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ORIGINAL ARTICLE

Lower-limb Aerobic Exercises Improve Physical Function in Frail Older Adults:
A Randomized Controlled Pilot Trial

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ABSTRACT

It is still unclear whether the effects of lower-limb aerobic exercise (Kohzuki Exercise Program; KEP) are effective in improving physical function as an exercise program for frail older adults. The aim of this study was to determine the effect of the 6-month structured KEP on physical function in frail older adults. The KEP group participants engaged in a total of 72 sessions, 3 times a week for 6 months. The KEP consisted of 5 minutes of warm-up and stretching, 30 minutes of lower-limb aerobic exercise, and 5 minutes of cool-down and relaxation. The control group (CON group) participants were asked to maintain their normal behavior over the same 6-month period.

Physical function as an outcome was measured using the Short Physical Performance Battery (SPPB). A total of 23 participants (KEP group: n=12; CON group: n=11) who participated in this study. The analysis of outcomes was performed by Friedman test and Wilcoxon signed rank post-hoc test with Bonferroni correction for the comparison between the time; baseline, 3 months and 6 months. There was a significant changed in physical function over the baseline, 3 and 6-month in the KEP group for SPPB total score ($p<0.01$), balance time ($p<0.05$), gait speed time ($p<0.01$), and chair stand time ($p<0.01$) at 6-month.

In summary, the 6-month KEP intervention targeting physical function is an effective, long-term, and sustainable program for frail older adults.

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I. Introduction

Frailty is a physiological syndrome that is different from normal aging or disability [1,2]. Unlike normal aging, frailty has vulnerabilities that easily lead to various diseases and disorders, even under the same stressor event [3-5]. According to previous studies, the risks of falls, fractures, and death were 1.38 times, 1.4 times, and 1.82 times higher, respectively, among the frail elderly than healthy older adults[6]. In recent years, several studies have been made to measure the state of frailty more objectively[7,8]. However, the specific indicators for measuring frailty still vary between countries and researchers[8]. Of the various frailty measurements[9-11], the most widely and commonly used diagnostic criteria in worldwide is the Cardiovascular Health Study (CHS) Index[12]. The CHS frailty phenotype diagnoses people as pre-frail if they meet specified cut-offs for 1 or 2 of 5 criteria, and as frail if they meet specified cut-offs for 3 or more of the five criteria: slow gait speed, weak grip strength, exhaustion, low energy expenditure, and weight loss[4,5].

Evidence indicates that exercise is the most effective preventive strategy for counteracting the decline in age-related muscle mass, muscle strength, fat mass, cardiopulmonary function, and immune function[13,14]. Aerobic exercise is one of the most effective exercises to improve and maintain the physical activity of older adults[15]. Clinical studies have shown that individuals aged over 65 years can benefit from aerobic exercise (40 minute, 2 times per week for 12 weeks) to increase mobility in older adults[16].

We have demonstrated that the Kohzuki Exercise Program (KEP). The KEP is a lower-limb aerobic exercise program designed to fit the age and physical functions of older people, using the Terasuerugo® (Showadenki Co., Ltd., Osaka, Japan). Terasuerugo® is a newly developed cycle ergometer, has a quantitative 7-step pedal power modulation dial of 10 to 75 watt, it is designed to be used without swaying even when lying down or sitting, and it is portable, and it is easy to handle. Existing ergometers are large in size, heavy in weight, and require a lot of space. However, the Terasuerugo® used in this study is small in size and so does not require much space for exercise. According to previous studies on KEP, is reported that improve physical function in older people over 65 years[17], and can improve cognitive function in Alzheimer's patients over 65 years[18].

As an additional study, we need to investigate whether KEP is suitable as an exercise program for frail older people and whether it is effective in improving physical function in frail older people. Also, we need to investigate whether KEP is applicable.

Therefore, the aim of this study was to determine the effect of a 6-month structured KEP on physical function in frail older adults. The hypothesis was that the KEP would improve physical function in frail older adults.

