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主論文

Novel gait training using a dual-belt treadmill in older adults: A randomized controlled trial

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Highlights

- We developed gait training for volitional and reactive multidirectional stepping.
- The novel dual-belt treadmill training differs from conventional gait training.
- Dual-belt treadmill training showed greater task-specific effects in older adults.
- Gait training to enhance dynamic balance based on open skills should be recommended.

Abstract

Objective: Conventional gait training may induce less adaptive motor strategies to improve balance. In this study, we developed gait training for volitional and reactive multidirectional stepping on a dual-belt treadmill to train dynamic balance and examined the effects of this training on balance functions in older adults.

Methods: Participants were older adults aged >65 years who were randomly assigned to either a dual-belt treadmill training (DBT group, n = 43) or conventional gait training (control group, n = 43) group. The task of dual-belt treadmill training was to transfer between the left and right lanes of a treadmill, while walking and sequentially pressing a button corresponding to a number randomly presented on a monitor. Conventional gait training consisted of walking on a single-belt treadmill (forward and sideways) and tandem walking on level ground (forward and backward). Gait training was performed once a week for a duration of 20 min for 3 months. After training, conventional gait training was performed for 1 month as a follow-up for both groups. Changes in scores from baseline in the Community Balance and Mobility Scale (CB&M), comfortable gait speed, and stride length were compared between groups.

Results: After training, a significant difference was noted in the change in the CB&M between groups (P = 0.025), as well as in the change in the CB&M after follow-up (P = 0.048).

Conclusion: These results indicate that a novel gait training using a dual-belt treadmill improves balance, even at low frequency.

The study protocol is registered in the UMIN Clinical Trials Registry (UMIN000034107).

Keywords

older adults, balance, gait training, open skill

Abbreviations

CB&M, Community balance and mobility scale

1. Introduction

Falls in older adults are a critical issue in rehabilitation (Avin et al., 2015; Ganz & Latham, 2020; Sherrington et al., 2019). Although various causes of falls have been reported, impaired balance and gait disorders are the highest risk factors in older adults (Ganz & Latham, 2020). Therefore, an effective training method to improve walking balance to prevent falls should be established.

Previous studies on interventions to prevent falls have reported that some training methods, such as balance and functional exercises, are effective (Ng et al., 2019; Sherrington et al., 2019). High-dosage (3 h or more per week) and challenging balance tasks are recommended for exercise programs for older adults (Sherrington et al., 2017). Walking is often included in fall prevention programs; however, some studies have shown that walking alone does not prevent falls (Sherrington et al., 2019, 2017; Voukelatos et al., 2015). One possible reason for these negative results is that the task difficulty of a walking program is insufficient. Older adults are particularly prone to falls due to poor recovery in challenging tasks such as unpredictable environments (Sturnieks et al., 2013). Thus, training should focus on improvement in dynamic balance in unpredictable environments for adaptive motor strategies, such as postural responses, multi-sensory integration, and anticipatory postural adjustments (Blumen, Cavallari, Mourey, & Yiou, 2020; Okubo, Schoene, & Lord, 2017; Shimada, Obuchi, Furuna, & Suzuki, 2004).

Perturbation-based balance training is one type of challenging balance training intervention that incorporates exposure to repeated postural perturbations to evoke rapid balance reactions, enabling the individual to improve control of these reactions with practice (Mansfield, Wong, Bryce, Knorr, & Patterson, 2015). This training provides unpredictable stimuli to induce reactive stepping during standing and walking; however, external stimuli are typically limited to those in the anterior-posterior direction during treadmill walking (Gerards, McCrum, Mansfield, & Meijer, 2017; Mansfield et al., 2015; Okubo et al., 2017). Because medial and lateral stability are also reduced in older adults (Maki, Edmondstone, & McIlroy, 2000), it is crucial to train multidirectional steps during walking (Gerards et al., 2017; Mansfield et al., 2015). Volitional step interventions using stepping targets have also been conducted (Okubo et al., 2017); however, because these are usually performed in a standing position, it is difficult to train postural control by applying various gait rhythms. Furthermore, controlling the upper body as well as the lower limbs is essential for dynamic balance (Kang & Dingwell, 2009; Tang & Woollacott, 1998). Older adults adopt a more conservative, cautious gait pattern than younger people, possibly in an attempt to minimize the displacement of the upper body as a compensatory strategy (Menz, Lord, & Fitzpatrick, 2003). Therefore, it would be practical to promote functional tasks with the trunk and upper limbs while walking.

Considering the presented problems, we developed gait training for volitional and reactive multidirectional stepping on a dual-belt treadmill to train challenging dynamic balance. This study examined dual-belt treadmill training (DBT) effectiveness on balance function in older adults compared to conventional gait training. We predicted superior task-specific effects from DBT on balance function, especially on challenging balance tasks that are difficult for older adults.

2. Materials and Methods

2.1. Study Design

This study was a randomized control study conducted at Kansai Medical University Kori Hospital and was approved by the Ethics Committee of Kansai Medical University (2018025). All procedures followed the Declaration of Helsinki, and all participants provided written informed consent prior to enrollment. The study protocol is registered in the UMIN Clinical Trials Registry (UMIN000034107).

2.2. Setting and Participants

Our rehabilitation center offers a wide range of rehabilitation services, including inpatient rehabilitation and extensive outpatient programs. This study was conducted on older adults who attended the center using long-term care insurance. The eligibility for this insurance is determined based on their care or support level in activities of daily living. Certified older adults who chose to undergo rehabilitation at our center attended once or twice a week. The duration of each session was 40 min and consisted of gait training, strength training, and aerobic exercise.

The recruitment and registration periods were from September 2018 to December 2019. We included those who attended once or twice a week. For recruitment, the physical therapist at the center screened the participants using the following criteria, and those that met the criteria were confirmed their intent to participate in the study. The eligibility criteria were 1) age >65 years and 2) the ability to independently walk indoors without a walking aid. The exclusion criteria were 1) pain while walking due to osteoarticular disease; 2) somatosensory, vestibular, or visual impairments that affected balance; and 3) an inability to understand the instructions due to cognitive deficit (Mini-Mental State Examination score <18) (Folstein, Folstein, & McHugh, 1975). The diagnosed disease was ascertained from the medical record. Musculoskeletal and sensory dysfunctions affecting balance were also assessed in the clinical by a physical therapist.

