

International Journal of Gerontology



journal homepage: http://www.sgecm.org.tw/ijge/

Original Article

The Effect of Foot Functional Training on Gait Ability in Older Adults with Activities of Daily Living Disability: A Randomized Controlled Trial

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ARTICLEINFO	S U M M A R Y		
Accepted 29 June 2020	Background: Physical training can prevent gait ability decline in older adults. However, it is unknown whether foot functional training improves gait ability in older adults with activities of daily living (ADL)		
Keywords:	disability. Therefore, this study aimed to investigate the effects of foot functional training on gait ability		
bone,	in older adults with ADL disability.		
exercise training,	Methods: We conducted a single-center randomized controlled study involving 27 older Japanese adults		
gait,	(\geq 75 years) with ADL disability between December, 2017 and March, 2018. Participants were randomly		
long-term care	assigned to an intervention group or a control group. The intervention group underwent 60-min foot		
	functional training twice weekly for 4 months, in addition to routine activities that the nursing home typically offered to attendees.		
	Results: Gait speed and speed of sound significantly increased after the 4-month training in the inter-		
	vention group (gait speed: before vs. after, 0.61 \pm 0.22 m/s vs. 0.84 \pm 0.26 m/s, p < 0.001; speed of		
	sound: before vs. after, 1536 \pm 16 m/s vs. 1550 \pm 19 m/s), but not in the control group. The change in the		
	peak pressure of the forefoot at the propulsive phase of gait was significantly higher in the intervention		
	group than in the control group (p = 0.003). Gait speed was significantly correlated with the peak		
	pressures of the forefoot ($r = 0.27$, $p = 0.048$) in the propulsive phase.		
	Conclusion: The foot functional training significantly improved gait speed, bone strength, and plantar		
	pressure distribution in older adults with ADL disability.		
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1. Introduction

Gait is one of the fundamental indicators for maintaining the ability to perform activities of daily living (ADL).¹ However, gait ability in older adults with ADL disability is very low.² For example, a gait speed of 1.0 m/s has been shown to reflect the likelihood of good health and better survival but the gait speed of older adults with ADL disability is reportedly 0.47 m/s.² This implies that older adults with ADL disability are at risk of suffering a decline in health, mobility, autonomy, social contacts, and mental well-being.² Thus, the improvement of gait ability is especially important in this population.

Physical training can prevent or reduce the decline of gait ability in older adults.^{3,4} Previous studies have suggested that gait ability was improved in older adults with ADL disability by using multicomponent physical training that was focused on resistance and balance training.^{5–8} However, Arrieta et al. noted that many older adults with ADL disability were hesitant to implement these exercise programs due to fear of injury.⁵ Therefore, there is a need to develop a physical training that poses no risk of injury and can be performed while sitting on the floor or on a chair. A previous study investigated whether foot functional training called "Building Osteo Neatly Exercise" improved bone strength and plantar pressure distribution in college-age women.⁹ This previous study reported that performing this training while sitting on the floor or on a chair significantly improved bone strength, which was measured using the quantitative ultrasound system (QUS), and plantar pressure distribution.⁹ Gait ability is greatly affected by foot functions such as plantar pressure distribution and bone strength.^{10,11} Therefore, improved plantar pressure distribution and bone strength following foot functional training would improve gait ability. However, it is unknown whether this program improves gait ability, plantar pressure distribution, and bone strength in older adults with ADL disability. Moreover, clinicians are faced with the challenge of providing evidence-based recommendations for the foot functional exercise program.

Therefore, the purpose of the present study was to examine the effects of foot functional training on gait ability, plantar pressure distribution, and bone strength in older adults with ADL disability. Based on a previous study,⁹ we hypothesized that foot functional training would improve plantar pressure distribution and bone strength in the foot, resulting in increased gait ability.

2. Materials and methods

2.1. Participants and experimental design

This study was a 4-month single-center randomized controlled

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trial conducted at a nursing care home between December, 2017 and March, 2018. The study was approved by the Research Ethics Committee of the Graduate School of Education, Hiroshima University (no IRB/reference number was granted), and all participants provided written informed consent to participate in the present study.

