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Perturbation-based balance training of older adults and effects on physiological, cognitive, and sociopsychological factors: A secondary analysis from a randomised controlled trial with 12-month follow-up

Abstract

Background: Perturbation-based balance training (PBT) has shown promising, although diverging, fall preventive effects; however, the effects on important physical, cognitive, and sociopsychological factors are currently unknown.

Methods: This was a pre-planned secondary analysis from a randomised, controlled trial performed in Aalborg, Denmark, between March 2021 and November 2022. The study's primary outcome was daily life fall rates, and is reported elsewhere. Older adults aged ≥65 years were randomly assigned to participate in four sessions of either PBT (intervention) or regular treadmill walking (control). Each PBT session consisted of 40 slips and/or trips induced by treadmill belt. All participants were assigned to four testing sessions: pre-training, post-training, six-month follow-up, and 12-month follow-up. At these sessions, assessments of physical functions, including 1) single and dual-task gait, 2) single and dual-task static balance, 3) choice stepping reaction time, and 4) the short physical performance battery, were performed. Cognitive functions, including executive function, were also assessed, as well as sociopsychological measures, such as 1) concerns about falling and 2) health-related quality of life. All outcomes were analysed using a linear mixed-effects model.

Results: In total, 140 participants were randomly allocated to either the PBT or control group. Short-term (pre- to post-training) between-group differences were seen for choice stepping reaction time, dual-task walking speed, and the short physical performance battery favouring the PBT group. However, these improvements were not sustained at the six- and 12-month follow-ups.

Conclusions: This study showed that PBT, in the short term, improves choice stepping reaction time among community-dwelling older adults. Yet, these improvements were not retained for six or 12 months. Moreover, none of the other physical, cognitive, or sociopsychological measures were

improved by PBT. The findings of this study indicate that PBT has limited effects on physical-, cognitive-, and sociopsychological functions important for the well-being of older adults.

Trial registration: ClinicalTrials.gov NCT04733222

Strengths and limitations of this study:

- This randomized controlled trial was pre-registered in clinicaltrails.gov, a protocol was published, and it followed consort statement.
- Due to practical limitations and the nature of training interventions, the outcome assessor of these secondary outcomes and participants were not blinded for group allocation.
- The study population was a convenience sample of low-risk older adults with no specific physical, cognitive, or sociopsychological problems.

Keywords (MeSH): Aged, Randomized Controlled Trial, Gait, Exercise Therapy, Accidental Falls, Exercise Test, Neuropsychological Tests

Introduction

Ageing leads to deteriorations in physical and cognitive functions, increasing the risk of falls and fall-related injuries, such as fractures.[1–3] However, falls not only leads to physical but also psychological consequences, as falling has been associated with developing concerns about falling.[4] These physical and cognitive consequences of falls collectively lead to disability and loss of independence, which greatly impact the quality of life of older adults.[5] Additionally, society is substantially burdened by fall-related costs, accounting for approximately 1% (0.8 to 1.5%) of healthcare expenses in developed countries [6]. Thus, effective and sustainable fall preventive interventions are needed to improve the well-being of older adults and limit societal costs.[7]

Currently, physical exercise is considered the most effective fall-preventive intervention.[8] A systematic review of 64 randomised, controlled trials on general physical exercise identified a 23% reduction in fall rates.[9] Most the studies in this review employed conventional training approaches

targeting specific physical functions associated with fall risk such as muscle strength or balance.[9] Thus, besides preventing falls, they also help maintain activities of daily life function which is important for preserving the independence and quality of life of older adults.[10,11] However, indirectly targeting falls by improving risk factors may not be the most effective approach.[9] Indeed, the well-established principle of task-specificity states that training paradigms are most effective when they closely simulate the desired task.[12–14] Among community-dwelling older adults, most falls are caused by slips and trips during walking.[2,15,16] Hence, interventions emphasizing rapid compensatory reactions following slips and trips may prove more effective in fall prevention compared to conventional approaches.[15,17]

One such intervention is perturbation-based balance training (PBT), in which the participants are exposed to repeated, unexpected postural disturbances while wearing a body harness to ensure their safety [18]. It is well documented that PBT leads to considerable reactive balance adaptations after even short exposures, which can be retained for up to a year in laboratory settings.[18–21] Yet, divergent effects of PBT on daily life falls have been reported, with some showing an approximate 50% decrease while others find no effects, including the primary analysis from the current study, which showed a nonsignificant decrease in fall rates of 22% (IRR: 0.78, 95% CI 0.44 to 1.39).[18,22–24] Moreover, additional benefits of PBT on other physical, cognitive, and socio-psychological factors are vastly unknown. Considering that the laboratory reactive balance adaptations are long-lasting, evaluating the long-term maintenance of additional adaptations is of special interest. Yet, no previous PBT studies have evaluated such outcomes after a detraining period.

Therefore, this pre-planned secondary analysis of a randomised, controlled trial with a 12-month follow-up aimed to evaluate the effects of a four-session PBT intervention on physical (gait, static balance, choice stepping reaction time, lower extremity performance), cognitive (executive function), and sociopsychological (concerns about falling and quality of life) measures among community-dwelling older adults aged 65 years or older, compared to regular treadmill walking.

Methods

Trail design and ethics

This article reports secondary results from a parallel group (1:1 ratio), randomised, controlled trial with a 12-month follow-up. A trial protocol and statistical analysis plan have been preregistered at ClinicalTrials.gov (NCT04733222), and a protocol has been published.[25] The primary outcome was fall rates and these results have already been reported.[26] There were no deviations from the protocol. The reporting of this article adheres to the CONSORT 2010 guidelines.[27] The study was performed following the Declaration of Helsinki and was approved by the North Denmark Region Committee on Human Research Ethics (N-20200089) and the Danish Data Protection Agency (2021-014). All participants gave written informed consent before enrolment.

Participants

Eligible participants had to be 1) 65 years or older, 2) community-dwelling, and 3) able to walk without a walking aid. Individuals were excluded if they 1) had an unstable medical condition that prevents safe participation, 2) had a severe cognitive impairment (defined as a score of 8 or less on the Short Orientation-Memory-Concentration test), 3) were currently participating in another fall preventive trial, or 4) had any of the following self-reported conditions: Orthopaedic surgery within the past 12 months, osteoporosis or history of osteoporosis-related fractures (low impact hip, spine, and wrist fracture), or progressive neurological disease (e.g., Parkinson, multiple sclerosis).

The participants were recruited through advertisements on local radio and national television spots. Testing and training sessions were conducted at a laboratory at Aalborg University (Department of Health, Science, and Technology, Fredrik Bajers Vej 7A2-107, DK-9000, Aalborg, Denmark).

Interventions

All participants were assigned to four training sessions (see Figure 1). The initial two sessions were conducted on the first day at the laboratory. A week later, the third training session was performed, while the fourth served as a booster-session 6-months after the third session.

Insert Figure 1 - Study Design about here.

The training interventions were performed on the same Woodway split-belt treadmill, moving uniformly (Split 70/157/ASK; Woodway, Weil am Rhein, Germany). Before training commencement, the preferred treadmill walking speed was determined by increasing and decreasing the belt speed until the upper and lower boundary of comfortable walking was identified. The preferred walking speed was then defined as the average of this upper and lower boundary.

Perturbation-based balance training (intervention)

A detailed description of the PBT protocol has been published elsewhere.[25] In brief, participants allocated to the PBT group were exposed to 40 perturbations applied bilaterally at each session. The first session consisted only of slips, the second only trips, while the third and the fourth had randomly mixed slips and trips. The timing (10-50 steps) and side (left or right) of the perturbations were randomised to enhance their unpredictability. The slips (backward loss of balance) were induced by a sudden forward acceleration resulting in a reversal in the belt movement direction at the heel strike. The trips (forward loss of balance) were provoked by an initial small deceleration followed by a larger backward acceleration at the mid-swing phase of the gait cycle. The perturbations were triggered by a heel contact placed under the sole of the left foot using the computer software Mr. Kick III (Knud Larsen, Department of Health, Science, and Technology, Aalborg University, Denmark).

The perturbation intensity depended on the preferred walking speed and was divided into five levels with progressively increasing duration for the slips and acceleration for the trips. After every fourth perturbation, participants rated the perceived anxiety and difficulty of the previous perturbations on a scale from 1 to 5, with a higher score indicating higher perceived anxiety and difficulty. The intensity was increased if three criteria were fulfilled: 1) the combined perceived anxiety and difficulty were rated four or less, 2) the participant successfully recovered from the four prior perturbations, and 3) the participant was willing to increase the difficulty. If any criteria were violated, the training intensity would remain at the highest tolerable level.

Treadmill walking training (control)

Participants allocated to the treadmill walking group walked for 20 minutes at their preferred walking speed, matching the time spent on the treadmill by the PBT group.

Outcomes

This study reports pre-planned secondary outcomes, including physical, cognitive, and sociopsychological measures collected at the pre-training, post-training, 6-month follow-up, and 12-month follow-up test (see Figure 1). All outcomes were assessed by the same researcher, who was not blinded for group allocation. A detailed description of the tests and the instructions provided are available in Supplementary Material 1.

The physical outcomes are all associated with fall risk and included single and dual task gait, single and dual task static balance, choice stepping reaction time, and the short physical performance battery (SPPB).[28–33] The gait assessment consisted of three single task and three dual task trials of eight-meter walking at a preferred walking speed, with the middle six meters timed using a handheld stopwatch.[32,34,35] As the dual task, the participants were instructed to count backwards in threes from a random three-digit number. No instructions to either prioritise the walking or counting task were provided. The average gait speed of the three trials was used in the analyses. The balance assessment was conducted on a Wii balance board using the FysioMeter software (FysioMeter, V.1.2.1.4, Denmark).[36–38] Participants were instructed to stand as still as possible for 30 seconds, three times as a single task and three times as a dual task. The dual task involved naming items from specific grocery store sections (dairy, produce, and butchery), with no instruction to focus on the balance or cognitive task. The average centre of pressure displacement area and speed from the three trials were used in the analysis. The choice stepping reaction test was also conducted using the Wii balance board and involved reacting as fast as possible to visual clues given on a computer screen by tapping the foot on the correct side of the Wii balance board.[29,39] Seven reactions were collected, and the average reaction time of the initial six was used in the analyses. The SPPB was used to evaluate lower extremity performance and involved three elements: 1) balance with three different foot positions (side-by-side, semi-tandem, and tandem), 2) two four-meter walks, and 3) five sit-to-stands [31,40]. A score was calculated (range: 0 to 12; higher score indicates better performance) and used in the analyses. Further, the time used in the five sit-to-stands was also analysed as a measure of functional strength.[41]

Cognitive function, known as executive function, was evaluated using the trail making test (TMT) part A and part B.[42,43] Participants sequentially connected numbers (part A) or alternating numbers and letters (part B). Part A assessed visual search, motor speed skills, and attention, while Part B evaluated working memory and task-shifting.[43] The time to complete part B minus part A (ΔTMT) was used in the analyses.[44,45]

Sociopsychological outcomes included concerns about falling and health-related quality of life. The concerns about falling were evaluated using the short-fall efficacy scale, and the score was used in the analyses (range: 7 to 28; a higher score indicates higher concern).[46] Moreover, the health-related quality of life was assessed using EQ-5D-5L [47,48]. The EQ-5D-5L index score (range: -1 to 1; higher index indicates better quality of life) and visual analogue scale score (range: 0-100; higher score indicates better quality of life) were used in the analyses.

Sample size

The sample size was calculated based on an expected decrease in the study's primary outcome in fall rates. Therefore, the sample size calculation was based on Poisson's regression model in G*Power (version 3.1.9.4, University of Kiel, Kiel, German). An expected 50% effect size from a base fall rate of 0.85 with an 80% power and 5% significance level necessitated 70 participants in each group, assuming a 20% drop-out.

Randomisation

Immediately after pre-training assessments, participants were allocated to either the PBT or control group using a blocked randomisation module generated in STATA and uploaded in REDCap. The module was created by research staff not involved in any other trial activities. Random block sizes of two, four, six, and eight were used to conceal the allocation sequence. The nature of training interventions and practical limitations led to neither the participant nor the outcome assessor being blinded for group allocation.

Statistical methods

All statistical analyses were conducted following the preregistered statistical analysis plan in collaboration with an external biostatistician. The primary statistical analyses were performed following the intention-to-treat principle. The analyses were conducted in STATA (Version 17.0, Stata Corp., Col- lege Station, TX), and p-values of <0.05 were considered statistically significant.

Demographic data are presented as a mean and standard deviation, median and interquartile range, or number and percentage, where appropriate. A linear mixed-effects model was used to evaluate the between-group differences in the physical, cognitive, and sociopsychological measures. In the model, group and time were set as fixed, and record ID as random effects. Further, missing data were appraised missing at random; thus, multiple imputations were not conducted as it does not add any benefits to the linear mixed-effects model.[49] We did not correct for multiple adjustments; thus, the results should be interpreted as explorative.[50]

Results

Participant flow

Of the 199 screened older adults, 140 were enrolled and randomised to either the PBT or control group between March and November 2021. The baseline characteristics of both groups can be found in Table 1. Loss to follow-up was 4 (6%) and 3 (4%) at the post-training test, 6 (9%) and 11 (16%) at the 26-week follow-up, and 10 (14%) and 16 (23%) at the 52-week follow-up in the PBT and control group, respectively. At least one data point was missing for 13 (19%) in the PBT group and 18 (26%) in the control group. There were similar reasons for drop-out and demographic characteristics between groups among participants with missing data (see Supplementary Material 3). The PBT group had a 90% adherence to training, while the control group completed 93% of the assigned sessions. Moreover, 90% of the PBT group and 97% of the control group completed at least 75% of the intervention, which was the limit for being included in the per-protocol analyses.

Table 1 – demographic data

Table 1 – Baseline characteristics of participants		
	PBT group (n = 70)	Control group (n = 70)
Age (years), mean (SD)	72.7 (4.7)	72.0 (4.7)
Sex, no. female (%)	41 (59)	38 (54)
Frailty*, median (IQR)	2 (1-3)	2 (1-3)
Living arrangement, no. living alone (%)	23 (33)	24 (34)
Daily activity level, low activity level (%)	4 (6)	6 (9)
Medication, median (IQR)	2 (0-4)	3 (0-4)
Function of daily activities♦, median (IQR)	2 (1-2)	2 (1-2)
Previous fallers, no. fallen (%)	28 (40)	29 (41)
Cognition♣, median (IQR)	26 (24-28)	26 (24-28)
Physical function•, median (IQR)	12 (11-12)	12 (11-12)
Habitual gait speed (m/s), mean (SD)	1.3 (0.2)	1.3 (0.2)
Executive function©, median (IQR)	47.3 (26.1-63.5)	40.7 (29.1-61.8)

* Tilburg Frailty indicator (score 0-15; lower is better); ♦ The Vulnerable Elderly-13 Survey (score 0-10; lower is better); ♣ The Short Orientation-Memory-Concentration Test (score 0-28; higher is better); • The Short Physical Performance Battery (0-12; higher is better); © Trail Making Test Part A subtracted from Part B (lower score implied better performance); IQR = interquartile range; PBT = perturbation-based balance training

Outcomes and estimation

All results from the unadjusted model regarding the physical, cognitive, and sociopsychological measures are presented in Table 2. Multiple within-group differences were found; however, this section only contains the results of the between-group differences. Among the physical functions, a significant difference from the pre-training to post-training test favouring the PBT group was found in choice stepping reaction time (-53 ms, 95% CI -80 to -27), the SPPB (0.2, 95% CI 0.0 to 0.4), and dual-task gait speed (0.05 m/s, 95% CI 0.02 to 0.09). However, none of these improvements were retained for the six or 12-month follow-up. There were no significant between-group differences in any of the other physical, cognitive, or sociopsychological factors.

Insert table 2 about here

Ancillary analyses

When adjusting for age, sex, and previous falls, the analyses identified significant changes from the pre-training to post-training test favouring the PBT group in single-task gait speed (0.03 m/s, 95% CI 0.00 to 0.06) and five sit-to-stands (-0.54 s, 95% CI -0.97 to -0.01). Otherwise, the analyses led to similar results as the unadjusted model. Lastly, analysing the data using a per-protocol approach did not lead to different estimates than the intention-to-treat analyses. All results of the sensitivity analyses can be found in Supplementary Material 3.

Discussion

This secondary analysis from a randomised, controlled trial showed that four sessions of treadmill perturbation-based balance training (PBT) did not lead to long-term improvements in the evaluated physical, cognitive, or sociopsychological measures. However, there was a significant improvement from the pre-training to post-training test in choice stepping reaction time, short physical performance battery (SPPB), and dual task gait speed favouring the PBT group.

Short-term effects of perturbation-based balance training

PBT led to significantly greater improvements in the choice stepping reaction time from pre-training to post-training than regular treadmill walking (-53 ms, 95% CI -80 to -27). Choice stepping reaction time is a composite measure of fall risk that evaluates the ability to make quick and appropriate voluntary stepping responses to visual cues.[29] The improvement found in our study contrasts with Okubo et al. 2019, which showed that three slip and trip overground walkway PBT sessions had no beneficial effects on the choice stepping reaction time.[51] This discrepancy may be due to Okubo et al. 2019 having four stepping options in the reaction test, while our test only had two.[51] This may lead to the performance being more reliant on executive functions, which this and previous PBT studies have shown limited effects on.[52] However, in line with our results, Kurz et al. 2016 showed treadmill PBT significantly improved voluntary step execution onto one of two targets triggered by a somatosensory cue.[53] This improvement in voluntary step execution was achieved by a faster step initiation time which implies an enhanced central processing speed.[53] Furthermore, other PBT studies have also reported significant improvements in stepping reactions following either

somatosensory or auditory cues.[54–56] Our study, however, is the first to show that PBT improves voluntary stepping performance to visual cues. Collectively, PBT may induce adaptations within the CNS that benefit gait adaptability, which is important in fall prevention [57]. Still, while there is no established minimally clinically important difference regarding choice stepping reaction time, the 7% improvement after PBT is smaller than the 13% difference previously found between fallers and non-fallers.[29]

Our results also identified significant improvements from the pre-training to post-training test favouring PBT in the SPPB (0.2, 95% CI 0.0 to 0.4) and dual-task gait speed (0.05 m/s, 95% CI 0.02 to 0.09); yet, these improvements were below the limit of minimal clinically important difference (SPPB: 0.3-0.8 and gait speed: 0.10 m/s).[58,59] No other physical and cognitive measures showed a between-group difference following PBT. Supporting these findings, studies applying multidirectional perturbations within three to five sessions showed no improvements in physical measures of strength, static balance, and gait.[23,51,60] Likewise, a single session of 96 waist pull perturbations on a treadmill did not lead to changes in the executive function evaluated using the TMT.[52] Collectively, these results underline that adaptations to physical training interventions are highly task-specific.[13,14,18]

Lastly, the PBT intervention failed to show significant between-group differences in the sociopsychological measures. However, close-to-perfect concerns about falling and quality of life scores at pre-training enforced a ceiling effect leaving almost no room for improvement. Therefore, future studies should evaluate these parameters in participants exposed to substantial concerns about falling and low quality of life.

Long-term effects of perturbation-based balance training

A key component of PBT is the well-documented long-term retention of reactive balance adaptations following even small training dosages.[18–20] Improvements in choice stepping reaction time must also be retained throughout the detraining period to be relevant. While choice stepping reaction time in the PBT group remained significantly lower at the six- and 12-month follow-up compared to the pre-training test, these improvements were not significantly different from the control group (see Table 2). Thus, there were no long-term effects of PBT on any physical, cognitive, or

sociopsychological measures. These results align with our primary findings that PBT did not lead to a significant decrease in daily life fall rate.[26] Our findings also support the current detraining literature, which points to a decline in physical performance following training cessation in older adults.[61–63]

Practical implications

While the primary results of this study showed a sustained improvement in reactive balance control over 12 months in laboratory settings (-63% laboratory fall rate at the 12-month follow-up), we only identified a partial transfer of adaptations to daily life (a nonsignificant 22% decrease in fall rates).[26] Moreover, the findings reported in this paper also show that PBT may have limited effects on other important physical, cognitive, and sociopsychological factors. This indicates that PBT should not be regarded as a single intervention but as part of a multicomponent training program. Considering the task-specificity of training adaptations, it is not surprising that multicomponent training programs have proven most effective in improving overall physical and cognitive functions.[64,65] It has recently been recommended that fall preventive training programs should include balance challenging and functional exercises with additional Tai Chi and progressive strength training.[7] Adding PBT to multicomponent training programs could potentially improve the fall preventive effect with only slightly higher training dosages.[13,18,57] However, this remains speculative until studies have shown the effectiveness of such multicomponent interventions.

LIMITATIONS

The results of this study should be interpreted considering the study's limitations. First, due to practical limitations and the nature of training interventions, the outcome assessor of these secondary outcomes and participants were not blinded for group allocation. Second, participants were convenience sampled, low-risk older adults with no specific physical, cognitive, or sociopsychological problems. They were, therefore, not the targeted population for fall preventive training according to the recent world guidelines of fall prevention and management in older adults.[7] Moreover, this population may have a limited potential for improvement, possibly explaining the lack of effect. Future PBT studies should investigate a frailer population to evaluate the potential effect among those prone to fall-related injuries. Finally, we did not correct for multiple

comparisons, which may have led to false positive results due to mass significance; thus, the results should be seen as explorative only.

Conclusion

Secondary analyses from a randomised, controlled trial showed that PBT led to short-term improvements in choice stepping reaction time. However, this improvement was not retained at the six or 12-month follow-up tests. Moreover, PBT did not cause clinically important improvements in the other evaluated physical, cognitive, or socio-psychological measures. These findings underline that adaptations to physical exercise are task specific. However, the healthy state of the study's population may have imposed a ceiling effect limiting the ability to show any beneficial effects. Further studies adding PBT to multicomponent training programs and studies on more frail older adults with a greater potential for improvements are needed.

Other information

Author contributions

Concept and design: JEN, MGJ, JR, AJTS, JA, MBD, ASO, SA. *Acquisition:* JEN. *Drafting of manuscript*: JEN. *Critical revision of the manuscript for important intellectual content:* MGJ, SA, MBD, JR, AJTS, JA, ASO. *Statistical analysis:* JEN. *Obtained funding:* MGJ, SA. *Administrative, technical, or material support:* JEN, AJTS. *Supervision:* JEN, MGJ. Final approvement of manuscript: JEN, MGJ, SA, MBD, JR, AJTS, JA

Conflict of interest

None of the author have any conflict of interest to declare.

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Additional Contributions

We thank all the volunteering participants for committing to making this study possible.

Registration number and name of trial registry

The study protocol (before study commencement) and statistical analysis plan (before last patient last visit) were preregistered at ClinicalTrials.gov: NCT04733222

Data statement

The data uptained in this study can be accessed upon request from the corresponding author.

Patient and Public Involvement

Patients or the public were not involved in the design, or conduct, or reporting, or dissemination plans of our research

References

1 Manini T. Development of Physical Disability in Older Adults. *Curr Aging Sci* 2012;**4**:184–91. doi:10.2174/1874609811104030184

2 Peel NM, Peel NM. Epidemiology of falls in older age. *Can J Aging* 2011;**30**:7–19. doi:10.1017/S071498081000070X

3 London AJ, Cigolle CT, Ha J, *et al.* The epidemiologic data on falls, 1998-2010: More older Americans report falling. *JAMA Intern Med* 2015;**175**:443–5. doi:10.1001/jamainternmed.2014.7533

4 Friedman SM, Munoz B, West SK, *et al.* Falls and fear of falling: Which comes first? A longitudinal prediction model suggests strategies for primary and secondary prevention. *J Am Geriatr Soc* 2002;**50**:1329–35. doi:10.1046/j.1532-5415.2002.50352.x

5 Stenhagen M, Ekström H, Nordell E, *et al.* Accidental falls, health-related quality of life and life satisfaction: A prospective study of the general elderly population. *Arch Gerontol Geriatr* 2014;**58**:95–100. doi:10.1016/j.archger.2013.07.006

6 Heinrich S, Rapp K, Rissmann U, *et al.* Cost of falls in old age: a systematic review. *Osteoporos Int* 2010;**21**:891–902. doi:10.1007/s00198-009-1100-1

7 Montero-Odasso M, van der Velde N, Martin FC, *et al.* World guidelines for falls prevention and management for older adults: a global initiative. *Age Ageing* 2022;**51**:1–36. doi:10.1093/ageing/afac205

8 Falck RS, Davis JC, Best JR, *et al.* Impact of exercise training on physical and cognitive function among older adults: a systematic review and meta-analysis. *Neurobiol Aging* 2019;**79**:119–30. doi:10.1016/j.neurobiolaging.2019.03.007

9 Sherrington C, Fairhall N, Kwok W, *et al.* Evidence on physical activity and falls prevention for people aged 65+ years: systematic review to inform the WHO guidelines on physical activity and sedentary behaviour. *Int J Behav Nutr Phys Act* 2020;**17**:1–9. doi:10.1186/s12966-

020-01041-3

10 Lee H, Chang K, Tsauo J. Effects of a Multifactorial Fall Prevention Program on Fall Incidence and Physical Function in Community-Dwelling Older Adults With Risk of Falls. *Arch Phys Med Rehabil* 2013;**94**:606-615.e1. doi:10.1016/j.apmr.2012.11.037

11 Chou CH, Hwang CL, Wu YT. Effect of exercise on physical function, daily living activities, and quality of life in the frail older adults: A meta-analysis. *Arch Phys Med Rehabil* 2012;**93**:237–44. doi:10.1016/j.apmr.2011.08.042

12 Buford TW, Anton SD, Clark DJ, *et al.* Optimizing the Benefits of Exercise on Physical Function in Older Adults. *PM&R* 2014;**6**:528–43. doi:10.1016/j.pmrj.2013.11.009

13 Grabiner MD, Crenshaw JR, Hurt CP, *et al.* Exercise-based fall prevention: Can you be a bit more specific? *Exerc Sport Sci Rev* 2014;**42**:161–8. doi:10.1249/JES.0000000000000023

14 Giboin LS, Gruber M, Kramer A. Task-specificity of balance training. *Hum Mov Sci* 2015;**44**:22–31. doi:10.1016/j.humov.2015.08.012

15 Berg WP, Alessio HM, Mills EM, *et al.* Circumstances and consequences of falls in independent community-dwelling older adults. *Age Ageing* 1997;**26**:261–8. doi:10.1093/ageing/26.4.261

16 Talbot LA, Musiol RJ, Witham EK, *et al.* Falls in young, middle-aged and older community dwelling adults: Perceived cause, environmental factors and injury. *BMC Public Health* 2005;**5**:1–9. doi:10.1186/1471-2458-5-86

17 Luukinen H, Herala M, Koski K, *et al.* Fracture risk associated with a fall according to type of fall among the elderly. *Osteoporos Int* 2000;**11**:631–4. doi:10.1007/s001980070086

18 McCrum C, Bhatt TS, Gerards MHG, *et al.* Perturbation-based balance training: Principles, mechanisms and implementation in clinical practice. *Front Sport Act Living* 2022;**4**:1015394. doi:10.3389/fspor.2022.1015394

19 Pai YC, Yang F, Bhatt T, *et al.* Learning from laboratory-induced falling: long-term motor retention among older adults. *Age (Omaha)* 2014;**36**:1367–76. doi:10.1007/s11357-014-9640-

5

20 Epro G, Mierau A, Mc Crum C, *et al.* Retention of gait stability improvements over 1.5 years in older adults: Effects of perturbation exposure and triceps surae neuromuscular exercise. *J Neurophysiol* 2018;**119**:2229–40. doi:10.1152/jn.00513.2017

21 Lee A, Bhatt T, Liu X, *et al.* Can treadmill slip-perturbation training reduce longer-term fall risk upon overground slip exposure? *J Appl Biomech* 2020;**36**:298–306. doi:10.1123/JAB.2019-0211

22 Pai YC, Bhatt T, Yang F, *et al.* Perturbation training can reduce community-dwelling older adults' annual fall risk: A randomized controlled trial. *Journals Gerontol - Ser A Biol Sci Med Sci* 2014;**69**:1586–94. doi:10.1093/gerona/glu087

23 Lurie JD, Zagaria AB, Ellis L, *et al.* Surface Perturbation Training to Prevent Falls in Older Adults: A Highly Pragmatic, Randomized Controlled Trial. *Phys Ther* 2020;**100**:1153–62. doi:10.1093/ptj/pzaa023

