357/420 (85.0)	1175/1224 (95.9)
Aerobic exercise				
Number of participants [n (%)]	40 (97.5)	36 (87.8)	36 (87.8)	35 (85.4)
Exercise diary fill-in days[d] (d)	25.9±5.43	25.7±7.51	25.3±7.52	76.6±20.3
Number of participants reached target steps	17 (42.5)	16 (44.4)	16 (44.4)	13 (36.1)
Percent complete of target steps[e]	70.8 (29.2,131.2)	83.3 (18.7,114.1)	70.8 (10.4,125)	83.3 (38.8,110.3)
Effective walking steps (steps/day)	2913±2070	2804±2185	3207±2308[††]	2941±2101
Effective walking time (minutes/day)	26.5±18.9	26.3±20.3	28.8±21.6[††]	26.9±19.5
Physical activity walking steps (steps/day)	6998±2761	6635±3448	6562±3611[††]	6732±3119
Physical activity walking time (minutes/day)	160.3±65.8	142.7±78.7	148.3±79.3[††]	150.4±69.7

Notes: [a,d]Expected exercise diary fill-in days (3 days per week × number of weeks) for the four periods were 12, 12, 12, and 36 days, respectively. [b]Percent complete of exercise movements = (actual exercise groups per day × actual repetitions per group × actual exercise days)/[prescribed exercise groups per day (3 groups) ×prescribed repetitions per group (10 repetitions) × prescribed completed days] [c]Actual completed days = actual completed days × total number of subjects completed in this period, prescribed days = prescribed completed days × total number of subjects completed in this period.[e]Percent complete of target steps = actual days met the target steps per week/required days met the target steps per week (three days). [††]There were no significant differences in one-way repeated-measures analysis of variance for the four periods.

In addition, three unforeseen incidents (one bone spur, one lumbar disc herniation, and one hospitalization) were reported by three participants during the intervention. These three participants were hospitalized for treatment and the incidents were determined to be unrelated to the study after the doctors' examination.

Discussion

In our study, a home-based progressive aerobic combined with resistance exercise program was applied to community-dwelling older adults with sarcopenia for 12 weeks, and was found to be effective in improving multiple aspects of physical fitness, including muscle strength and function, cardiorespiratory fitness, balance, and flexibility. However, it did not exert significant benefits on body composition or quality of life.

As a major result, we found that the knee extensor and flexor muscle strength, 30s chair stand and 30s bicep curl times in the IG were significantly larger than those in the CG after intervention, which indicated the remarkable beneficial effects of the exercise intervention on muscle strength and function. The resistance exercise applied in our study included both lower and upper limb movements, and the sandbag load was individually adjusted every four weeks. These may result in the increase in all the parameters of muscle strength and function we tested. However, we cannot exclude the contribution of the combined aerobic walking exercises. The improvement in lower limb muscle strength may also be attributed to aerobic walking exercises in the program. Hayao et al[37] found that 17 weeks of progressive walking exercise improved knee extensor and flexor muscle strength in older adults without regular exercise, whereas the intervention group with additional stair climbing did not show better results than the single walking group, suggesting that regular walking exercise can improve lower-extremity muscle function in older adults. In our study, the upper limb resistance training movements (straight arm lift, chest expansion) primarily target the isotonic strength of the arm and back muscles, respectively. This may explain why there was no significant change in handgrip strength, a measure of isometric muscle strength.

The 6MWD is now recognized as an important indicator for evaluating cardiopulmonary fitness and daily living ability.[27] In our study, the intervention showed an improvement effect on the 6MWD, which was similar to the results of muscle strength mentioned above. The 6MWD is closely associated with lower limb muscle strength,[38] thereby, it is not surprising to see improved 6MWD when there is an increase in lower limb muscle strength. Consistently, the study among older Thai individuals with sarcopenia by Yuenyongchaiwat et al found that a 12 weeks of pedometer-based intervention program (the intervention group was required to wear a pedometer and walk 7500 steps/day for 5 days/week) and

TheraBand resistance exercise (twice a week) improved the 6MWD significantly (the mean difference between the interneuron and control group was 51.83 m, which is close to our result of 57.68 m).[39] Another study in patients with obesity[40] which included an easy, structured, and home-based exercise program combined resistance and walking exercise also reported a significant increase of 6MWD after the intervention (430±69.7 vs 481.2±68.8 before and after intervention), which was similar to our finding. However, 6MGS did not show significant change, and this may be related to the characters of the test. 6MGS is a test requiring little effort and may not be optimal in detecting the change. However, it showed an improved trend after intervention. With a larger sample or longer time of intervention, it probably shows a significant change.

Our study confirmed the effectiveness of the exercise program for the older adults with sarcopenia in improving 6MWD. However, due to the lack of separated aerobic or resistance exercises for comparison, we could not clarify the respective contribution from resistance exercise and aerobic exercise. The study by Wanderley et al found a significant increase in 6MWD in older adults in the aerobic exercise group but not in resistance exercise and control groups.[41] However, one study in older breast cancer survivors found that the 6MWD was elevated after 12 months of supervised resistance training but not aerobic and stretching training, and another study in frail older adults found that resistance training alone was found to be able to improve 6MWD and the higher intensity and volume of resistance caused greater improvement.[42] In the future, more studies are needed to clarify the different improvement effects on 6MWD by different exercise modalities, such as resistance, aerobic and concurrent exercise.

Apart from muscle strength and aerobic capacity, this exercise program improved dynamic balance and flexibility in older adults but had no significant effect on static balance. On one hand, there were fewer balance training components contained in this program. Moreover, although the resistance exercises included one-leg standing movements, most participants held onto a support to prevent falls during the exercise, which may have limited the improvement in static balance. The improvement in flexibility might also be related to stretching movements during the cool-down exercise. In a study by Geng et al,[43] apparatus-based resistance combined with a walking exercise program with stretching movements as cool-down exercises significantly improved flexibility in middle-aged adults.