A flowchart of the present study is shown in Figure 1. Initially, 36 subjects were recruited for the study from a long-term nursing home. Assessments to determine the eligibility of the subjects for the study included physical performance tests. The inclusion criteria for the study were 1) age, 75 years or older, 2) ability to walk 6 m without a walking aid, 3) ability to comprehend the study procedures, 4) noncontraindication for participation in the study, 5) absence of a rapidly progressive or terminal illness, and 6) support level 2 or care level 1-4 diagnosis of ADL disability by a medical doctor, according to the definition of the Japanese government.¹² Difficulty in ADL or instrumental ADL in each level was defined as below: doing housework at the support level 2, daily decision-making and shopping at the care level 1, walking at the care level 2, dressing, bathing, and toileting at the care level 3, and transferring at the care level 4.12 After eligibility assessments, two subjects did not meet the criteria. Finally, 34 participants were recruited for the study. Participants were randomly allocated to either the intervention group (n = 17) or the control group (n = 17). The allocation was performed after the completion of all baseline measurements. An experimenter (YY), who was not involved in the intervention or assessment, performed separate randomization via lottery draw using sealed opaque envelopes. Two experimenters (SM and SK), who were blinded to the intervention assignment, measured outcomes before and after the 4-month intervention period.

2.2. Control group activities

The control group participated in the routine activities that the nursing home typically offered to attendees. These activities included playing "Go" and "Shogi", reading, and singing. All activities were low intensity.

2.3. Foot functional training

The intervention group underwent foot functional training for 60 min twice a week over the course of 4 months, in addition to the activities of the control group. The training was handled by an experienced physical trainer (SM) and was performed through supervised sessions (i.e., group training) between 0900 h and 1000 h. The foot functional training called "Building Osteo Neatly Exercise" is summarized in Figure 2. This functional training was indicated by a previous study.⁹ It was designed to apply mechanical loads and vibration to the bones of the foot. This training comprises 12 steps; four sets of each step is performed (two sets for each foot) and the training focuses on strengthening the bones of two important functional points of the foot – the arches and forefoot. Steps 1–4 were performed while sitting on the floor, while steps 5-12 were performed while sitting on a chair. Loading was performed within the pain-free range of the individual and was adjusted on an individual basis.

2.4. Measurements

The primary outcome was gait speed. Gait speed was measured using the fast 6-m gait time. The time required to complete a 6-m

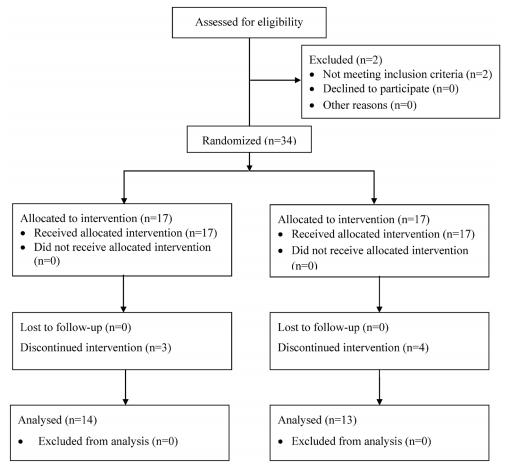


Figure 1. The flow of the randomized controlled study.

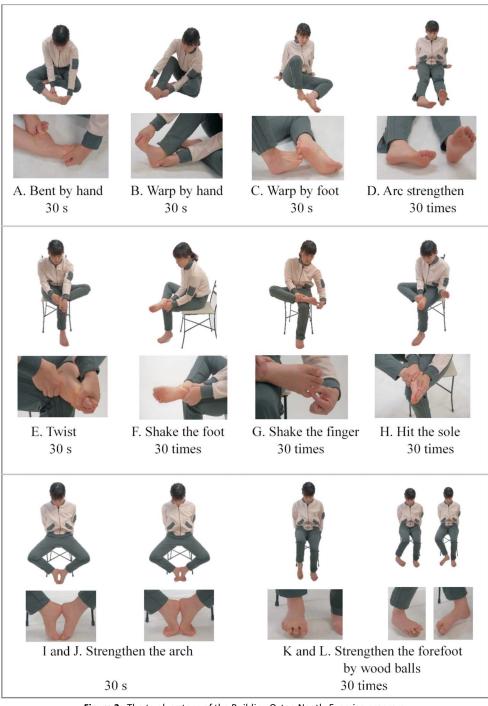


Figure 2. The twelve steps of the Building Osteo Neatly Exercise program.