2.3. Randomization and Blinding

Enrollment was performed by the physical therapist, following which participants were randomly assigned to either the dual-belt treadmill training group (DBT group) or the conventional gait training group (control group). Assignment into each group was determined by the block randomization method generating random numbers through a computer. The allocation ratio was set at 1:1, and the block size was fixed at 4. The allocator (K. A.) was not involved in the determination of eligibility, training interventions, or outcome assessment. We used adaptive randomization for the last 15 participants by the same allocator to ensure that the number of participants completing the training was equal. The physical therapists who measured outcomes were also blinded.

2.4. Interventions

As a feasible training protocol in the rehabilitation service using long-term care insurance, we prescribed gait training supervised by a physical therapist within the assigned group for 20 min once a week for 3 months. The remaining 20 min were designated for self-training, either strength training or aerobic exercise. Strength training was prioritized, but aerobic exercise was performed if participants refused due to fatigue or other reasons. Participants who attended the center twice a week performed both lower limb strength training and aerobic exercise for 20 min each per session on the day alternate to gait training. Lower limb strength training consisted of hip abduction, adduction, and leg press using machines (H01AA004; H01AA002, Alexandave Industries. Co. Ltd., New Taipei, Taiwan). The intensity of the exercise was set at a level that was considered as slightly severe by the participants: 6 seconds of movement followed by 6 seconds of reverse movement using machines repeated 10 times, with a 1-minute interval between sessions, for a total of three sessions. Aerobic exercise was performed using bicycle ergometers (BT-6572, Superweigh Enterprise. Co., Ltd, Nantou, Taiwan; BioStep™ 2, Biodex Medical Systems. Inc, NY, USA) for 20 min with 50 revolutions per minute at an intensity that the participant perceived as somewhat hard (Borg Scale 13). The intensity of strength training and aerobic exercise was set by a physical therapist or care worker who adjusted the intensity if the participants had difficulty practicing; they did not provide specific instructions during training.

We also examined the sustained effects of the 3-month DBT. Since the participants were older adults attending the rehabilitation center using long-term care insurance, we determined that an appropriate follow-up period would be 1 month in order to not increase the number of dropouts. Therefore, after 3 months of training, conventional gait training was performed in both groups once a week for 20 min for 1 month as follow-up to examine whether the any effects in the DBT group returned to baseline.

2.5. Dual-belt treadmill training (DBT)

Participants walked on either the left or right lanes of a split-belt treadmill (Anima. Inc., Chofu, Tokyo, Japan), while sequentially pressing one of the four buttons corresponding to the same number presented on a monitor randomly (Figure 1). Each belt was 105 cm long and 37 cm wide. Participants were instructed to: observe the number on the monitor; move to the lane corresponding to the button's side without stepping on the plank between the lanes; and press the button with the hand on the same side as the lane, as quickly as possible.

We conducted preliminary experiments on the DBT protocol. Considering the adaptation and fatigue caused by the training, we designed the DBT to consist of four trials per session, with each trial duration set to 3 min. Prior to the trial, the belt speed was set by a physical therapist so that the participant could safely walk as fast as possible over both lanes. In the first trial, both belt speeds were the same. In the second trial, the left and right lane belt speeds were set to +20% and -20% of the first trial speed, respectively. In the third trial, the left and right lane belt speeds were set to -20% and +20% of the first trial speed, respectively. In the fourth trial, both belt speeds were set to +20% of the first trial speed. The number indicating the button to be pressed was programmed to display on the monitor randomly, and the next number was presented when the button was pressed correctly. During the training, participants were instructed to refrain as much as possible from grasping the handrails unless they lost their balance. Participants wore a waist belt and were supported, as needed, by a physical therapist who stood behind them to prevent falls. Participants rested for 2–3 min by sitting between each trial to minimize the effects of fatigue, with a total session time of approximately 20 min.

2.6. Conventional Gait Training

Conventional gait training, including multidirectional walking that is often performed in clinical practice, was conducted by a physical therapist for 20 min per session. This training consisted of 15-min walking on a single-belt treadmill and 5 min of tandem walking on the ground. The treadmill (T655MS, SportsArt. Inc., Mukilteo, WA, USA) belt size was 157 cm long and 56 cm wide; participants trained for 10 min of forward walking and 2.5 min of side walking on each side with a harness (BDX-UWSZ, Biodex Medical System Inc., Shirley, NY, USA) and while grasping the handrails. The belt speed in each walking direction was set individually by a physical therapist to a level that the participant considered as slightly severe and had difficulty maintaining a consistent stepping rhythm. Participants also practiced the tandem walking on the level ground 5-m walkway for 2.5 min each in the forward and backward directions. While walking on the ground, participants wore a waist belt and were closely supervised by a physical therapist.

2.7. Outcome Measures

Primary outcomes were the Community Balance and Mobility Scale (CB&M), comfortable gait speed, and step length. Blinded physical therapists measured outcomes at baseline, after training, and after follow-up.

The CB&M used to assess balance and mobility required for daily living consists of 13 items, and the total score ranges from 0 to 96, with higher scores indicating higher balance ability (Howe, Inness, Venturini, Williams, & Verrier, 2006). The CB&M has been reported to be a reliable and valid measure of balance ability and is less likely to show a ceiling effect in older adults (Balasubramanian, 2015; Weber et al., 2018). The most sensitive (90% sensitivity) cut-off as a predictive measure of falls is estimated to be 45 points (Balasubramanian, 2015).

