



Toe Clearance Rehabilitative Slippers for Older Adults With Fall Risk: A Randomized Controlled Trial

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Abstract

Introduction: To evaluate fall-prevention rehabilitative slippers for use by self-caring, independent older adults. **Materials and Methods:** This assessor-blinded, randomized, and controlled 1-year study included 59 self-caring, independent participants (49 women) who attended day services. The mean age of participants was 84.0 ± 5.3 years. Participants were randomly selected from 8 nursing homes. We tested slippers top-weighted with a lead bead (200, 300, or 400 g). Intervention group participants walked while wearing the slippers for 10-20 min, 1-3 days/week at the day service center. Fall risk was measured using the Berg Balance Scale and the Tinetti Performance-Oriented Mobility Assessment (POMA) before and at 3-month intervals after the intervention/control phase. **Results:** After 12 months, the intervention group demonstrated significant improvement. Berg Balance and POMA compared to the control group ($p < .05$ $p < .01$, respectively). Mobility scores improved significantly for both measurements in the intervention group before and after ($p < .01$), but the control group had significantly lower scores. **Discussion:** Overall, falls decreased in the intervention group from 10 to 7, and control group falls increased from 9 to 16 ($p = .02$). No adverse events related to the intervention were reported. **Conclusions:** Rehabilitation training slippers may reduce falls in older adults.

Keywords

balance, fall, older adults, prevent, training

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Introduction

In Japan, the reported annual rate of falls among older adults is 10-30%. Falls are a pivotal cause of bone fracture and mortality, warranting the establishment of preventive measures against falls to decrease the number of bed-ridden older adults. One of the causes of falls for older people is the impairment of corticospinal transmissions to the anterior tibial muscle dorsiflexor foot muscles caused by advancing age.¹

Chiba et al² reported that impairment in toe clearance, maximal sole inclination, and dynamic trunk sway reflect quantifiable mechanisms that, if improved, may result in effective interventions to prevent falls. Satoh et al³ reported on a simple rehabilitative training slipper with a space on top with lead beads (400 g) and observed a significant reduction in fall risks in self-care-dependent older adults. The mechanism by which the slipper stimulates the anterior tibial muscle is simple: adding a weight on the top of the foot induces a torque secondary to gravity and the distance of the weight's center of mass to the ankle joint.

The purpose of this study was to evaluate fall-prevention rehabilitation slippers for self-care-independent older adults.

Methods

In this study, we developed an improved rehabilitative slipper for self-care-independent older adults with a choice of preferred lead bead weight (200, 300, or 400 g). The slipper

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includes a back and ankle strap to stop it from coming off while walking. Participants were recruited from 8 nursing homes. Seventy-eight people registered for participation. Eligible participants were community-dwelling elderly people aged 70 and over who were certified as needing support care at Levels 1 and 2. The support level was followed by care insurance established by the Ministry of Health, Labour and Welfare in Japan (from Grades 1 to 2, with higher points indicating a more severe care level). Additional selection criteria were a Mini-Mental State Examination score of greater than 24⁴ and a life expectancy of more than 12 months. The exclusion criteria were dementia and the inability to walk 3 meters. Six participants did not meet inclusion criteria and 2 participants declined to participate. We randomly selected 70 self-care-independent participants (57 women, 13 men; mean age 84.4 ± 6.8 years) attending day services at 8 nursing homes. This trial was approved by the ethics committee of Hirosaki University of Health and Welfare and all participants provided written informed consent.

Participants were randomly assigned to either the intervention or control groups using a random number table at each of the 8 nursing homes. At the day service, both the intervention and control groups received routine training for fall-prevention. The intervention group received rehabilitative slippers in addition to attending the planned training at the nursing home. As a joint intervention, we provided the staff at each participating nursing home instructional training on the method and frequency of the slippers' use, as well as the duration for each use. The presence or absence of adverse events was recorded by the day service staff.

The study protocol was previously published.³ Outcomes were assessed by 2 nurses and physical therapy experts who were unaware of the purpose of the study at baseline and at 3-, 6-, 9- and 12-months follow-up. The risk of falls was measured using the Berg Balance Scale,⁵ (range, 0-56; higher points indicating less risk of fall), and the Tinetti Performance-Oriented Mobility Assessment (POMA),⁶ (range, 0-28; higher points indicating less risk of fall). The Lawton Instrumental Activities of Daily Living⁷ (range, 0-8; higher scores indicate better skills) assessed independent living skills and global cognitive function was measured with the Mini-Mental State Examination⁸ (range, 0-30; higher scores indicate better performance); Mini-Mental State Examination score of at least 24 indicate normal cognition. For the duration of the study, falls were monitored and checked by day service staff at each visit and noted on the daily fall calendar. Participants were investigated for their current illness by each home doctor.