24 Gerards MHGG, Mccrum C, Mansfield A, *et al.* Perturbation-based balance training for falls reduction among older adults: Current evidence and implications for clinical practice. *Geriatr Gerontol Int* 2017;**17**:2294–303. doi:10.1111/ggi.13082

25 Nørgaard JE, Andersen S, Ryg J, *et al.* Effects of treadmill slip and trip perturbation-based balance training on falls in community-dwelling older adults (STABILITY): Study protocol for a randomised controlled trial. *BMJ Open* 2022;**12**:1–10. doi:10.1136/bmjopen-2021-052492

26 Nørgaard JE, Andersen S, Ryg J, *et al.* Effect of Treadmill Perturbation-Based Balance Training on Fall Rates in Community-Dwelling Older Adults: A Randomized Clinical Trial. *JAMA Netw Open* 2023;**6**:E238422. doi:10.1001/jamanetworkopen.2023.8422

27 Schulz KF, Altman DG, Moher D. CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials. *BMC Med* 2010;**8**:18(1-9). doi:10.1186/1741-7015-8-18

28 Muir-Hunter SW, Wittwer JE. Dual-task testing to predict falls in community-dwelling older adults: A systematic review. *Physiother (United Kingdom)* 2016;**102**:29–40. doi:10.1016/j.physio.2015.04.011

29 Lord SR, Fitzpatrick RC. Choice stepping reaction time: A composite measure of falls risk in older people. *Journals Gerontol - Ser A Biol Sci Med Sci* 2001;**56**:627–32. doi:10.1093/gerona/56.10.M627

30 Johansson J, Nordström A, Gustafson Y, *et al.* Increased postural sway during quiet stance as a risk factor for prospective falls in community-dwelling elderly individuals. *Age Ageing* 2017;**46**:964–70. doi:10.1093/ageing/afx083

31 Veronese N, Bolzetta F, Toffanello ED, *et al.* Association between short physical performance battery and falls in older people: The progetto veneto anziani study. *Rejuvenation Res* 2014;**17**:276–84. doi:10.1089/rej.2013.1491

32 Cullen S, Montero-Odasso M, Bherer L, *et al.* Guidelines for gait assessments in the canadian consortium on neurodegeneration in aging (CCNA). *Can Geriatr J* 2018;**21**:157–65. doi:10.5770/cgj.21.298

33 Montero-Odasso M, Almeida QJ, Bherer L, *et al.* Consensus on shared measures of mobility and cognition: From the Canadian Consortium on Neurodegeneration in Aging (CCNA). *Journals Gerontol - Ser A Biol Sci Med Sci* 2019;**74**:897–909. doi:10.1093/gerona/gly148

34 Montero-Odasso M, Sarquis-Adamson Y, Kamkar N, *et al.* Dual-task gait speed assessments with an electronic walkway and a stopwatch in older adults. A reliability study. *Exp Gerontol* 2020;**142**:111102. doi:10.1016/j.exger.2020.111102

35 Lyons JG, Heeren T, Stuver SO, *et al.* Assessing the agreement between 3-meter and 6-meter walk tests in 136 community-dwelling older adults. *J Aging Health* 2015;**27**:594–605. doi:10.1177/0898264314556987

36 Clark RA, Mentiplay BF, Pua YH, *et al.* Reliability and validity of the Wii Balance Board for assessment of standing balance: A systematic review. *Gait Posture* 2018;**61**:40–54.

doi:10.1016/j.gaitpost.2017.12.022

37 Jorgensen MG, Laessoe U, Hendriksen C, *et al.* Intra-rater reproducibility and validity of Nintendo Wii balance testing in community-dwelling older adults. *Eur Geriatr Med* 2013;**4**:S87. doi:10.1016/j.eurger.2013.07.284

38 Bonnechère B, Van Hove O, Jansen B, *et al.* Validation of the Wii Balance Board to assess static balance during dual-task activity in healthy subjects. *Med Nov Technol Devices* 2019;**1**:100003. doi:10.1016/j.medntd.2019.100003

39 Jorgensen MG, Paramanathan S, Ryg J, *et al.* Novel use of the Nintendo Wii board as a measure of reaction time: A study of reproducibility in older and younger adults. *BMC Geriatr* 2015;**15**:1–8. doi:10.1186/s12877-015-0080-6

40 Freire AN, Guerra RO, Alvarado B, *et al.* Validity and reliability of the short physical performance battery in two diverse older adult populations in Quebec and Brazil. *J Aging Health* 2012;**24**:863–78. doi:10.1177/0898264312438551

41 Goldberg A, Chavis M, Watkins J, *et al.* The five-times-sit-to-stand test: Validity, reliability and detectable change in older females. *Aging - Clin Exp Res* 2012;**24**:339–44. doi:10.1007/BF03325265

42 Gullickson T. Review of A Compendium of Neuropsychological Tests: Administration, Norms, and Commentary. *Contemp Psychol A J Rev* 1992;**37**:385–385. doi:10.1037/032065

43 Montero-odasso M. *Falls and Cognition in Older Persons*. Cham: : Springer International Publishing 2020. doi:10.1007/978-3-030-24233-6

44 Delbaere K, Close JCT, Heim J, *et al.* A multifactorial approach to understanding fall risk in older people. *J Am Geriatr Soc* 2010;**58**:1679–85. doi:10.1111/j.1532-5415.2010.03017.x

45 Lezak M, Howieson D, Loring D. *Neuropsychological Assessment*. 4th ed. New York: : Oxford University Press, inc. 2004.

46 Marques-Vieira CMA, Sousa LMM, Severino S, *et al.* Cross-cultural validation of the falls efficacy scale international in elderly: Systematic literature review. *J Clin Gerontol Geriatr*

2016;**7**:72–6. doi:10.1016/j.jcgg.2015.12.002

47 Sørensen J, Davidsen M, Gudex C, *et al.* Danish EQ-5D population norms. *Scand J Public Health* 2009;**37**:467–74. doi:10.1177/1403494809105286

48 Feng YS, Kohlmann T, Janssen MF, *et al.* Psychometric properties of the EQ-5D-5L: a systematic review of the literature. *Qual Life Res* 2021;**30**:647–73. doi:10.1007/s11136-020-02688-y

49 Peters SAE, Bots ML, Den Ruijter HM, *et al.* Multiple imputation of missing repeated outcome measurements did not add to linear mixed-effects models. *J Clin Epidemiol* 2012;**65**:686–95. doi:10.1016/j.jclinepi.2011.11.012

50 Rothman KJ. No adjustments are needed for multiple comparisons. *Epidemiology* 1990;**1**:43–6. doi:https://www.jstor.org/stable/20065622

51 Okubo Y, Sturnieks DL, Brodie MA, *et al.* Effect of Reactive Balance Training Involving Repeated Slips and Trips on Balance Recovery among Older Adults: A Blinded Randomized Controlled Trial. *Journals Gerontol - Ser A Biol Sci Med Sci* 2019;**74**:1489–96. doi:10.1093/gerona/glz021

52 Martelli D, Vashista V, Micera S, *et al.* Direction-Dependent Adaptation of Dynamic Gait Stability Following Waist-Pull Perturbations. *IEEE Trans Neural Syst Rehabil Eng* 2016;**24**:1304–13. doi:10.1109/TNSRE.2015.2500100

53 Kurz I, Gimmon Y, Shapiro A, *et al.* Unexpected perturbations training improves balance control and voluntary stepping times in older adults - A double blind randomized control trial. *BMC Geriatr* 2016;**16**:1–11. doi:10.1186/s12877-016-0223-4

54 Mansfield A, Peters AL, Liu BA, *et al.* Effect of a Perturbation-Based Balance Training Program on Compensatory Stepping and Grasping Reactions in Older Adults: A Randomized Controlled Trial. *Phys Ther* 2010;**90**:476–91. doi:10.2522/ptj.20090070

55 Parijat P, Lockhart TE. Effects of moveable platform training in preventing slip-induced falls in older adults. *Ann Biomed Eng* 2012;**40**:1111–21. doi:10.1007/s10439-011-0477-0

56 Shimada H, Obuchi S, Furuna T, *et al.* New intervention program for preventing falls among frail elderly people: The effects of perturbed walking exercise using a bilateral separated treadmill. *Am J Phys Med Rehabil* 2004;**83**:493–9. doi:10.1097/01.PHM.0000130025.54168.91

57 Nørgaard JE, Jorgensen MG, Ryg J, *et al.* Effects of gait adaptability training on falls and fall-related fractures in older adults: a systematic review and meta-analysis. *Age Ageing* Published Online First: 2021. doi:10.1093/ageing/afab105

58 Kwon S, Perera S, Pahor M, *et al.* What is a meaningful change in physical performance? Findings from a clinical trial in older adults (the LIFE-P study). *J Nutr Heal Aging* 2009;**13**:538–44. doi:10.1007/s12603-009-0104-z

59 Chui K, Hood E, Klima D. Meaningful change in walking speed. *Top Geriatr Rehabil* 2012;**28**:97–103. doi:10.1097/TGR.0b013e3182510195

60 Allin LJ, Brolinson PG, Beach BM, *et al.* Perturbation-based balance training targeting both slip- And trip-induced falls among older adults: A randomized controlled trial. *BMC Geriatr* 2020;**20**:1–13. doi:10.1186/s12877-020-01605-9

61 Blasco-Lafarga C, Cordellat A, Forte A, *et al.* Short and long-term trainability in older adults: Training and detraining following two years of multicomponent cognitive—physical exercise training. *Int J Environ Res Public Health* 2020;**17**:1–16. doi:10.3390/ijerph17165984

62 Fernández-García ÁI, Gómez-Cabello A, Gómez-Bruton A, *et al.* Effects of multicomponent training and detraining on the fitness of older adults with or at risk of frailty: results of a 10-month quasi-experimental study. *Eur J Sport Sci* 2022;**0**:1–14. doi:10.1080/17461391.2022.2104657

63 Vogler CM, Menant JC, Sherrington C, *et al.* Evidence of detraining after 12-week home-based exercise programs designed to reduce fall-risk factors in older people recently discharged from hospital. *Arch Phys Med Rehabil* 2012;**93**:1685–91. doi:10.1016/j.apmr.2012.03.033

64 Giné-Garriga M, Roqué-Fíguls M, Coll-Planas L, *et al.* Physical Exercise Interventions For Improving Performance-Based Measures of Physical Function in Community-Dwelling Frail Older Adults. *Med Sci Sport Exerc* 2014;**46**:134. doi:10.1016/j.apmr.2013.11.007

65 Schoene D, Valenzuela T, Lord SR, *et al.* The effect of interactive cognitive-motor training in reducing fall risk in older people: A systematic review. *BMC Geriatr* 2014;**14**:107(1-22). doi:10.1186/1471-2318-14-107

Figure headings and legends

Figure 1 heading:

Figure 1 - Study Design

Figure 1 legend:

Figure 1 – The study design. Dark grey boxes show the flow of the PBT group. Light grey boxes show the flow of the control group. White boxes indicate that all participants were assigned. SPPB: Short physical performance battery. TMT: Trial making test. EQ5D: EuroQoL 5-dimensions, 5-levels. s-FES: Short falls efficacy scale. PBT: Perturbation-based balance training. TW: Treadmill walking.

Figure 2 heading:

Figure 2 - CONSORT Flow chart

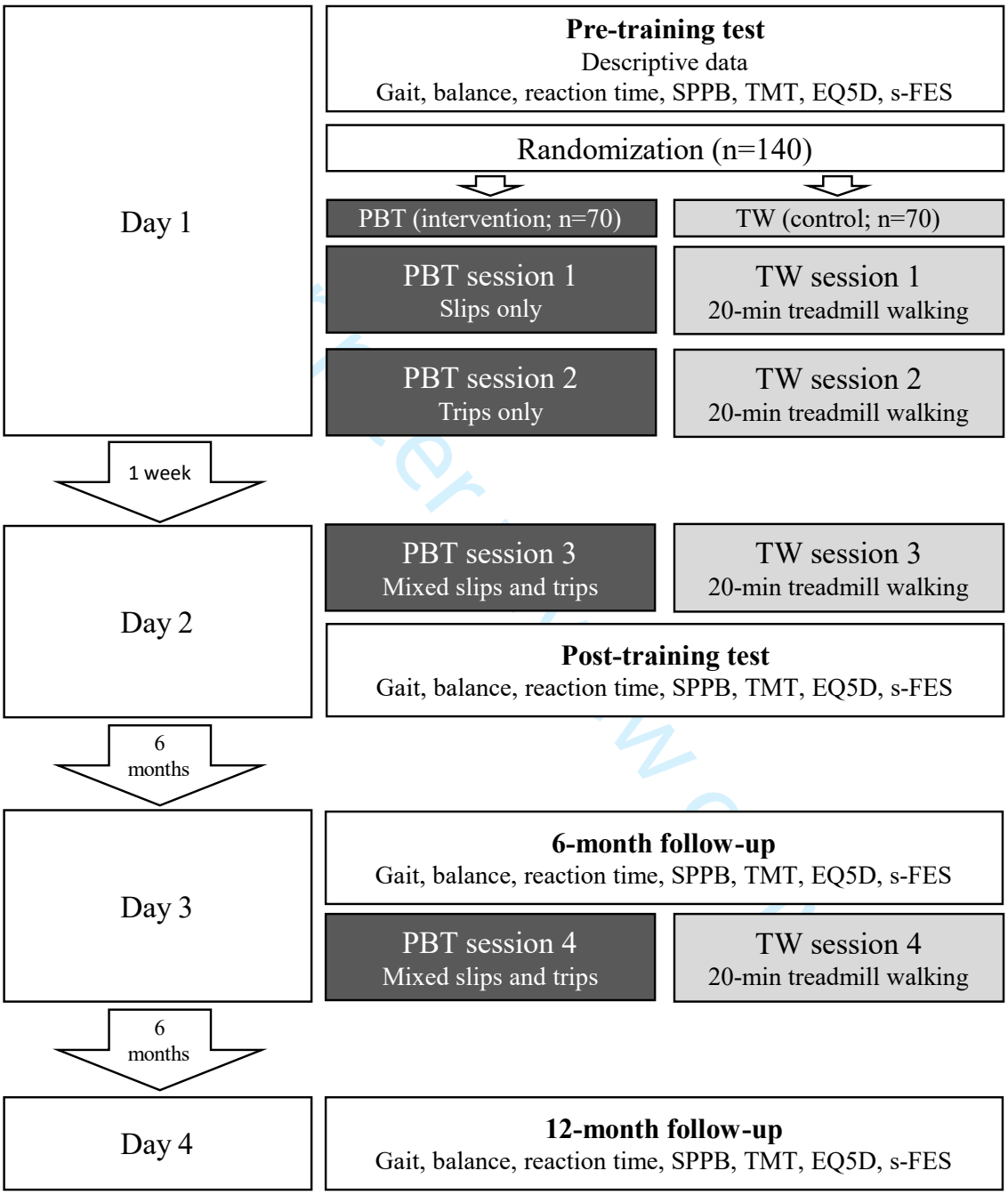
Figure 2 legend:

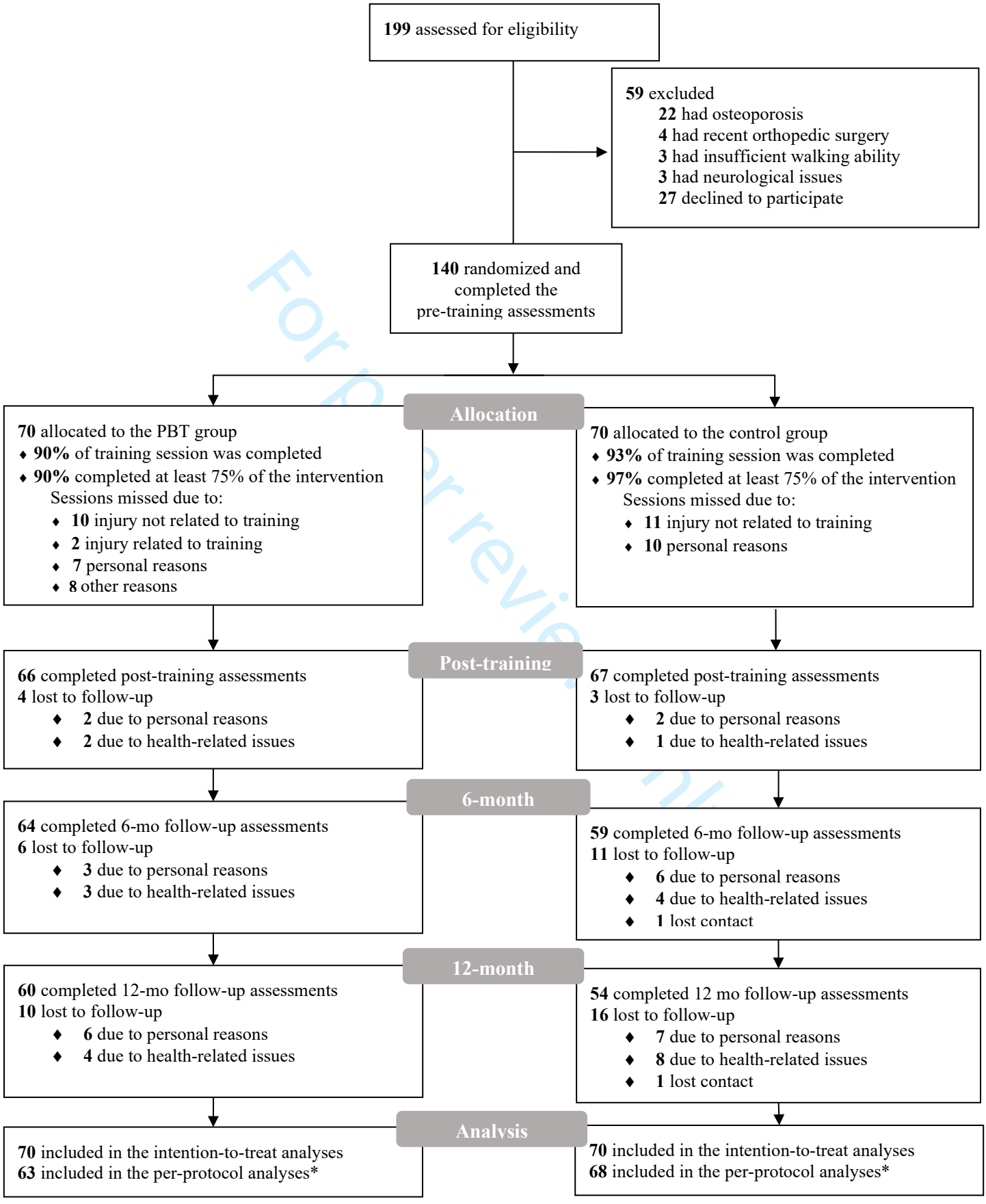
Figure 2 – CONSORT Flow chart of the participant flow through the present study. *Per-protocol analysis only included participants that completed at least 75% (3 of 4 sessions) of the assigned intervention.

Table 2 – Results of fall-related risk factors for each testing session as well as group differences at post-training, 6-month follow-up, and 12-month follow-up

	PBT Group				Control group				Between-group differences		
	Pre-training (n = 70)	Post-training (n = 66)	6-month follow-up (n = 64)	12-month follow-up (n = 60)	Pre-training (n = 70)	Post-training (n = 67)	6-month follow-up (n = 59)	12-month follow-up (n = 54)	Pre-training to post-training (95% CI)	Pre-training to 6-month follow-up (95% CI)	Pre-training to 12-month follow-up (95% CI)
Physical measures											
Gait speed, single task, m/s Mean (SD)	1.28 (0.17)	1.29 (0.18)	1.27 (0.18)	1.25* (0.17)	1.26 (0.17)	1.24 (0.16)	1.24* (0.17)	1.21* (0.18)	0.03 (-0.00 to 0.06)	0.01 (-0.02 to 0.04)	-0.02 (-0.02 to 0.05)
Gait speed, dual task, m/s Mean (SD)	1.12 (0.20)	1.17* (0.21)	1.14 (0.21)	1.14 (0.20)	1.12 (0.20)	1.12 (0.18)	1.11 (0.19)	1.08 (0.21)	**0.05♣ (0.02 to 0.09)**	0.02 (-0.02 to 0.06)	0.03 (-0.01 to 0.08)
Sway area, single task, mm^2 Median (IQR)	22.6 (14.6-30.5)	22.3 (13.3-32.6)	18.5 (12.6-31.6)	22.8 (14.7-30.5)	23.1 (15.1-40.1)	25.7 (16.3-40.3)	21.7 (13.1-38.5)	21.2 (12.1-37.2)	-2.2 (-6.4 to 1.93)	-2.0 (-6.4 to 2.35)	2.6 (-3.2 to 8.4)
Sway area, dual task, mm^2 Median (IQR)	32.2 (16.9-51.2)	24.8 (15.5-58.5)	29.0 (16.3-50.1)	27.05 (18.9-41.5)	35.4 (21.5-64.3)	37.1 (21.1-72.7)	30.2 (19.8-43.2)	25.5 (16.9-58.1)	-9.9 (-23.6 to 3.7)	3.8 (-9.3 to 16.8)	11.2 (-18.7 to 41.2)
Sway speed, single task, mm/s Median (IQR)	14.8 (11.7-19.5)	13.1* (11.1-17.8)	14.3 (11.9-18.9)	14.8 (12.3-19.6)	14.7 (12.4-20.4)	13.8* (11.7-18.9)	14.6 (12.0-19.3)	14.6 (11.8-18.9)	0.2 (-0.9 to 1.3)	0.2 (-1.0 to 1.3)	0.1 (-1.3 to 1.4)
Sway speed, dual task, mm/s Median (IQR)	19.8 (14.2-25.9)	18.0* (13.3-21.7)	19.6 (15.6-24.3)	19.4 (15.8-25.0)	18.8 (15.3-27.9)	18.4 (15.2-23.9)	18.2 (15.6-25.2)	17.5 (14.0-26.3)	-1.4 (-3.1 to 0.2)	-0.1 (-2.1 to 1.9)	1.2 (-1.4 to 3.8)
Choice stepping reaction time, ms, Mean (SD)	891 (112)	817* (103)	841* (110)	825* (106)	904 (121)	879 (117)	866* (126)	861* (116)	**-53♣ (-80 to -27)**	-23 (-56 to 9.6)	-24 (-58 to 10)
SPPB score• Median (IQR)	12 (11-12)	12* (12-12)	12 (11-12)	12 (12-12)	12 (11-12)	12 (11-12)	12 (11-12)	12 (11-12)	**0.2♣ (0.0 to 0.4)**	0.2 (-0.1 to 0.4)	0.0 (-0.2 to 0.3)
Five sit-to-stand[µ], s Mean (SD)	10.64 (2.27)	9.75* (1.89)	10.06* (1.99)	9.34* (2.00)	11.24 (2.76)	10.58* (2.40)	10.78 (2.34)	10.15* (2.46)	-0.48 (-0.97 to 0.01)	-0.38 (-0.92 to 0.39)	-0.35 (-0.92 to 0.21)
Cognitive measures											
TMT ΔAB, s Median (IQR)	47.32 (29.11-61.77)	45.43 (26.91-66.18)	43.56 (28.90-63.76)	38.47 (31.02-56.24)	40.70 (26.07-63.52)	36.48 (24.19-56.05)	33.43* (23.50-48.41)	37.35 (23.96-67.59)	-2.78 (-16.38 to 10.82)	4.28 (-7.90 to 16.46)	-2.77 (-15.38 to 9.85)
Sociopsychological measures											
Fear of Falling, score▪ Median (IQR)	7 (7-8)	8 (7-9)	7* (7-9)	7 (7-9)	7 (7-8)	7* (7-9)	8 (7-9)	7 (7-9)	-0 (-1 to 0)	-0 (-0 to 0)	-0 (-1 to 0)
EQ5D, index[▯] Median (IQR)	0.94 (0.92-1.00)	1.00 (0.92-1.00)	0.94 (0.92-1.00)	0.94* (0.88-1.00)	0.94 (0.94-1.00)	0.94 (0.94-1.00)	0.94* (0.90-1.00)	0.94 (0.94-1.00)	0.01 (-0.01 to 0.04)	0.02 (-0.00 to 0.04)	-0.01 (-0.03 to 0.02)
EQ5D, VAS[□] Median (IQR)	85 (80-95)	90* (80-96)	90 (80-95)	90 (82.5-95)	90 (80-95)	90* (85-95)	90 (80.5-96.5)	90 (85-95)	-0 (-2 to 2)	-1 (-3 to 2)	-1 (-2 to 3)

* Significant within-group difference from pre-training test; ♣ Significant difference favouring the PBT group; • SPPB score ranges between 0 and 12, 12 is the best score; ▪ s-FES score ranges between 7 and 28, 28 is the best score; [▯] EQ5D Index ranges between 0 and 1, 1 is the best score; [□] EQ5D VAS ranges between 0 and 100, 100 is the best score; [µ] Collected as part of the short physical performance battery





SUPPLEMENTARY MATERIAL 1: DETAILED DESCRIPTION OF TESTS

This supplementary material describes the tests used in the pre-training, post-training, 26-week follow-up, and 52-week follow-up tests. Moreover, the instructions given to the participants are also outlined. During the trial, all instructions were provided in Danish; however, this supplementary material is directly translated into English.

The order of the test was identical at each testing session at was as follows: 1) Trial-making-test, 2) balance, 3) choice stepping reaction time, 4) gait, 5) short physical performance battery, and 6) questionnaires.

TABLE OF CONTENT

TRIAL MAKING TEST

Description

The executive function is evaluated using the Trial-Making-Test (TMT) Part A and B. Part A involves sequentially connecting 25 randomly arranged numbers (1- 2- 3-…-25) on paper with a pen. In Part B, 25 randomly placed numbers and letters (1- A- 2- B-…-12- L) are connected alternatingly. The time to complete Part A and Part B was recorded using a handheld stopwatch, and the number of mistakes was registered.

Instruction

"[Show the practice sheet of Part A] In this test, you must sequentially connect the numbers; from 1 to 2, from 2 to 3, and so on [point on the paper]. This is a practice sheet before we move on to the actual test. [participant performs practice sheet]. If you make a mistake, I will highlight it by making a perpendicular line, and you will return to the previous number. I will not tell you what the mistake was."

"[Show the test sheet of Part B] Now we move on to the actual test. In this test, you must connect 25 numbers in the same manner as on the practice sheet. You will begin at 1 [point at number 1] and finish at 25 [point at number 25]. You must connect the numbers as fast as possible and with as few mistakes as possible. I will count from 3, and you may start on "go". "

"[Show the practice sheet of Part B] In the next part of the test, you must alternatingly connect the numbers and letters; from 1 to A, from A to 2, from 2 to B, and so on [point on the paper]. This is a practice sheet before we move on to the actual test [participant performs practice sheet]."

"[Show the test sheet for Part B] Now we move on to the actual test. In this test, you must connect the 25 numbers or letters in the same manner as on the practice sheet. You will begin at 1 [point at number 1] and finish at "L" [point at "L"]. You must connect the numbers as fast as possible and with as few mistakes as possible. I will count from 3, and you may start on "go". "

BALANCE TEST

Description

The balance test was conducted using a Wii balance board (WBB) and the Fysiometer software. Participants stood as still as possible for 30 seconds for three trials under single- and dual-task conditions, respectively. The dual task condition involves naming grocery items from specific supermarket sections. During the test, the participant was instructed to look at a fixed mark at eye height three meters in front of the participant. The area and speed of the centre of pressure displacement were registered in the FysioMeter software.

Instruction

"During the balance test, you must step onto the Wii balance board and place your feet so the outside of your foot is aligned with the edge of the Wii balance board [guide the foot placement of participant]. You will have to stand as still as possible for 30 seconds while looking at the mark in front of you [pointing at the mark] and holding your wrist [illustrate the arm position]. You will have to perform three trials only focusing on standing still, and then three times while simultaneous mentioning grocery items from the supermarket. Are you ready for the first 30 seconds?"

[Immediately before each 30-second trial, the following is instructed] "Look at the mark in front of you and attempt to stand as still as possible; the 30 seconds will start in 3, 2, 1, now."

"For the next three trials, you will have to stand in the same position as before [make sure foot placement is correct] as still as possible for 30 seconds while also mentioning as many grocery items as possible. Before each trial, I will tell you which supermarket section you must mention items. Are you ready for the first 30 seconds?"