Gait speed is also widely used to assess mobility in older adults and is regarded as a fall risk factor (Abellan Van Kan et al., 2009; Ganz & Latham, 2020; Quach et al., 2011). A previous study reported that a significant change (effect size = 0.5) in older adults' walking speed was 0.12–0.13 m/s (Perera, Mody, Woodman, & Studenski, 2006). For the walking test, participants were instructed to walk along a 12-m walkway at a comfortable speed (Morio et al., 2019). The time taken to walk the 10 m distance in the middle of the 12-m walkway was measured using a digital stopwatch. The number of steps used for the 10-m walk was obtained. Gait speed and step length were calculated by recording the time and the number of steps. The measurements were taken twice, and the faster value was adopted.

The CB&M and gait assessments were conducted by three blinded physical therapists. These therapists confirmed and trained the assessment protocol prior to the study to ensure consistency on the tasks and scoring methods.

The number of gait training and total training sessions were recorded in both groups. Adverse events, such as falls, trauma, and pain during training, were also recorded. If the participants stopped the training, the reason was recorded.

2.8. Sample Size

According to our investigation, there is no published data on minimal detectable change or minimal clinically important difference of CB&M in older adults. Liu-Ambrose et al.(2004) assigned older adults to three groups of strength, agility, and stretching training, and examined the effects on fall risk parameters at 13 and 25 weeks. They reported a significant improvement in CB&M (11.6 points) in the agility training group compared to the other two groups after 13 weeks. The number of participants in the agility training group was 34, and the effect size of CB&M between baseline and after 13 weeks of training was 0.66 (moderate). Applying this study design, assuming $\alpha = 0.05$, $\beta = 0.8$, and effect size = 0.7, the required sample size would be 34 for each group. Therefore, we decided to recruit 86 participants, considering a consent acquisition rate of 90% and a dropout rate of 10%.

2.9. Statistical Analyses

We analyzed the data based on the modified intention-to-treat principle. If a participant attended fewer than 12 sessions, due to absences or other reasons, we included them in the analyses. However, participants who dropped out and could not be assessed after the 3-month training were excluded from the analyses. Conversely, in the follow-up assessment, missing data due to dropouts during the follow-up period were included in the analyses using the multiple imputation method. We also included the data loss of the participants in the analyses by the multiple imputation method.

The data were analyzed using R software (ver. 4.0.3, R Foundation for Statistical Computing, Vienna, Austria). Normality tests for each parameter were performed by the Shapiro-Wilk test before statistical analyses, and appropriate tests were used according to the parametric or non-parametric data. To confirm whether the demographic characteristics of the two groups were matched, the baseline parameters were compared between groups using the Student's t-test, Wilcoxon rank-sum test, or chi-square test, as appropriate. The training frequency and number of sessions were also compared between groups using the Wilcoxon rank-sum test or chi-square test.

For the analyses of primary outcomes, the change scores from baseline in CB&M, comfortable gait speed, and step length after training and follow-up were compared between the groups using two-sample t-tests with multiple imputation method to examine DBT effects. The Cohen's d effect size of each parameter was also calculated, and effect sizes of 0.2, 0.5, and 0.8 indicated small, medium, and large effect sizes, respectively (Cohen, 1988). Moreover, to confirm the robustness of the statistical results, the change scores were compared between the groups using a linear mixed model. A multiple imputation approach was implemented with baseline age, height, weight, frailty index (total Kihon Checklist score; 0–25 points) (Satake et al., 2016), Mini-Mental State Examination score (0–30 points), and trial session number (0–12 times) used as factors to create a data set of 20 using R package 'Amelia'. These variables were also applied to the random factors in the linear mixed model using R package 'lme4'. The treatment group was entered as a fixed factor.

To examine the change in balance performance, the changes in CB&M subcategories from baseline were compared in both groups using Wilcoxon signed-rank test. To examine the task performance during DBT, the belt speed and number of pressed buttons at the fourth trial were compared between the first and final sessions using paired t-test. The statistical significance level was set at 5%.

3. Results

We screened 260 participants; 90 met the eligibility criteria, of whom 86 were randomly assigned; 43 were allocated to the DBT group and the remaining 43 to the control group (Figure 2). Eight participants in the DBT group and nine in the control group dropped out during the 3-month training. Thirty-five participants in the DBT group and 34 in the control group completed the training. One participant in the DBT group experienced worsened hip pain due to osteoarthritis despite completing the training and follow-up sessions. This participant was excluded from the analyses because of eligible for the exclusion criteria. Therefore, 34 participants in the DBT group and 34 in the control group were included in the analyses. During the follow-up, two participants in the DBT group and five in the control group dropped out. These missing data were included in the analyses with multiple imputation methods. Additionally, the following data were missing in the baseline assessment; one participant for CB&M and gait data, one participant for CB&M in the

DBT group, and one participant for gait data in the control group. These were analyzed using the multiple imputation method.

The participants' mean age was 79.0 (SD, 5.4) years, and 63% were female (Table 1). Most participants were pre-frail (60.3%). The mean MMSE score was 26.3 (2.6) points, the mean CB&M score was 41.4 (15.2) points, and the mean gait speed was 1.05 (0.25) m/sec. Most of the participants in this study were older, slightly frail, and had impaired balance. No participants had difficulty in understanding the instructions due to cognitive dysfunction resulting in an inability to perform the training.

The number of participants who attended the center once or twice a week were 22 and 12 in the DBT group and 19 and 15 in the control group, respectively ($P = 0.457$). During the training, the mean number of gait training sessions was 10.6 (1.6) in the DBT group and 10.8 (1.9) in the control group ($P = 0.498$). During the follow-up, the mean number of gait training sessions was 2.6 (0.7) in the DBT group and 2.4 (0.9) in the control group ($P = 0.564$). The mean number of total sessions for those who attended twice a week was not significant between the groups (training period: DBT group: 14.1 (5.0), control group: 14.9 (5.2), $P = 0.347$; follow-up period: DBT group: 3.9 (1.9), control group: 3.8 (2.2), $P = 0.756$).