The difference in fall risk between the intervention and control groups at baseline, and at after 3-, 6-, 9- and 12-months was determined by the Mann-Whitney's U test. The statistical difference in changes in fall risk before and after the intervention and control studies was determined by the Friedman test. The statistical differences in relation to the physical characteristics of participants and number of falls before and after intervention were calculated using the Chi-squared test. The pre- to post-intervention difference for the

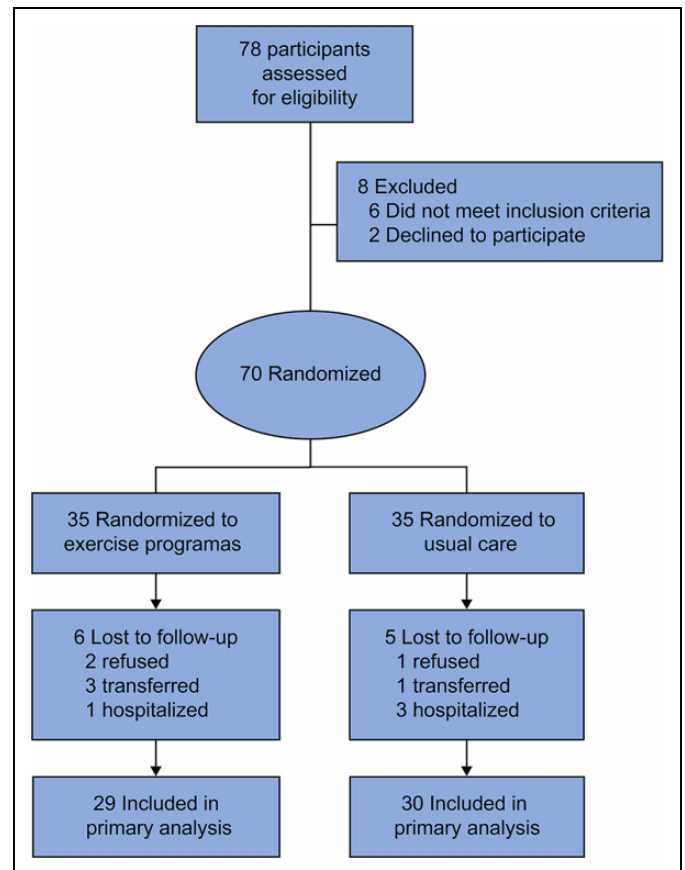


Figure 1. Participant flow in trial of rehabilitative slippers exercise vs usual exercise at day-service for fall prevention group.

Lawton Instrumental Activities of Daily Living⁶ and Mini-Mental State Examination⁷ results were calculated using the *t*-test. The differences were regarded as statistically significant at $p < .05$.

Results

Among the 35 participants in the intervention group, 2 refused to participate, 3 transferred to another facility, and 1 was hospitalized for poor physical condition; hence, 29 participants completed the entire 1-year intervention study. Of the 29 intervention group participants, 8 chose 200 g beads, 4 chose 300 g, and 17 chose 400 g. Among the 35 control patients, 1 refused to participate, 1 transferred to another facility, and 3 were hospitalized for poor physical condition; hence, 30 participants completed the 1-year observation examination (Figure 1). There were no study disruptions due to fall injury. There were no interruptions in the measurements of 29 participants in the intervention group and 30 participants in the control group, and all completed the 1-year test.

Physical characteristics of both groups are presented in Table 1. Participants were a mean age of 84.0 ± 5.3 years and 49 (83%) were women. The intervention and control groups attended the nursing home day service once, twice, or thrice per week; the attendance level for both groups was

Table 1. Physical Characteristics of Patients.