gait on a straight line from a static start was measured. The within-subject coefficient of variation for gait speed was 4.7 \pm 3.3% in the pilot work.

The bone strength of the right calcaneus was evaluated using a QUS (Benus Evo, Shibuya Corp., Japan).⁹ This study evaluated the bone strength of the calcaneus by speed of sound (SOS), which represents the velocity of ultrasound transmission through the calcaneus.¹³ The within-subject coefficient of variation for SOS was $0.4 \pm 0.5\%$ in the pilot work.

To measure the plantar pressure distribution, each participant was required to walk on a Metascan pressure mat (Footmaxx Co., Roanoke, USA) using five trials of six steps each (three steps on each foot). Plantar pressure was measured for the rearfoot, including the midfoot and the heel, and for the forefoot, including the 1st–5th

metatarsophalangeal joints, the hallux, and the lesser toes. The contact time during gait was normalized as 0 (the first contact of the foot) to 100% (the end of the contact). The peak pressures of the forefoot and rearfoot at 0 to 50% and at 51 to 100% of the contact time (the contact and propulsive phases, respectively) were calculated. The within-subject coefficient of variation for plantar pressure distribution was $6.7 \pm 5.1\%$ in the pilot work.

The rating of perceived exertion (RPE; 6 [very, very light] to 20 [maximal exertion]),¹⁴ affective valence (-5 [the most displeasure you have ever felt] to 5 [the most pleasure you have ever felt]),¹⁵ and perceived activation (1 [lowest activation] to 6 [highest activation])¹⁶ were measured before and after the training intervention using previously established methods when participants first experienced the program.

Foot Functional Training and Gait Ability

2.5. Statistical analyses

The sample size was estimated via G*Power 3,¹⁷ using data from a previous study.⁵ To detect improvements in gait ability with a power of 80% and an alpha level of 5%, a sample size of \geq 26 participants was required. All statistical analyses were performed using SPSS (version 25.0, SPSS Japan Inc., Japan). Unless otherwise stated, all values are expressed as mean \pm standard deviation (SD). The Shapiro-Wilk test was used to check for normality of distribution. Gait speed and SOS values were normally distributed and were therefore analyzed using a repeated-measures two-factor (group \times time) analysis of variance to examine differences between the groups. Where significant interactions were detected, post-hoc multiple comparisons were made using the unpaired or paired t-test. Gait speed and SOS values were also analyzed using Cohen's d effect sizes, in which \geq 0.8 was categorized as a large effect, 0.5 to 0.79 as a moderate effect, and < 0.49 as a small effect.¹⁸ Due to the violation of the normality assumption for plantar pressure distribution and perceptual values, the magnitudes of changes (Δ) in these values during the experiment were calculated and analyzed using the Mann-Whitney U test. Correlation coefficients were determined using Pearson's product-moment test. Statistical significance was set at p < 0.05.

3. Results

In the present study, 27 participants (79%) in the intervention (n = 14 [support level 2, n = 1; care level 1, n = 8; care level 2, n = 2; care level 3, n = 2; care level 4, n = 1]) and control (n = 13 [support level 2, n = 1; care level 1, n = 5; care level 2, n = 5; care level 3, n = 2]) groups completed the 4-month follow-up and assessment. The age, sex, and baseline anthropometric characteristics of the participants are summarized in Table 1. There were no significant differences between the groups.

3.1. Gait speed

There was a group \times time interaction for gait speed (p < 0.001).