[Immediately before each 30-second trial, the following is instructed] "Look at the mark in front of you, hold your wrist, and attempt to stand as still as possible, while also mentioning as many items from the [insert supermarket section (dairy, greens, or butchers department)]; the 30 seconds will start in 3, 2, 1, now.

CHOICE STEPPING REACTION TEST

Description

The choice stepping reaction test was conducted using a Wii balance board and the FysioMeter software. The participants had to react as fast as possible by tapping the correct side of the WBB with the correct foot in response to a visual cue presented on a computer screen seven times. The WBB was placed approximately five cm in front of the participants' feet, and the computer screen was one meter away. A WBB was shown on the computer screen, and the cue was a green light on either the right or left of the WBB. The timing (1-4 seconds) and side were random to maximize the unpredictability. The time from the cue was given to the correct response was performed was recorded with the FysioMeter software.

Instruction

“For the reaction test, you must stand with the feet behind each side of the Wii balance board [guide the foot placement of participant]. A Wii balance board is illustrated on the screen in front of you. When I press “start”, the left or right side will turn green after one to four seconds. You must tap on the correct side, as fast as possible, with the correct foot. If it is the left side, you must use the left foot, and vice versa. Before we begin, you will have three practice trials. Remember to focus on being as fast as possible.”

[Participants get three attempts]

“Now we progress to the real test, and you will have to perform seven reaction trials. Remember to be as fast as possible.”

GAIT TEST

Description

The gait test involved walking eight meters at the preferred walking speed for a total of six trials. The initial three were conducted as a single task, while the last three were under a dual-task condition. The dual task involved continuously subtracting three from a random three digits number. The middle six meters will be recorded using a handheld watch.

Instruction

"During the gait test, you must walk 8 meters from the initial line through the end line [pointing at the two lines]. You will have to walk six times, the first three trials only focusing on walking, while the last three will also involve arithmetics. During the trials, you will have to walk at your regular pace. I will say "3, 2, 1, go", and on "go", you can walk."

[Participant completes three trials as a single task]

"During the next three trials, you will have to walk at your regular pace and simultaneously perform arithmetics. Before each trial, I will tell you a number, which could, for example, be 150. You will then have to continuously subtract three from that number while walking at your regular pace. If the number is 150, it will look like this [illustrate the test by walking and subtracting three]; 147, 144, 141, 138, and so on until you are at the end of the path [pointing at the end]"'

[Participant completes three trials as a dual task with three different numbers]

THE SHORT PHYSICAL PERFORMANCE BATTERY

Description

The short physical performance battery consists of a balance, gait, and strength component. The balance component includes standing in three foot positions (side-by-side, semi-tandem, and tandem) for ten seconds. The gait component involves two four-meter walks at a preferred walking speed, and the strength component consists of five sit-to-stands as fast as possible. Each element is scored based on performance and collected in a composite score (0-12; higher scores indicate better performance).

Instruction

“First, you have to perform a balance test. You have to stand for ten seconds with three different foot positions. During the ten seconds, you are not allowed to move your feet or grab any obstacles to regain balance. The first foot position is a side-by-side position [show the foot position and correct the participant's position]. When you feel in balance, say “go,” and the ten seconds will begin.”

[If the participants complete progress to the next foot position, if not, the balance test is over]

“The next foot position is a semi-tandem foot position [show the foot position and correct the participant's position]. When you feel in balance, say “go,” and the ten seconds will begin.”

[If the participants complete progress to the next foot position, if not, the balance test is over]

“The next foot position is a tandem foot position [show the foot position and correct the participant's position]. When you feel in balance, say “go,” and the ten seconds will begin.”

“The next test is a 4-meter waking test; you must walk 4 meters from the initial line through the end line [point at the two lines] two times at your regular pace. I will count from 3, and on “go”, you begin.”

“The last part of this test battery is a strength test, where you must stand up from a chair five times as fast as possible. Please sit in the chair and cross your hands in front of your chest [illustrate the arm position]. Now stand up and sit down once. You will have to repeat those five times as fast as possible. I will count from 3, and the time begins on “go”. When you stand up the fifth time, the time will stop.” [count for each repetition].

QUESTIONNAIRES

Instruction

"You must fill out this questionnaire which involves a variety of questions that relates to the risk of falling and your well-being. You must read the questions thoroughly and provide a response that describes you the best. If you have any questions regarding understanding the question, you are welcome to ask me; however, I will not be able to help you answer the questions."

SUPPLEMENTARY MATERIAL 2: RESULTS

This supplementary includes the results of the sensitivity analyses and the stata code used for both the primary analyses and the sensitivity analyses.

TABLE OF CONTENT

EFFECT SIZES

Table SM2.1 – The effects sizes for the differences between groups

	Between group differences		
	Pre-training to post-training (95% CI)	Pre-training to 26-week follow-up (95% CI)	Pre-training to 52-week follow-up (95% CI)
Physical measures			
Gait speed, single task, m/s Mean (SD)	0.03 (-0.00 to 0.06)	0.01 (-0.02 to 0.05)	0.01 (-0.03 to 0.05)
Gait speed, dual task, m/s Mean (SD)	**0.05♣** **(0.02 to 0.09)**	0.03 (-0.01 to 0.07)	0.03 (-0.02 to 0.08)
Sway area, single task, mm^2 Median (IQR)	-2.2 (-6.5 to 2.0)	-1.8 (-6.2 to 2.7)	3.2 (-2.9 to 9.2)
Sway area, dual task, mm^2 Median (IQR)	-10.2 (-24.2 to 3.9)	4.7 (-9.0 to 18.4)	12.9 (-18.8 to 44.5)
Sway speed, single task, mm/s Median (IQR)	0.1 (-1.0 to 1.3)	0.3 (-0.9 to 1.5)	0.1 (-1.3 to 1.5)
Sway speed, dual task, mm/s Median (IQR)	-1.6 (-3.2 to 0.1)	0.1 (-2.0 to 2.2)	1.4 (-1.3 to 4.0)
Reaction time, ms Mean (SD)	**-57♣** **(-84 to -30)**	-31 (-64 to 2)	-31 (-64 to 2)
SPPB, score• Median (IQR)	**0.2♣** **(0.0 to 0.4)**	0.2 (-0.1 to 0.4)	-0.0 (-0.2 to 0.3)
Five sit-to-stand[µ], s Mean (SD)	-0.48 (-0.97 to 0.01)	-0.38 (-0.92 to 0.16)	-0.35 (-0.92 to 0.21)
Cognitive measures			
TMT ΔAB, s Median (IQR)	-2.78 (-16.38 to 10.82)	4.28 (-7.90 to 16.46)	-2.77 (-15.38 to 9.85)
Sociopsychological measures			
Fear of Falling, score▪ Median (IQR)	-0 (-1 to 1)	-0 (-0 to 0)	-0 (-1 to 0)
EQ5D, index[▯] Median (IQR)	0.01 (-0.01 to 0.04)	0.02 (-0.00 to 0.04)	-0.01 (-0.03 to 0.02)
EQ5D, VAS[□] Median (IQR)	-0 (-2 to 2)	-0 (-3 to 2)	1 (-2 to 3)

* Significant difference from pre-training test; ♣ Significant difference between groups; • SPPB score ranges between 0 and 12, 12 is the best score; ▪ s-FES score ranges between 7 and 28, 28 is the best score; ▯ EQ5D Index ranges between 0 and 1, 1 is the best score; □ EQ5D VAS ranges between 0 and 100, 100 is the best score; µ Collected as part of the short physical performance battery.

PER-PROTOCOL ANALYSES

Table SM2.2 – Results of fall-related risk factors using a per-protocol approach which only included participants who completed at least 75% of the intervention

	Between group differences		
	Pre-training to post-training (95% CI)	Pre-training to 26-week follow-up (95% CI)	Pre-training to 52-week follow-up (95% CI)
Physical measures			
Gait speed, single task, m/s Mean (SD)	0.03 (-0.00 to 0.06)	0.01 (-0.02 to 0.05)	0.01 (-0.03 to 0.05)
Gait speed, dual task, m/s Mean (SD)	**0.05♣** **(0.02 to 0.09)**	0.03 (-0.01 to 0.07)	0.03 (-0.02 to 0.08)
Sway area, single task, mm^2 Median (IQR)	-2.2 (-6.5 to 2.0)	-1.8 (-6.2 to 2.7)	3.2 (-2.9 to 9.2)
Sway area, dual task, mm^2 Median (IQR)	-10.2 (-24.2 to 3.9)	4.7 (-9.0 to 18.4)	12.9 (-18.8 to 44.5)
Sway speed, single task, mm/s Median (IQR)	0.1 (-1.0 to 1.3)	0.3 (-0.9 to 1.5)	0.1 (-1.3 to 1.5)
Sway speed, dual task, mm/s Median (IQR)	-1.6 (-3.2 to 0.1)	0.1 (-2.0 to 2.2)	1.4 (-1.3 to 4.0)
Reaction time, ms Mean (SD)	**-57♣** **(-84 to -30)**	-31 (-64 to 2)	-31 (-64 to 2)
SPPB, score• Median (IQR)	**0.2♣** **(0.0 to 0.4)**	0.2 (-0.1 to 0.4)	-0.0 (-0.2 to 0.3)
Five sit-to-stand$^{\mu}$, s Mean (SD)	-0.48 (-0.97 to 0.01)	-0.38 (-0.92 to 0.16)	-0.35 (-0.92 to 0.21)
Cognitive measures			
TMT ΔAB, s Median (IQR)	-2.78 (-16.38 to 10.82)	4.28 (-7.90 to 16.46)	-2.77 (-15.38 to 9.85)
Sociopsychological measures			
Fear of Falling, score▪ Median (IQR)	-0 (-1 to 1)	-0 (-0 to 0)	-0 (-1 to 0)
EQ5D, index$^{\square}$ Median (IQR)	0.01 (-0.01 to 0.04)	0.02 (-0.00 to 0.04)	-0.01 (-0.03 to 0.02)
EQ5D, VAS$^{\square}$ Median (IQR)	-0 (-2 to 2)	-0 (-3 to 2)	1 (-2 to 3)

* Significant difference from pre-training test; ♣ Significant difference between groups; • SPPB score ranges between 0 and 12, 12 is the best score; ▪ s-FES score ranges between 7 and 28, 28 is the best score; $^{\square}$ EQ5D Index ranges between 0 and 1, 1 is the best score; $^{\square}$ EQ5D VAS ranges between 0 and 100, 100 is the best score; $^{\mu}$ Collected as part of the short physical performance battery.

SENSITIVITY ANALYSES: ADJUSTED FOR AGE, SEX, AND PERVIOUS FALLS

Table SM2.3 – Results of fall-related risk factors for each testing session as well as group differences at post-training, 26-week follow-up and 52-week follow-up for the adjusted model (age, sex, and previous falls)

	Between group differences		
	Pre-training to post-training (95% CI)	Pre-training to 26-week follow-up (95% CI)	Pre-training to 52-week follow-up (95% CI)
Physical measure			
Gait speed, single task, m/s Mean (SD)	**0.03♣** **(0.00 to 0.06)**	0.02 (-0.02 to 0.05)	0.02 (-0.02 to 0.05)
Gait speed, dual task, m/s Mean (SD)	**0.06♣** **(0.02 to 0.09)**	0.03 (-0.01 to 0.07)	0.04 (-0.01 to 0.08)
Sway area, single task, mm^2 Median (IQR)	-2.8 (-6.8 to 1.3)	-2.6 (-6.8 to 1.7)	2.2 (-3.6 to 7.9)
Sway area, dual task, mm^2 Median (IQR)	-11.5 (-24.9 to 1.95)	2.1 (-10.5 to 14.8)	10.1 (-19.3 to 39.4)
Sway speed, single task, mm/s Median (IQR)	0.1 (-1.0 to 1.1)	-0.0 (-1.1 to 1.1)	-0.1 (-1.5 to 1.2)
Sway speed, dual task, mm/s Median (IQR)	-1.6 (-3.3 to 0.1)	0.3 (-2.3 to 1.7)	1.1 (-1.5 to 3.6)
Reaction time, ms Mean (SD)	**-57♣** **(-83 to -30)**	-27 (-58 to 5)	-27 (-59 to 6)
SPPB, score• Median (IQR)	**0.2♣** **(0.0 to 0.4)**	0.2 (-0.1 to 0.4)	-0.1 (-0.2 to 0.3)
Five sit-to-stand[µ], s Mean (SD)	**-0.54♣** **(-0.97 to -0.01)**	-0.44 (-0.98 to 0.10)	-0.40 (-0.93 to 0.14)
Cogntive measure			
TMT ΔAB, s Median (IQR)	-3.80 (-18.18 to 10.57)	3.30 (-9.47 to 16.07)	-3.79 (-17.22 to 9.64)
Sociopsychological measure			
Fear of Falling, score▪ Median (IQR)	-0 (-1 to 0)	-0 (-1 to 0)	-0 (-1 to 0)
EQ5D, index[▯] Median (IQR)	0.01 (-0.01 to 0.04)	0.02 (-0.00 to 0.04)	-0.01 (-0.03 to 0.02)
EQ5D, VAS[▯] Median (IQR)	-0 (-2 to 2)	-1 (-3 to 2)	0 (-2 to 3)

♣ Significant between-group difference favouring the PBT group; • SPPB score ranges between 0 and 12, 12 is the best score; ▪ s-FES score ranges between 7 and 28, 28 is the best score; ▯ EQ5D Index ranges between 0 and 1, 1 is the best score; ▯ EQ5D VAS ranges between 0 and 100, 100 is the best score; µ Collected as part of the short physical performance battery.

STATA CODES USED FOR ANALYSIS

All the statistical tests was conducted in STATA version 17.0. The outcomes was adjusted for the baseline values for the same outcome. This code was used for all the outcomes in this study:

mixed [insert variable] i.time##i.intervention baseline_[insert variable] || record_id:, vce(robust)

Model adjusting for age, sex, and previous falls:

mixed [insert variable] i.time##i.intervention baseline_[insert variable] age i.sex i.prev_faller || record_id:, vce(robust)

SUPPLEMENTARY MATERIAL 3: MISSING DATA

TABLE OF CONTENT

MISSING DATA

Table SM3.1 – Missing data for each outcome

Outcome	PBT group				Control group			
	Pre-training	Post-training	6-month follow-up	12-month follow-up	Pre-training	Post-training	6-month follow-up	12-month follow-up
Gait	0 (0)	4 (6)	6 (9%)	10 (14%)	0 (0)	3 (4%)	12 (16%)	16 (23%)
Balance	0 (0)	4 (6)	6 (9%)	10 (14%)	0 (0)	3 (4%)	12 (16%)	16 (23%)
Reaction	0 (0)	4 (6)	6 (9%)	10 (14%)	0 (0)	3 (4%)	12 (16%)	16 (23%)
SPPB	0 (0)	4 (6)	6 (9%)	10 (14%)	0 (0)	3 (4%)	12 (16%)	16 (23%)
TMT	0 (0)	4 (6)	6 (9%)	10 (14%)	0 (0)	3 (4%)	11 (14%)	16 (23%)
FES	0 (0)	4 (6)	6 (9%)	10 (14%)	0 (0)	3 (4%)	11 (14%)	16 (23%)
EQ5D	0 (0)	4 (6)	6 (9%)	10 (14%)	0 (0)	3 (4%)	11 (14%)	16 (23%)

Table SM3.2 – Summary of reasons for missing data in each group

Reason	PBT group (n =13)	Control group (n = 18)
Injury/illness	6	9
Personal reasons*	7	9

* Personal reasons include logistical issues, lack of motivation, and changes in personal relations forcing stoppage in participation

Table SM3.4 – Baseline characteristics of participants with at least one missing data point compared to participants with no missing data

	With missing (n = 33)	Without missing (n = 108)	p-values
Age (years), Mean (SD)	72 (5.1)	72 (4.6)	0.52[α]
Sex, no. female (%)	18 (55)	61 (56)	1.00[γ]
Frailty*, median (IQR)	2 (1-3)	1 (1-3)	0.07[β]
Medication, median (IQR)	3 (1-5)	2 (0-4)	0.25[β]
Function of daily activities♦, median (IQR)	2 (1-2)	2 (1-3)	0.55[β]
Previous fallers, No. fallen (%)	12 (39)	45 (41)	0.84[γ]
Fear of falling, Median (IQR)	7 (7-8)	8 (7-9)	0.57[β]
Cognition♣, median (IQR)	24 (24-26)	26 (24-26)	0.32[β]
Physical function•, Median (IQR)	11 (11-12)	12 (11-12)	0.45[β]
Habitual gait speed (m/s), Mean (SD)	1.2 (0.1)	1.3 (0.2)	0.12[α]
Dual-task gait speed (m/s) Mean (SD)	1.0 (0.2)	1.2 (0.2)	**0.03**[α]
Single-task balance, sway speed (mm/s) Median (IQR)	13.83 (10.97-19.03)	15.60 (12.00-25.67)	0.37[β]
Dual-task balance, sway speed (mm/s) Median (IQR)	20.30 (15.78-25.93)	23.67 (15.77-25.93)	0.19[β]
Reaction time (ms), Mean (SD)	904 (148)	959 (128)	0.86[α]
Executive function© (s), median (IQR)	59.18 (51.73-63.78)	45.93 (28.83-78.88)	0.12[β]

* Tilburg Frailty indicator; ♦ The Vulnerable Elderly-13 Survey; ♣ The Short Orientation-Memory-Concentration Test; • The Short Physical Performance Battery; © Trail Making Test Part A subtracted from Part B; bold text indicates significant group differences. [α] Unpaired sample t-test; [β] Wilcoxon signed rank test; [γ] Fisher's exact test; bold text indicates significant between group differences

Fear of falling, Median (IQR)	8 (7-9)	7 (7-8)	0.57 β
Cognition♣, median (IQR)	26 (24-26)	26 (24-28)	0.12 β
Physical function♦, Median (IQR)	12 (11-12)	12 (11-12)	0.28 β
Habitual gait speed (m/s), Mean (SD)	1.3 (0.2)	1.3 (0.2)	0.25 α
Dual-task gait speed (m/s) Mean (SD)	1.1 (0.2)	1.1 (0.2)	0.47 α
Single-task balance, sway speed (mm/s) Median (IQR)	14.3 (11.7-20.7)	14.9 (12.0-19.2)	0.89 β
Dual-task balance, sway speed (mm/s) Median (IQR)	21.8 (14.4-27.3)	18.0 (14.9-25.1)	0.25 β
Reaction time (ms), Mean (SD)	927 (140)	889 (108)	0.95 α
Executive function© (s), median (IQR)	54.8 (36.3-74.2)	37.5 (25.5-58.4)	0.06 β

* Tilburg Frailty indicator; ♦ The Vulnerable Elderly-13 Survey; ♣ The Short Orientation-Memory-Concentration Test; • The Short Physical Performance Battery; © Trail Making Test Part A subtracted from Part B; bold text indicates significant group differences. α Unpaired sample t-test; β Wilcoxon signed rank test; γ Fisher's exact test; bold text indicates significant between group differences

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance, see CONSORT for abstracts)	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	4
	2b	Specific objectives or hypotheses	4
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	4-5
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	5
Participants	4a	Eligibility criteria for participants	5
	4b	Settings and locations where the data were collected	4
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	5-6 + Supp. 1
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	6-7
	6b	Any changes to trial outcomes after the trial commenced, with reasons	N/A
Sample size	7a	How sample size was determined	7-8
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	5
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	5
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	5
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	5

Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	7
	11b	If relevant, description of the similarity of interventions	N/A
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	8
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	8
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	9 + Figure 2
	13b	For each group, losses and exclusions after randomisation, together with reasons	Figure 2
Recruitment	14a	Dates defining the periods of recruitment and follow-up	5
	14b	Why the trial ended or was stopped	N/A
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 1
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	9 + Figure 2
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	9-20 + Table 2 + Figure 3 + supp. 3
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	Table 2
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	9-10 + supp. 4
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	10 + supp. 4
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	13
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	11-12
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	11-12
Other information			
Registration	23	Registration number and name of trial registry	2 + 5
Protocol	24	Where the full trial protocol can be accessed, if available	5
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	14

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org

BMJ Open

Perturbation-based balance training of older adults and effects on physiological, cognitive, and sociopsychological factors: A secondary analysis from a randomised controlled trial with 12-month follow-up

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Perturbation-based balance training of older adults and effects on physiological, cognitive, and sociopsychological factors: A secondary analysis from a randomised controlled trial with 12-month follow-up

Abstract

Background: Perturbation-based balance training (PBT) has shown promising, although diverging, fall-preventive effects; however, the effects on important physical, cognitive, and sociopsychological factors are currently unknown. The study aimed to evaluate these effects on PBT at three different time points (post-training, six months, and 12 months) in community-dwelling older adults compared to regular treadmill walking.

Methods: This was a pre-planned secondary analysis from a randomised, controlled trial performed in Aalborg, Denmark, between March 2021 and November 2022. Community-dwelling older adults aged ≥65 were randomly assigned to participate in four sessions (lasting 20 mins each) of either PBT (intervention) or regular treadmill walking (control). All participants were assigned to four testing sessions: pre-training, post-training, six-month follow-up, and 12-month follow-up. At these sessions, physical, cognitive, and sociopsychological measures were assessed.

Results: In total, 140 participants were randomly allocated to either the PBT or control group. Short-term (pre- to post-training) between-group differences were seen for choice stepping reaction time (-49 ms, 95% CI -80 to -18), dual-task gait speed (0.05 m/s, 95% CI 0.01 to 0.09) favouring the PBT group. However, these improvements were not sustained at the six- and 12-month follow-up. No significant between-group differences were found in other physical, cognitive, or sociopsychological factors.

Conclusions: This study showed that PBT, in the short term, improved choice stepping reaction time and dual-task gait speed among community-dwelling older adults. Yet, these improvements were not retained for six or 12 months. The healthy state of the study's population may have imposed a ceiling effect limiting the ability to show any clinically relevant effects of PBT.

Trial registration: ClinicalTrials.gov NCT04733222

Strengths and limitations of this study:

- This randomized controlled trial was pre-registered in clinicaltrails.gov, a protocol was published, and it followed consort statement.
- Due to practical limitations and the nature of training interventions, the outcome assessor of these secondary outcomes and participants were not blinded for group allocation.
- The study population was a convenience sample of low-risk older adults with no specific physical, cognitive, or sociopsychological problems.

Keywords (MeSH): Aged, Randomized Controlled Trial, Gait, Exercise Therapy, Accidental Falls, Exercise Test, Neuropsychological Tests

Introduction

Ageing leads to deteriorations in physical and cognitive functions, increasing the risk of falls and fall-related injuries, such as fractures.[1–3] However, falls not only leads to physical but also psychological consequences, as falling has been associated with developing concerns about falling.[4] These physical and cognitive consequences of falls collectively lead to disability and loss of independence, which greatly impact the quality of life of older adults.[5] Additionally, society is substantially burdened by fall-related costs, accounting for approximately 1% (0.8 to 1.5%) of healthcare expenses in developed countries [6]. Thus, effective and sustainable fall preventive interventions are needed to improve the well-being of older adults and limit societal costs.[7]

Currently, physical exercise is considered the most effective fall-preventive intervention.[8] A systematic review of 64 randomised, controlled trials on general physical exercise identified a 23%

reduction in fall rates.[9] Most the studies in this review employed conventional training approaches targeting specific physical functions associated with fall risk such as muscle strength or balance.[9] Thus, besides preventing falls, they also help maintain activities of daily life function which is important for preserving the independence and quality of life of older adults.[10,11] However, indirectly targeting falls by improving risk factors may not be the most effective approach.[9] Indeed, the well-established principle of task-specificity states that training paradigms are most effective when they closely simulate the desired task.[12–14] Among community-dwelling older adults, most falls are caused by slips and trips during walking.[2,15,16] Hence, interventions emphasizing rapid compensatory reactions following slips and trips may prove more effective in fall prevention compared to conventional approaches.[15,17]

One such intervention is perturbation-based balance training (PBT), in which the participants are exposed to repeated, unexpected postural disturbances while wearing a body harness to ensure their safety [18]. It is well documented that PBT leads to considerable reactive balance adaptations after even short exposures, which can be retained for up to a year in laboratory settings.[18–21] Yet, divergent effects of PBT on daily life falls have been reported, with some showing an approximate 50% decrease while others find no effects, including the primary analysis from the current study, which showed a nonsignificant decrease in fall rates of 22% (IRR: 0.78, 95% CI 0.44 to 1.39).[18,22–24] Moreover, additional benefits of PBT on other physical, cognitive, and socio-psychological factors are vastly unknown. Considering that the laboratory reactive balance adaptations are long-lasting, evaluating the long-term (> 6 months) maintenance of additional adaptations is of special interest. The long-term effects of PBT have previously been explored in patients with Parkinson's disease and spinal cord injury [25–28]), and short-term effects in community-dwelling older adults[29] Therefore, this pre-planned secondary analysis of a randomised, controlled trial with a 12-month follow-up aimed to evaluate the short- and long-term effects of a four-session PBT intervention on physical (gait, static balance, choice stepping reaction time, lower extremity performance), cognitive (executive function), and sociopsychological (concerns about falling and quality of life) measures among community-dwelling older adults aged 65 years or older, compared to regular treadmill walking.

Methods

Trial design

This article reports secondary results from a parallel group (1:1 ratio), randomised, controlled trial with a 12-month follow-up. A trial protocol and statistical analysis plan have been preregistered at ClinicalTrials.gov (NCT04733222), and a protocol has been published.[30] The primary outcome was fall rates and these results have already been reported.[31] There were no deviations from the protocol. The reporting of this article adheres to the CONSORT 2010 guidelines.[32]

Participants

Eligible participants had to be 1) 65 years or older, 2) community-dwelling, and 3) able to walk without a walking aid. Individuals were excluded if they 1) had an unstable medical condition that prevents safe participation, 2) had a severe cognitive impairment (defined as a score of 8 or less on the Short Orientation-Memory-Concentration test), 3) were currently participating in another fall preventive trial, or 4) had any of the following self-reported conditions: Orthopaedic surgery within the past 12 months, osteoporosis or history of osteoporosis-related fractures (low impact hip, spine, and wrist fracture), or progressive neurological disease (e.g., Parkinson, multiple sclerosis).

The participants were recruited through advertisements on local radio and national television spots. Testing and training sessions were conducted at a laboratory at Aalborg University (Department of Health, Science, and Technology, Fredrik Bajers Vej 7A2-107, DK-9000, Aalborg, Denmark).

Interventions

All participants were assigned to four training sessions (see Figure 1). The initial two sessions were conducted on the first day at the laboratory. A week later, the third training session was performed, while the fourth served as a booster-session 6-months after the third session.

Insert Figure 1 - Study Design about here.

The training interventions were performed on the same Woodway split-belt treadmill, moving uniformly (Split 70/157/ASK; Woodway, Weil am Rhein, Germany). Before training commencement, the preferred treadmill walking speed was determined by increasing and decreasing the belt speed until the upper and lower boundary of comfortable walking was identified. The preferred walking speed was then defined as the average of this upper and lower boundary.

Perturbation-based balance training (intervention)

A detailed description of the PBT protocol has been published elsewhere.[30] In brief, participants allocated to the PBT group were exposed to 40 perturbations applied bilaterally at each session. The first session consisted only of slips, the second only trips, while the third and the fourth had randomly mixed slips and trips. The timing (10-50 steps) and side (left or right) of the perturbations were randomised to enhance their unpredictability. The slips (backward loss of balance) were induced by a sudden forward acceleration resulting in a reversal in the belt movement direction at the heel strike. The trips (forward loss of balance) were provoked by an initial small deceleration followed by a larger backward acceleration at the mid-swing phase of the gait cycle. The perturbations were triggered by a heel contact placed under the sole of the left foot using the computer software Mr. Kick III (Knud Larsen, Department of Health, Science, and Technology, Aalborg University, Denmark).

The perturbation intensity depended on the preferred walking speed and was divided into five levels with progressively increasing duration for the slips and acceleration for the trips. After every fourth perturbation, participants rated the perceived anxiety and difficulty of the previous perturbations on a scale from 1 to 5, with a higher score indicating higher perceived anxiety and difficulty. The intensity was increased if three criteria were fulfilled: 1) the combined perceived anxiety and difficulty were rated four or less, 2) the participant successfully recovered from the four prior perturbations, and 3) the participant was willing to increase the difficulty. If any criteria were violated, the training intensity would remain at the highest tolerable level.