In our study, TUGT was used to assess dynamic balance. TUGT is a compound movement that includes various aspects of body movements related to balance function, muscle strength, walking, and body coordination. Based on these characteristics, we have reasons to believe that various kinds of exercise could improve performance. Results of a meta-analysis showed that resistance training, comprehensive training, and comprehensive training under self-management all improved TUGT significantly in older adults with sarcopenia.[44] TUGT time was also found to be associated with 6MWD[45] and muscle strength.[46] Therefore, with significantly improved muscle strength and 6MWD, the better performance in TUGT meets expectation. Better performance of TUGT, together with walking speed, and muscle strength are closely associated with fewer falls.[47] Therefore, the improvement in TUGT, muscle strength, and 6MWD in our study strongly indicates the benefit of the exercise program in preventing falls in these patients.

Our study did not find an improvement in body composition after 12 weeks of intervention. A meta-analysis of randomized controlled studies revealed a positive effect of resistance training on the reduction of fat mass and increase in muscle mass.[48] Almost half of the randomized controlled trials in the meta-analysis had an intervention period of >12 weeks, which is longer than that in our study, and the population in the meta-analysis included pre-sarcopenia, sarcopenia, pre-frailty, or frailty, while our study included all participants with sarcopenia. These differences may explain the diversity of the results. With a longer intervention period and wider selection of the study population, the exercise program in our study may have an improvement effect on body composition.

In our study, SF-36 scores did not show different changes in the two groups, which was consistent with the results observed in other studies.[49,50] However, the score of vitality had a difference close to be significant, which suggests that the exercise program might be potentially effective in improving quality of life. Vasconcelos et al's study[50] reported that there was no significant difference in quality of life (SF-36 scores) between and within groups after a 10-week resistance exercise program, which is similar to our study. It is reported in a meta-analysis[6] that the combination of resistance exercise with aerobic and balance training was the most effective intervention for improving quality of life in older people with sarcopenic obesity. However, more than half of the studies in the meta-analysis had an intervention period >12 weeks. The shorter intervention period could probably be the reason for the non-significant effect of the exercise program on the quality of life in this study. Additionally, the lack of a significant difference in quality of life in our study may be related to the relatively high baseline levels. With the quite good baseline conditions, it was difficult to improve after a short-term intervention. It is possible that a longer intervention period may lead to significant differences in the quality of life.

The adherence was generally good in terms of exercise attendance and completion. In aerobic walking exercise, the percent complete of target steps was high (83.3%); however, only 13 participants achieved the prescribed target steps during all phases of the exercise. These results might be related to the fact that some participants had overexercised, offsetting the shortfall of those who underexercised when calculating the adherence results. In addition, it was possible that the frequency of exercise was not uniform, resulting in much greater or lesser amount of exercise being completed in different weeks than prescribed. In the exercise intervention study, the exercise volume in the control group was one of the most important confounding factors. Our results showed a decreasing trend, but not a statistically significant change, in the exercise volume in the control group. Exercise volume in the IG was significantly larger than that in the CG after the intervention. However, owing to limited time and energy, the researchers were unable to conduct on-site supervision each time, making it difficult to ensure the accuracy of the exercise diary recording.

This home-based aerobic combined with resistance exercise program is simple, graded, progressive, and comprehensive, which is in line with the recommended principles of exercise for older adults with sarcopenia.[51] The current study also proved its safety, good compliance, and feasibility. The study used intentional-to-treat analysis, including participants who dropped out in the final data analysis, thus conforming to the principle of randomization and ensuring a balanced trial design.

The limitations of this study are as follows. First, the intervention period was short and there was no separate group of single aerobic exercise or resistance exercise for comparison; therefore, the contribution of either type of exercise was unknown. Second, the number of participants may not reach the stipulated sample size, and the participants in this study were mostly in good health conditions, thereby the feasibility to extend the results to different population remains to be tested. Third, biochemical and endocrine indicators were not collected in this study, which makes it difficult to explain the underlying mechanisms.

Conclusion

The home-based progressive aerobic combined with resistance exercise program demonstrated positive improvements in muscle strength, balance, flexibility, and cardiorespiratory fitness in community-dwelling older adults with sarcopenia and good exercise adherence. The effects of intervention with longer period wait for further study to be determined.

Abbreviations

ASM, appendicular skeletal muscle mass; ASWG, Asian Sarcopenia Working Group; BIA, bioelectrical impedance analysis; CG, control group; GEE, generalized estimated equation; HR, heart rate; IG, intervention group; RPE, Rating perceived exertion; SMI, skeletal muscle mass index; 6MWD, six-minute walk distance; SD, standard deviation; TUGT, timed up-and-go test; WMA, World Medical Association.

Data Sharing Statement

Data available on request from the authors. The data that support the findings of this study are available from the corresponding author, [LW], upon reasonable request.

Ethics

The research was approved by the Ethics Committee of Soochow University (ECSU-2019000161) and registered at the Chinese Clinical Trial Registry (ChiCTR1900027960, http://www.chictr.org.cn/showproj.aspx?proj=45968).

Acknowledgments

We would like to thank all volunteers who participated in this study for their time and effort.

Funding

This study was funded by the Humanities and Social Sciences Research Project of Soochow University [grant number 21XM2012, LW] and the Medical and Health Technology Plan Youth Innovation Project in Zhejiang Province [grant number 2023RC029]. The funding source had no role in study design, data collection, data analysis, decision to publish, or manuscript preparation.

Disclosure

The authors report no conflicts of interest in this work.

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