Table 1

Descriptive characteristics of study participants.							
	Intervention group (n = 14)	Control group (n = 13)					
Age (years)	$\textbf{86.1} \pm \textbf{5.2}$	84.6 ± 6.1					
Women (number)	10	10					
Body mass (kg)	49.8 ± 8.5	$\textbf{46.8} \pm \textbf{8.1}$					
Body height (cm)	$\textbf{152.9} \pm \textbf{7.1}$	148.1 ± 9.0					
BMI (kg/m²)	$\textbf{21.2}\pm\textbf{2.3}$	$\textbf{21.3} \pm \textbf{2.5}$					

Data are expressed as mean \pm standard deviation. BMI: body mass index.

Table 2

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No significant difference was observed for gait speed between before and after the training period in the control group (p = 0.078, d = 0.29, Table 2). However, in the intervention group, gait speed after the training significantly increased compared to before the training (p < 0.001, d = 0.98). The gait speed after the training period was significantly higher in the intervention group than in the control group (p = 0.047, d = 0.80).

Gait speed was correlated with SOS and the peak pressures of the forefoot and rearfoot at the propulsive phase (SOS: r = 052, p <0.001; forefoot: r = 0.27, p = 0.048; rearfoot: r = -0.43, p = 0.001).

3.2. Speed of sound

There was a group \times time interaction for SOS (p < 0.001). In the control group, SOS after the training period significantly decreased compared to before the training period (p = 0.001, d = 0.39, Table 2). However, in the intervention group, SOS after the training significantly increased compared to before the training (p < 0.001, d =0.79). The SOS after the training period was significantly higher in the intervention group than in the control group (p = 0.042, d =0.83).

3.3. Plantar pressure distribution

Figure 3 shows the mean changes of plantar pressure distribution before and after the training in the intervention group. Before the intervention, the pressure of the rearfoot was observed throughout the gait. However, after the intervention, this pressure was not observed during the propulsive phase. Δ peak pressure of the forefoot at the propulsive phase was significantly higher in the intervention group than in the control group (p = 0.003, Table 2).

3.4. Perceptual index

There were no significant differences in Δ RPE between the groups. However, Δ affective valence and Δ perceived activation were significantly higher in the intervention group than in the control group (Δ affective valence: intervention 2 [-2–5], control 0 [-4–0], p < 0.001; ∆perceived activation: intervention 3 [0–5], control 0 [-4–2], p = 0.001; median [minimum-maximum]).

4. Discussion

The present study aimed to examine whether foot functional training improved gait ability, plantar pressure distribution, and bone strength in older adults with ADL disability. To the best of our

	Intervention group (n = 14)			Control group (n = 13)		
	Before	After	Δ	Before	After	Δ
Gait speed (m/s)	$\textbf{0.61} \pm \textbf{0.22}$	$0.84 \pm 0.26^{*^{\#}}$	-	0.72 ± 0.33	$\textbf{0.63} \pm \textbf{0.27}$	-
SOS (m/s)	1536 ± 16	$1550 \pm 19^{*^{\#}}$	-	1542 ± 29	$\textbf{1530} \pm \textbf{28}^{\texttt{\#}}$	-
Peak pressure (%)						
Fore foot						
Contact phase	39.4 (0.0-86.3)	36.6 (0.0-80.5)	1.0 (-51.2–51.5)	43.5 (14.4–74.8)	54.4 (9.8–69.4)	3.1 (-44.4–52.6)
Propulsive phase	65.8 (0.0-81.3)	70.9 (51.4–87.8)	2.9* (-12.5–59.7)	71.9 (34.4–83.6)	63.8 (7.1–85.0)	-7.0 (-38.2–26.2)
Rear foot						
Contact phase	103.2 (39.4–138.5)	90.8 (63.6-284.2)	0.5 (-39.6–153.0)	106.9 (83.6–67.3)	91.4 (26.6–150.8)	0.0 (-90.4–62.0)
Propulsive phase	14.3 (0.0–126.9)	0.0 (0.0-31.4)	-14.3 (-119.6–29.0)	11.3 (0.0-162.6)	3.9 (0.0–139.4)	-8.1 (-59.4-59.9)

Gait speed and SOS data are expressed as mean \pm standard deviation (n = 27).