3.1. Primary Outcomes

Table 2 shows the results of each parameter after training and follow-up for each group. In the multiple imputation model, significant differences were noted in the changes in CB&M between the groups after training (95% CI, 0.5–7.6; $P = 0.025$) and in the changes in CB&M after follow-up (95% CI, 0.0–7.8; $P = 0.048$). Conversely, no significant differences were noted in the changes in comfortable gait speed and step length at any time point. Similar results were observed in the linear mixed model, as well as in the listwise deletion (complete-case analysis) and multiple imputation that excluded the four participants with missing data in the baseline assessment (Supplemental material).

3.2. CB&M Subcategories

For the DBT group, nine of 13 subcategories significantly improved after follow-up, while one subcategory improved after training ($P < 0.05$) (Table 3). For the control group, only one subcategory significantly improved after training and follow-up ($P < 0.05$). These significantly improved subcategories differed between the groups.

3.3. Task Performance During DBT

The initial belt speed in the DBT group ranged from 0.3 to 1.8 km/h. Figure 3 shows the trend of belt speed at the fourth trial of sessions during the training period. The average belt speed at the fourth trial was significantly increased from 1.0 (0.3) km/h to 2.4 (0.7) km/h in the first and final sessions, respectively ($P < 0.001$). The mean number of pressed buttons at the fourth trial was 90.0 (21.9) times and 92.3 (28.6) times in the first and final sessions, respectively, with no significant difference between the sessions ($P = 0.512$).

3.4. Adverse Events

In the DBT group, one participant stopped training due to worsening lumbar pain; one participant in the control group stopped training due to worsening knee pain. One participant in the DBT group fell during the post-training CB&M assessment; however, there was no pain or injury, so the assessment was continued and included in the analyses.

4. Discussion

In the present study, we developed DBT to train challenging dynamic balance combined volitional and reactive multidirectional stepping. The treadmill walking and moving sideways between the lanes aimed to facilitate volitional multidirectional stepping. The left and right belt speed differences were intended to facilitate reactive stepping and agile regulation of gait rhythm. The reaching task also aimed to train the upper limb and trunk control while walking. Additionally, these dynamic balance controls are trained in an unpredictable environment by randomly presenting the buttons to be pressed. The DBT is a new practice that differs from conventional gait training in that it comprehensively includes the required adaptive motor strategies of balance. The change in CB&M in the DBT group was significantly greater than that in the control group after training and follow-up, indicating the effectiveness of DBT on balance function in older adults.

The CB&M includes challenging tasks to assess specific aspects of balance and mobility that are necessary to function independently within the community (Balasubramanian, 2015; Howe et al., 2006; Weber et al., 2018). The change in CB&M after the 3-month training showed a moderate effect (Cohen's d = 0.56). In a previous study, the most sensitive (90% sensitivity) cut-off point for using CB&M as a predictive indicator of falls was 45 points (Balasubramanian, 2015). The baseline mean score of CB&M in the DBT group was 43.3 points, whereas the mean change was +4.7 and +7.4 points after training and follow-up, respectively. Therefore, the DBT was deemed meaningful for the participants of this study. However, no significant difference was noted in the change in comfortable gait speed and step length at any time point. Neither group reached a meaningful change in walking speed (0.12 to 0.13 m/s) (Perera et al., 2006). One possible reason is that DBT is not primarily focused on fast walking. In this training, the belt speed was set as fast as possible while moving to the left and right lanes. Therefore, the DBT may have the potential for task-specific improvements in balance and mobility skills needed in daily life, rather than walking speed. For the control group, the exercise dosage may have affected the results. A previous meta-analysis has reported that therapeutic exercise can improve gait speed in community-dwelling older adults and that intensity and dosage are important contributing factors (Lopopolo, Greco, Sullivan, Craik, & Mangione, 2006). According to this study, high-dosage exercise was defined as more than 3 h per week of exercise, but the exercise dosage in this study was less than 3 h per week and, therefore, did not meet this criterion.

A previous review has shown that older adults retain the ability to adapt to movements predictably and responsively through disturbance repetition (Bohm, Mademli, Mersmann, & Arampatzis, 2015), and our results are consistent with these findings. One of the most notable findings of DBT is that balance improvement was obtained despite the low frequency (20 min, once a week, for 3 months). The effectiveness, even at low frequency, is beneficial for older adults who have difficulty with frequent visits to a rehabilitation institution. A previous review reported that effective exercise programs to improve balance are generally performed three times per week for 3 months and include dynamic training in a standing position (Howe et al., 2011). Sherrington et al.(2017) suggested that fall prevention training for older adults should include a challenging balance task (progressively increasing in difficulty) and high frequency (3 h or more per week). In the present study, gait training was conducted for 20 min once a week. The total exercise time was 1 h 20 min per week, even with the additional exercise time for those who attended twice a week. Therefore, even low-frequency interventions of DBT seemed to have a significant effect because of the challenging task by inducing combined volitional and reactive multidirectional stepping in unpredictable environments. The increase in the belt speed for 3 months indicates that the DBT group could train progressively increasing in difficulty to adapt to the higher belt speed.

Interestingly, the change in CB&M was significantly greater in the DBT group at follow-up, even after changing to conventional gait training. Besides, the number of CB&M subcategories that improved significantly compared to baseline increased from 1 to

9 of 13 after follow-up. This result may indicate that the DBT has a more beneficial impact on implementing adaptive motor strategies. Motor skills can be categorized as open or closed skills. Open skills are performed in a dynamic and changing environment, while closed skills take place in a predictable and static environment (Di Russo et al., 2010; Gu, Zou, Loprinzi, Quan, & Huang, 2019; Wang et al., 2013). Open-skill exercises involve unpredictable environments, active decision making, and ongoing adaptability in which participants must alter responses to randomly occurring external stimuli (Di Russo et al., 2010; Gu et al., 2019; Wang et al., 2013). The DBT is deemed to be based on open skills because it can induce dynamic balance controls in an unpredictable environment, by randomly presenting the buttons to be pressed. The results of this study suggest that open-skill-based training is effective in improving the adaptability of balance in older adults. Remarkably, the significantly improved CB&M subcategories were different between the groups, indicating the task-specific improvement according to the gait training regime. The control group underwent applied gait training, which is often performed in clinical practice. In particular, consecutive walking sideways on the treadmill seemed to be a difficult task for older adults. This training might contribute to the improvement in the "lateral dogging" of the CB&M subcategory at follow-up.