Treadmill walking training (control)

Participants allocated to the treadmill walking group walked for 20 minutes at their preferred walking speed, matching the time spent on the treadmill by the PBT group.

Outcomes

This study reports pre-planned secondary outcomes, including physical, cognitive, and sociopsychological measures collected at the pre-training, post-training, 6-month follow-up, and 12-month follow-up test (see Figure 1). All outcomes were assessed by the same researcher, who was not blinded for group allocation. A detailed description of the tests and the instructions provided are available in Supplementary Material 1.

The physical outcomes are all associated with fall risk and include single and dual task gait, single and dual task static balance, choice stepping reaction time, and lower extremity performance.[33–38] The gait assessment consisted of three single task and three dual task trials of eight-meter walking at a preferred walking speed, with the middle six meters timed using a handheld stopwatch.[37,39,40] As the dual task, the participants were instructed to count backwards in threes from a random three-digit number. No instructions to either prioritise the walking or counting task were provided. The average gait speed of the three trials was used in the analyses. The balance assessment was conducted on a Wii balance board using the FysioMeter software (FysioMeter, V.1.2.1.4, Denmark).[41–43] Participants were instructed to stand as still as possible for 30 seconds, three times as a single task and three times as a dual task. The dual task involved naming items from specific grocery store sections (dairy, produce, and butchery), with no instruction to focus on the balance or cognitive task. The average centre of pressure displacement area and speed from the three trials were used in the analysis. The choice stepping reaction test was also conducted using the Wii balance board and involved reacting as fast as possible to visual clues given on a computer screen by tapping the foot on the correct side of the Wii balance board.[34,44] Seven reactions were collected, and the average reaction time of the initial six was used in the analyses. The Short Physical Performance Battery (SPPB) was used to evaluate lower extremity performance and involved three elements: 1) balance with three different foot positions (side-by-side, semi-tandem, and tandem), 2) two four-meter walks, and 3) five sit-to-stands [36,45]. A score was calculated (range: 0 to 12; higher score indicates better performance) and used in the analyses. Further, the time used in the five sit-to-stands was also analysed as a measure of functional strength.[46]

Cognitive function, known as executive function, was evaluated using the trail making test (TMT) part A and part B.[47,48] Participants sequentially connected numbers (part A) or alternating numbers and letters (part B). Part A assessed visual search, motor speed skills, and attention, while Part B evaluated working memory and task-shifting.[48] The time to complete part B minus part A (ΔTMT) was used in the analyses.[49,50]

Sociopsychological outcomes included concerns about falling and health-related quality of life. The concerns about falling were evaluated using the Short Falls Efficacy Scale-International (short FES-I), and the score was used in the analyses (range: 7 to 28; a higher score indicates higher concern).[51] Moreover, the health-related quality of life was assessed using EQ-5D-5L [52,53]. The EQ-5D-5L index score (range: -1 to 1; higher index indicates better quality of life) and visual analogue scale score (range: 0-100; higher score indicates better quality of life) were used in the analyses.

Sample size

The sample size was calculated based on an expected decrease in the study's primary outcome in fall rates. Therefore, the sample size calculation was based on Poisson's regression model in G*Power (version 3.1.9.4, University of Kiel, Kiel, German). An expected 50% effect size from a base fall rate of 0.85 with an 80% power and 5% significance level necessitated 70 participants in each group, assuming a 20% drop-out.

Randomisation

Immediately after pre-training assessments, participants were allocated to either the PBT or control group using a blocked randomisation module generated in STATA and uploaded in REDCap. The module was created by research staff not involved in any other trial activities. Random block sizes of two, four, six, and eight were used to conceal the allocation sequence. The nature of training interventions and practical limitations led to neither the participant nor the outcome assessor being blinded for group allocation.

Statistical methods

All statistical analyses were conducted following the preregistered statistical analysis plan in collaboration with an external biostatistician[54] The primary statistical analyses were performed following the intention-to-treat principle. A per-protocol analysis was conducted for participants who completed at least 75% of the intervention. The analyses were conducted in STATA (Version 17.0, Stata Corp., Col- lege Station, TX), and p-values of <0.05 were considered statistically significant.

Demographic data are presented as a mean and standard deviation, median and interquartile range, or number and percentage, where appropriate. A linear mixed-effects regression model with the REML estimation procedure was used to evaluate the between-group differences in the physical, cognitive, and sociopsychological measures. In the model, group and time were set as fixed and included together with the interaction term. Record ID was set as a random effect. The results will be presented as estimates of the between-group differences of the within-group changes (pre- to post-training, pre-training to 6 months, and pre-training to 12 months). Model assumptions were checked by inspection of residual plots, and deviations will be mentioned, but will not affect the analysis. Further, missing data were appraised missing at random; thus, multiple imputations were not conducted as it does not add any benefits to the linear mixed-effects model.[55] We did not correct for multiple adjustments; thus, the results should be interpreted as explorative.[56]

Patient and Public Involvement

Patients or the public were not involved in the design, or conduct, or reporting, or dissemination plans of our research

Results

Participant flow

Of the 199 screened older adults, 140 were enrolled and randomised to either the PBT or control group between March and November 2021 (see Figure 2). The baseline characteristics of both groups can be found in Table 1. Loss to follow-up was 4 (6%) and 3 (4%) at the post-training test, 6 (9%) and

11 (16%) at the 26-week follow-up, and 10 (14%) and 16 (23%) at the 52-week follow-up in the PBT and control group, respectively. At least one data point was missing for 13 (19%) in the PBT group and 18 (26%) in the control group. There were similar reasons for drop-out and demographic characteristics between groups among participants with missing data (see Supplementary Material 2). The PBT group had a 90% adherence to training, while the control group completed 93% of the assigned sessions. Moreover, 90% of the PBT group and 97% of the control group completed at least 75% of the intervention, which was the limit for being included in the per-protocol analyses.

Table 1 – demographic data

Table 1 – Baseline characteristics of participants		
	PBT group (n = 70)	Control group (n = 70)
Age (years), mean (SD)	72.7 (4.7)	72.0 (4.7)
Sex, no. female (%)	41 (59)	38 (54)
Frailty*, median (IQR)	2 (1-3)	2 (1-3)
Living arrangement, no. living alone (%)	23 (33)	24 (34)
Daily activity level, sitting downΩ (hours)	4 (6)	6 (9)
Medication, median (IQR)	2 (0-4)	3 (0-4)
Function of daily activities♦, median (IQR)	2 (1-2)	2 (1-2)
Fall within the past 12 months, no. fall (%)	28 (40)	29 (41)
Cognition♣, median (IQR)	26 (24-28)	26 (24-28)
Physical function•, median (IQR)	12 (11-12)	12 (11-12)
Habitual gait speed (m/s), mean (SD)	1.3 (0.2)	1.3 (0.2)
Executive function©, median (IQR)	47.3 (26.1-63.5)	40.7 (29.1-61.8)

* Tilburg Frailty indicator (score 0-15; lower is better); Ω International Physical Activity Questionnaire – time spent sitting down on average per day; ♦ The Vulnerable Elderly-13 Survey (score 0-10; lower is better); ♣ The Short Orientation-Memory-Concentration Test (score 0-28; higher is better); • The Short Physical Performance Battery (0-12; higher is better); © Trail Making Test Part A subtracted from Part B (lower score implied better performance); IQR = interquartile range; PBT = perturbation-based balance training

Outcomes and estimation

All results from the unadjusted model regarding the physical, cognitive, and sociopsychological measures are presented in Supplementary Table 1. Multiple within-group differences were found; however, this section only contains the results of the between-group differences. Among the physical functions, a significant difference from the pre-training to post-training test favouring the PBT group was found in choice stepping reaction time (-49 ms, 95% CI -80 to -18), and dual-task gait speed (0.05 m/s, 95% CI 0.01 to 0.09). However, none of these improvements were retained for the six or 12-month follow-up. There were no significant between-group differences in any of the other physical, cognitive, or sociopsychological factors.

Ancillary analyses

When adjusting for age, sex, and previous falls, the analyses identified significant changes from the pre-training to post-training test favouring the PBT group in single-task gait speed (0.03 m/s, 95% CI 0.00 to 0.06) and five sit-to-stands (-0.54 s, 95% CI -0.97 to -0.01). Otherwise, the analyses led to

similar results as the unadjusted model. Lastly, analysing the data using a per-protocol approach did not lead to different estimates than the intention-to-treat analyses. All results of the sensitivity analyses can be found in Supplementary Material 3.

Discussion

This secondary analysis from a randomised, controlled trial showed that four sessions of treadmill perturbation-based balance training (PBT) did not lead to long-term (≥ 6 months) improvements in the evaluated physical, cognitive, or sociopsychological measures. However, there was a significant short-term improvement from the pre- to post-training test in choice stepping reaction time, and dual-task gait speed favouring the PBT group.

Short-term effects of perturbation-based balance training

PBT led to significantly greater improvements in the choice stepping reaction time from pre-training to post-training than regular treadmill walking (-49 ms, 95% CI -80 to -18). Choice stepping reaction time is a composite measure of fall risk that evaluates the ability to make quick and appropriate voluntary stepping responses to visual cues.[34] The improvement found in our study contrasts with Okubo et al. 2019, which showed that three slip and trip overground walkway PBT sessions had no beneficial effects on the choice stepping reaction time.[57] This discrepancy may be due to Okubo et al. 2019 having four stepping options in the reaction test, while our test only had two.[57] This may lead to the performance being more reliant on executive functions, which this and previous PBT studies have shown limited effects on.[58] However, in line with our results, Kurz et al. 2016 showed treadmill PBT significantly improved voluntary step execution onto one of two targets triggered by a somatosensory cue.[59] This improvement in voluntary step execution was achieved by a faster step initiation time which implies an enhanced central processing speed (CNS).[59] Furthermore, other PBT studies have also reported significant improvements in stepping reactions following either somatosensory or auditory cues.[60–62] Our study, however, is the first to show that PBT improves voluntary stepping performance to visual cues. Collectively, PBT may induce adaptations within the CNS that benefit gait adaptability, which is important in fall prevention [63]. Still, while there is no

established minimally clinically important difference regarding choice stepping reaction time, the 7% improvement after PBT is smaller than the 13% difference previously found between fallers and non-fallers.[34]

Our results also identified significant improvements from the pre-training to post-training test favouring PBT in dual-task gait speed (0.05 m/s, 95% CI 0.01 to 0.09); yet, these improvements were below the limit of minimal clinically important difference (gait speed: 0.10 m/s).[64,65] No other physical and cognitive measures showed a between-group difference following PBT. Supporting these findings, studies applying multidirectional perturbations within three to five sessions showed no improvements in physical measures of strength, static balance, and gait.[23,57,66] Likewise, a single session of 96 waist pull perturbations on a treadmill did not lead to changes in the executive function evaluated using the TMT.[58] However, in contrast to our results, studies including longer training intervention (≥4 weeks) in community-dwelling older adults and Parkinson's patients have been able to show improvements in various physical, cognitive, and sociopsychological measures. [25,27,28]]. In summary, our results indicate that adaptations to PBT interventions are highly task-specific, but some research may imply that higher dosages could lead to better transfer effects.[13,14,18]

Lastly, the PBT intervention failed to show significant between-group differences in the sociopsychological measures. However, close-to-perfect concerns about falling and quality of life scores at pre-training enforced a ceiling effect leaving almost no room for improvement. Therefore, future studies should evaluate these parameters in participants exposed to substantial concerns about falling and low quality of life.

Long-term effects of perturbation-based balance training

A key component of PBT is the well-documented long-term retention of reactive balance adaptations following even small training dosages.[18–20] Improvements in choice stepping reaction time must also be retained throughout the detraining period to be relevant. While choice stepping reaction time in the PBT group remained significantly lower at the six- and 12-month follow-up compared to the pre-training test, these improvements were not significantly different from the control group (see Supplementary Table 1). Thus, there were no long-term effects of PBT on any physical, cognitive, or

sociopsychological measures. These results align with our primary findings that PBT did not lead to a significant decrease in daily life fall rate.[31] Our findings also support the current detraining literature, which points to a decline in physical performance following training cessation in older adults.[67–69]

Practical implications

While the previously published results of the primary outcome paper showed a sustained improvement in reactive balance control over 12 months in laboratory settings (-63% laboratory fall rate at the 12-month follow-up), we only identified a partial transfer of adaptations to daily life (a nonsignificant 22% decrease in fall rates).[31] Moreover, the findings reported in this paper also show that PBT may have limited effects on other important physical, cognitive, and sociopsychological factors. This indicates that PBT should not be regarded as a single intervention but as part of a multicomponent training program. Considering the task-specificity of training adaptations, it is not surprising that multicomponent training programs have proven most effective in improving overall physical and cognitive functions.[70,71] It has recently been recommended that fall preventive training programs should include balance challenging and functional exercises with additional Tai Chi and progressive strength training.[7] Adding PBT to multicomponent training programs could potentially improve the fall preventive effect with only slightly higher training dosages.[13,18,63] However, this remains speculative until studies have shown the effectiveness of such multicomponent interventions.

LIMITATIONS

The results of this study should be interpreted considering the study's limitations. First, due to practical limitations and the nature of training interventions, the outcome assessor of these secondary outcomes and participants were not blinded for group allocation. Second, participants were convenience sampled, low-risk older adults with no specific physical, cognitive, or sociopsychological problems. They were, therefore, not the targeted population for fall preventive training according to the recent world guidelines of fall prevention and management in older adults.[7] Moreover, this population may have a limited potential for improvement, possibly

explaining the lack of effect. Future PBT studies should investigate a frailer population to evaluate the potential effect among those prone to fall-related injuries. Finally, we did not correct for multiple comparisons, which may have led to false positive results due to mass significance; thus, the results should be seen as explorative only.

Conclusion

Secondary analyses from a randomised, controlled trial showed that PBT led to short-term improvements in choice stepping reaction time and dual-task walking speed. However, these improvements were not retained at the six or 12-month follow-up tests. Moreover, PBT did not cause clinically important improvements in the other evaluated physical, cognitive, or socio-psychological measures. These findings underline that adaptations to physical exercise are task-specific. However, the healthy state of the study's population may have imposed a ceiling effect limiting the ability to show any beneficial effects. Further studies adding PBT to multicomponent training programs and studies on more frail older adults with a greater potential for improvements are needed.

Other information

Author contributions

Concept and design: JEN, MGJ, JR, AJTS, JA, MBD, ASO, SA. *Acquisition:* JEN. *Drafting of manuscript*: JEN. *Critical revision of the manuscript for important intellectual content:* MGJ, SA, MBD, JR, AJTS, JA, ASO. *Statistical analysis:* JEN. *Obtained funding:* MGJ, SA. *Administrative, technical, or material support:* JEN, AJTS. *Supervision:* JEN, MGJ. Final approvement of manuscript: JEN, MGJ, SA, MBD, JR, AJTS, JA

Conflict of interest

None of the author have any conflict of interest to declare.

Ethics Approval

The study was performed following the Declaration of Helsinki. North Denmark Region Committee on Human Research Ethics (N-20200089) and the Danish Data Protection Agency (2021-014) approved the study. All participants gave written informed consent before enrolment.

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Additional Contributions

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Registration number and name of trial registry

The study protocol (before study commencement) and statistical analysis plan (before last patient last visit) were preregistered at ClinicalTrials.gov: NCT04733222

Data statement

The data uptained in this study can be accessed upon request from the corresponding author.

References

1 Manini T. Development of Physical Disability in Older Adults. *Current Aging Sciencee*. 2012;4:184–91.

2 Peel NM, Peel NM. Epidemiology of falls in older age. *Canadian Journal on Aging*. 2011;30:7–19.

3 London AJ, Cigolle CT, Ha J, *et al.* The epidemiologic data on falls, 1998-2010: More older Americans report falling. *JAMA Intern Med*. 2015;175:443–5.

4 Friedman SM, Munoz B, West SK, *et al.* Falls and fear of falling: Which comes first? A longitudinal prediction model suggests strategies for primary and secondary prevention. *J Am Geriatr Soc*. 2002;50:1329–35.

5 Stenhagen M, Ekström H, Nordell E, *et al.* Accidental falls, health-related quality of life and life satisfaction: A prospective study of the general elderly population. *Arch Gerontol Geriatr*. 2014;58:95–100.

6 Heinrich S, Rapp K, Rissmann U, *et al.* Cost of falls in old age: a systematic review. *Osteoporosis International*. 2010;21:891–902.

7 Montero-Odasso M, van der Velde N, Martin FC, *et al.* World guidelines for falls prevention and management for older adults: a global initiative. *Age Ageing*. 2022;51:1–36.

8 Falck RS, Davis JC, Best JR, *et al.* Impact of exercise training on physical and cognitive function among older adults: a systematic review and meta-analysis. *Neurobiol Aging*. 2019;79:119–30.

9 Sherrington C, Fairhall N, Kwok W, *et al.* Evidence on physical activity and falls prevention for people aged 65+ years: systematic review to inform the WHO guidelines on physical activity and sedentary behaviour. *International Journal of Behavioral Nutrition and Physical Activity*. 2020;17:1–9.

10 Lee H, Chang K, Tsauo J. Effects of a Multifactorial Fall Prevention Program on Fall Incidence and Physical Function in Community-Dwelling Older Adults With Risk of Falls. *Arch Phys Med Rehabil*. 2013;94:606-615.e1.

11 Chou CH, Hwang CL, Wu YT. Effect of exercise on physical function, daily living activities, and quality of life in the frail older adults: A meta-analysis. *Arch Phys Med Rehabil*. 2012;93:237–44.

12 Buford TW, Anton SD, Clark DJ, *et al.* Optimizing the Benefits of Exercise on Physical Function in Older Adults. *PM&R*. 2014;6:528–43.

13 Grabiner MD, Crenshaw JR, Hurt CP, *et al.* Exercise-based fall prevention: Can you be a bit more specific? *Exerc Sport Sci Rev*. 2014;42:161–8.

14 Giboin LS, Gruber M, Kramer A. Task-specificity of balance training. *Hum Mov Sci*. 2015;44:22–31.

15 Berg WP, Alessio HM, Mills EM, *et al.* Circumstances and consequences of falls in independent community-dwelling older adults. *Age Ageing*. 1997;26:261–8.

16 Talbot LA, Musiol RJ, Witham EK, *et al.* Falls in young, middle-aged and older community dwelling adults: Perceived cause, environmental factors and injury. *BMC Public Health*. 2005;5:1–9.

17 Luukinen H, Herala M, Koski K, *et al.* Fracture risk associated with a fall according to type of fall among the elderly. *Osteoporosis International*. 2000;11:631–4.

18 McCrum C, Bhatt TS, Gerards MHG, *et al.* Perturbation-based balance training: Principles, mechanisms and implementation in clinical practice. *Front Sports Act Living*. 2022;4:1015394.

19 Pai YC, Yang F, Bhatt T, *et al.* Learning from laboratory-induced falling: long-term motor retention among older adults. *Age (Omaha)*. 2014;36:1367–76.

20 Epro G, Mierau A, Mc Crum C, *et al.* Retention of gait stability improvements over 1.5 years in older adults: Effects of perturbation exposure and triceps surae neuromuscular exercise. *J Neurophysiol*. 2018;119:2229–40.

21 Lee A, Bhatt T, Liu X, *et al.* Can treadmill slip-perturbation training reduce longer-term fall risk upon overground slip exposure? *J Appl Biomech*. 2020;36:298–306.

22 Pai YC, Bhatt T, Yang F, *et al.* Perturbation training can reduce community-dwelling older adults' annual fall risk: A randomized controlled trial. *Journals of Gerontology - Series A Biological Sciences and Medical Sciences*. 2014;69:1586–94.

23 Lurie JD, Zagaria AB, Ellis L, *et al.* Surface Perturbation Training to Prevent Falls in Older Adults: A Highly Pragmatic, Randomized Controlled Trial. *Phys Ther*. 2020;100:1153–62.

24 Gerards MHGG, Mccrum C, Mansfield A, *et al.* Perturbation-based balance training for falls reduction among older adults: Current evidence and implications for clinical practice. *Geriatr Gerontol Int*. 2017;17:2294–303.

25 Shen X, Mak MKY. Technology-assisted balance and gait training reduces falls in patients with Parkinson's disease: a randomized controlled trial with 12-month follow-up. *Neurorehabil Neural Repair*. 2015;29:103–11.

26 Unger J, Chan K, Lee JW, *et al.* The Effect of Perturbation-Based Balance Training and Conventional Intensive Balance Training on Reactive Stepping Ability in Individuals With Incomplete Spinal Cord Injury or Disease: A Randomized Clinical Trial. *Front Neurol*. 2021;12:620367.

27 Steib S, Klamroth S, Gaßner H, *et al.* Perturbation During Treadmill Training Improves Dynamic Balance and Gait in Parkinson's Disease: A Single-Blind Randomized Controlled Pilot Trial. *Neurorehabil Neural Repair*. 2017;31:758–68.

28 Smania N, Corato E, Tinazzi M, *et al.* Effect of balance training on postural instability in patients with idiopathic Parkinson's disease. *Neurorehabil Neural Repair*. 2010;24:826–34.

29 Rieger MM, Papegaaij S, Steenbrink F, *et al.* Effects of Perturbation-Based Treadmill Training on Balance Performance, Daily Life Gait, and Falls in Older Adults: REACT Randomized Controlled Trial. *Phys Ther*. 2024;104. doi: 10.1093/ptj/pzad136

30 Nørgaard JE, Andersen S, Ryg J, *et al.* Effects of treadmill slip and trip perturbation-based balance training on falls in community-dwelling older adults (STABILITY): Study protocol for a randomised controlled trial. *BMJ Open*. 2022;12:1–10.

31 Nørgaard JE, Andersen S, Ryg J, *et al.* Effect of Treadmill Perturbation-Based Balance Training on Fall Rates in Community-Dwelling Older Adults: A Randomized Clinical Trial. *JAMA Netw Open*. 2023;6:E238422.

32 Schulz KF, Altman DG, Moher D. CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials. *BMC Med*. 2010;8:18(1-9).

33 Muir-Hunter SW, Wittwer JE. Dual-task testing to predict falls in community-dwelling older adults: A systematic review. *Physiotherapy (United Kingdom)*. 2016;102:29–40.

34 Lord SR, Fitzpatrick RC. Choice stepping reaction time: A composite measure of falls risk in older people. *Journals of Gerontology - Series A Biological Sciences and Medical Sciences*. 2001;56:627–32.

35 Johansson J, Nordström A, Gustafson Y, *et al.* Increased postural sway during quiet stance as a risk factor for prospective falls in community-dwelling elderly individuals. *Age Ageing*. 2017;46:964–70.

36 Veronese N, Bolzetta F, Toffanello ED, *et al.* Association between short physical performance battery and falls in older people: The progetto veneto anziani study. *Rejuvenation Res*. 2014;17:276–84.

37 Cullen S, Montero-Odasso M, Bherer L, *et al.* Guidelines for gait assessments in the canadian consortium on neurodegeneration in aging (CCNA). *Canadian Geriatrics Journal*. 2018;21:157–65.

38 Montero-Odasso M, Almeida QJ, Bherer L, *et al.* Consensus on shared measures of mobility and cognition: From the Canadian Consortium on Neurodegeneration in Aging (CCNA). *Journals of Gerontology - Series A Biological Sciences and Medical Sciences*. 2019;74:897–909.

39 Montero-Odasso M, Sarquis-Adamson Y, Kamkar N, *et al.* Dual-task gait speed assessments with an electronic walkway and a stopwatch in older adults. A reliability study. *Exp Gerontol*. 2020;142:111102.

40 Lyons JG, Heeren T, Stuver SO, *et al.* Assessing the agreement between 3-meter and 6-meter walk tests in 136 community-dwelling older adults. *J Aging Health*. 2015;27:594–605.

41 Clark RA, Mentiplay BF, Pua YH, *et al.* Reliability and validity of the Wii Balance Board for assessment of standing balance: A systematic review. *Gait Posture*. 2018;61:40–54.

42 Jorgensen MG, Laessoe U, Hendriksen C, *et al.* Intra-rater reproducibility and validity of Nintendo Wii balance testing in community-dwelling older adults. *Eur Geriatr Med*. 2013;4:S87.

43 Bonnechère B, Van Hove O, Jansen B, *et al.* Validation of the Wii Balance Board to assess static balance during dual-task activity in healthy subjects. *Med Nov Technol Devices*. 2019;1:100003.

44 Jorgensen MG, Paramanathan S, Ryg J, *et al.* Novel use of the Nintendo Wii board as a measure of reaction time: A study of reproducibility in older and younger adults. *BMC Geriatr*. 2015;15:1–8.

45 Freire AN, Guerra RO, Alvarado B, *et al.* Validity and reliability of the short physical performance battery in two diverse older adult populations in Quebec and Brazil. *J Aging Health*. 2012;24:863–78.

46 Goldberg A, Chavis M, Watkins J, *et al.* The five-times-sit-to-stand test: Validity, reliability and detectable change in older females. *Aging Clin Exp Res*. 2012;24:339–44.

47 Gullickson T. Review of A Compendium of Neuropsychological Tests: Administration, Norms, and Commentary. *Contemporary Psychology: A Journal of Reviews*. 1992;37:385–385.

48 Montero-odasso M. *Falls and Cognition in Older Persons*. Cham: Springer International Publishing 2020. https://doi.org/10.1007/978-3-030-24233-6

49 Delbaere K, Close JCT, Heim J, *et al.* A multifactorial approach to understanding fall risk in older people. *J Am Geriatr Soc*. 2010;58:1679–85.

50 Lezak M, Howieson D, Loring D. *Neuropsychological Assessment*. 4th ed. New York: Oxford University Press, inc. 2004.

51 Marques-Vieira CMA, Sousa LMM, Severino S, *et al.* Cross-cultural validation of the falls efficacy scale international in elderly: Systematic literature review. *Journal of Clinical Gerontology and Geriatrics*. 2016;7:72–6.

52 Sørensen J, Davidsen M, Gudex C, *et al.* Danish EQ-5D population norms. *Scand J Public Health*. 2009;37:467–74.

53 Feng YS, Kohlmann T, Janssen MF, *et al.* Psychometric properties of the EQ-5D-5L: a systematic review of the literature. *Quality of Life Research*. 2021;30:647–73.

54 Nørgaard JE, Andersen S, Ryg J, *et al.* Effects of treadmill slip and trip perturbation-based balance training on falls in community-dwelling older adults (STABILITY): study protocol for a randomised controlled trial. *BMJ Open*. 2022;12:e052492.

55 Peters SAE, Bots ML, Den Ruijter HM, *et al.* Multiple imputation of missing repeated outcome measurements did not add to linear mixed-effects models. *J Clin Epidemiol*. 2012;65:686–95.

56 Rothman KJ. No adjustments are needed for multiple comparisons. *Epidemiology*. 1990;1:43–6.

57 Okubo Y, Sturnieks DL, Brodie MA, *et al.* Effect of Reactive Balance Training Involving Repeated Slips and Trips on Balance Recovery among Older Adults: A Blinded Randomized Controlled Trial. *Journals of Gerontology - Series A Biological Sciences and Medical Sciences*. 2019;74:1489–96.

58 Martelli D, Vashista V, Micera S, *et al.* Direction-Dependent Adaptation of Dynamic Gait Stability Following Waist-Pull Perturbations. *IEEE Transactions on Neural Systems and Rehabilitation Engineering*. 2016;24:1304–13.

59 Kurz I, Gimmon Y, Shapiro A, *et al.* Unexpected perturbations training improves balance control and voluntary stepping times in older adults - A double blind randomized control trial. *BMC Geriatr*. 2016;16:1–11.

60 Mansfield A, Peters AL, Liu BA, *et al.* Effect of a Perturbation-Based Balance Training Program on Compensatory Stepping and Grasping Reactions in Older Adults: A Randomized Controlled Trial. *Phys Ther*. 2010;90:476–91.

61 Parijat P, Lockhart TE. Effects of moveable platform training in preventing slip-induced falls in older adults. *Ann Biomed Eng*. 2012;40:1111–21.

62 Shimada H, Obuchi S, Furuna T, *et al.* New intervention program for preventing falls among frail elderly people: The effects of perturbed walking exercise using a bilateral separated treadmill. *Am J Phys Med Rehabil*. 2004;83:493–9.