Peak pressure data are expressed as median (minimum-maximum) (n = 27).

* Significant difference between the groups (p < 0.05), # Significant difference from the Pre (p < 0.05).

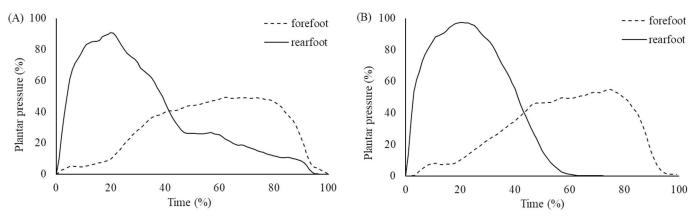


Figure 3. The plantar pressure distribution of the mean values before (A) and after (B) the physical training in the intervention group. Data are expressed as mean (n = 27). Error bars are omitted for clarity.

knowledge, there is no previous study that investigated the effect of foot functional training on these outcomes in older adults with ADL disability. Therefore, the present study is novel because the intervention was centered on foot function. The main finding of this study was that foot functional training for 60 min twice a week over 4 months improved gait speed by 39%. The improvement in gait speed is especially important for older adults with ADL disability because a decline in gait speed may be associated with several adverse outcomes.^{19,20} Previous studies suggested that a slower gait speed can predict accelerated functional and health declines, falls, institu-tionalization, and mortality in older adults.^{19,20} Abellan Van Kan et al. suggested that a 0.1 m/s increase in gait speed after physical training reduced the absolute risk of death by 17.7%.²⁰ The present study demonstrated a 0.2 m/s increase in gait speed after the 4month foot functional training. The rate of increase in gait speed following foot functional training in the present study is higher than those of recently published studies in which multi-component physical training was used (in studies by Arrieta et al. and Cadore et al., the rates were 14% and 5%, respectively).^{5,6} These findings suggest that foot functional training may be effective for increasing gait speed and may reduce the risk of future health-related events (i.e., a reduction of absolute risk of death) in older adults with ADL disability.

The SOS at the heel can predict non-spine fractures in older Japanese adults.²¹ Thus, the maintenance and/or improvement of the SOS at the heel may be important for preventing non-spine fractures in older Japanese adults. Many studies have suggested that physical training can increase bone strength or prevent the decline of bone strength in older adults.^{22,23} The present study also reported that the 4-month foot functional training improved bone strength according to the SOS-based evidence. The magnitude of increase in SOS after the 4-month foot functional training was approximately 1 SD in the intervention group. According to Fujiwara et al.,²¹ a decrease of 1 SD in SOS was associated with a risk ratio of 2.50 for hip fracture, 1.44 for wrist fracture, and 1.54 for non-spine fracture in older Japanese adults. The observed SOS improvement in the present study could, therefore, have clinical importance for older adults with ADL disability. In addition, although the participants in our study are older (86.1 \pm 5.2 years) than those of a previous study (64.5 \pm 5.5 years), the rate of increase of SOS at the foot in the present study is higher than that in the previous study (0.9% and 0.2%, respectively).²⁴ Mechanical loadings, including tension, compression, and fluid shear stress are stimuli that play essential roles in increasing bone strength.²⁵ Moreover, bone strength increases only at sites where these stimuli are applied.²⁶ Thus, foot functional training, which was aimed to apply mechanical loads to the foot, may be more effective for increasing bone strength in the foot compared to a previous physical training. $^{\rm 24}$