Although the DBT significantly improved CB&M in older adults, the neurophysiological mechanisms by which DBT improves balance are unclear. Postural control is a complex motor skill based on the interaction of dynamic sensorimotor processes and involves the selection of motor responses that maintain or recover the balance of the body (Horak, 2006). Tang & Woollacott (1998) have reported that postural response to unexpected forward slip in older adults is characterized by a longer onset latency, smaller burst magnitude, and longer agonist/antagonist coactivation duration of the lower limb and trunk muscles. To improve these posture control problems, they suggested that the following aspects should be considered during training; 1) including dynamic tasks that require fast and powerful muscle activity generation, 2) emphasizing interlimb coordination as well as the coordination between the lower extremities and upper body to increase the number of movement strategies, and 3) incorporating the use of upper extremity equilibrium and protective reactions. The DBT is considered to be advantageous because it includes these aspects. Although the effects of perturbation-based balance training have been reported (Lurie, Zagaria, Pidgeon, Forman, & Spratt, 2013; Mansfield, Peters, Liu, & Maki, 2010; Shimada et al., 2004), a previous review has suggested that it is practical to include variety perturbations in the types and directions (Gerards et al., 2017). We believe that the DBT is unique because it provides challenging dynamic balance tasks, including repetitive volitional and reactive multidirectional steps and reaching movements while processing treadmill perturbations. The results of increasing the belt speed over time have indicated that the DBT contributed to the improvement in dynamic balance. In the future, it is necessary to validate the postural control acquired during the DBT using neurophysiological and motion analysis and comparing to other perturbation-based balance training.

One participant in the DBT group dropped out due to exacerbation of lumbar pain. This participant could walk on level ground but had osteoarthritis of the lumbar spine with kyphosis, which may have been exacerbated by the reaching task or multidirectional stepping. One participant in the DBT group was able to complete the task despite having kyphosis, and in this case, CB&M improved from 43 to 57 points. Because kyphosis does not necessarily cause pain, we did not recommend that participants with kyphosis be excluded from the DBT. Rather, it was essential to carefully monitor each participant's condition while performing the tasks. The reason why most participants could complete the DBT was probably because the difficulty level was adjusted by adapting the walking speed according to each participant. The initial belt speed in the DBT group ranged from 0.3 to

1.8 km/h. The strength of the DBT was that it could provide a challenging task for each participant.

Our study has some limitations. First, since this study was conducted in a rehabilitation center using long-term care insurance, the recruited participants tended to be older with reduced balance. The results of this study should be applied with caution to a wider population of older adults. In the future, further studies should be conducted with a larger sample size that includes younger older adults to determine the effects of the DBT on balance. A sub-analysis on cognitive function and balance should also be conducted. Second, we did not examine physical factors, such as motor functions, sensory functions, and body composition that led to improved balance function. Further studies are needed to evaluate these functions, particularly muscle strength, agility, and proprioception. In addition, neurophysiological and motion analyses are also needed for performance during DBT and gait assessment. Finally, the participants underwent rehabilitation once or twice a week, and the number and content of the exercises other than gait training could not be strictly controlled. Further studies should be conducted to control these factors to examine the effect on fall prevention, the mechanism of balance improvement, and the cost-effectiveness from a long-term perspective.

5. Conclusions

We developed gait training for volitional and reactive multidirectional stepping on a dual-belt treadmill to train challenging dynamic balance. This training showed significantly greater task-specific effects on balance function than conventional gait training in older adults after 3 months of training, even at a low frequency. Furthermore, the change in balance function was significantly greater after 1-month of follow-up. This training, even at low frequency, is beneficial for older adults who have difficulty with frequent visits to a rehabilitation institution. Our findings indicate that open-skill-based challenging balance training has a more beneficial impact on implementing adaptive motor strategies in older adults.

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Declaration of Competing Interest

The authors report no declarations of interest.

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Figure Legends

Figure 1. Dual-belt treadmill system

(A) The device consists of a dual-belt split treadmill; each belt is 105 cm long and 37 cm wide; with handrails at the front and sides. The space between the two belts is 20 cm, covered by a seat that enables participants to transfer between each belt. Four touch buttons are located on the front/back/left/right of the handrails. (B-E) Training scenes. The front monitor is programmed to present numbers 1 to 4 at random. The participants observe the numbers, and push the corresponding button, while transferring between each lane without stepping on the plank between the lanes.

Figure 2. Flow chart of the study

DBT, dual-belt treadmill training

Figure 3. Belt speed and the number of pressed buttons in the DBT group

The thin solid line shows the trend for each participant, and the thick solid line shows the trend for the average of the participants.