63 Nørgaard JE, Jorgensen MG, Ryg J, *et al.* Effects of gait adaptability training on falls and fall-related fractures in older adults: a systematic review and meta-analysis. *Age Ageing*. Published Online First: 2021. doi: 10.1093/ageing/afab105

64 Kwon S, Perera S, Pahor M, *et al.* What is a meaningful change in physical performance? Findings from a clinical trial in older adults (the LIFE-P study). *J Nutr Health Aging*. 2009;13:538–44.

65 Chui K, Hood E, Klima D. Meaningful change in walking speed. *Top Geriatr Rehabil*. 2012;28:97–103.

66 Allin LJ, Brolinson PG, Beach BM, *et al.* Perturbation-based balance training targeting both slip- And trip-induced falls among older adults: A randomized controlled trial. *BMC Geriatr*. 2020;20:1–13.

67 Blasco-Lafarga C, Cordellat A, Forte A, *et al.* Short and long-term trainability in older adults: Training and detraining following two years of multicomponent cognitive—physical exercise training. *Int J Environ Res Public Health*. 2020;17:1–16.

68 Fernández-García ÁI, Gómez-Cabello A, Gómez-Bruton A, *et al.* Effects of multicomponent training and detraining on the fitness of older adults with or at risk of frailty: results of a 10-month quasi-experimental study. *Eur J Sport Sci*. 2022;0:1–14.

69 Vogler CM, Menant JC, Sherrington C, *et al.* Evidence of detraining after 12-week home-based exercise programs designed to reduce fall-risk factors in older people recently discharged from hospital. *Arch Phys Med Rehabil*. 2012;93:1685–91.

70 Giné-Garriga M, Roqué-Fíguls M, Coll-Planas L, *et al.* Physical Exercise Interventions For Improving Performance-Based Measures of Physical Function in Community-Dwelling Frail Older Adults. *Med Sci Sports Exerc*. 2014;46:134.

71 Schoene D, Valenzuela T, Lord SR, *et al.* The effect of interactive cognitive-motor training in reducing fall risk in older people: A systematic review. *BMC Geriatr*. 2014;14:107(1-22).

Figure headings and legends

Figure 1 heading:

Figure 1 - Study Design

Figure 1 legend:

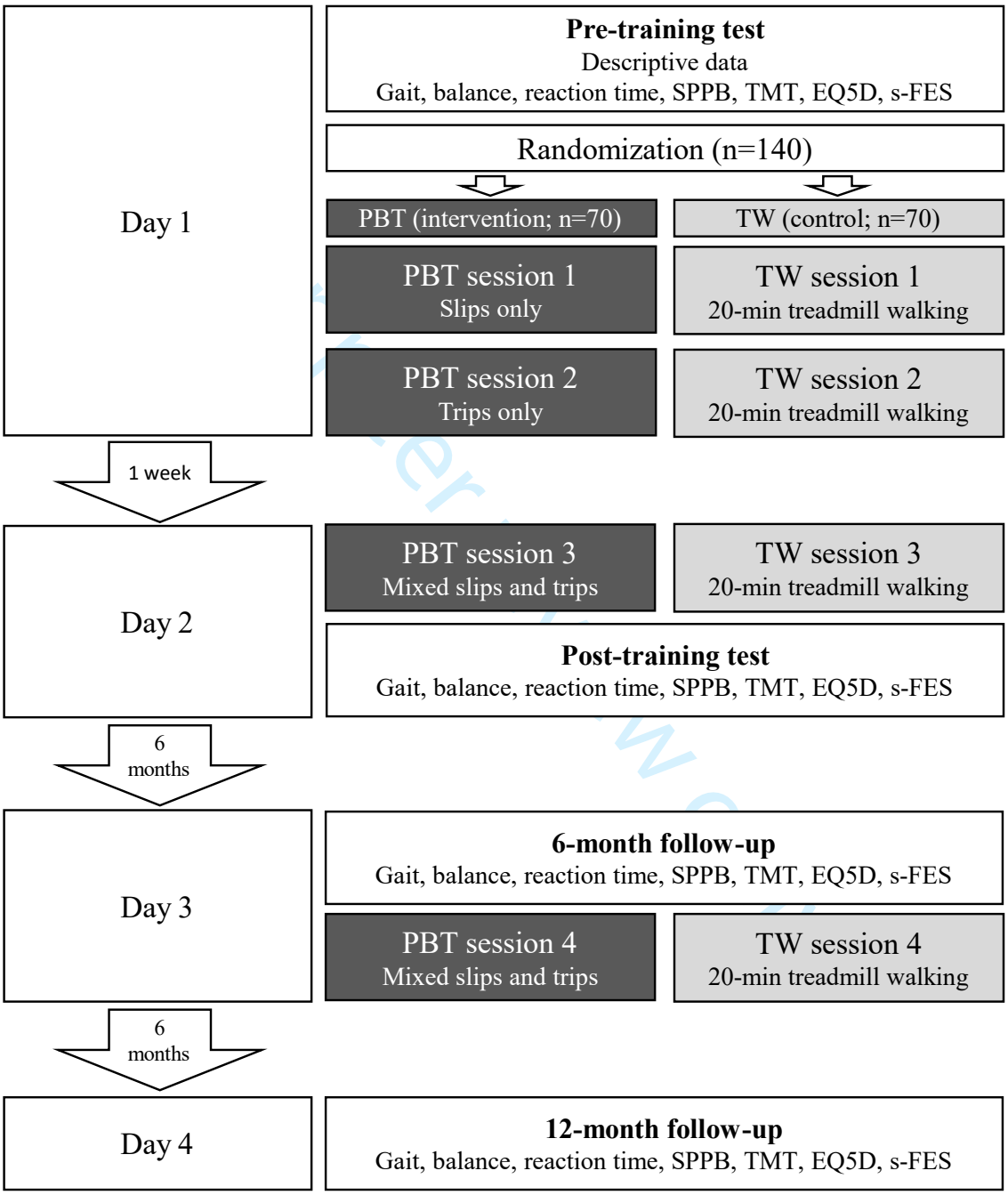
Figure 1 – The study design. Dark grey boxes show the flow of the PBT group. Light grey boxes show the flow of the control group. White boxes indicate that all participants were assigned. SPPB: Short physical performance battery. TMT: Trial making test. EQ5D: EuroQoL 5-dimensions, 5-levels. s-FES: Short falls efficacy scale. PBT: Perturbation-based balance training. TW: Treadmill walking.

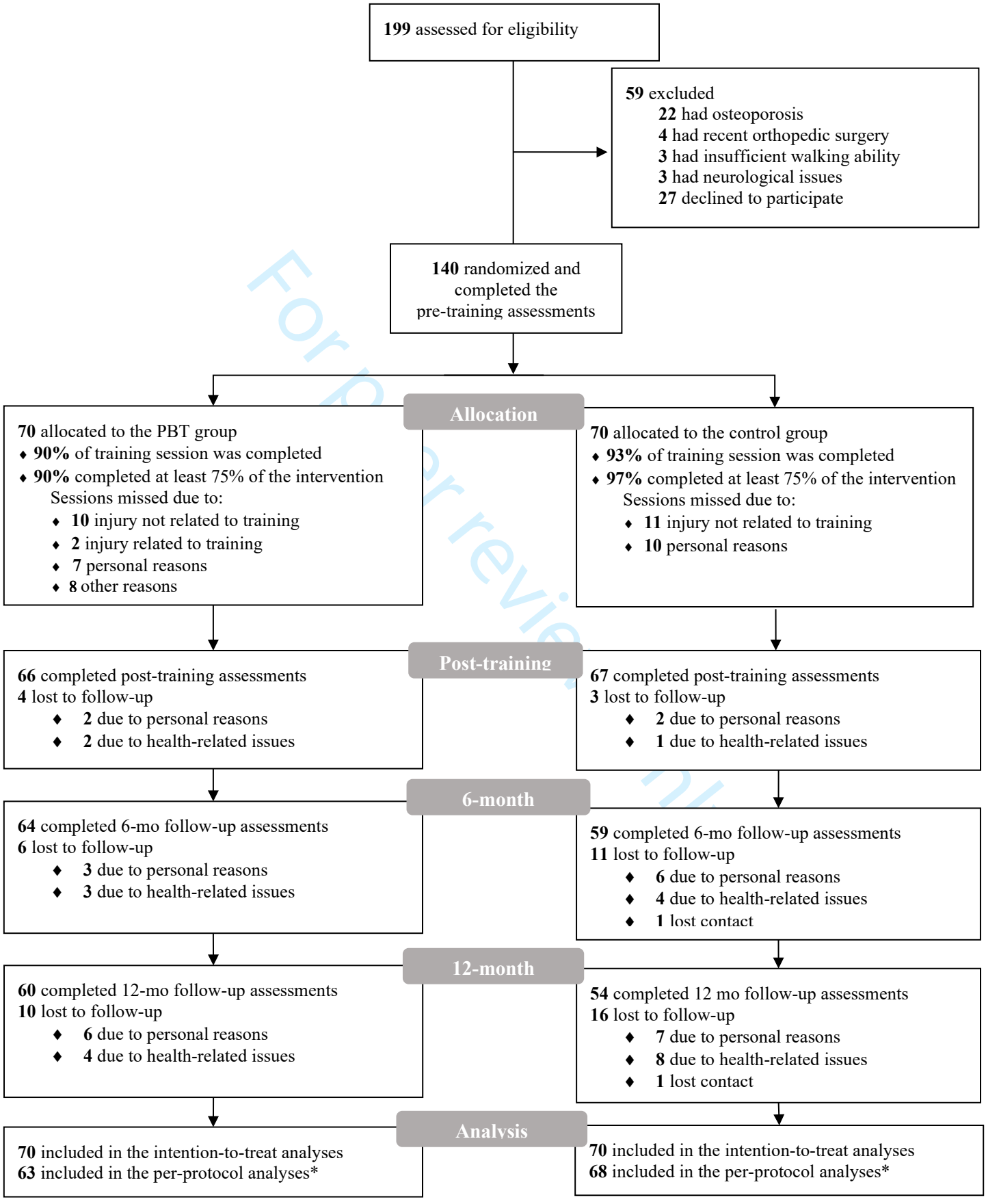
Figure 2 heading:

Figure 2 - CONSORT Flow chart

Figure 2 legend:

Figure 2 – CONSORT Flow chart of the participant flow through the present study. *Per-protocol analysis only included participants that completed at least 75% (3 of 4 sessions) of the assigned intervention.





Supplementary Table 1 – Results from the linear mixed effects model of fall-related risk factors for each testing session as well as group differences at post-training, 6-month follow-up, and 12-month follow-up

	PBT Group Δ				Control group Δ				Between-group differences Ω		
	Pre-training (n = 70)	Post-training (n = 66)	6-month follow-up (n = 64)	12-month follow-up (n = 60)	Pre-training (n = 70)	Post-training (n = 67)	6-month follow-up (n = 59)	12-month follow-up (n = 54)	Pre-training to post-training	Pre-training to 6-month follow-up	Pre-training to 12-month follow-up
Physical measures											
Gait speed, single task, m/s	1.28 [1.24;1.32]	1.29 [1.25;1.33]	1.26 [1.22;1.31]	1.24* [1.20;1.28]	1.26 [1.22;1.30]	1.24 [1.20;1.28]	1.24* [1.20;1.28]	1.22* [1.17;1.26]	0.03 [-0.00;0.06]	0.01 [-0.02;0.04]	0.01 [-0.02;0.04]
Gait speed, dual task, m/s	1.12 [1.07;1.16]	1.17* [1.12;1.21]	1.13 [1.08;1.18]	1.13 [1.08;1.18]	1.12 [1.07;1.17]	1.12 [1.07;1.17]	1.11 [1.06;1.16]	1.10 [1.05;1.15]	**0.05*** **[0.01;0.09]**	0.02 [-0.02;0.06]	0.03 [-0.01;0.07]
Sway area, single task, mm^2 ∞	25.18 [19.90;30.47]	25.00 [19.66;30.35]	23.54 [18.16;28.92]	27.71 [22.26;33.15]	32.28 [27.00;37.57]	32.30 [26.96;37.63]	30.65 [25.18;36.12]	30.16 [24.60;35.72]	-0.19 [-5.69;5.30]	-0.01 [-5.67;5.65]	4.65 [-1.16;10.45]
Sway area, dual task, mm^2 ∞	45.75 [29.86;61.65]	39.12 [22.97;55.28]	46.97 [30.68;63.27]	59.20 [42.64;75.77]	61.43 [45.54;77.33]	57.13 [41.03;73.22]	53.31 [36.64;69.97]	57.73 [40.66;74.79]	-4.32 [-24.22;15.57]	9.34 [-11.13;29.81]	17.15 [-3.85;38.16]
Sway speed, single task, mm/s ∞	15.98 [14.09;17.87]	14.86* [12.96;16.76]	16.35 [14.44;18.25]	16.83 [14.91;18.74]	18.21 [16.32;20.10]	17.74* [15.84;19.64]	18.31 [16.39;20.23]	18.90 [16.97;20.83]	0.35 [-0.89;1.60]	0.27 [-1.01;1.56]	0.16 [-1.15;1.48]
Sway speed, dual task, mm/s ∞	21.64 [19.03;24.26]	19.11* [16.48;21.75]	21.83 [19.19;24.47]	22.99 [20.33;25.65]	22.95 [20.33;25.56]	21.62 [18.97;24.24]	23.02 [20.35;25.69]	22.87 [20.18;25.57]	-1.20 [-3.25;0.85]	0.11 [-2.00;2.22]	1.42 [-0.75;3.58]
Choice stepping reaction time, ms,	890 [863;917]	821* [793;849]	841* [813;869]	832* [803;860]	903 [876;931]	883 [856;911]	873* [844;901]	863* [834;892]	**-48.84*** **[-79.88;-17.79]**	-18.19 [-50.06;13.67]	-18.12 [-50.92;14.68]
SPPB score • ∞	11.53 [11.34;11.72]	11.73* [11.53;11.92]	11.59 [11.39;11.79]	11.63 [11.43;11.83]	11.34 [11.15;11.54]	11.42 [11.22;11.61]	11.32 [11.12;11.53]	11.48 [11.28;11.69]	0.13 [-0.11;0.36]	0.08 [-0.16;0.32]	-0.04 [-0.29;0.21]
Five sit-to-stand, s ᵘ	10.64 [10.09;11.19]	9.79* [9.23;10.34]	10.14* [9.58;10.70]	9.43* [8.86;10.00]	11.24 [10.69;11.79]	10.68* [10.13;11.24]	10.93 [10.37;11.50]	10.20* [9.63;10.78]	-0.30 [-0.82;0.23]	-0.20 [-0.74;0.34]	-0.17 [-0.73;0.38]
Cognitive measures											
TMT ΔAB, s ∞	57.32 [42.20;72.44]	53.84 [38.62;69.06]	56.99 [41.67;72.30]	55.69 [40.28;71.10]	59.31 [44.22;74.41]	55.21 [40.02;71.40]	50.57 [35.14;65.99]	56.72 [41.08;72.36]	-0.37 [-13.21;12.46]	8.41 [-4.80;21.63]	0.96 [-12.61;14.54]
Sociopsychological measures											
Fear of Falling, score ▪ ∞	7.79 [7.45;8.12]	7.98 [7.64;8.33]	8.13* [7.79;8.48]	7.91 [7.55;8.26]	7.90 [7.56;8.24]	8.31* [7.97;8.65]	8.23* [7.87;8.58]	8.18 [7.82;8.55]	-0.21 [-0.64;0.22]	0.02 [-0.42;0.46]	-0.16 [-0.61;0.29]
EQ5D, index ⊕ ∞	0.95 [0.93;0.97]	0.95 [0.93;0.97]	0.94 [0.93;0.96]	0.93* [0.91;0.95]	0.95 [0.93;0.96]	0.94 [0.92;0.95]	0.92* [0.90;0.94]	0.93 [0.91;0.95]	0.01 [-0.01;0.04]	0.02 [-0.00;0.04]	-0.01 [-0.03;0.02]
EQ5D, VAS □ ∞	86.73 [84.46;89.00]	88.40 [86.09;90.71]	87.78 [85.45;90.11]	88.53 [86.16;90.89]	87.00 [84.73;89.27]	88.75 [86.47;91.05]	88.48 [86.11;90.85]	88.11 [85.67;90.55]	-0.08 [-2.95;2.78]	-0.42 [-3.37;2.52]	0.69 [-2.34;3.71]

Δ Estimated means and 95% confidence intervals from the mixed model; * Significant within-group difference from pre-training test; ***** Significant difference favouring the PBT group; • SPPB score ranges between 0 and 12, 12 is the best score; ▪ s-FES score ranges between 7 and 28, 7 is the best score; ⊕ EQ5D Index ranges between 0 and 1, 1 is the best score; □ EQ5D VAS ranges between 0 and 100, 100 is the best score; ᵘ Collected as part of the short physical performance battery, Ω Estimation from mixed models of between-group difference in within-group differences with 95% confidence intervals; ∞ model assumptions not completely fulfilled

SUPPLEMENTARY MATERIAL 1: DETAILED DESCRIPTION OF TESTS

This supplementary material describes the tests used in the pre-training, post-training, 26-week follow-up, and 52-week follow-up tests. Moreover, the instructions given to the participants are also outlined. During the trial, all instructions were provided in Danish; however, this supplementary material is directly translated into English.

The order of the test was identical at each testing session at was as follows: 1) Trial-making-test, 2) balance, 3) choice stepping reaction time, 4) gait, 5) short physical performance battery, and 6) questionnaires.

TABLE OF CONTENT

TRIAL MAKING TEST

Description

The executive function is evaluated using the Trial-Making-Test (TMT) Part A and B. Part A involves sequentially connecting 25 randomly arranged numbers (1- 2- 3-…-25) on paper with a pen. In Part B, 25 randomly placed numbers and letters (1- A- 2- B-…-12- L) are connected alternatingly. The time to complete Part A and Part B was recorded using a handheld stopwatch, and the number of mistakes was registered.

Instruction

"[Show the practice sheet of Part A] In this test, you must sequentially connect the numbers; from 1 to 2, from 2 to 3, and so on [point on the paper]. This is a practice sheet before we move on to the actual test. [participant performs practice sheet]. If you make a mistake, I will highlight it by making a perpendicular line, and you will return to the previous number. I will not tell you what the mistake was."

"[Show the test sheet of Part B] Now we move on to the actual test. In this test, you must connect 25 numbers in the same manner as on the practice sheet. You will begin at 1 [point at number 1] and finish at 25 [point at number 25]. You must connect the numbers as fast as possible and with as few mistakes as possible. I will count from 3, and you may start on "go". "

"[Show the practice sheet of Part B] In the next part of the test, you must alternatingly connect the numbers and letters; from 1 to A, from A to 2, from 2 to B, and so on [point on the paper]. This is a practice sheet before we move on to the actual test [participant performs practice sheet]."

"[Show the test sheet for Part B] Now we move on to the actual test. In this test, you must connect the 25 numbers or letters in the same manner as on the practice sheet. You will begin at 1 [point at number 1] and finish at "L" [point at "L"]. You must connect the numbers as fast as possible and with as few mistakes as possible. I will count from 3, and you may start on "go". "

BALANCE TEST

Description

The balance test was conducted using a Wii balance board (WBB) and the Fysiometer software. Participants stood as still as possible for 30 seconds for three trials under single- and dual-task conditions, respectively. The dual task condition involves naming grocery items from specific supermarket sections. During the test, the participant was instructed to look at a fixed mark at eye height three meters in front of the participant. The area and speed of the centre of pressure displacement were registered in the FysioMeter software.

Instruction

"During the balance test, you must step onto the Wii balance board and place your feet so the outside of your foot is aligned with the edge of the Wii balance board [guide the foot placement of participant]. You will have to stand as still as possible for 30 seconds while looking at the mark in front of you [pointing at the mark] and holding your wrist [illustrate the arm position]. You will have to perform three trials only focusing on standing still, and then three times while simultaneous mentioning grocery items from the supermarket. Are you ready for the first 30 seconds?"

[Immediately before each 30-second trial, the following is instructed] "Look at the mark in front of you and attempt to stand as still as possible; the 30 seconds will start in 3, 2, 1, now."

"For the next three trials, you will have to stand in the same position as before [make sure foot placement is correct] as still as possible for 30 seconds while also mentioning as many grocery items as possible. Before each trial, I will tell you which supermarket section you must mention items. Are you ready for the first 30 seconds?"

[Immediately before each 30-second trial, the following is instructed] "Look at the mark in front of you, hold your wrist, and attempt to stand as still as possible, while also mentioning as many items from the [insert supermarket section (dairy, greens, or butchers department)]; the 30 seconds will start in 3, 2, 1, now.

CHOICE STEPPING REACTION TEST

Description

The choice stepping reaction test was conducted using a Wii balance board and the FysioMeter software. The participants had to react as fast as possible by tapping the correct side of the WBB with the correct foot in response to a visual cue presented on a computer screen seven times. The WBB was placed approximately five cm in front of the participants' feet, and the computer screen was one meter away. A WBB was shown on the computer screen, and the cue was a green light on either the right or left of the WBB. The timing (1-4 seconds) and side were random to maximize the unpredictability. The time from the cue was given to the correct response was performed was recorded with the FysioMeter software.

Instruction

“For the reaction test, you must stand with the feet behind each side of the Wii balance board [guide the foot placement of participant]. A Wii balance board is illustrated on the screen in front of you. When I press “start”, the left or right side will turn green after one to four seconds. You must tap on the correct side, as fast as possible, with the correct foot. If it is the left side, you must use the left foot, and vice versa. Before we begin, you will have three practice trials. Remember to focus on being as fast as possible.”

[Participants get three attempts]

“Now we progress to the real test, and you will have to perform seven reaction trials. Remember to be as fast as possible.”

GAIT TEST

Description

The gait test involved walking eight meters at the preferred walking speed for a total of six trials. The initial three were conducted as a single task, while the last three were under a dual-task condition. The dual task involved continuously subtracting three from a random three digits number. The middle six meters will be recorded using a handheld watch.

Instruction

"During the gait test, you must walk 8 meters from the initial line through the end line [pointing at the two lines]. You will have to walk six times, the first three trials only focusing on walking, while the last three will also involve arithmetics. During the trials, you will have to walk at your regular pace. I will say "3, 2, 1, go", and on "go", you can walk."

[Participant completes three trials as a single task]

"During the next three trials, you will have to walk at your regular pace and simultaneously perform arithmetics. Before each trial, I will tell you a number, which could, for example, be 150. You will then have to continuously subtract three from that number while walking at your regular pace. If the number is 150, it will look like this [illustrate the test by walking and subtracting three]; 147, 144, 141, 138, and so on until you are at the end of the path [pointing at the end]"'

[Participant completes three trials as a dual task with three different numbers]

THE SHORT PHYSICAL PERFORMANCE BATTERY

Description

The short physical performance battery consists of a balance, gait, and strength component. The balance component includes standing in three foot positions (side-by-side, semi-tandem, and tandem) for ten seconds. The gait component involves two four-meter walks at a preferred walking speed, and the strength component consists of five sit-to-stands as fast as possible. Each element is scored based on performance and collected in a composite score (0-12; higher scores indicate better performance).

Instruction

“First, you have to perform a balance test. You have to stand for ten seconds with three different foot positions. During the ten seconds, you are not allowed to move your feet or grab any obstacles to regain balance. The first foot position is a side-by-side position [show the foot position and correct the participant's position]. When you feel in balance, say “go,” and the ten seconds will begin.”

[If the participants complete progress to the next foot position, if not, the balance test is over]

“The next foot position is a semi-tandem foot position [show the foot position and correct the participant's position]. When you feel in balance, say “go,” and the ten seconds will begin.”

[If the participants complete progress to the next foot position, if not, the balance test is over]

“The next foot position is a tandem foot position [show the foot position and correct the participant's position]. When you feel in balance, say “go,” and the ten seconds will begin.”

“The next test is a 4-meter waking test; you must walk 4 meters from the initial line through the end line [point at the two lines] two times at your regular pace. I will count from 3, and on “go”, you begin.”

“The last part of this test battery is a strength test, where you must stand up from a chair five times as fast as possible. Please sit in the chair and cross your hands in front of your chest [illustrate the arm position]. Now stand up and sit down once. You will have to repeat those five times as fast as possible. I will count from 3, and the time begins on “go”. When you stand up the fifth time, the time will stop.” [count for each repetition].

QUESTIONNAIRES

Instruction

"You must fill out this questionnaire which involves a variety of questions that relates to the risk of falling and your well-being. You must read the questions thoroughly and provide a response that describes you the best. If you have any questions regarding understanding the question, you are welcome to ask me; however, I will not be able to help you answer the questions."

SUPPLEMENTARY MATERIAL 2: MISSING DATA

TABLE OF CONTENT

MISSING DATA

Table SM3.1 – Missing data for each outcome

Outcome	PBT group				Control group			
	Pre-training	Post-training	6-month follow-up	12-month follow-up	Pre-training	Post-training	6-month follow-up	12-month follow-up
Gait	0 (0)	4 (6)	6 (9%)	10 (14%)	0 (0)	3 (4%)	12 (16%)	16 (23%)
Balance	0 (0)	4 (6)	6 (9%)	10 (14%)	0 (0)	3 (4%)	12 (16%)	16 (23%)
Reaction	0 (0)	4 (6)	6 (9%)	10 (14%)	0 (0)	3 (4%)	12 (16%)	16 (23%)
SPPB	0 (0)	4 (6)	6 (9%)	10 (14%)	0 (0)	3 (4%)	12 (16%)	16 (23%)
TMT	0 (0)	4 (6)	6 (9%)	10 (14%)	0 (0)	3 (4%)	11 (14%)	16 (23%)
FES	0 (0)	4 (6)	6 (9%)	10 (14%)	0 (0)	3 (4%)	11 (14%)	16 (23%)
EQ5D	0 (0)	4 (6)	6 (9%)	10 (14%)	0 (0)	3 (4%)	11 (14%)	16 (23%)

Table SM3.2 – Summary of reasons for missing data in each group

Reason	PBT group (n =13)	Control group (n = 18)
Injury/illness	6	9
Personal reasons*	7	9

* Personal reasons include logistical issues, lack of motivation, and changes in personal relations forcing stoppage in participation

Table SM3.3 – Baseline characteristics of participants with at least one missing data point in each group

	PBT group (n = 13)	Control group (n = 18)	p-values
Age (years), Mean (SD)	73 (5.0)	72 (5)	0.66[α]
Sex, no. female (%)	9 (69)	9 (50)	0.46[γ]
Frailty*, median (IQR)	3 (2-4)	2 (1-3)	0.13[β]
Medication, median (IQR)	4 (2-7)	2 (0-4)	0.19[β]
Function of daily activities♦, median (IQR)	2 (2-3)	2 (1-3)	0.45[β]
Previous fallers, No. fallen (%)	6 (46)	6 (33)	0.71[γ]
Fear of falling, Median (IQR)	7 (7-8)	8 (7-9)	0.57[β]
Cognition♣, median (IQR)	24 (24-26)	26 (24-26)	0.32[β]
Physical function•, Median (IQR)	11 (11-12)	12 (11-12)	0.45[β]
Habitual gait speed (m/s), Mean (SD)	1.2 (0.1)	1.3 (0.2)	0.12[α]
Dual-task gait speed (m/s) Mean (SD)	1.0 (0.2)	1.2 (0.2)	**0.03**[α]
Single-task balance, sway speed (mm/s) Median (IQR)	13.83 (10.97-19.03)	15.60 (12.00-25.67)	0.37[β]
Dual-task balance, sway speed (mm/s) Median (IQR)	20.30 (15.78-25.93)	23.67 (15.77-25.93)	0.19[β]
Reaction time (ms), Mean (SD)	904 (148)	959 (128)	0.86[α]
Executive function© (s), median (IQR)	59.18 (51.73-63.78)	45.93 (28.83-78.88)	0.12[β]

* Tilburg Frailty indicator; ♦ The Vulnerable Elderly-13 Survey; ♣ The Short Orientation-Memory-Concentration Test; •The Short Physical Performance Battery; © Trail Making Test Part A subtracted from Part B; bold text indicates significant group differences. [α] Unpaired sample t-test; [β] Wilcoxon signed rank test; [γ] Fisher's exact test; bold text indicates significant between group differences

Table SM3.4 – Baseline characteristics of participants with at least one missing data point compared to participants with no missing data

	With missing (n = 31)	Without missing (n = 109)	p-values
Age (years), Mean (SD)	72 (5.1)	72 (4.6)	0.52[α]
Sex, no. female (%)	18 (58)	61 (56)	1.0[γ]
Frailty*, median (IQR)	2 (1-3)	1 (1-3)	0.07[β]
Medication, median (IQR)	3 (1-5)	2 (0-4)	0.25[β]
Function of daily activities♦, median (IQR)	2 (1-2)	2 (1-3)	0.55[β]
Previous fallers, No. fallen (%)	12 (39)	45 (41)	0.84[γ]
Fear of falling, Median (IQR)	8 (7-9)	7 (7-8)	0.57[β]
Cognition♣, median (IQR)	26 (24-26)	26 (24-28)	0.12[β]
Physical function•, Median (IQR)	12 (11-12)	12 (11-12)	0.28[β]
Habitual gait speed (m/s), Mean (SD)	1.3 (0.2)	1.3 (0.2)	0.25[α]
Dual-task gait speed (m/s) Mean (SD)	1.1 (0.2)	1.1 (0.2)	0.47[α]
Single-task balance, sway speed (mm/s) Median (IQR)	14.3 (11.7-20.7)	14.9 (12.0-19.2)	0.89[β]
Dual-task balance, sway speed (mm/s) Median (IQR)	21.8 (14.4-27.3)	18.0 (14.9-25.1)	0.25[β]
Reaction time (ms), Mean (SD)	927 (140)	889 (108)	0.95[α]
Executive function© (s), median (IQR)	54.8 (36.3-74.2)	37.5 (25.5-58.4)	0.06[β]

* Tilburg Frailty indicator; ♦ The Vulnerable Elderly-13 Survey; ♣ The Short Orientation-Memory-Concentration Test; •The Short Physical Performance Battery; © Trail Making Test Part A subtracted from Part B; bold text indicates significant group differences. [α] Unpaired sample t-test; [β] Wilcoxon signed rank test; [γ] Fisher's exact test; bold text indicates significant between group differences

SUPPLEMENTARY MATERIAL 2: RESULTS

This supplementary includes the results of the sensitivity analyses and the stata code used for both the primary analyses and the sensitivity analyses.