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II. Methods

1. Study Design and Ethical approval

This study was designed a prospective, a randomized controlled trial (RCT) using the KEP was conducted among 53 frail older adults. Ethical approval was obtained from the Ethics Committees of Tohoku University Graduate School of Medicine and the "Smairu" facility(UMIN-CTR; UMIN000023909).

2. Randomization

Following a baseline assessment, research staff randomized participants into the KEP group (KEP group) or control group (CON group) by identification number, which were assigned on the basis of order of enrollment. A sequence of computer-generated random numbers from 1 to 40 was used. Those who received an odd number were assigned to the exercise group, and those who received and even number were assigned to the control group. Forty participants were randomized to participate in the KEP group(n=20) and CON group(n=20).

3. Participants

Participants were recruited through an advertisement and poster in the "Smairu" facility in Mie city, Japan. The eligibility criteria for inclusion were (i) 65 years or older; (ii) According to Fried et al.(2001), frail (meeting the specified cut-off for three or more of the CHS frailty criteria: slow gait, weak grip, exhaustion, low energy expenditure, and weight loss) ; (iii) Mini-Mental State Examination score >21; and (iv) absence of participation in aerobic exercise and strength training. The exclusion criteria for the participants were (i) any acute cardiorespiratory episode within 1 year before the study; (ii) neurological or neuromuscular disease that could interfere with the proper performance of assessment and/or exercise protocol; and (iii) dementia or psychiatric disorders. All participants were informed of the risks and benefits of the study and agreed to participate by signing a consent form.

Of the 20 participants in the KEP group, 4 dropped out due by declining to be interviewed and 4 dropped out due to loss of motivation. Of the 20 participants in the CON group, 6 participants dropped out by declining to be interviewed, 2 dropped out due to loss of motivation, and 1 dropped out due to relocation. Twenty-three participants were analyzed at the 6-month post-intervention assessment: in the KEP group(n=12) and CON group(n=11).

4. Intervention

The KEP group participants engaged in a total of 72 sessions, 3 times a week for 6 months. All sessions began with 5 minutes of warm-up and stretching, followed by 30 minutes of lower-limb aerobic exercise using a Terasuerugo® (Showadenki Co., Ltd.,

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Osaka, Japan), and 5 minutes of cool-down and relaxation (72 sessions in all). CON group participants were asked to maintain their normal behavior over the same 6-month period. The intensity of training was targeted at a heart rate of 40–60% of maximum. In addition, using Borg's scale[19], participants were asked to exercise at an intensity of 11 (i.e., 60% effort, "fairly light") to 13 (i.e., 70% effort, "somewhat hard") [17,18].

5. Physical Function Outcome Measures

Participants were assessed at baseline, 3 months, and 6 months by the research staff.

Physical function was measured using the Short Physical Performance Battery (SPPB)[20], which was specifically developed for older adults. The SPPB assesses the ability to stand (for 10 seconds) with the feet together in side-by-side, semi-tandem, and tandem positions; time to walk 4 meters; and time to stand from a chair and return to the seated position five times. Each of the three tests have scores ranging from 0 to 4. The SPPB total score (0–12; 0 is poor performance, 12 is excellent performance) is calculated by adding the three test scores[20].

6. Statistical Analysis

All analyses were conducted using Statistical Package for the Social Science (SPSS) version 28 (IBM Corp., Chicago, IL, USA). Descriptive statistics calculated the means and standard deviations (SD). The Shapiro–Wilk test was used to check normality. The baseline characteristics of the participants in the two groups (KEP and CON group) were compared using Mann-Whitney U-test for continuous variables and the chi-square test for categorical variables. The analysis of outcomes concerned within-subject effects group the significance of the Comparison between the time using Friedman test. The significance level was set at $p<0.05$.

III. Results

1. Baseline Characteristics

The total number of 23 participants (KEP group=12, CON group=11) were analyzed at the 6-month post-intervention assessment. There was no statistically significant difference between the KEP and CON group including age, sex, height, weight, body mass index(BMI), medical history, and physical function (Table 1).