Figure 1

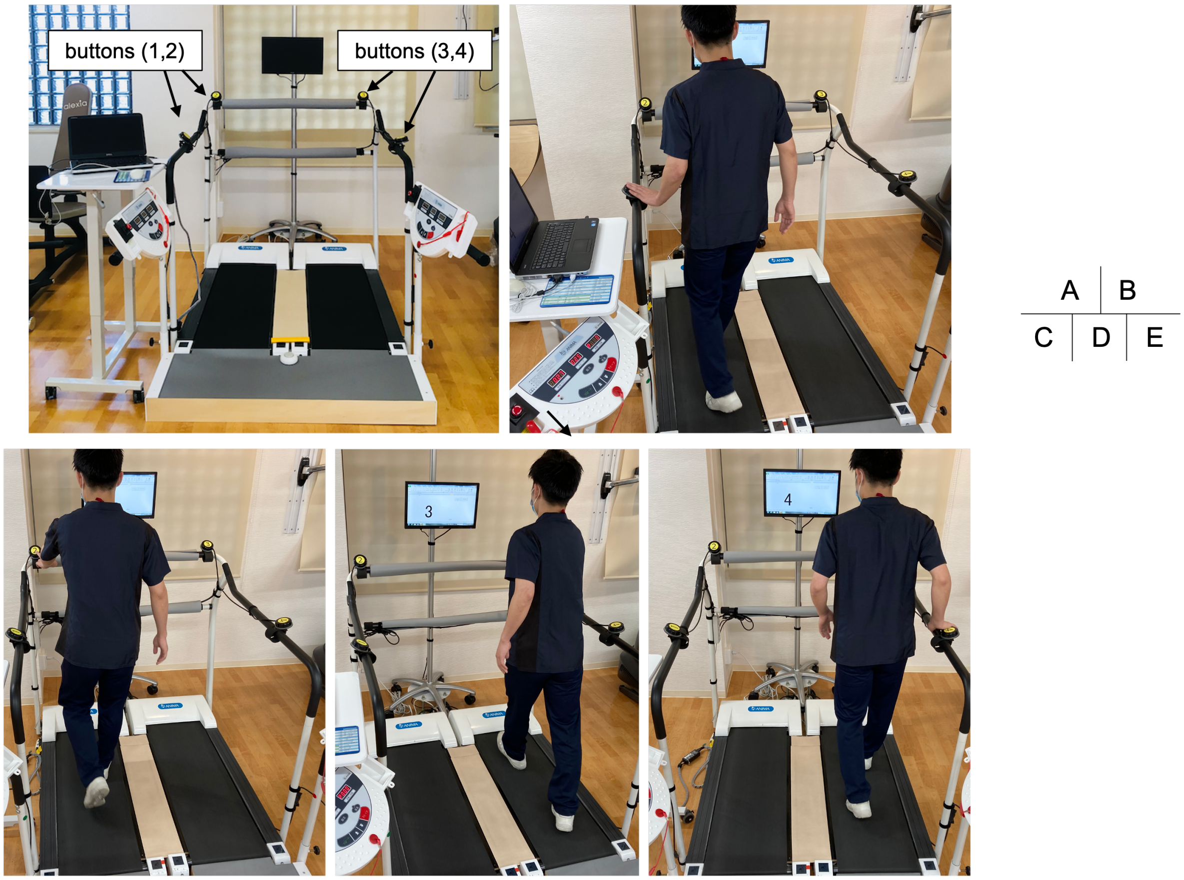
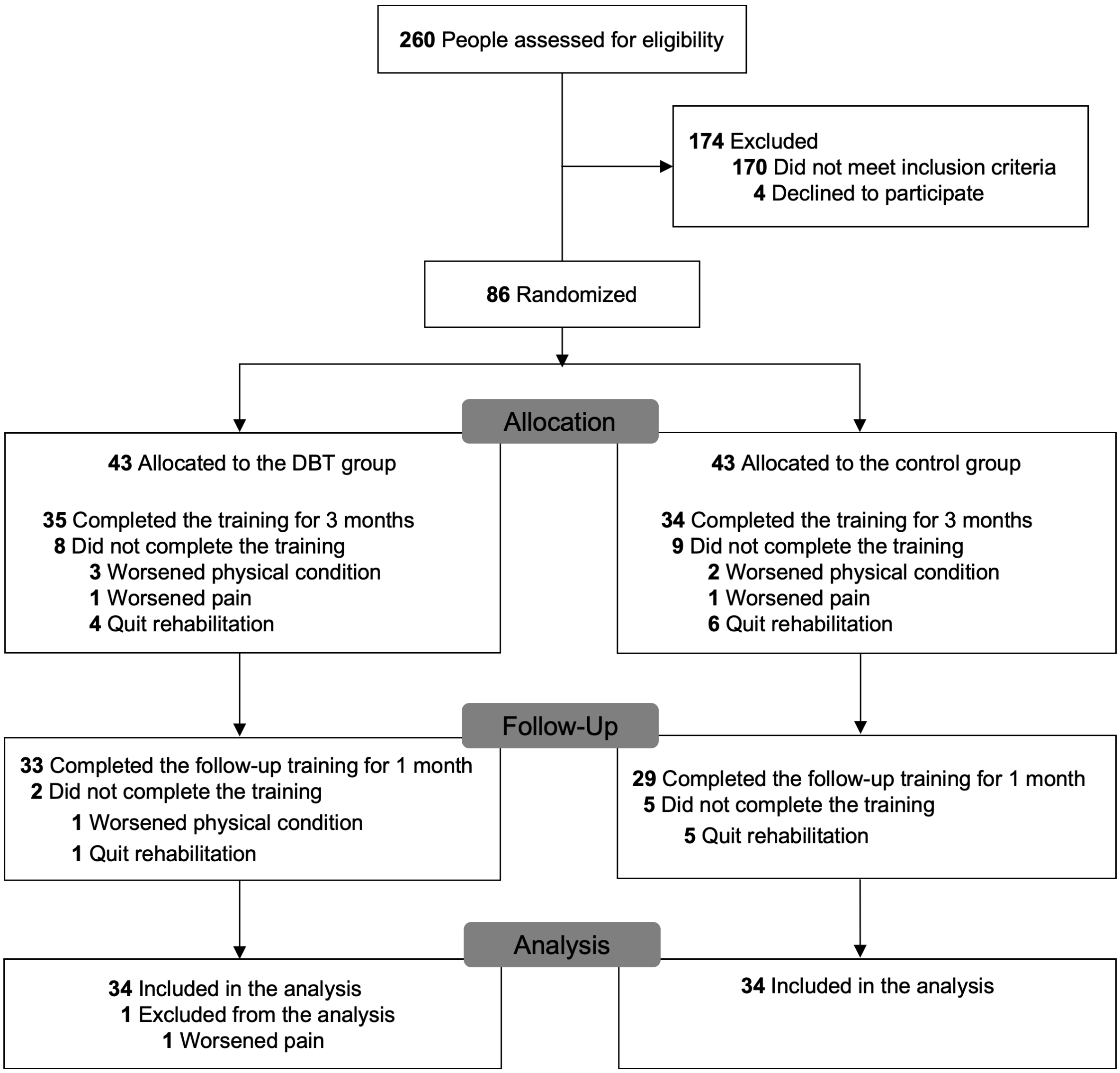