TABLE OF CONTENT

PER-PROTOCOL ANALYSES

Table SM2.2 – Results of fall-related risk factors using a per-protocol approach which only included participants who completed at least 75% of the intervention

	Between group differences		
	Pre-training to post-training (95% CI)	Pre-training to 26-week follow-up (95% CI)	Pre-training to 52-week follow-up (95% CI)
Physical measures			
Gait speed, single task, m/s Mean (SD)	0.03 (-0.00 to 0.06)	0.01 (-0.02 to 0.05)	0.01 (-0.03 to 0.05)
Gait speed, dual task, m/s Mean (SD)	**0.05♣** **(0.02 to 0.09)**	0.03 (-0.01 to 0.07)	0.03 (-0.02 to 0.08)
Sway area, single task, mm^2 Median (IQR)	-2.2 (-6.5 to 2.0)	-1.8 (-6.2 to 2.7)	3.2 (-2.9 to 9.2)
Sway area, dual task, mm^2 Median (IQR)	-10.2 (-24.2 to 3.9)	4.7 (-9.0 to 18.4)	12.9 (-18.8 to 44.5)
Sway speed, single task, mm/s Median (IQR)	0.1 (-1.0 to 1.3)	0.3 (-0.9 to 1.5)	0.1 (-1.3 to 1.5)
Sway speed, dual task, mm/s Median (IQR)	-1.6 (-3.2 to 0.1)	0.1 (-2.0 to 2.2)	1.4 (-1.3 to 4.0)
Reaction time, ms Mean (SD)	**-57♣** **(-84 to -30)**	-31 (-64 to 2)	-31 (-64 to 2)
SPPB, score• Median (IQR)	**0.2♣** **(0.0 to 0.4)**	0.2 (-0.1 to 0.4)	-0.0 (-0.2 to 0.3)
Five sit-to-stand$^{\mu}$, s Mean (SD)	-0.48 (-0.97 to 0.01)	-0.38 (-0.92 to 0.16)	-0.35 (-0.92 to 0.21)
Cognitive measures			
TMT ΔAB, s Median (IQR)	-2.78 (-16.38 to 10.82)	4.28 (-7.90 to 16.46)	-2.77 (-15.38 to 9.85)
Sociopsychological measures			
Fear of Falling, score▪ Median (IQR)	-0 (-1 to 1)	-0 (-0 to 0)	-0 (-1 to 0)
EQ5D, index$^{\oplus}$ Median (IQR)	0.01 (-0.01 to 0.04)	0.02 (-0.00 to 0.04)	-0.01 (-0.03 to 0.02)
EQ5D, VAS$^{\square}$ Median (IQR)	-0 (-2 to 2)	-0 (-3 to 2)	1 (-2 to 3)

* Significant difference from pre-training test; ♣ Significant difference between groups; • SPPB score ranges between 0 and 12, 12 is the best score; ▪ s-FES score ranges between 7 and 28, 28 is the best score; $^{\oplus}$ EQ5D Index ranges between 0 and 1, 1 is the best score; $^{\square}$ EQ5D VAS ranges between 0 and 100, 100 is the best score; $^{\mu}$ Collected as part of the short physical performance battery.

SENSITIVITY ANALYSES: ADJUSTED FOR AGE, SEX, AND PERVIOUS FALLS

Table SM2.3 – Results of fall-related risk factors for each testing session as well as group differences at post-training, 26-week follow-up and 52-week follow-up for the adjusted model (age, sex, and previous falls)

	Between group differences		
	Pre-training to post-training (95% CI)	Pre-training to 26-week follow-up (95% CI)	Pre-training to 52-week follow-up (95% CI)
Physical measure			
Gait speed, single task, m/s Mean (SD)	**0.03♣** **(0.00 to 0.06)**	0.02 (-0.02 to 0.05)	0.02 (-0.02 to 0.05)
Gait speed, dual task, m/s Mean (SD)	**0.06♣** **(0.02 to 0.09)**	0.03 (-0.01 to 0.07)	0.04 (-0.01 to 0.08)
Sway area, single task, mm^2 Median (IQR)	-2.8 (-6.8 to 1.3)	-2.6 (-6.8 to 1.7)	2.2 (-3.6 to 7.9)
Sway area, dual task, mm^2 Median (IQR)	-11.5 (-24.9 to 1.95)	2.1 (-10.5 to 14.8)	10.1 (-19.3 to 39.4)
Sway speed, single task, mm/s Median (IQR)	0.1 (-1.0 to 1.1)	-0.0 (-1.1 to 1.1)	-0.1 (-1.5 to 1.2)
Sway speed, dual task, mm/s Median (IQR)	-1.6 (-3.3 to 0.1)	0.3 (-2.3 to 1.7)	1.1 (-1.5 to 3.6)
Reaction time, ms Mean (SD)	**-57♣** **(-83 to -30)**	-27 (-58 to 5)	-27 (-59 to 6)
SPPB, score• Median (IQR)	**0.2♣** **(0.0 to 0.4)**	0.2 (-0.1 to 0.4)	-0.1 (-0.2 to 0.3)
Five sit-to-stand$^{\mu}$, s Mean (SD)	**-0.54♣** **(-0.97 to -0.01)**	-0.44 (-0.98 to 0.10)	-0.40 (-0.93 to 0.14)
Cogntive measure			
TMT ΔAB, s Median (IQR)	-3.80 (-18.18 to 10.57)	3.30 (-9.47 to 16.07)	-3.79 (-17.22 to 9.64)
Sociopsychological measure			
Fear of Falling, score▪ Median (IQR)	-0 (-1 to 0)	-0 (-1 to 0)	-0 (-1 to 0)
EQ5D, index$^{\oplus}$ Median (IQR)	0.01 (-0.01 to 0.04)	0.02 (-0.00 to 0.04)	-0.01 (-0.03 to 0.02)
EQ5D, VAS$^{\square}$ Median (IQR)	-0 (-2 to 2)	-1 (-3 to 2)	0 (-2 to 3)

♣ Significant between-group difference favouring the PBT group; • SPPB score ranges between 0 and 12, 12 is the best score; ▪ s-FES score ranges between 7 and 28, 28 is the best score; $^{\oplus}$ EQ5D Index ranges between 0 and 1, 1 is the best score; $^{\square}$ EQ5D VAS ranges between 0 and 100, 100 is the best score; $^{\mu}$ Collected as part of the short physical performance battery.

STATA CODES USED FOR ANALYSIS

All the statistical tests was conducted in STATA version 17.0. The outcomes was adjusted for the baseline values for the same outcome. This code was used for all the outcomes in this study:

mixed [insert variable] i.time##i.intervention baseline_[insert variable] || record_id:, vce(robust)

Model adjusting for age, sex, and previous falls:

mixed [insert variable] i.time##i.intervention baseline_[insert variable] age i.sex i.prev_faller || record_id:, vce(robust)

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance, see CONSORT for abstracts)	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	4
	2b	Specific objectives or hypotheses	4
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	4-5
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	5
Participants	4a	Eligibility criteria for participants	5
	4b	Settings and locations where the data were collected	4
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	5-6 + Supp. 1
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	6-7
	6b	Any changes to trial outcomes after the trial commenced, with reasons	N/A
Sample size	7a	How sample size was determined	7-8
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	5
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	5
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	5
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	5

Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	7
	11b	If relevant, description of the similarity of interventions	N/A
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	8
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	8
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	9 + Figure 2
	13b	For each group, losses and exclusions after randomisation, together with reasons	Figure 2
Recruitment	14a	Dates defining the periods of recruitment and follow-up	5
	14b	Why the trial ended or was stopped	N/A
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 1
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	9 + Figure 2
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	9-20 + Table 2 + Figure 3 + supp. 3
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	Table 2
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	9-10 + supp. 4
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	10 + supp. 4
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	13
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	11-12
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	11-12
Other information			
Registration	23	Registration number and name of trial registry	2 + 5
Protocol	24	Where the full trial protocol can be accessed, if available	5
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	14

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

BMJ Open

Perturbation-based balance training of older adults and effects on physiological, cognitive, and sociopsychological factors: A secondary analysis from a randomised controlled trial with 12-month follow-up

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Perturbation-based balance training of older adults and effects on physiological, cognitive, and sociopsychological factors: A secondary analysis from a randomised controlled trial with 12-month follow-up

Abstract

Background: Perturbation-based balance training (PBT) has shown promising, although diverging, fall-preventive effects; however, the effects on important physical, cognitive, and sociopsychological factors are currently unknown. The study aimed to evaluate these effects on PBT at three different time points (post-training, six months, and 12 months) in community-dwelling older adults compared to regular treadmill walking.

Methods: This was a pre-planned secondary analysis from a randomised, controlled trial performed in Aalborg, Denmark, between March 2021 and November 2022. Community-dwelling older adults aged ≥65 were randomly assigned to participate in four sessions (lasting 20 mins each) of either PBT (intervention) or regular treadmill walking (control). All participants were assigned to four testing sessions: pre-training, post-training, six-month follow-up, and 12-month follow-up. At these sessions, physical, cognitive, and sociopsychological measures were assessed.

Results: In total, 140 participants were randomly allocated to either the PBT or control group. Short-term (pre- to post-training) between-group differences were seen for choice stepping reaction time (-49 ms, 95% CI -80 to -18), dual-task gait speed (0.05 m/s, 95% CI 0.01 to 0.09) favouring the PBT group. However, these improvements were not sustained at the six- and 12-month follow-up. No significant between-group differences were found in other physical, cognitive, or sociopsychological factors.

Conclusions: This study showed that PBT, in the short term, improved choice stepping reaction time and dual-task gait speed among community-dwelling older adults. Yet, these improvements were not retained for six or 12 months. The healthy state of the study's population may have imposed a ceiling effect limiting the ability to show any clinically relevant effects of PBT.

Trial registration: ClinicalTrials.gov NCT04733222

Strengths and limitations of this study:

- This randomized controlled trial was pre-registered in clinicaltrails.gov, a protocol was published, and it followed consort statement.
- Due to practical limitations and the nature of training interventions, the outcome assessor of these secondary outcomes and participants were not blinded for group allocation.
- The study population was a convenience sample of low-risk older adults with no specific physical, cognitive, or sociopsychological problems.

Keywords (MeSH): Aged, Randomized Controlled Trial, Gait, Exercise Therapy, Accidental Falls, Exercise Test, Neuropsychological Tests

Introduction

Ageing leads to deteriorations in physical and cognitive functions, increasing the risk of falls and fall-related injuries, such as fractures.[1–3] However, falls not only leads to physical but also psychological consequences, as falling has been associated with developing concerns about falling.[4] These physical and cognitive consequences of falls collectively lead to disability and loss of independence, which greatly impact the quality of life of older adults.[5] Additionally, society is substantially burdened by fall-related costs, accounting for approximately 1% (0.8 to 1.5%) of healthcare expenses in developed countries [6]. Thus, effective and sustainable fall preventive interventions are needed to improve the well-being of older adults and limit societal costs.[7]

Currently, physical exercise is considered the most effective fall-preventive intervention.[8] A systematic review of 64 randomised, controlled trials on general physical exercise identified a 23%

reduction in fall rates.[9] Most the studies in this review employed conventional training approaches targeting specific physical functions associated with fall risk such as muscle strength or balance.[9] Thus, besides preventing falls, they also help maintain activities of daily life function which is important for preserving the independence and quality of life of older adults.[10,11] However, indirectly targeting falls by improving risk factors may not be the most effective approach.[9] Indeed, the well-established principle of task-specificity states that training paradigms are most effective when they closely simulate the desired task.[12–14] Among community-dwelling older adults, most falls are caused by slips and trips during walking.[2,15,16] Hence, interventions emphasizing rapid compensatory reactions following slips and trips may prove more effective in fall prevention compared to conventional approaches.[15,17]

One such intervention is perturbation-based balance training (PBT), in which the participants are exposed to repeated, unexpected postural disturbances while wearing a body harness to ensure their safety [18]. It is well documented that PBT leads to considerable reactive balance adaptations after even short exposures, which can be retained for up to a year in laboratory settings.[18–21] Yet, divergent effects of PBT on daily life falls have been reported, with some showing an approximate 50% decrease while others find no effects, including the primary analysis from the current study, which showed a nonsignificant decrease in fall rates of 22% (IRR: 0.78, 95% CI 0.44 to 1.39).[18,22–24] Moreover, additional benefits of PBT on other physical, cognitive, and socio-psychological factors are vastly unknown. Considering that the laboratory reactive balance adaptations are long-lasting, evaluating the long-term (> 6 months) maintenance of additional adaptations is of special interest. The long-term effects of PBT have previously been explored in patients with Parkinson's disease and spinal cord injury [25–28]), and short-term effects in community-dwelling older adults[29] Therefore, this pre-planned secondary analysis of a randomised, controlled trial with a 12-month follow-up aimed to evaluate the short- and long-term effects of a four-session PBT intervention on physical (gait, static balance, choice stepping reaction time, lower extremity performance), cognitive (executive function), and sociopsychological (concerns about falling and quality of life) measures among community-dwelling older adults aged 65 years or older, compared to regular treadmill walking.

Methods

Trial design

This article reports secondary results from a parallel group (1:1 ratio), randomised, controlled trial with a 12-month follow-up. A trial protocol and statistical analysis plan have been preregistered at ClinicalTrials.gov (NCT04733222), and a protocol has been published.[30] The primary outcome was fall rates and these results have already been reported.[31] There were no deviations from the protocol. The reporting of this article adheres to the CONSORT 2010 guidelines.[32]

Participants

Eligible participants had to be 1) 65 years or older, 2) community-dwelling, and 3) able to walk without a walking aid. Individuals were excluded if they 1) had an unstable medical condition that prevents safe participation, 2) had a severe cognitive impairment (defined as a score of 8 or less on the Short Orientation-Memory-Concentration test), 3) were currently participating in another fall preventive trial, or 4) had any of the following self-reported conditions: Orthopaedic surgery within the past 12 months, osteoporosis or history of osteoporosis-related fractures (low impact hip, spine, and wrist fracture), or progressive neurological disease (e.g., Parkinson, multiple sclerosis).

The participants were recruited through advertisements on local radio and national television spots. Testing and training sessions were conducted at a laboratory at Aalborg University (Department of Health, Science, and Technology, Fredrik Bajers Vej 7A2-107, DK-9000, Aalborg, Denmark).

Interventions

All participants were assigned to four training sessions (see Figure 1). The initial two sessions were conducted on the first day at the laboratory. A week later, the third training session was performed, while the fourth served as a booster-session 6-months after the third session.

Insert Figure 1 - Study Design about here.

The training interventions were performed on the same Woodway split-belt treadmill, moving uniformly (Split 70/157/ASK; Woodway, Weil am Rhein, Germany). Before training commencement, the preferred treadmill walking speed was determined by increasing and decreasing the belt speed until the upper and lower boundary of comfortable walking was identified. The preferred walking speed was then defined as the average of this upper and lower boundary.

Perturbation-based balance training (intervention)

A detailed description of the PBT protocol has been published elsewhere.[30] In brief, participants allocated to the PBT group were exposed to 40 perturbations applied bilaterally at each session. The first session consisted only of slips, the second only trips, while the third and the fourth had randomly mixed slips and trips. The timing (10-50 steps) and side (left or right) of the perturbations were randomised to enhance their unpredictability. The slips (backward loss of balance) were induced by a sudden forward acceleration resulting in a reversal in the belt movement direction at the heel strike. The trips (forward loss of balance) were provoked by an initial small deceleration followed by a larger backward acceleration at the mid-swing phase of the gait cycle. The perturbations were triggered by a heel contact placed under the sole of the left foot using the computer software Mr. Kick III (Knud Larsen, Department of Health, Science, and Technology, Aalborg University, Denmark).

The perturbation intensity depended on the preferred walking speed and was divided into five levels with progressively increasing duration for the slips and acceleration for the trips. After every fourth perturbation, participants rated the perceived anxiety and difficulty of the previous perturbations on a scale from 1 to 5, with a higher score indicating higher perceived anxiety and difficulty. The intensity was increased if three criteria were fulfilled: 1) the combined perceived anxiety and difficulty were rated four or less, 2) the participant successfully recovered from the four prior perturbations, and 3) the participant was willing to increase the difficulty. If any criteria were violated, the training intensity would remain at the highest tolerable level.

Treadmill walking training (control)

Participants allocated to the treadmill walking group walked for 20 minutes at their preferred walking speed, matching the time spent on the treadmill by the PBT group.

Outcomes

This study reports pre-planned secondary outcomes, including physical, cognitive, and sociopsychological measures collected at the pre-training, post-training, 6-month follow-up, and 12-month follow-up test (see Figure 1). All outcomes were assessed by the same researcher, who was not blinded for group allocation. A detailed description of the tests and the instructions provided are available in Supplementary Material 1.

The physical outcomes are all associated with fall risk and include single and dual task gait, single and dual task static balance, choice stepping reaction time, and lower extremity performance.[33–38] The gait assessment consisted of three single task and three dual task trials of eight-meter walking at a preferred walking speed, with the middle six meters timed using a handheld stopwatch.[37,39,40] As the dual task, the participants were instructed to count backwards in threes from a random three-digit number. No instructions to either prioritise the walking or counting task were provided. The average gait speed of the three trials was used in the analyses. The balance assessment was conducted on a Wii balance board using the FysioMeter software (FysioMeter, V.1.2.1.4, Denmark).[41–43] Participants were instructed to stand as still as possible for 30 seconds, three times as a single task and three times as a dual task. The dual task involved naming items from specific grocery store sections (dairy, produce, and butchery), with no instruction to focus on the balance or cognitive task. The average centre of pressure displacement area and speed from the three trials were used in the analysis. The choice stepping reaction test was also conducted using the Wii balance board and involved reacting as fast as possible to visual clues given on a computer screen by tapping the foot on the correct side of the Wii balance board.[34,44] Seven reactions were collected, and the average reaction time of the initial six was used in the analyses. The Short Physical Performance Battery (SPPB) was used to evaluate lower extremity performance and involved three elements: 1) balance with three different foot positions (side-by-side, semi-tandem, and tandem), 2) two four-meter walks, and 3) five sit-to-stands [36,45]. A score was calculated (range: 0 to 12; higher score indicates better performance) and used in the analyses. Further, the time used in the five sit-to-stands was also analysed as a measure of functional strength.[46]

Cognitive function, known as executive function, was evaluated using the trail making test (TMT) part A and part B.[47,48] Participants sequentially connected numbers (part A) or alternating numbers and letters (part B). Part A assessed visual search, motor speed skills, and attention, while Part B evaluated working memory and task-shifting.[48] The time to complete part B minus part A (ΔTMT) was used in the analyses.[49,50]

Sociopsychological outcomes included concerns about falling and health-related quality of life. The concerns about falling were evaluated using the Short Falls Efficacy Scale-International (short FES-I), and the score was used in the analyses (range: 7 to 28; a higher score indicates higher concern).[51] Moreover, the health-related quality of life was assessed using EQ-5D-5L [52,53]. The EQ-5D-5L index score (range: -1 to 1; higher index indicates better quality of life) and visual analogue scale score (range: 0-100; higher score indicates better quality of life) were used in the analyses.

Sample size

The sample size was calculated based on an expected decrease in the study's primary outcome in fall rates. Therefore, the sample size calculation was based on Poisson's regression model in G*Power (version 3.1.9.4, University of Kiel, Kiel, German). An expected 50% effect size from a base fall rate of 0.85 with an 80% power and 5% significance level necessitated 70 participants in each group, assuming a 20% drop-out.

Randomisation

Immediately after pre-training assessments, participants were allocated to either the PBT or control group using a blocked randomisation module generated in STATA and uploaded in REDCap. The module was created by research staff not involved in any other trial activities. Random block sizes of two, four, six, and eight were used to conceal the allocation sequence. The nature of training interventions and practical limitations led to neither the participant nor the outcome assessor being blinded for group allocation.

Statistical methods

All statistical analyses were conducted following the preregistered statistical analysis plan in collaboration with an external biostatistician[54] The primary statistical analyses were performed following the intention-to-treat principle. A per-protocol analysis was conducted for participants who completed at least 75% of the intervention. The analyses were conducted in STATA (Version 17.0, Stata Corp., Col- lege Station, TX), and p-values of <0.05 were considered statistically significant.

Demographic data are presented as a mean and standard deviation, median and interquartile range, or number and percentage, where appropriate. A linear mixed-effects regression model with the REML estimation procedure was used to evaluate the between-group differences in the physical, cognitive, and sociopsychological measures. In the model, group and time were set as fixed and included together with the interaction term. Record ID was set as a random effect. The results will be presented as estimates of the between-group differences of the within-group changes (pre- to post-training, pre-training to 6 months, and pre-training to 12 months). Model assumptions were checked by inspection of residual plots, and deviations will be mentioned, but will not affect the analysis. Further, missing data were appraised missing at random; thus, multiple imputations were not conducted as it does not add any benefits to the linear mixed-effects model.[55] We did not correct for multiple adjustments; thus, the results should be interpreted as explorative.[56]

Patient and Public Involvement

Patients or the public were not involved in the design, or conduct, or reporting, or dissemination plans of our research

Results

Participant flow

Of the 199 screened older adults, 140 were enrolled and randomised to either the PBT or control group between March and November 2021 (see Figure 2). The baseline characteristics of both groups can be found in Table 1. Loss to follow-up was 4 (6%) and 3 (4%) at the post-training test, 6 (9%) and

11 (16%) at the 26-week follow-up, and 10 (14%) and 16 (23%) at the 52-week follow-up in the PBT and control group, respectively. At least one data point was missing for 13 (19%) in the PBT group and 18 (26%) in the control group. There were similar reasons for drop-out and demographic characteristics between groups among participants with missing data (see Supplementary Material 2). The PBT group had a 90% adherence to training, while the control group completed 93% of the assigned sessions. Moreover, 90% of the PBT group and 97% of the control group completed at least 75% of the intervention, which was the limit for being included in the per-protocol analyses.

Table 1 – demographic data

Table 1 – Baseline characteristics of participants		
	PBT group (n = 70)	Control group (n = 70)
Age (years), mean (SD)	72.7 (4.7)	72.0 (4.7)
Sex, no. female (%)	41 (59)	38 (54)
Frailty*, median (IQR)	2 (1-3)	2 (1-3)
Living arrangement, no. living alone (%)	23 (33)	24 (34)
Daily activity level, sitting downΩ (hours)	4 (6)	6 (9)
Medication, median (IQR)	2 (0-4)	3 (0-4)
Function of daily activities♦, median (IQR)	2 (1-2)	2 (1-2)
Fall within the past 12 months, no. fall (%)	28 (40)	29 (41)
Cognition♣, median (IQR)	26 (24-28)	26 (24-28)
Physical function•, median (IQR)	12 (11-12)	12 (11-12)
Habitual gait speed (m/s), mean (SD)	1.3 (0.2)	1.3 (0.2)
Executive function©, median (IQR)	47.3 (26.1-63.5)	40.7 (29.1-61.8)

* Tilburg Frailty indicator (score 0-15; lower is better); Ω International Physical Activity Questionnaire – time spent sitting down on average per day; ♦ The Vulnerable Elderly-13 Survey (score 0-10; lower is better); ♣ The Short Orientation-Memory-Concentration Test (score 0-28; higher is better); • The Short Physical Performance Battery (0-12; higher is better); © Trail Making Test Part A subtracted from Part B (lower score implied better performance); IQR = interquartile range; PBT = perturbation-based balance training

Outcomes and estimation

All results from the unadjusted model regarding the physical, cognitive, and sociopsychological measures are presented in Supplementary Table 1. Multiple within-group differences were found; however, this section only contains the results of the between-group differences. Among the physical functions, a significant difference from the pre-training to post-training test favouring the PBT group was found in choice stepping reaction time (-49 ms, 95% CI -80 to -18), and dual-task gait speed (0.05 m/s, 95% CI 0.01 to 0.09). However, none of these improvements were retained for the six or 12-month follow-up. There were no significant between-group differences in any of the other physical, cognitive, or sociopsychological factors.

Ancillary analyses

When adjusting for age, sex, and previous falls, the analyses identified significant changes from the pre-training to post-training test favouring the PBT group in single-task gait speed (0.03 m/s, 95% CI 0.00 to 0.06) and five sit-to-stands (-0.54 s, 95% CI -0.97 to -0.01). Otherwise, the analyses led to

similar results as the unadjusted model. Lastly, analysing the data using a per-protocol approach did not lead to different estimates than the intention-to-treat analyses. All results of the sensitivity analyses can be found in Supplementary Material 3.

Discussion

This secondary analysis from a randomised, controlled trial showed that four sessions of treadmill perturbation-based balance training (PBT) did not lead to long-term (≥ 6 months) improvements in the evaluated physical, cognitive, or sociopsychological measures. However, there was a significant short-term improvement from the pre- to post-training test in choice stepping reaction time, and dual-task gait speed favouring the PBT group.

Short-term effects of perturbation-based balance training

PBT led to significantly greater improvements in the choice stepping reaction time from pre-training to post-training than regular treadmill walking (-49 ms, 95% CI -80 to -18). Choice stepping reaction time is a composite measure of fall risk that evaluates the ability to make quick and appropriate voluntary stepping responses to visual cues.[34] The improvement found in our study contrasts with Okubo et al. 2019, which showed that three slip and trip overground walkway PBT sessions had no beneficial effects on the choice stepping reaction time.[57] This discrepancy may be due to Okubo et al. 2019 having four stepping options in the reaction test, while our test only had two.[57] This may lead to the performance being more reliant on executive functions, which this and previous PBT studies have shown limited effects on.[58] However, in line with our results, Kurz et al. 2016 showed treadmill PBT significantly improved voluntary step execution onto one of two targets triggered by a somatosensory cue.[59] This improvement in voluntary step execution was achieved by a faster step initiation time which implies an enhanced central processing speed (CNS).[59] Furthermore, other PBT studies have also reported significant improvements in stepping reactions following either somatosensory or auditory cues.[60–62] Our study, however, is the first to show that PBT improves voluntary stepping performance to visual cues. Collectively, PBT may induce adaptations within the CNS that benefit gait adaptability, which is important in fall prevention [63]. Still, while there is no

established minimally clinically important difference regarding choice stepping reaction time, the 7% improvement after PBT is smaller than the 13% difference previously found between fallers and non-fallers.[34]

Our results also identified significant improvements from the pre-training to post-training test favouring PBT in dual-task gait speed (0.05 m/s, 95% CI 0.01 to 0.09); yet, these improvements were below the limit of minimal clinically important difference (gait speed: 0.10 m/s).[64,65] No other physical and cognitive measures showed a between-group difference following PBT. Supporting these findings, studies applying multidirectional perturbations within three to five sessions showed no improvements in physical measures of strength, static balance, and gait.[23,57,66] Likewise, a single session of 96 waist pull perturbations on a treadmill did not lead to changes in the executive function evaluated using the TMT.[58] However, in contrast to our results, studies including longer training intervention (≥4 weeks) in community-dwelling older adults and Parkinson's patients have been able to show improvements in various physical, cognitive, and sociopsychological measures. [25,27,28]]. In summary, our results indicate that adaptations to PBT interventions are highly task-specific, but some research may imply that higher dosages could lead to better transfer effects.[13,14,18]

Lastly, the PBT intervention failed to show significant between-group differences in the sociopsychological measures. However, close-to-perfect concerns about falling and quality of life scores at pre-training enforced a ceiling effect leaving almost no room for improvement. Therefore, future studies should evaluate these parameters in participants exposed to substantial concerns about falling and low quality of life.