We considered plantar pressure distribution because previous studies did not address whether physical trainings could affect plantar pressure in older adults with ADL disability. In the plantar pressure force curve during gait, a bimodal waveform with peaks ranging from 1.0 to 1.5 body weights is usually observed after a small initial peak.¹¹ Notably, a bimodal waveform, which is observed at 70% contact time, is important for fast gait because it is related to the horizontal component of the ground reaction force for gait.¹¹ Moreover, the peak pressure of the forefoot (the magnitude of a bimodal waveform) was associated with gait speed in a previous study.²⁷ Furthermore, in the present study, the correlations between gait speed and the peak pressures of the forefoot at the propulsive phase support this previous finding. However, since it is difficult for older adults to leave the heel on the ground at the propulsive phase, a bimodal waveform was not observed.²⁸ This suggests that older adults may be unable to gain shearing forces for fast gait. Although, in the present study, the entire foot was in contact with the ground throughout gait before the intervention (Figure 3A), the foot functional training decreased the plantar pressure distribution at the rearfoot in the propulsive phase (Figure 3B). Moreover, the peak pressures of the forefoot in the propulsive phase were improved by the foot functional training (Table 2). Thus, an increase in gait speed following the foot functional training may be attributed to improved plantar pressure distribution at the propulsive phase.

We did not investigate the mechanisms underlying the improvement in plantar pressure distribution following the foot functional training. It could be hypothesized that the flexibility of the metatarsophalangeal joints and the plantar flexor muscle strength of the toes may have increased following the foot functional training. A previous study reported that increased peak pressure of the forefoot was associated with increases in the range of motion of the metatarsophalangeal joints and the strength of the plantar flexor muscles.²⁷ A previous study reported that a 4-week physical training, which involved stretching and strengthening exercises for the first metatarsophalangeal joint, could improve the flexibility of the metatarsophalangeal joints.²⁹ Similarly, the foot functional training in the present study included stretching exercises for the metatarsophalangeal joints and strengthening exercises for the plantar flexor muscles of the toes (Figure 2). However, we cannot ascertain whether the flexibility of the metatarsophalangeal joints and strength of the plantar flexor muscles were improved by the exercises.

A strength of the foot functional training was that no risk of injury was associated with the training because it was performed while sitting on the floor or on a chair. Aditionally, no adverse events were observed in the intervention group. Many older adults with ADL disability are hesitant to implement exercise programs due to the fear of injury.⁵ Although the foot functional training did not increase the RPE, it increased the affective valence and perceived activation. These results support the clinical application of the foot functional training.

There are some limitations of the study that should be addressed. First, the results have limited generalizability because there was a narrow range of physical function among the participants. A previous study reported that significant improvements in physical function were observed following physical trainings in participants with worse physical function before the training; however, only few training effects were noted in participants with better physical function before the training.⁵ In the present study, the pre-intervention gait speed was comparable to that of participants in a previous study who had worse physical function before training.⁵ Thus, it is unclear to determine whether the present results may be obtained in individuals with higher physical function compared to our study participants. Moreover, although improvements in gait ability were observed in the participants of the present study, restrictions in other activities were not investigated. A previous review suggested that physical training improved standardized measures of ADL in older adults with ADL disability.³⁰ Thus, future research should investigate whether foot functional training affects restrictions in other activities. Finally, although QUS is not the best measure for bone mineral density, it was used in the present study. Dual-energy X-ray absorptiometry (DXA) is a better measure for bone strength. However, QUS, unlike DXA, assesses bone quality and can provide independent information regarding fracture risk.^{31,32} A previous study suggested that QUS appeared to be superior to DXA in predicting hip fractures.^{21,33} Moreover, in the present study, we did not measure other parameters of QUS, such as broadband ultrasound attenuation, due to the inability of our QUS device to assess this variable. However, in a Japanese population, SOS may be a better predictor of hip fracture than broadband ultrasound attenuation.²¹ Thus, the improvement in SOS observed in the present study has clinical importance.

In conclusion, foot functional training significantly improved bone strength in the foot and plantar pressure distribution. These improvements resulted in increased gait speed. The 4-month foot functional training should be recommended for older adults with ADL disability.

Acknowledgments

The authors thank the participants and nursing care home for their cooperation. This work was supported by JSPS KAKENHI Grant Number 19K11718, the Kao foundation for health & science, and the Daiwa Securities Health Foundation.

Declaration of conflicts of interest

The authors report no conflict of interest.

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