Variable	Intervention Mean \pm SD or <i>n</i>	Control Mean \pm SD or <i>n</i>	<i>p</i>
Number	29	30	
Sex			
Female/male	23/6	26/4	NS
Age (years)	83.6 \pm 5.7	84.2 \pm 5.9	NS
Height (cm)	148.2 \pm 7.6	149.5 \pm 9.0	NS
Weight (kg)	51.5 \pm 9.9	53.4 \pm 11.7	NS
BMI (kg/m ²)	23.8 \pm 3.2	24.5 \pm 4.2	NS
Level of help required			
Level 1	11	14	NS
Level 2	18	16	NS
Number of nursing home visits			
Once a week	8	11	NS
Twice a week	16	15	NS
Thrice a week	5	4	NS
Main diagnosis of patients (overlapped)			
Hypertension	19	13	NS
Cardiovascular disease	9	10	NS
Diabetes mellitus	7	9	NS
Brain stroke	4	5	NS
Habitual exercise (at least 3 times a week)	16	14	NS
Pre-intervention			
IADL	5.3 \pm 1.9	5.2 \pm 1.3	NS
MMSE	27.3 \pm 1.9	27.1 \pm 1.6	NS
Fall history (last 6 months)	10	9	NS
Post-intervention			
IADL	5.7 \pm 1.5	5.4 \pm 2.0	NS
MMSE	26.5 \pm 3.4	25.5 \pm 3.6	NS
Fall history (last 1 year)	7	16	*

Abbreviations: BMI, body mass index; IADL, The Lawton Instrumental Activities of Daily Living; MMSE, Mini-Mental State Examination; NS, not significant.

*Significant at $p < .05$ between the pre- and post-intervention using Chi-squared test.

almost the same. The principal diseases suffered by the participants were hypertension, cardiovascular disease, diabetes mellitus, and stroke. The intervention and control groups had the same number of diseases. The Lawton Instrumental Activities of Daily Living and Mini-Mental State Examination results did not change from pre- to post-intervention in either group.

The study period was 1 year (June 1, 2018, to May 31, 2019). Throughout the study period, the intervention group wore the rehabilitative slippers while walking for 10-20 min on 1-3 days each week at a self-determined, comfortable walking speed only in the day service center. After 12 months, the intervention group had significantly improved Berg Balance and POMA compared to the control group ($p < .05$, $p < .01$, respectively) (Table 2). Figure 2 shows the serial points of fall risk scores. Friedman's test analysis of the scales' results showed a significant improvement in the intervention group using the rehabilitative slipper ($p < .01$). The control group had significantly lower Balance Scale and POMA scores ($p < .05$

and $p < .01$, respectively). During the 1-year observation period, the total number of falls were 47 and 9 out of 30 participants in the control group fell more than twice, compared to 3 out of 29 participants in the intervention group. Falls were experienced in the control group (baseline: 9 participants, increased to 16 after a 12-month period) and in the intervention group (baseline: 10 participants, decreased to 7 after a 12-month period) ($p = .02$).

There were no fractures due to falls. The fall risk scale results were not associated with the weight of the slippers or with the number of visits to the nursing home. Several participants in the intervention group reported improved stability, balance, and endurance (increased walking periods) following their exercise. No 1 of the 29 in the intervention group complained about the training, many said their mood lightened, and 14 commented that they would continue to use the slippers even after the study was completed. No adverse events related to the intervention were reported.

Discussion

Significant reductions in fall risks were observed in participants using the rehabilitative slipper. Although the mechanisms involved in the reduced fall risk are unclear, the slippers may contribute to improved anterior tibia function, thereby increasing toe clearance and reducing the risk of falls from tripping.⁹ They may also contribute to improved balance. Horak et al¹⁰ found that the resting equilibrium is improved by moving the body around the ankle joint when the body swings back and forth. Therefore, wearing slippers with weights may stimulate the muscles around the ankle joint to exert compensation torque and restore body balance. Several participants expressed that their body became stable when they put on the slippers.

Curran-Groome et al¹¹ investigated post-discharge falls in 199 elderly people aged 65 years and older who were hospitalized for surgery and had no history of falls. The results show that 52 of the 199 subjects experienced 1 or more falls within a year of their first fall. In addition, half had repeated falls within 90 days of their first fall. Additionally, many falls occur indoors, so it is important to prevent the recurrence of falls with proper intervention. Smith et al¹² reported that fall-prevention strategies should be targeted at those receiving care in a home. Considering these reports, training using fall-prevention slippers is recommended to improve fall-prevention among older people in the home care population as well as in their own homes.