Long-term effects of perturbation-based balance training

A key component of PBT is the well-documented long-term retention of reactive balance adaptations following even small training dosages.[18–20] Improvements in choice stepping reaction time must also be retained throughout the detraining period to be relevant. While choice stepping reaction time in the PBT group remained significantly lower at the six- and 12-month follow-up compared to the pre-training test, these improvements were not significantly different from the control group (see Supplementary Table 1). Thus, there were no long-term effects of PBT on any physical, cognitive, or

sociopsychological measures. These results align with our primary findings that PBT did not lead to a significant decrease in daily life fall rate.[31] Our findings also support the current detraining literature, which points to a decline in physical performance following training cessation in older adults.[67–69]

Practical implications

While the previously published results of the primary outcome paper showed a sustained improvement in reactive balance control over 12 months in laboratory settings (-63% laboratory fall rate at the 12-month follow-up), we only identified a partial transfer of adaptations to daily life (a nonsignificant 22% decrease in fall rates).[31] Moreover, the findings reported in this paper also show that PBT may have limited effects on other important physical, cognitive, and sociopsychological factors. This indicates that PBT should not be regarded as a single intervention but as part of a multicomponent training program. Considering the task-specificity of training adaptations, it is not surprising that multicomponent training programs have proven most effective in improving overall physical and cognitive functions.[70,71] It has recently been recommended that fall preventive training programs should include balance challenging and functional exercises with additional Tai Chi and progressive strength training.[7] Adding PBT to multicomponent training programs could potentially improve the fall preventive effect with only slightly higher training dosages.[13,18,63] However, this remains speculative until studies have shown the effectiveness of such multicomponent interventions.

LIMITATIONS

The results of this study should be interpreted considering the study's limitations. First, due to practical limitations and the nature of training interventions, the outcome assessor of these secondary outcomes and participants were not blinded for group allocation. Second, participants were convenience sampled, low-risk older adults with no specific physical, cognitive, or sociopsychological problems. They were, therefore, not the targeted population for fall preventive training according to the recent world guidelines of fall prevention and management in older adults.[7] Moreover, this population may have a limited potential for improvement, possibly

explaining the lack of effect. Future PBT studies should investigate a frailer population to evaluate the potential effect among those prone to fall-related injuries. Finally, we did not correct for multiple comparisons, which may have led to false positive results due to mass significance; thus, the results should be seen as explorative only.

Conclusion

Secondary analyses from a randomised, controlled trial showed that PBT led to short-term improvements in choice stepping reaction time and dual-task walking speed. However, these improvements were not retained at the six or 12-month follow-up tests. Moreover, PBT did not cause clinically important improvements in the other evaluated physical, cognitive, or socio-psychological measures. These findings underline that adaptations to physical exercise are task-specific. However, the healthy state of the study's population may have imposed a ceiling effect limiting the ability to show any beneficial effects. Further studies adding PBT to multicomponent training programs and studies on more frail older adults with a greater potential for improvements are needed.

Other information

Author contributions

Concept and design: JEN, MGJ, JR, AJTS, JA, MBD, ASO, SA. *Acquisition:* JEN. *Drafting of manuscript*: JEN. *Critical revision of the manuscript for important intellectual content:* MGJ, SA, MBD, JR, AJTS, JA, ASO. *Statistical analysis:* JEN. *Obtained funding:* MGJ, SA. *Administrative, technical, or material support:* JEN, AJTS. *Supervision:* JEN, MGJ. Final approvement of manuscript: JEN, MGJ, SA, MBD, JR, AJTS, JA. Jens Eg Nørgaard (JEN) is the guarantor.

Conflict of interest

None of the author have any conflict of interest to declare.

Ethics Approval

The study was performed following the Declaration of Helsinki. North Denmark Region Committee on Human Research Ethics (N-20200089) and the Danish Data Protection Agency (2021-014) approved the study. All participants gave written informed consent before enrolment.

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Additional Contributions

We thank all the volunteering participants for committing to making this study possible. Further, we would like to thank Statistian Regitze Gyldenholm Skals for helping in analysing the data.

Registration number and name of trial registry

The study protocol (before study commencement) and statistical analysis plan (before last patient last visit) were preregistered at ClinicalTrials.gov: NCT04733222

Data statement

De-identified trial results data will be available upon reasonable request for non-commercial use up to 5 years after the publication of the trial findings. The available data will include (but is not limited to) deidentified individual participant data, the study protocol, the Statistical Analysis Plan (SAP), informed consent forms, and analytic codes used. Requests for access will be reviewed by a designated data access committee to ensure they are for non-commercial, scientific purposes and that requesters agree to abide by data protection protocols. Data sharing agreements will be required. Please note that the data sharing plan outlined in the trial registration is outdated and cannot be changed.

References

1 Manini T. Development of Physical Disability in Older Adults. *Current Aging Sciencee*. 2012;4:184–91.

2 Peel NM, Peel NM. Epidemiology of falls in older age. *Canadian Journal on Aging*. 2011;30:7–19.

3 London AJ, Cigolle CT, Ha J, *et al.* The epidemiologic data on falls, 1998-2010: More older Americans report falling. *JAMA Intern Med*. 2015;175:443–5.

4 Friedman SM, Munoz B, West SK, *et al.* Falls and fear of falling: Which comes first? A longitudinal prediction model suggests strategies for primary and secondary prevention. *J Am Geriatr Soc*. 2002;50:1329–35.

5 Stenhagen M, Ekström H, Nordell E, *et al.* Accidental falls, health-related quality of life and life satisfaction: A prospective study of the general elderly population. *Arch Gerontol Geriatr*. 2014;58:95–100.

6 Heinrich S, Rapp K, Rissmann U, *et al.* Cost of falls in old age: a systematic review. *Osteoporosis International*. 2010;21:891–902.

7 Montero-Odasso M, van der Velde N, Martin FC, *et al.* World guidelines for falls prevention and management for older adults: a global initiative. *Age Ageing*. 2022;51:1–36.

8 Falck RS, Davis JC, Best JR, *et al.* Impact of exercise training on physical and cognitive function among older adults: a systematic review and meta-analysis. *Neurobiol Aging*. 2019;79:119–30.

9 Sherrington C, Fairhall N, Kwok W, *et al.* Evidence on physical activity and falls prevention for people aged 65+ years: systematic review to inform the WHO guidelines on physical activity and sedentary behaviour. *International Journal of Behavioral Nutrition and Physical Activity*. 2020;17:1–9.

10 Lee H, Chang K, Tsauo J. Effects of a Multifactorial Fall Prevention Program on Fall Incidence and Physical Function in Community-Dwelling Older Adults With Risk of Falls. *Arch Phys Med Rehabil*. 2013;94:606-615.e1.

11 Chou CH, Hwang CL, Wu YT. Effect of exercise on physical function, daily living activities, and quality of life in the frail older adults: A meta-analysis. *Arch Phys Med Rehabil*. 2012;93:237–44.

12 Buford TW, Anton SD, Clark DJ, *et al.* Optimizing the Benefits of Exercise on Physical Function in Older Adults. *PM&R*. 2014;6:528–43.

13 Grabiner MD, Crenshaw JR, Hurt CP, *et al.* Exercise-based fall prevention: Can you be a bit more specific? *Exerc Sport Sci Rev*. 2014;42:161–8.

14 Giboin LS, Gruber M, Kramer A. Task-specificity of balance training. *Hum Mov Sci*. 2015;44:22–31.

15 Berg WP, Alessio HM, Mills EM, *et al.* Circumstances and consequences of falls in independent community-dwelling older adults. *Age Ageing*. 1997;26:261–8.

16 Talbot LA, Musiol RJ, Witham EK, *et al.* Falls in young, middle-aged and older community dwelling adults: Perceived cause, environmental factors and injury. *BMC Public Health*. 2005;5:1–9.

17 Luukinen H, Herala M, Koski K, *et al.* Fracture risk associated with a fall according to type of fall among the elderly. *Osteoporosis International*. 2000;11:631–4.

18 McCrum C, Bhatt TS, Gerards MHG, *et al.* Perturbation-based balance training: Principles, mechanisms and implementation in clinical practice. *Front Sports Act Living*. 2022;4:1015394.

19 Pai YC, Yang F, Bhatt T, *et al.* Learning from laboratory-induced falling: long-term motor retention among older adults. *Age (Omaha)*. 2014;36:1367–76.

20 Epro G, Mierau A, Mc Crum C, *et al.* Retention of gait stability improvements over 1.5 years in older adults: Effects of perturbation exposure and triceps surae neuromuscular exercise. *J Neurophysiol*. 2018;119:2229–40.

21 Lee A, Bhatt T, Liu X, *et al.* Can treadmill slip-perturbation training reduce longer-term fall risk upon overground slip exposure? *J Appl Biomech*. 2020;36:298–306.

22 Pai YC, Bhatt T, Yang F, *et al.* Perturbation training can reduce community-dwelling older adults' annual fall risk: A randomized controlled trial. *Journals of Gerontology - Series A Biological Sciences and Medical Sciences*. 2014;69:1586–94.

23 Lurie JD, Zagaria AB, Ellis L, *et al.* Surface Perturbation Training to Prevent Falls in Older Adults: A Highly Pragmatic, Randomized Controlled Trial. *Phys Ther*. 2020;100:1153–62.

24 Gerards MHGG, Mccrum C, Mansfield A, *et al.* Perturbation-based balance training for falls reduction among older adults: Current evidence and implications for clinical practice. *Geriatr Gerontol Int*. 2017;17:2294–303.

25 Shen X, Mak MKY. Technology-assisted balance and gait training reduces falls in patients with Parkinson's disease: a randomized controlled trial with 12-month follow-up. *Neurorehabil Neural Repair*. 2015;29:103–11.

26 Unger J, Chan K, Lee JW, *et al.* The Effect of Perturbation-Based Balance Training and Conventional Intensive Balance Training on Reactive Stepping Ability in Individuals With Incomplete Spinal Cord Injury or Disease: A Randomized Clinical Trial. *Front Neurol*. 2021;12:620367.

27 Steib S, Klamroth S, Gaßner H, *et al.* Perturbation During Treadmill Training Improves Dynamic Balance and Gait in Parkinson's Disease: A Single-Blind Randomized Controlled Pilot Trial. *Neurorehabil Neural Repair*. 2017;31:758–68.

28 Smania N, Corato E, Tinazzi M, *et al.* Effect of balance training on postural instability in patients with idiopathic Parkinson's disease. *Neurorehabil Neural Repair*. 2010;24:826–34.

29 Rieger MM, Papegaaij S, Steenbrink F, *et al.* Effects of Perturbation-Based Treadmill Training on Balance Performance, Daily Life Gait, and Falls in Older Adults: REACT Randomized Controlled Trial. *Phys Ther*. 2024;104. doi: 10.1093/ptj/pzad136

30 Nørgaard JE, Andersen S, Ryg J, *et al.* Effects of treadmill slip and trip perturbation-based balance training on falls in community-dwelling older adults (STABILITY): Study protocol for a randomised controlled trial. *BMJ Open*. 2022;12:1–10.

31 Nørgaard JE, Andersen S, Ryg J, *et al.* Effect of Treadmill Perturbation-Based Balance Training on Fall Rates in Community-Dwelling Older Adults: A Randomized Clinical Trial. *JAMA Netw Open*. 2023;6:E238422.

32 Schulz KF, Altman DG, Moher D. CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials. *BMC Med*. 2010;8:18(1-9).

33 Muir-Hunter SW, Wittwer JE. Dual-task testing to predict falls in community-dwelling older adults: A systematic review. *Physiotherapy (United Kingdom)*. 2016;102:29–40.

34 Lord SR, Fitzpatrick RC. Choice stepping reaction time: A composite measure of falls risk in older people. *Journals of Gerontology - Series A Biological Sciences and Medical Sciences*. 2001;56:627–32.

35 Johansson J, Nordström A, Gustafson Y, *et al.* Increased postural sway during quiet stance as a risk factor for prospective falls in community-dwelling elderly individuals. *Age Ageing*. 2017;46:964–70.

36 Veronese N, Bolzetta F, Toffanello ED, *et al.* Association between short physical performance battery and falls in older people: The progetto veneto anziani study. *Rejuvenation Res*. 2014;17:276–84.

37 Cullen S, Montero-Odasso M, Bherer L, *et al.* Guidelines for gait assessments in the canadian consortium on neurodegeneration in aging (CCNA). *Canadian Geriatrics Journal*. 2018;21:157–65.

38 Montero-Odasso M, Almeida QJ, Bherer L, *et al.* Consensus on shared measures of mobility and cognition: From the Canadian Consortium on Neurodegeneration in Aging (CCNA). *Journals of Gerontology - Series A Biological Sciences and Medical Sciences*. 2019;74:897–909.

39 Montero-Odasso M, Sarquis-Adamson Y, Kamkar N, *et al.* Dual-task gait speed assessments with an electronic walkway and a stopwatch in older adults. A reliability study. *Exp Gerontol*. 2020;142:111102.

40 Lyons JG, Heeren T, Stuver SO, *et al.* Assessing the agreement between 3-meter and 6-meter walk tests in 136 community-dwelling older adults. *J Aging Health*. 2015;27:594–605.

41 Clark RA, Mentiplay BF, Pua YH, *et al.* Reliability and validity of the Wii Balance Board for assessment of standing balance: A systematic review. *Gait Posture*. 2018;61:40–54.

42 Jorgensen MG, Laessoe U, Hendriksen C, *et al.* Intra-rater reproducibility and validity of Nintendo Wii balance testing in community-dwelling older adults. *Eur Geriatr Med*. 2013;4:S87.

43 Bonnechère B, Van Hove O, Jansen B, *et al.* Validation of the Wii Balance Board to assess static balance during dual-task activity in healthy subjects. *Med Nov Technol Devices*. 2019;1:100003.

44 Jorgensen MG, Paramanathan S, Ryg J, *et al.* Novel use of the Nintendo Wii board as a measure of reaction time: A study of reproducibility in older and younger adults. *BMC Geriatr*. 2015;15:1–8.

45 Freire AN, Guerra RO, Alvarado B, *et al.* Validity and reliability of the short physical performance battery in two diverse older adult populations in Quebec and Brazil. *J Aging Health*. 2012;24:863–78.

46 Goldberg A, Chavis M, Watkins J, *et al.* The five-times-sit-to-stand test: Validity, reliability and detectable change in older females. *Aging Clin Exp Res*. 2012;24:339–44.

47 Gullickson T. Review of A Compendium of Neuropsychological Tests: Administration, Norms, and Commentary. *Contemporary Psychology: A Journal of Reviews*. 1992;37:385–385.

48 Montero-odasso M. *Falls and Cognition in Older Persons*. Cham: Springer International Publishing 2020. https://doi.org/10.1007/978-3-030-24233-6

49 Delbaere K, Close JCT, Heim J, *et al.* A multifactorial approach to understanding fall risk in older people. *J Am Geriatr Soc*. 2010;58:1679–85.

50 Lezak M, Howieson D, Loring D. *Neuropsychological Assessment*. 4th ed. New York: Oxford University Press, inc. 2004.

51 Marques-Vieira CMA, Sousa LMM, Severino S, *et al.* Cross-cultural validation of the falls efficacy scale international in elderly: Systematic literature review. *Journal of Clinical Gerontology and Geriatrics*. 2016;7:72–6.

52 Sørensen J, Davidsen M, Gudex C, *et al.* Danish EQ-5D population norms. *Scand J Public Health*. 2009;37:467–74.

53 Feng YS, Kohlmann T, Janssen MF, *et al.* Psychometric properties of the EQ-5D-5L: a systematic review of the literature. *Quality of Life Research*. 2021;30:647–73.

54 Nørgaard JE, Andersen S, Ryg J, *et al.* Effects of treadmill slip and trip perturbation-based balance training on falls in community-dwelling older adults (STABILITY): study protocol for a randomised controlled trial. *BMJ Open*. 2022;12:e052492.

55 Peters SAE, Bots ML, Den Ruijter HM, *et al.* Multiple imputation of missing repeated outcome measurements did not add to linear mixed-effects models. *J Clin Epidemiol*. 2012;65:686–95.

56 Rothman KJ. No adjustments are needed for multiple comparisons. *Epidemiology*. 1990;1:43–6.

57 Okubo Y, Sturnieks DL, Brodie MA, *et al.* Effect of Reactive Balance Training Involving Repeated Slips and Trips on Balance Recovery among Older Adults: A Blinded Randomized Controlled Trial. *Journals of Gerontology - Series A Biological Sciences and Medical Sciences*. 2019;74:1489–96.

58 Martelli D, Vashista V, Micera S, *et al.* Direction-Dependent Adaptation of Dynamic Gait Stability Following Waist-Pull Perturbations. *IEEE Transactions on Neural Systems and Rehabilitation Engineering*. 2016;24:1304–13.

59 Kurz I, Gimmon Y, Shapiro A, *et al.* Unexpected perturbations training improves balance control and voluntary stepping times in older adults - A double blind randomized control trial. *BMC Geriatr*. 2016;16:1–11.

60 Mansfield A, Peters AL, Liu BA, *et al.* Effect of a Perturbation-Based Balance Training Program on Compensatory Stepping and Grasping Reactions in Older Adults: A Randomized Controlled Trial. *Phys Ther*. 2010;90:476–91.

61 Parijat P, Lockhart TE. Effects of moveable platform training in preventing slip-induced falls in older adults. *Ann Biomed Eng*. 2012;40:1111–21.

62 Shimada H, Obuchi S, Furuna T, *et al.* New intervention program for preventing falls among frail elderly people: The effects of perturbed walking exercise using a bilateral separated treadmill. *Am J Phys Med Rehabil*. 2004;83:493–9.

63 Nørgaard JE, Jorgensen MG, Ryg J, *et al.* Effects of gait adaptability training on falls and fall-related fractures in older adults: a systematic review and meta-analysis. *Age Ageing*. Published Online First: 2021. doi: 10.1093/ageing/afab105

64 Kwon S, Perera S, Pahor M, *et al.* What is a meaningful change in physical performance? Findings from a clinical trial in older adults (the LIFE-P study). *J Nutr Health Aging*. 2009;13:538–44.

65 Chui K, Hood E, Klima D. Meaningful change in walking speed. *Top Geriatr Rehabil*. 2012;28:97–103.

66 Allin LJ, Brolinson PG, Beach BM, *et al.* Perturbation-based balance training targeting both slip- And trip-induced falls among older adults: A randomized controlled trial. *BMC Geriatr*. 2020;20:1–13.

67 Blasco-Lafarga C, Cordellat A, Forte A, *et al.* Short and long-term trainability in older adults: Training and detraining following two years of multicomponent cognitive—physical exercise training. *Int J Environ Res Public Health*. 2020;17:1–16.

68 Fernández-García ÁI, Gómez-Cabello A, Gómez-Bruton A, *et al.* Effects of multicomponent training and detraining on the fitness of older adults with or at risk of frailty: results of a 10-month quasi-experimental study. *Eur J Sport Sci*. 2022;0:1–14.

69 Vogler CM, Menant JC, Sherrington C, *et al.* Evidence of detraining after 12-week home-based exercise programs designed to reduce fall-risk factors in older people recently discharged from hospital. *Arch Phys Med Rehabil*. 2012;93:1685–91.

70 Giné-Garriga M, Roqué-Fíguls M, Coll-Planas L, *et al.* Physical Exercise Interventions For Improving Performance-Based Measures of Physical Function in Community-Dwelling Frail Older Adults. *Med Sci Sports Exerc*. 2014;46:134.

71 Schoene D, Valenzuela T, Lord SR, *et al.* The effect of interactive cognitive-motor training in reducing fall risk in older people: A systematic review. *BMC Geriatr*. 2014;14:107(1-22).

Figure headings and legends

Figure 1 heading:

Figure 1 - Study Design

Figure 1 legend:

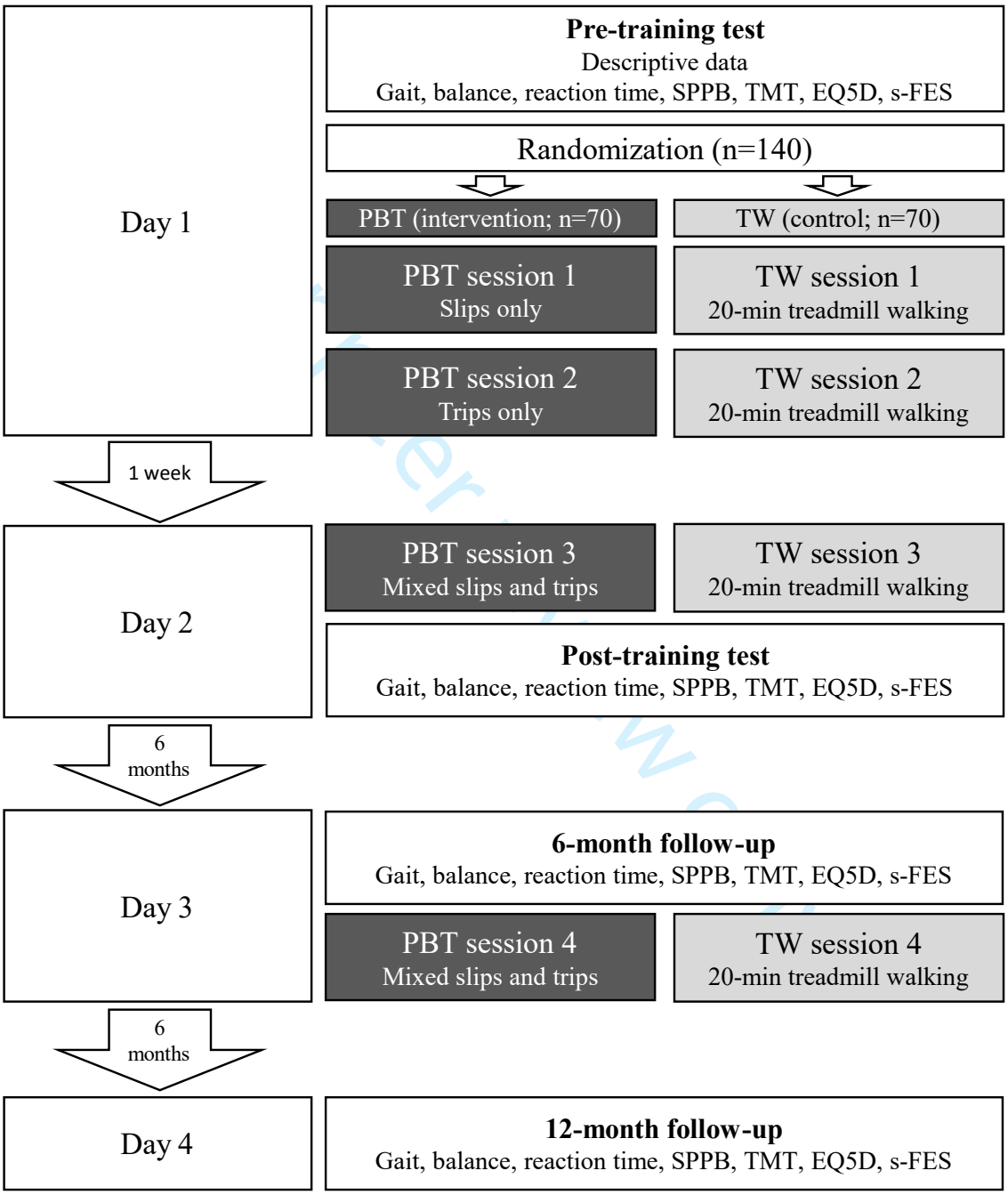
Figure 1 – The study design. Dark grey boxes show the flow of the PBT group. Light grey boxes show the flow of the control group. White boxes indicate that all participants were assigned. SPPB: Short physical performance battery. TMT: Trial making test. EQ5D: EuroQoL 5-dimensions, 5-levels. s-FES: Short falls efficacy scale. PBT: Perturbation-based balance training. TW: Treadmill walking.

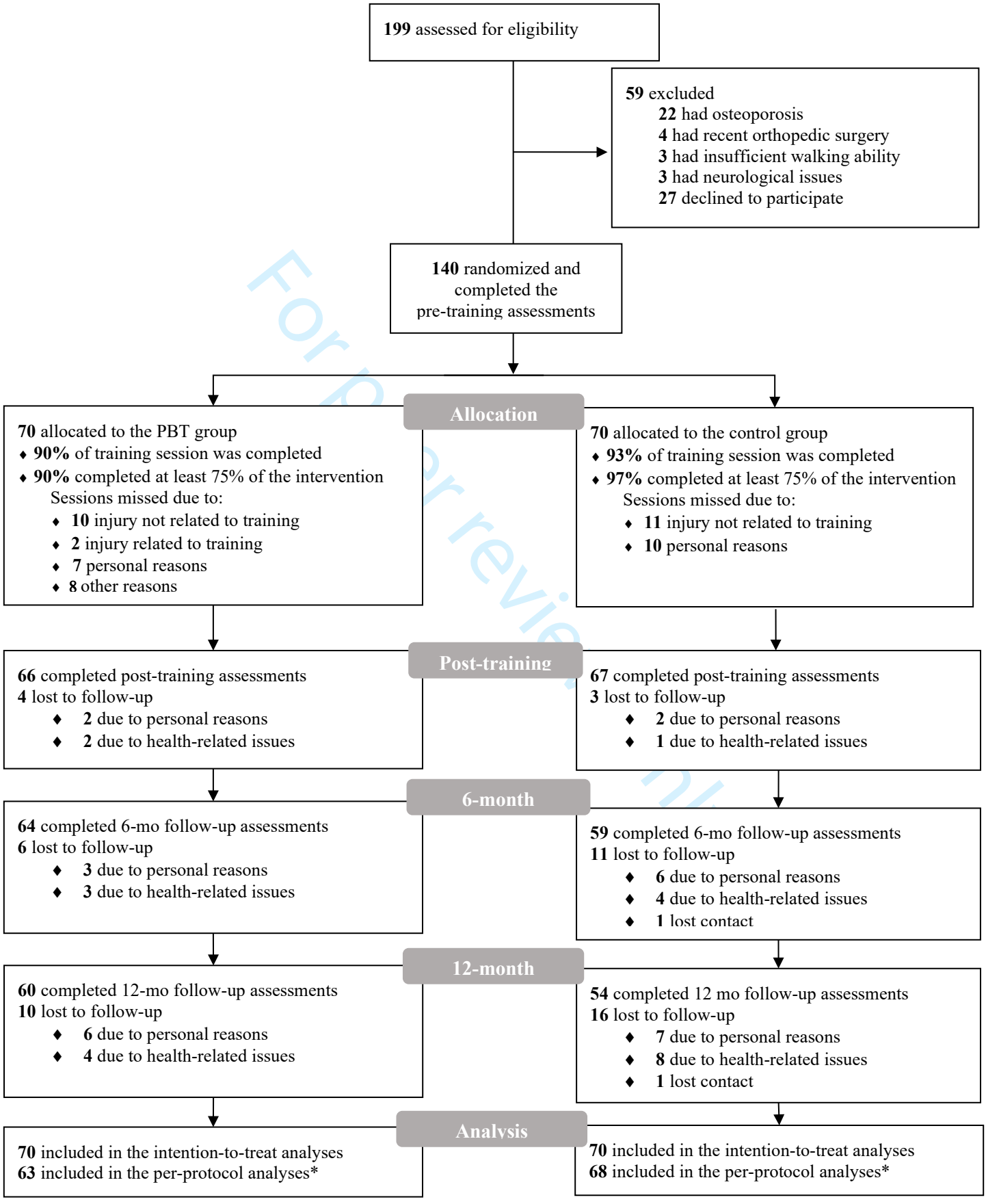
Figure 2 heading:

Figure 2 - CONSORT Flow chart

Figure 2 legend:

Figure 2 – CONSORT Flow chart of the participant flow through the present study. *Per-protocol analysis only included participants that completed at least 75% (3 of 4 sessions) of the assigned intervention.