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<Table 1> Baseline Characteristics of participant

Variable	KEP Group (n=12)	CON Group (n=11)	p-value
Characteristics			
Age (years)	83.5(7.1)	81.9(7.4)	n.s
Female, n(%)	9(75.0)	9(81.8)	n.s
Height (cm)	154.3(5.2)	154.2(7.9)	n.s
Weight (kg)	56.3(8.4)	55.4(7.9)	n.s
BMI (kg/m^2)	23.7(3.8)	23.3(2.7)	n.s
Smoking History, n(%)	0(0)	1(0)	
Drinking History, n(%)	3(25.0)	4(36.3)	n.s
Hypertension, n(%)	6(50.0)	3(27.3)	n.s
Diabetes, n(%)	1(8.3)	0(0)	
Dyslipidemia, n(%)	4(33.3)	4(27.3)	n.s
MMSE Score (0-30)[a]	26.9(1.8)	27.4(0.9)	n.s
Physical Function			
SPPB (0-12)[a]	6.3(1.2)	5.8(1.3)	n.s
Balance Score (0-4)[a]	2.4(0.5)	2.4(0.7)	n.s
Gait Speed Score (0-4)[a]	2.1(0.5)	1.9(0.3)	n.s
Chair Stand Score (0-4)[a]	1.8(0.6)	1.6(0.7)	n.s
Balance Time (sec) [a]	25.8(3.9)	26.3(4.5)	n.s
Gait Speed Time (sec) [b]	7.4(0.8)	7.7(0.7)	n.s
Chair Stand Time (sec) [b]	15.7(1.6)	14.8(5.1)	n.s

Note: BMI, Body Mass Index; MMSE, Mini-Mental Status Examination; SPPB, Short Physical Performance Battery; n.s., no significant.

Data are expressed as mean (SD) or n(%).

[a] Higher score indicates better functioning.

[b] Lower score indicates better functioning.

[c] Mann-Whitney U-test; p-value.

2. Physical Function Outcome Measures

The results of the SPPB for physical function are shown in Table 2,3. Table 2 shows changed physical function in the KEP group over the baseline, 3 and 6-month. SPPB total score ($p<0.01$), balance time ($p<0.05$), gait speed time ($p<0.01$), and chair stand time ($p<0.01$) were significantly difference at 6 months. Table 3 shows a comparison of the baseline and 6-month physical function levels between the KEP and the CON groups. The

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SPPB total score (<0.01), balance time (<0.001), gait speed time (p<0.001), and chair stand time (p<0.001) had significantly different between the KEP group and the CON group.

<Table2> Baseline scores and changes in KEP group physical function

Physical Function (n=12)	Baseline	3-month	6-month	p-value[c]
SPPB Total Score (0-12)[a]	6.3±1.2	6.6±1.1	7.1±1.1	<0.01
Balance Score (0-4) [a]	2.4±0.5	2.6±0.5	2.8±0.5	n.s
Gait Speed Score (0-4) [a]	2.1±0.5	2.2±0.4	2.3±0.5	n.s
Chair Stand Score (0-4) [a]	1.8±0.6	1.8±0.6	2±0.6	n.s
Balance Time (sec)[a]	25.8±3.9	26±3.7	26.5±3.5	<0.05
	7.4±0.8	7.1±0.9	6.8±0.9	<0.01
Chair Stand Time (sec)[b]	15.7±1.6	15.1±1.4	14.8±1.4	<0.01

Note: n.s., no significant. Data are expressed as mean ± SD.

[a] Higher score indicates better functioning.

[b] Lower score indicates better functioning.

[c] Friedman Test; p-value.