Figure 2



260 People assessed for eligibility
174 Excluded
170 Did not meet inclusion criteria
4 Declined to participate
86 Randomized
Allocation
43 Allocated to the DBT group
35 Completed the training for 3 months
8 Did not complete the training
3 Worsened physical condition
1 Worsened pain
4 Quit rehabilitation
43 Allocated to the control group
34 Completed the training for 3 months
9 Did not complete the training
2 Worsened physical condition
1 Worsened pain
6 Quit rehabilitation
Follow-Up
33 Completed the follow-up training for 1 month
2 Did not complete the training
1 Worsened physical condition
1 Quit rehabilitation
29 Completed the follow-up training for 1 month
5 Did not complete the training
5 Quit rehabilitation
Analysis
34 Included in the analysis
1 Excluded from the analysis
1 Worsened pain
34 Included in the analysis

Figure 3

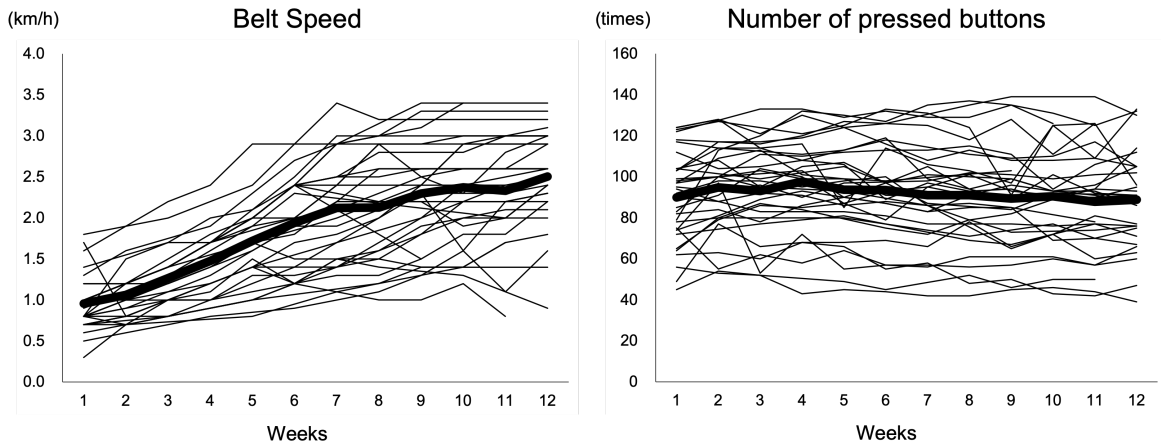

(km/h)
Belt Speed
4.0
3.5
3.0
2.5
2.0
1.5
1.0
0.5
0.0
1 2 3 4 5 6 7 8 9 10 11 12
Weeks
(times)
Number of pressed buttons
160
140
120
100
80
60
40
20
0
1 2 3 4 5 6 7 8 9 10 11 12
Weeks

Table 1. Baseline descriptive data of participants

	DBT group (n = 34)	Control group (n = 34)	*P* value
Age, mean (SD), y	78.0 (5.7)	80.1 (4.9)	0.113
Sex, n (%)			
Male	12 (35.3)	13 (38.2)	0.801
Female	22 (64.7)	21 (61.8)	
Height, mean (SD), cm	154.4 (7.4)	153.9 (9.9)	0.791
Weight, mean (SD), kg	57.4 (9.2)	57.0 (11.1)	0.883
Body mass index, mean (SD)	24.2 (4.0)	24.1 (4.3)	0.829
Frailty status[a] (robust/pre-frail/frail), n	6/19/9	6/22/6	
Mini-Mental State Examination score, mean (SD)	26.0 (3.1)	26.5 (2.1)	0.621
CB&M, mean (SD)[b]	43.3 (13.5)	39.5 (16.6)	0.309
Gait speed, mean (SD), m/s	1.10 (0.24)	1.01 (0.27)	0.172
Step length, mean (SD), cm	54.1 (9.2)	51.3 (11.5)	0.273

[a]Assessed using the total Kihon Checklist score

[b]Data of 32 participants, due to missing data for two participants

CB&M, Community Balance and Mobility Scale; DBT, dual-belt treadmill training; SD, standard deviation

Table 2. Change scores from baseline at 3-month training and 1-month follow-up

	Multiple imputation					**Linear mixed model**	
	DBT group (n = 34)	**Control group (n = 34)**	**Estimated difference 95% CI**	***P* value**	***Cohen's d***	**Estimated difference (95% CI)**	***P* value**
3-Month training							
CB&M, mean (SD)	4.74 (8.05)	0.68 (6.43)	0.53 to 7.59	0.025*	0.56	4.24 (0.83 to 7.66)	0.016*
Gait speed, mean (SD), m/s	0.09 (0.18)	0.04 (0.14)	-0.03 to 0.13	0.195	0.32	0.07 (-0.01 to 0.14)	0.080
Step length, mean (SD), cm	2.26 (7.40)	0.66 (6.05)	-1.69 to 4.89	0.335	0.24	1.62 (-1.57 to 4.82)	0.314
1-Month follow-up							
CB&M, mean (SD)	7.38 (7.84)	3.44 (8.58)	0.03 to 7.83	0.048*	0.48	4.36 (0.34 to 8.38)	0.034*
Gait speed, mean (SD), m/s	0.05 (0.19)	0.07 (0.14)	-0.10 to 0.07	0.786	-0.07	0.03 (-0.06 to 0.11)	0.488
Step length, mean (SD), cm	2.23 (6.93)	2.64 (6.38)	-3.73 to 2.90	0.804	-0.06	-0.16 (-3.35 to 3.03)	0.919