Supplementary Table 1 – Results from the linear mixed effects model of fall-related risk factors for each testing session as well as group differences at post-training, 6-month follow-up, and 12-month follow-up

	PBT Group Δ				Control group Δ				Between-group differences Ω		
	Pre-training (n = 70)	Post-training (n = 66)	6-month follow-up (n = 64)	12-month follow-up (n = 60)	Pre-training (n = 70)	Post-training (n = 67)	6-month follow-up (n = 59)	12-month follow-up (n = 54)	Pre-training to post-training	Pre-training to 6-month follow-up	Pre-training to 12-month follow-up
Physical measures											
Gait speed, single task, m/s	1.28 [1.24;1.32]	1.29 [1.25;1.33]	1.26 [1.22;1.31]	1.24* [1.20;1.28]	1.26 [1.22;1.30]	1.24 [1.21;1.28]	1.24* [1.20;1.28]	1.22* [1.17;1.26]	0.03 [-0.00;0.06]	0.01 [-0.02;0.04]	0.01 [-0.02;0.04]
Gait speed, dual task, m/s	1.12 [1.07;1.16]	1.17* [1.12;1.21]	1.13 [1.08;1.18]	1.13 [1.08;1.18]	1.12 [1.07;1.17]	1.12 [1.08;1.17]	1.11 [1.06;1.16]	1.10 [1.05;1.15]	**0.05♣ [0.01;0.09]**	0.02 [-0.02;0.06]	0.03 [-0.01;0.07]
Sway area, single task, mm^2 ∞	25.18 [19.90;30.47]	25.00 [19.66;30.35]	23.54 [18.16;28.92]	27.71 [22.26;33.15]	32.28 [27.00;37.57]	32.30 [26.96;37.63]	30.65 [25.18;36.12]	30.16 [24.60;35.72]	-0.19 [-5.69;5.30]	-0.01 [-5.67;5.65]	4.65 [-1.16;10.45]
Sway area, dual task, mm^2 ∞	45.75 [29.86;61.65]	39.12 [22.97;55.28]	46.97 [30.68;63.27]	59.20 [42.64;75.77]	61.43 [45.54;77.33]	53.13 [37.03;69.22]	53.31 [36.64;69.97]	57.73 [40.66;74.79]	-4.32 [-24.22;15.57]	9.34 [-11.13;29.81]	17.15 [-3.85;38.16]
Sway speed, single task, mm/s ∞	15.98 [14.09;17.87]	14.86* [12.96;16.76]	16.35 [14.44;18.25]	16.83 [14.91;18.74]	18.21 [16.32;20.10]	17.74* [15.84;19.64]	18.31 [16.39;20.23]	18.90 [16.97;20.83]	0.35 [-0.89;1.60]	0.27 [-1.01;1.56]	0.16 [-1.15;1.48]
Sway speed, dual task, mm/s ∞	21.64 [19.03;24.26]	19.11* [16.48;21.75]	21.83 [19.19;24.47]	22.99 [20.33;25.65]	22.95 [20.33;25.56]	21.62 [18.97;24.24]	23.02 [20.35;25.69]	22.87 [20.18;25.57]	-1.20 [-3.25;0.85]	0.11 [-2.00;2.22]	1.42 [-0.75;3.58]
Choice stepping reaction time, ms,	890 [863;917]	821* [793;849]	841* [813;869]	832* [803;860]	903 [876;931]	883 [856;911]	873* [844;901]	863* [834;892]	**-48.84♣ [-79.88;-17.79]**	-18.19 [-50.06;13.67]	-18.12 [-50.92;14.68]
SPPB score • ∞	11.53 [11.34;11.72]	11.73* [11.53;11.92]	11.59 [11.39;11.79]	11.63 [11.43;11.83]	11.34 [11.15;11.54]	11.42 [11.22;11.61]	11.32 [11.12;11.53]	11.48 [11.28;11.69]	0.13 [-0.11;0.36]	0.08 [-0.16;0.32]	-0.04 [-0.29;0.21]
Five sit-to-stand, s ᵘ	10.64 [10.09;11.19]	9.79* [9.23;10.34]	10.14* [9.58;10.70]	9.43* [8.86;10.00]	11.24 [10.69;11.79]	10.68* [10.13;11.24]	10.93 [10.37;11.50]	10.20* [9.63;10.78]	-0.30 [-0.82;0.23]	-0.20 [-0.74;0.34]	-0.17 [-0.73;0.38]
Cognitive measures											
TMT ΔAB, s ∞	57.32 [42.20;72.44]	53.84 [38.62;69.06]	56.99 [41.67;72.30]	55.69 [40.28;71.10]	59.31 [44.22;74.41]	55.21 [40.02;71.40]	50.57 [35.14;65.99]	56.72 [41.08;72.36]	-0.37 [-13.21;12.46]	8.41 [-4.80;21.63]	0.96 [-12.61;14.54]
Sociopsychological measures											
Fear of Falling, score ▪ ∞	7.79 [7.45;8.12]	7.98 [7.64;8.33]	8.13* [7.79;8.48]	7.91 [7.55;8.26]	7.90 [7.56;8.24]	8.31* [7.96;8.65]	8.23* [7.87;8.58]	8.18 [7.82;8.55]	-0.21 [-0.64;0.22]	0.02 [-0.42;0.46]	-0.16 [-0.61;0.29]
EQ5D, index ⊕ ∞	0.95 [0.93;0.97]	0.95 [0.93;0.97]	0.94 [0.93;0.96]	0.93* [0.91;0.95]	0.95 [0.93;0.96]	0.94 [0.92;0.95]	0.92* [0.90;0.94]	0.93 [0.91;0.95]	0.01 [-0.01;0.04]	0.02 [-0.00;0.04]	-0.01 [-0.03;0.02]
EQ5D, VAS □ ∞	86.73 [84.46;89.00]	88.40 [86.09;90.71]	87.78 [85.45;90.11]	88.53 [86.16;90.89]	87.00 [84.73;89.27]	88.75 [86.45;91.05]	88.48 [86.11;90.85]	88.11 [85.67;90.55]	-0.08 [-2.95;2.78]	-0.42 [-3.37;2.52]	0.69 [-2.34;3.71]

Δ Estimated means and 95% confidence intervals from the mixed model; * Significant within-group difference from pre-training test; ♣ Significant difference favouring the PBT group; • SPPB score ranges between 0 and 12, 12 is the best score; ▪ s-FES score ranges between 7 and 28, 7 is the best score; ⊕ EQ5D Index ranges between 0 and 1, 1 is the best score; □ EQ5D VAS ranges between 0 and 100, 100 is the best score; ᵘ Collected as part of the short physical performance battery, Ω Estimation from mixed models of between-group difference in within-group differences with 95% confidence intervals; ∞ model assumptions not completely fulfilled

SUPPLEMENTARY MATERIAL 1: DETAILED DESCRIPTION OF TESTS

This supplementary material describes the tests used in the pre-training, post-training, 26-week follow-up, and 52-week follow-up tests. Moreover, the instructions given to the participants are also outlined. During the trial, all instructions were provided in Danish; however, this supplementary material is directly translated into English.

The order of the test was identical at each testing session at was as follows: 1) Trial-making-test, 2) balance, 3) choice stepping reaction time, 4) gait, 5) short physical performance battery, and 6) questionnaires.

TABLE OF CONTENT

TRIAL MAKING TEST

Description

The executive function is evaluated using the Trial-Making-Test (TMT) Part A and B. Part A involves sequentially connecting 25 randomly arranged numbers (1- 2- 3-…-25) on paper with a pen. In Part B, 25 randomly placed numbers and letters (1- A- 2- B-…-12- L) are connected alternatingly. The time to complete Part A and Part B was recorded using a handheld stopwatch, and the number of mistakes was registered.

Instruction

"[Show the practice sheet of Part A] In this test, you must sequentially connect the numbers; from 1 to 2, from 2 to 3, and so on [point on the paper]. This is a practice sheet before we move on to the actual test. [participant performs practice sheet]. If you make a mistake, I will highlight it by making a perpendicular line, and you will return to the previous number. I will not tell you what the mistake was."

"[Show the test sheet of Part B] Now we move on to the actual test. In this test, you must connect 25 numbers in the same manner as on the practice sheet. You will begin at 1 [point at number 1] and finish at 25 [point at number 25]. You must connect the numbers as fast as possible and with as few mistakes as possible. I will count from 3, and you may start on "go". "

"[Show the practice sheet of Part B] In the next part of the test, you must alternatingly connect the numbers and letters; from 1 to A, from A to 2, from 2 to B, and so on [point on the paper]. This is a practice sheet before we move on to the actual test [participant performs practice sheet]."

"[Show the test sheet for Part B] Now we move on to the actual test. In this test, you must connect the 25 numbers or letters in the same manner as on the practice sheet. You will begin at 1 [point at number 1] and finish at "L" [point at "L"]. You must connect the numbers as fast as possible and with as few mistakes as possible. I will count from 3, and you may start on "go". "

BALANCE TEST

Description

The balance test was conducted using a Wii balance board (WBB) and the Fysiometer software. Participants stood as still as possible for 30 seconds for three trials under single- and dual-task conditions, respectively. The dual task condition involves naming grocery items from specific supermarket sections. During the test, the participant was instructed to look at a fixed mark at eye height three meters in front of the participant. The area and speed of the centre of pressure displacement were registered in the FysioMeter software.

Instruction

"During the balance test, you must step onto the Wii balance board and place your feet so the outside of your foot is aligned with the edge of the Wii balance board [guide the foot placement of participant]. You will have to stand as still as possible for 30 seconds while looking at the mark in front of you [pointing at the mark] and holding your wrist [illustrate the arm position]. You will have to perform three trials only focusing on standing still, and then three times while simultaneous mentioning grocery items from the supermarket. Are you ready for the first 30 seconds?"

[Immediately before each 30-second trial, the following is instructed] "Look at the mark in front of you and attempt to stand as still as possible; the 30 seconds will start in 3, 2, 1, now."

"For the next three trials, you will have to stand in the same position as before [make sure foot placement is correct] as still as possible for 30 seconds while also mentioning as many grocery items as possible. Before each trial, I will tell you which supermarket section you must mention items. Are you ready for the first 30 seconds?"

[Immediately before each 30-second trial, the following is instructed] "Look at the mark in front of you, hold your wrist, and attempt to stand as still as possible, while also mentioning as many items from the [insert supermarket section (dairy, greens, or butchers department)]; the 30 seconds will start in 3, 2, 1, now.

CHOICE STEPPING REACTION TEST

Description

The choice stepping reaction test was conducted using a Wii balance board and the FysioMeter software. The participants had to react as fast as possible by tapping the correct side of the WBB with the correct foot in response to a visual cue presented on a computer screen seven times. The WBB was placed approximately five cm in front of the participants' feet, and the computer screen was one meter away. A WBB was shown on the computer screen, and the cue was a green light on either the right or left of the WBB. The timing (1-4 seconds) and side were random to maximize the unpredictability. The time from the cue was given to the correct response was performed was recorded with the FysioMeter software.

Instruction

“For the reaction test, you must stand with the feet behind each side of the Wii balance board [guide the foot placement of participant]. A Wii balance board is illustrated on the screen in front of you. When I press “start”, the left or right side will turn green after one to four seconds. You must tap on the correct side, as fast as possible, with the correct foot. If it is the left side, you must use the left foot, and vice versa. Before we begin, you will have three practice trials. Remember to focus on being as fast as possible.”

[Participants get three attempts]

“Now we progress to the real test, and you will have to perform seven reaction trials. Remember to be as fast as possible.”

GAIT TEST

Description

The gait test involved walking eight meters at the preferred walking speed for a total of six trials. The initial three were conducted as a single task, while the last three were under a dual-task condition. The dual task involved continuously subtracting three from a random three digits number. The middle six meters will be recorded using a handheld watch.

Instruction

"During the gait test, you must walk 8 meters from the initial line through the end line [pointing at the two lines]. You will have to walk six times, the first three trials only focusing on walking, while the last three will also involve arithmetics. During the trials, you will have to walk at your regular pace. I will say "3, 2, 1, go", and on "go", you can walk."

[Participant completes three trials as a single task]

"During the next three trials, you will have to walk at your regular pace and simultaneously perform arithmetics. Before each trial, I will tell you a number, which could, for example, be 150. You will then have to continuously subtract three from that number while walking at your regular pace. If the number is 150, it will look like this [illustrate the test by walking and subtracting three]; 147, 144, 141, 138, and so on until you are at the end of the path [pointing at the end]"'

[Participant completes three trials as a dual task with three different numbers]

THE SHORT PHYSICAL PERFORMANCE BATTERY

Description

The short physical performance battery consists of a balance, gait, and strength component. The balance component includes standing in three foot positions (side-by-side, semi-tandem, and tandem) for ten seconds. The gait component involves two four-meter walks at a preferred walking speed, and the strength component consists of five sit-to-stands as fast as possible. Each element is scored based on performance and collected in a composite score (0-12; higher scores indicate better performance).

Instruction

“First, you have to perform a balance test. You have to stand for ten seconds with three different foot positions. During the ten seconds, you are not allowed to move your feet or grab any obstacles to regain balance. The first foot position is a side-by-side position [show the foot position and correct the participant's position]. When you feel in balance, say “go,” and the ten seconds will begin.”

[If the participants complete progress to the next foot position, if not, the balance test is over]

“The next foot position is a semi-tandem foot position [show the foot position and correct the participant's position]. When you feel in balance, say “go,” and the ten seconds will begin.”

[If the participants complete progress to the next foot position, if not, the balance test is over]

“The next foot position is a tandem foot position [show the foot position and correct the participant's position]. When you feel in balance, say “go,” and the ten seconds will begin.”

“The next test is a 4-meter waking test; you must walk 4 meters from the initial line through the end line [point at the two lines] two times at your regular pace. I will count from 3, and on “go”, you begin.”

“The last part of this test battery is a strength test, where you must stand up from a chair five times as fast as possible. Please sit in the chair and cross your hands in front of your chest [illustrate the arm position]. Now stand up and sit down once. You will have to repeat those five times as fast as possible. I will count from 3, and the time begins on “go”. When you stand up the fifth time, the time will stop.” [count for each repetition].

QUESTIONNAIRES

Instruction

"You must fill out this questionnaire which involves a variety of questions that relates to the risk of falling and your well-being. You must read the questions thoroughly and provide a response that describes you the best. If you have any questions regarding understanding the question, you are welcome to ask me; however, I will not be able to help you answer the questions."

SUPPLEMENTARY MATERIAL 2: MISSING DATA

TABLE OF CONTENT

MISSING DATA

Table SM3.1 – Missing data for each outcome

Outcome	PBT group				Control group			
	Pre-training	Post-training	6-month follow-up	12-month follow-up	Pre-training	Post-training	6-month follow-up	12-month follow-up
Gait	0 (0)	4 (6)	6 (9%)	10 (14%)	0 (0)	3 (4%)	12 (16%)	16 (23%)
Balance	0 (0)	4 (6)	6 (9%)	10 (14%)	0 (0)	3 (4%)	12 (16%)	16 (23%)
Reaction	0 (0)	4 (6)	6 (9%)	10 (14%)	0 (0)	3 (4%)	12 (16%)	16 (23%)
SPPB	0 (0)	4 (6)	6 (9%)	10 (14%)	0 (0)	3 (4%)	12 (16%)	16 (23%)
TMT	0 (0)	4 (6)	6 (9%)	10 (14%)	0 (0)	3 (4%)	11 (14%)	16 (23%)
FES	0 (0)	4 (6)	6 (9%)	10 (14%)	0 (0)	3 (4%)	11 (14%)	16 (23%)
EQ5D	0 (0)	4 (6)	6 (9%)	10 (14%)	0 (0)	3 (4%)	11 (14%)	16 (23%)

Table SM3.2 – Summary of reasons for missing data in each group

Reason	PBT group (n =13)	Control group (n = 18)
Injury/illness	6	9
Personal reasons*	7	9

* Personal reasons include logistical issues, lack of motivation, and changes in personal relations forcing stoppage in participation

Table SM3.3 – Baseline characteristics of participants with at least one missing data point in each group

	PBT group (n = 13)	Control group (n = 18)	p-values
Age (years), Mean (SD)	73 (5.0)	72 (5)	0.66[α]
Sex, no. female (%)	9 (69)	9 (50)	0.46[γ]
Frailty*, median (IQR)	3 (2-4)	2 (1-3)	0.13[β]
Medication, median (IQR)	4 (2-7)	2 (0-4)	0.19[β]
Function of daily activities♦, median (IQR)	2 (2-3)	2 (1-3)	0.45[β]
Previous fallers, No. fallen (%)	6 (46)	6 (33)	0.71[γ]
Fear of falling, Median (IQR)	7 (7-8)	8 (7-9)	0.57[β]
Cognition♣, median (IQR)	24 (24-26)	26 (24-26)	0.32[β]
Physical function•, Median (IQR)	11 (11-12)	12 (11-12)	0.45[β]
Habitual gait speed (m/s), Mean (SD)	1.2 (0.1)	1.3 (0.2)	0.12[α]
Dual-task gait speed (m/s) Mean (SD)	1.0 (0.2)	1.2 (0.2)	**0.03**[α]
Single-task balance, sway speed (mm/s) Median (IQR)	13.83 (10.97-19.03)	15.60 (12.00-25.67)	0.37[β]
Dual-task balance, sway speed (mm/s) Median (IQR)	20.30 (15.78-25.93)	23.67 (15.77-25.93)	0.19[β]
Reaction time (ms), Mean (SD)	904 (148)	959 (128)	0.86[α]
Executive function© (s), median (IQR)	59.18 (51.73-63.78)	45.93 (28.83-78.88)	0.12[β]

* Tilburg Frailty indicator; ♦ The Vulnerable Elderly-13 Survey; ♣ The Short Orientation-Memory-Concentration Test; •The Short Physical Performance Battery; © Trail Making Test Part A subtracted from Part B; bold text indicates significant group differences. [α] Unpaired sample t-test; [β] Wilcoxon signed rank test; [γ] Fisher's exact test; bold text indicates significant between group differences

Table SM3.4 – Baseline characteristics of participants with at least one missing data point compared to participants with no missing data

	With missing (n = 31)	Without missing (n = 109)	p-values
Age (years), Mean (SD)	72 (5.1)	72 (4.6)	0.52[α]
Sex, no. female (%)	18 (58)	61 (56)	1.0[γ]
Frailty*, median (IQR)	2 (1-3)	1 (1-3)	0.07[β]
Medication, median (IQR)	3 (1-5)	2 (0-4)	0.25[β]
Function of daily activities♦, median (IQR)	2 (1-2)	2 (1-3)	0.55[β]
Previous fallers, No. fallen (%)	12 (39)	45 (41)	0.84[γ]
Fear of falling, Median (IQR)	8 (7-9)	7 (7-8)	0.57[β]
Cognition♣, median (IQR)	26 (24-26)	26 (24-28)	0.12[β]
Physical function•, Median (IQR)	12 (11-12)	12 (11-12)	0.28[β]
Habitual gait speed (m/s), Mean (SD)	1.3 (0.2)	1.3 (0.2)	0.25[α]
Dual-task gait speed (m/s) Mean (SD)	1.1 (0.2)	1.1 (0.2)	0.47[α]
Single-task balance, sway speed (mm/s) Median (IQR)	14.3 (11.7-20.7)	14.9 (12.0-19.2)	0.89[β]
Dual-task balance, sway speed (mm/s) Median (IQR)	21.8 (14.4-27.3)	18.0 (14.9-25.1)	0.25[β]
Reaction time (ms), Mean (SD)	927 (140)	889 (108)	0.95[α]
Executive function© (s), median (IQR)	54.8 (36.3-74.2)	37.5 (25.5-58.4)	0.06[β]

* Tilburg Frailty indicator; ♦ The Vulnerable Elderly-13 Survey; ♣ The Short Orientation-Memory-Concentration Test; •The Short Physical Performance Battery; © Trail Making Test Part A subtracted from Part B; bold text indicates significant group differences. [α] Unpaired sample t-test; [β] Wilcoxon signed rank test; [γ] Fisher's exact test; bold text indicates significant between group differences

SUPPLEMENTARY MATERIAL 2: RESULTS

This supplementary includes the results of the sensitivity analyses and the stata code used for both the primary analyses and the sensitivity analyses.

TABLE OF CONTENT

PER-PROTOCOL ANALYSES

Table SM2.2 – Results of fall-related risk factors using a per-protocol approach which only included participants who completed at least 75% of the intervention

	Between group differences		
	Pre-training to post-training (95% CI)	Pre-training to 26-week follow-up (95% CI)	Pre-training to 52-week follow-up (95% CI)
Physical measures			
Gait speed, single task, m/s Mean (SD)	0.03 (-0.00 to 0.06)	0.01 (-0.02 to 0.05)	0.01 (-0.03 to 0.05)
Gait speed, dual task, m/s Mean (SD)	**0.05♣** **(0.02 to 0.09)**	0.03 (-0.01 to 0.07)	0.03 (-0.02 to 0.08)
Sway area, single task, mm^2 Median (IQR)	-2.2 (-6.5 to 2.0)	-1.8 (-6.2 to 2.7)	3.2 (-2.9 to 9.2)
Sway area, dual task, mm^2 Median (IQR)	-10.2 (-24.2 to 3.9)	4.7 (-9.0 to 18.4)	12.9 (-18.8 to 44.5)
Sway speed, single task, mm/s Median (IQR)	0.1 (-1.0 to 1.3)	0.3 (-0.9 to 1.5)	0.1 (-1.3 to 1.5)
Sway speed, dual task, mm/s Median (IQR)	-1.6 (-3.2 to 0.1)	0.1 (-2.0 to 2.2)	1.4 (-1.3 to 4.0)
Reaction time, ms Mean (SD)	**-57♣** **(-84 to -30)**	-31 (-64 to 2)	-31 (-64 to 2)
SPPB, score• Median (IQR)	**0.2♣** **(0.0 to 0.4)**	0.2 (-0.1 to 0.4)	-0.0 (-0.2 to 0.3)
Five sit-to-stand$^{\mu}$, s Mean (SD)	-0.48 (-0.97 to 0.01)	-0.38 (-0.92 to 0.16)	-0.35 (-0.92 to 0.21)
Cognitive measures			
TMT ΔAB, s Median (IQR)	-2.78 (-16.38 to 10.82)	4.28 (-7.90 to 16.46)	-2.77 (-15.38 to 9.85)
Sociopsychological measures			
Fear of Falling, score▪ Median (IQR)	-0 (-1 to 1)	-0 (-0 to 0)	-0 (-1 to 0)
EQ5D, index$^{\oplus}$ Median (IQR)	0.01 (-0.01 to 0.04)	0.02 (-0.00 to 0.04)	-0.01 (-0.03 to 0.02)
EQ5D, VAS$^{\square}$ Median (IQR)	-0 (-2 to 2)	-0 (-3 to 2)	1 (-2 to 3)

* Significant difference from pre-training test; ♣ Significant difference between groups; • SPPB score ranges between 0 and 12, 12 is the best score; ▪ s-FES score ranges between 7 and 28, 28 is the best score; $^{\oplus}$ EQ5D Index ranges between 0 and 1, 1 is the best score; $^{\square}$ EQ5D VAS ranges between 0 and 100, 100 is the best score; $^{\mu}$ Collected as part of the short physical performance battery.

SENSITIVITY ANALYSES: ADJUSTED FOR AGE, SEX, AND PERVIOUS FALLS

Table SM2.3 – Results of fall-related risk factors for each testing session as well as group differences at post-training, 26-week follow-up and 52-week follow-up for the adjusted model (age, sex, and previous falls)

	Between group differences		
	Pre-training to post-training (95% CI)	Pre-training to 26-week follow-up (95% CI)	Pre-training to 52-week follow-up (95% CI)
Physical measure			
Gait speed, single task, m/s Mean (SD)	**0.03♣** **(0.00 to 0.06)**	0.02 (-0.02 to 0.05)	0.02 (-0.02 to 0.05)
Gait speed, dual task, m/s Mean (SD)	**0.06♣** **(0.02 to 0.09)**	0.03 (-0.01 to 0.07)	0.04 (-0.01 to 0.08)
Sway area, single task, mm^2 Median (IQR)	-2.8 (-6.8 to 1.3)	-2.6 (-6.8 to 1.7)	2.2 (-3.6 to 7.9)
Sway area, dual task, mm^2 Median (IQR)	-11.5 (-24.9 to 1.95)	2.1 (-10.5 to 14.8)	10.1 (-19.3 to 39.4)
Sway speed, single task, mm/s Median (IQR)	0.1 (-1.0 to 1.1)	-0.0 (-1.1 to 1.1)	-0.1 (-1.5 to 1.2)
Sway speed, dual task, mm/s Median (IQR)	-1.6 (-3.3 to 0.1)	0.3 (-2.3 to 1.7)	1.1 (-1.5 to 3.6)
Reaction time, ms Mean (SD)	**-57♣** **(-83 to -30)**	-27 (-58 to 5)	-27 (-59 to 6)
SPPB, score• Median (IQR)	**0.2♣** **(0.0 to 0.4)**	0.2 (-0.1 to 0.4)	-0.1 (-0.2 to 0.3)
Five sit-to-stand$^{\mu}$, s Mean (SD)	**-0.54♣** **(-0.97 to -0.01)**	-0.44 (-0.98 to 0.10)	-0.40 (-0.93 to 0.14)
Cogntive measure			
TMT ΔAB, s Median (IQR)	-3.80 (-18.18 to 10.57)	3.30 (-9.47 to 16.07)	-3.79 (-17.22 to 9.64)
Sociopsychological measure			
Fear of Falling, score▪ Median (IQR)	-0 (-1 to 0)	-0 (-1 to 0)	-0 (-1 to 0)
EQ5D, index$^{\oplus}$ Median (IQR)	0.01 (-0.01 to 0.04)	0.02 (-0.00 to 0.04)	-0.01 (-0.03 to 0.02)
EQ5D, VAS$^{\square}$ Median (IQR)	-0 (-2 to 2)	-1 (-3 to 2)	0 (-2 to 3)

♣ Significant between-group difference favouring the PBT group; • SPPB score ranges between 0 and 12, 12 is the best score; ▪ s-FES score ranges between 7 and 28, 28 is the best score; $^{\oplus}$ EQ5D Index ranges between 0 and 1, 1 is the best score; $^{\square}$ EQ5D VAS ranges between 0 and 100, 100 is the best score; $^{\mu}$ Collected as part of the short physical performance battery.

STATA CODES USED FOR ANALYSIS

All the statistical tests was conducted in STATA version 17.0. The outcomes was adjusted for the baseline values for the same outcome. This code was used for all the outcomes in this study:

mixed [insert variable] i.time##i.intervention baseline_[insert variable] || record_id:, vce(robust)

Model adjusting for age, sex, and previous falls:

mixed [insert variable] i.time##i.intervention baseline_[insert variable] age i.sex i.prev_faller || record_id:, vce(robust)

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance, see CONSORT for abstracts)	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	4
	2b	Specific objectives or hypotheses	4
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	4-5
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	5
Participants	4a	Eligibility criteria for participants	5
	4b	Settings and locations where the data were collected	4
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	5-6 + Supp. 1
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	6-7
	6b	Any changes to trial outcomes after the trial commenced, with reasons	N/A
Sample size	7a	How sample size was determined	7-8
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	5
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	5
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	5
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	5

Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	7
	11b	If relevant, description of the similarity of interventions	N/A
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	8
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	8
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	9 + Figure 2
	13b	For each group, losses and exclusions after randomisation, together with reasons	Figure 2
Recruitment	14a	Dates defining the periods of recruitment and follow-up	5
	14b	Why the trial ended or was stopped	N/A
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 1
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	9 + Figure 2
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	9-20 + Table 2 + Figure 3 + supp. 3
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	Table 2
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	9-10 + supp. 4
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	10 + supp. 4
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	13
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	11-12
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	11-12
Other information			
Registration	23	Registration number and name of trial registry	2 + 5
Protocol	24	Where the full trial protocol can be accessed, if available	5
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	14

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.