This study has several limitations. First, the gender distribution among participants was unbalanced; the number of women was overwhelming due to the gender difference of the subjects who attended the day service. Second, the staff recording falls did not blind. Third, we had only a small number of participants. Fourth, we used self-reporting, which means that it is possible that the participants did not report all falls to the staff. During the 1-year observation period, 9 and 3 participants in the control and the intervention groups,

Table 2. Fall Risk Scores of Participants.^a

Variable	1 month before the intervention period (baseline) Median (IQR Scores)	3 months after the intervention period Median (IQR Scores)	6 months after the intervention period Median (IQR Scores)	9 months after the intervention period Median (IQR Scores)	12 months after the intervention period Median (IQR Scores)	<i>p</i>
Intervention (<i>n</i> = 29)						
Berg balance	47 (41-52)	51 (44-54)	50 (44-52)	50 (43-53)	50 (47-54)*	.001
POMA	26 (25-28)	27 (26-28)	27 (25-28)	27 (26-28)	27 (26-28)**	.005
Control (<i>n</i> = 30)						
Berg balance	44 (43-47)	46 (40-49)	46 (42-49)	45 (39-50)	43 (40-48)*	.023
POMA	26 (24-27)	26 (24-28)	26 (23-28)	26 (22-28)	25 (22-26)**	.000

Abbreviations: IQR, interquartile range; POMA, Tinetti Performance-Oriented Mobility Assessment.

^aSignificant difference between scores of the intervention group compared with those of the control group score are at * $p < .05$ and ** $p < .01$.