<Table 3> Comparison between groups in the change of physical function

Physical function	Group	Baseline	6-month	Mean difference	p-value[c]
SPPB Total Score (0-12)[a]	KEP group	6.3±1.2	7.1±1.1	0.8±0.8	<0.01
	CON group	5.8±1.3	5.6±1.4	-0.2±0.4	
Balance Score (0-4) [a]	KEP group	2.4±0.5	2.8±0.5	0.3±0.5	n.s
	CON group	2.4±0.7	2.3±0.8	-0.1±0.3	
Gait Speed Score (0-4) [a]	KEP group	2.1±0.5	2.3±0.5	0.3±0.5	n.s
	CON group	1.9±0.3	1.9±0.3	0	
Chair Stand Score (0-4) [a]	KEP group	1.8±0.6	2±0.6	0.3±0.5	n.s
	CON group	1.5±0.7	1.5±0.7	-0.1±0.3	
Balance Time (sec)[a]	KEP group	25.8±3.9	26.5±3.5	0.8±0.9	<0.001
	CON group	26.3±4.5	25.5±4.2	-0.8±0.6	
Gait speed Time (sec)[b]	KEP group	7.4±0.8	6.8±0.9	-0.6±0.4	<0.001
	CON group	7.7±0.7	7.9±0.6	0.2±0.4	
Chair Stand Time (sec)[b]	KEP group	15.7±1.6	14.8±1.4	-0.8±0.5	<0.001
	CON group	14.8±5.1	15.2±5.1	0.4±0.5	

Note: n.s., no significant. Data are expressed as mean ± SD.

[a] Higher score indicates better functioning.

[b] Lower score indicates better functioning.

[c] Mann-Whitney U-test used to estimate mean difference (p) between groups.

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IV. Discussion

To the best of our knowledge, this is the first study to evaluate the effect of KEP intervention targeting frailty in physical function in older adults defined as frail using a validated measure of frailty. The hypothesis was that the 6-month KEP would improve physical function in frail older adults. The present RCT confirmed that a 6-month KEP that involves lower-limb aerobic exercise is effective in significantly improving physical function, based on the SPPB total score, balance time, gait speed time, and chair stand time in the KEP group.

Exercise has a physiological effect on skeletal muscle, physical function, and maintenance of independence [21,22]. The results of previous studies on the physical function improvement programs proposed for frail older adults have varied widely, as have the types of exercise, duration, frequency, and intensity used[23,24].

Our findings are consistent with previous studies that investigated the effects of aerobic exercise. Harber et al. (2009) showed significant improvements in muscle hypertrophy in older adults after 12 weeks of aerobic exercise intervention[14]. In addition, 12 weeks of aerobic exercise; 40 minutes, 2 times per week have been reported to increase mobility in older adults[15]. Our results showed that the KEP's lower-limb aerobic exercise may also be tolerated by frail older adults and may improve their physical function. However, unlike the present study, which was the result of long-term intervention, the results of previous studies are from short-term interventions[14,15], so it is likely that the exercise method used in this study will be more appropriate with regard to sustainability and safety. Moreover, during our study period, no participants experienced joint or muscle pain or injury from performing the KEP. Which means that the KEP has been shown to be a safe exercise program for frail older adults.

Previous studies of exercise for older people were often performed using community-dwelling people living in institution such as nursing homes[24,25]. These studies reported that exercise can improve physical function in terms of gait speed, muscle strength, or mobility [24,25]. Their results are consistent with our study, which showed that the KEP improved physical function in frail older people. It also showed that the KEP is an effective and sustainable exercise that can be used by community-dwelling people and in all types of care facility.

The strengths of our study were the use of a validated definition of frailty; the demonstration that KEP is an effective and safe exercise for frail older people, as well as for healthy older people[17] and older people with dementia [18]. However, several limitations of our study need to be mentioned. First, this study was not blinded, thus it is possible that the benefits reported from the KEP intervention were due to participant bias. Second, the study was limited to a single center. Further studies using randomized controlled multicenter trials are needed. Finally, the sample size was too small. Further studies with a larger sample size are needed.

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In conclusion, for frail older adults, the 6-month KEP intervention targeting physical function is a long-term, effective, and sustainable program for participants. The KEP intervention improved lower-limb function in balance, gait speed, and chair stand tests. It is recommended that future studies in frail older adults use randomized controlled multicenter trials, a longer period, and a larger sample size.

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