*: $P < 0.05$, **: $P < 0.01$

CB&M, Community Balance and Mobility Scale; CI, confidence interval; DBT, dual-belt treadmill training; SD, standard deviation

Table 3. Change in the subcategories of community balance and mobility scale

	Baseline	3-Month training	*P* value (vs. baseline)	1-Month follow-up	*P* value (vs. baseline)
DBT group					
Unilateral Stance	3.48 (2.11)	4.00 (2.02)	0.069	4.38 (2.66)	0.011*
Tandem Walking	2.64 (1.54)	2.76 (1.50)	0.577	3.34 (1.29)	0.044*
180-degree Tandem Pivot	2.42 (1.62)	2.76 (1.44)	0.188	2.75 (1.39)	0.429
Lateral Foot Scooting	1.70 (2.30)	2.15 (2.45)	0.072	2.59 (2.59)	0.035*
Hopping Forward	1.79 (1.90)	2.26 (2.21)	0.083	2.62 (2.08)	0.038*
Crouch and Walk	2.85 (1.25)	2.82 (1.22)	0.698	3.00 (1.05)	0.180
Lateral Dodging	2.39 (0.90)	2.53 (0.83)	0.417	2.38 (0.75)	0.301
Walking & Looking	5.94 (1.97)	6.79 (1.82)	0.007**	7.03 (1.84)	0.002**
Running with Controlled Stop	0.97 (0.59)	1.26 (0.96)	0.074	1.22 (0.97)	0.111
Forward to Backward Walking	2.61 (0.86)	2.76 (1.07)	0.296	3.09 (1.03)	0.013*
Walk, Look & Carry	6.12 (2.26)	6.79 (2.19)	0.053	7.28 (2.02)	0.003**
Descending Stairs	4.00 (1.84)	4.21 (2.20)	0.534	4.66 (2.03)	0.028*
Step-Ups x1 Step	5.73 (1.94)	5.85 (2.49)	0.345	6.41 (1.64)	0.005**

Control group					
Unilateral Stance	3.09 (2.57)	2.97 (2.57)	0.845	3.56 (2.14)	0.867
Tandem Walking	2.24 (1.79)	2.52 (1.48)	0.377	2.93 (1.62)	0.227
180-degree Tandem Pivot	1.88 (1.45)	2.55 (1.52)	0.005**	2.70 (1.59)	0.070
Lateral Foot Scooting	1.39 (1.98)	1.18 (1.69)	0.551	2.22 (2.75)	0.258
Hopping Forward	1.64 (2.03)	1.36 (1.80)	0.138	2.33 (2.04)	0.175
Crouch and Walk	2.79 (1.02)	2.64 (0.99)	0.462	3.07 (0.92)	0.334
Lateral Dodging	2.18 (1.10)	2.48 (0.87)	0.119	2.85 (0.53)	0.028*
Walking & Looking	6.15 (2.41)	6.52 (1.70)	0.478	6.93 (1.62)	0.485
Running with Controlled Stop	0.97 (0.92)	0.67 (0.65)	0.036*	1.07 (0.96)	0.884
Forward to Backward Walking	2.30 (0.95)	2.52 (0.76)	0.098	2.56 (0.70)	0.428
Walk, Look & Carry	5.91 (2.49)	6.21 (2.03)	0.467	6.70 (1.73)	0.702
Descending Stairs	3.97 (1.98)	3.88 (2.27)	0.580	4.15 (2.09)	0.401
Step-Ups x1 Step	5.58 (2.06)	5.27 (2.30)	0.456	5.89 (1.60)	0.872

*: $P < 0.05$, **: $P < 0.01$

DBT, dual-belt treadmill training

Appendix 1

Based on the null hypothesis that the measured data were MCAR (Missing completely at random), the Little's MCAR test was performed and the result was not significant with $P = 0.937$. Therefore, the Student t-test was performed using the complete data after listwise deletion of those with missing data. The results are shown in the table below.

Results of primary outcomes using listwise deletion

	Listwise deletion					
	DBT group	**n**	**Control group**	**n**	***P* value**	***Cohen's d***
3-Month training						
CB&M, mean (SD)	4.66 (7.91)	32	0.68 (6.43)	34	0.028*	0.55
Gait speed, mean (SD), m/s	0.09 (0.18)	33	0.04 (0.14)	33	0.207	0.31
Step length, mean (SD), cm	2.23 (7.39)	33	0.80 (5.99)	33	0.390	0.21
1-Month follow-up						
CB&M, mean (SD)	7.93 (7.32)	30	2.89 (8.35)	28	0.018*	0.64
Gait speed, mean (SD), m/s	0.06 (0.19)	31	0.06 (0.12)	28	0.315	-0.03
Step length, mean (SD), cm	2.28 (6.87)	31	2.13 (5.49)	28	0.474	0.02

*: $P < 0.05$

Furthermore, the results of the multiple imputation, excluding the four participants with missing values at baseline (three in the DBT group and one in the control group), are presented below.

	Multiple imputation				
	DBT group (n = 31)	**Control group (n = 33)**	**Estimated difference 95% CI**	***P* value**	***Cohen's d***
3-Month training					
CB&M, mean (SD)	4.66 (7.91)	0.61 (6.51)	0.45 to 7.65	0.028*	0.56
Gait speed, mean (SD), m/s	0.09 (0.18)	0.04 (0.14)	-0.03 to 0.13	0.198	0.32
Step length, mean (SD), cm	2.30 (7.49)	0.80 (5.99)	-1.87 to 4.88	0.377	0.22
1-Month follow-up					
CB&M, mean (SD)	7.70 (7.65)	3.34 (8.60)	0.25 to 8.47	0.038*	0.54
Gait speed, mean (SD), m/s	0.06 (0.20)	0.07 (0.14)	-0.10 to 0.08	0.832	-0.05
Step length, mean (SD), cm	2.35 (7.05)	2.65 (6.13)	-3.66 to 3.05	0.856	-0.05

*: $P < 0.05$