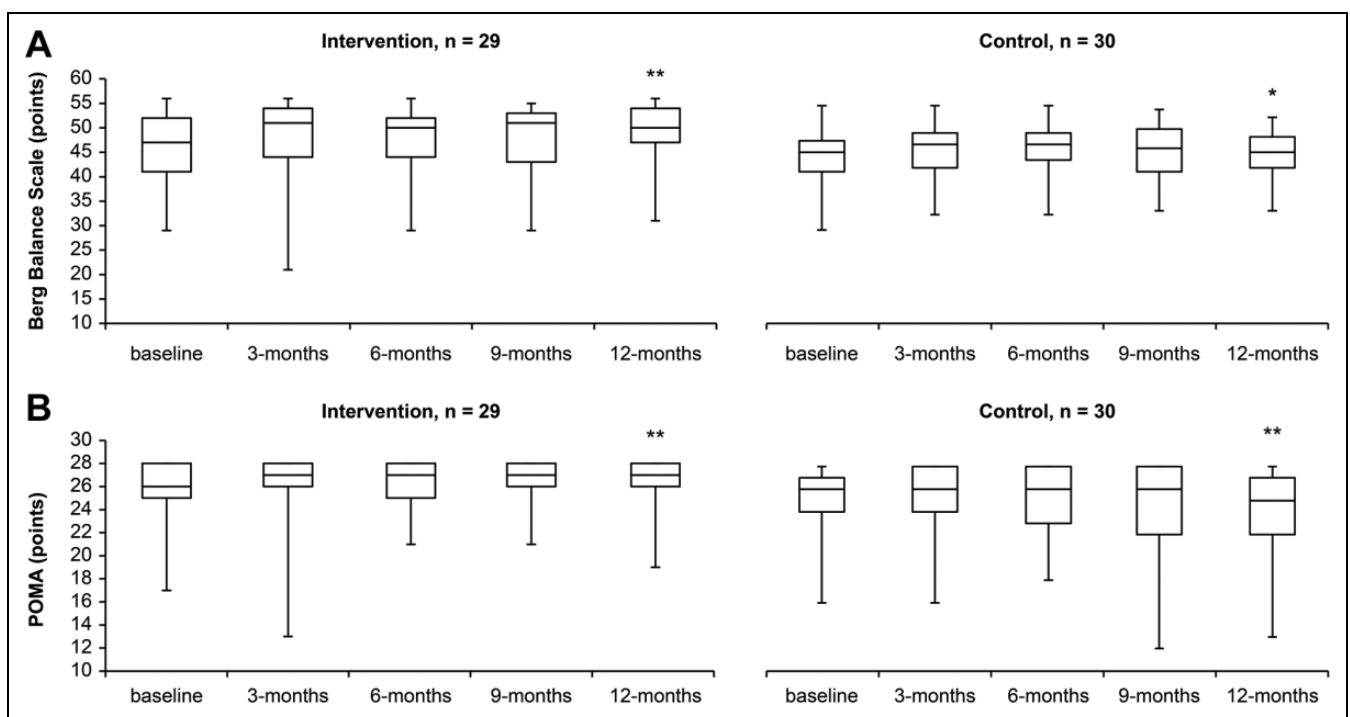


Figure 2. Participants' changes (25-75 percentile range) in fall risk values by the Berg Balance Scale (A) and the Tinetti Performance-Oriented Mobility Assessment (POMA) (B) for the intervention and control groups at the baseline and after 3-month, 6-month, 9-month, and 12-month periods. The Berg Balance Scale has a maximum value of 56 points; higher points indicate lower risk of fall. The POMA test has a maximum value of 28 points; higher points indicate lower risk of fall. Significance was * $p < .05$, ** $p < .01$, calculated using Friedman's test.

respectively, self-reported that they fell more than once. However, research from Gallouj et al¹³ showed that older adults' memory of falls was negative. Nonetheless, nursing home staff carefully assessed the significance of each reported fall by asking participants for an explanation. In addition, the mobility scores of the intervention group improved significantly.

Rehabilitation slippers are very simple, small, easy to use and inexpensive. Therefore, both care workers and patients can use them easily and continuously at home and in institutional rehabilitation. The rehabilitative slippers presented in this study would benefit elderly subjects who want to use a light load during exercise, without expensive machines that occupy a large space.

Authors' Note

This trial was approved by the ethics committee of Hirosaki University of Health and Welfare (authorisation number: 1018-4) and all participants provided written informed consent.


Declaration of Conflicting Interests

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References

1. Manini TM, Hong SL, Clark BC. Aging and muscle: a neuron's perspective. *Curr Opin Clin Nutr Metab Care*. 2013;16(1):21-26. doi:10.1097/MCO.0b013e32835b5880
2. Chiba H, Ebihara S, Tomita N, Sasaki H, Butler JP. Differential gait kinematics between fallers and non-fallers in community-dwelling elderly people. *Geriatr Gerontol Int*. 2005;5(2):127-134. doi:10.1111/j.1447-0594.2005.00281.x
3. Satoh A, Kudoh H, Fujita S, et al. Toe clearance rehabilitative slipper for fall risk in institutionalized older people. *Geriatr Gerontol Int*. 2012;12(2):361-363. doi:10.1111/j.1447-0594.2011.00773.x
4. Spreen O, Strauss E. *A Compendium of Neurological Tests*. 2nd ed. Oxford University Press; 1998.
5. Berg KO, Wood-Dauphinee SL, William JI, Maki B. Measuring balance in the elderly: validation of an instrument. *Can J Public Health*. 1992;83(Suppl 2):S7-S11.
6. Tinetti ME. Performance-oriented assessment of mobility problems in elderly patients. *J Am Geriatr Soc*. 1986;34(2):119-126. doi:10.1111/j.1532-5415.1986.tb05480.x
7. Lawton MP, Brody EM. Assessment of older people: self-maintaining and instrumental activities of daily living. *Gerontologist*. 1969;9(3):179-186.
8. Folstein MF, Folstein SE, McHugh PR. "Mini-Mental State": a practical method for grading the cognitive state of patients for the clinician. *J Psychiatr Res*. 1975;12(3):189-198.
9. Sato T, Ebihara S, Kudo H, Fujii M, Sasaki H, Butler JP. Toe clearance rehabilitative slipper for gait disorder in the elderly. *Geriatr Gerontol Int*. 2007;7(3):310-311. doi:10.1111/j.1447-0594.2007.00416.x
10. Horak FB, Nashner LM. Central programming of postural movements: adaptation to altered support-surface configurations. *J Neurophysiol*. 1986;55(6):1369-1381. doi:10.1152/jn.1986.55.6.1369
11. Curran-Groome W, Klein G, Miller SB, et al. Risk factors of recurrent falls among older adults admitted to the Trauma Surgery Department. *Geriatr Orthop Surg Rehabil*. 2020;11:1-8. doi:10.1177/2151459320943165
12. Smith J, Lewin G. Home care clients' participation in fall prevention activities. *Australas J Ageing*. 2008;27(1):38-42. doi:10.1111/j.1741-6612.2007.00270.x
13. Gallouj K, Altinas E, El Haj M. "I remember the fall": memory of falls in older adults. *Clin Gerontol*. 2020;6:1-9. doi:10.1080/07317115.2020.1787573