

BMJ Open 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

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ABSTRACT

Introduction Falls among older adults are most frequently caused by slips and trips and can have devastating consequences. Perturbation-based balance training (PBT) have recently shown promising fall preventive effects after even small training dosages. However, the fall preventive effects of PBT delivered on a treadmill are still unknown. Therefore, this parallel-group randomised controlled trial aims to quantify the effects of a four-session treadmill-PBT training intervention on falls compared with treadmill walking among community-dwelling older adults aged 65 years or more.

Methods and analysis 140 community-dwelling older adults will be recruited and randomised into either the treadmill-PBT or the treadmill walking group. Each group will undergo three initial training sessions within a week and an additional 'booster' session after 26 weeks. Participants in the treadmill-PBT group will receive 40 slip and/or trip perturbations induced by accurately timed treadmill belt accelerations at each training session. The primary outcome of interest is daily life fall rates collected using fall calendars for a follow-up period of 52 weeks. Secondary outcomes include physical, cognitive and social-psychological fall-related risk factors and will be collected at the pre-training and post-training test and the 26-week and 52-week follow-up tests. All outcomes will be analysed using the intention-to-treat approach by an external statistician. A Poisson's regressions with bootstrapping, to account for overdispersion, will be used to compare group differences in fall rates.

Ethics and dissemination The study protocol has been approved by the North Denmark Region Committee on Health Research Ethics (N-20200089). The results will be disseminated in peer-reviewed journals and at international conferences.

Trial registration number NCT04733222.

INTRODUCTION

Slips and trips accounts for 60% of accidental falls among older adults and often leads to serious consequences such as disability,

Strengths and limitations of this study

- Large-scale randomised controlled trial, powered to determine the effect of treadmill perturbation-based balance training (treadmill-PBT) on daily life fall rates among older adults (65+ years of age).
- Assessor-blinded, prospective, 52-week daily life fall data monitoring using fall calendars as recommended by ProFaNE (Prevention of Falls Network Europe).
- Effects of treadmill-PBT will be explored on numerous fall-related risk factors and important socio-psychological aspects.
- Blinding of participants will not be possible, potentially leading to response bias.
- The assessor of the secondary fall risk factors will not be blinded, which could introduce observer bias.

institutionalisation, decreased quality of life and premature death.¹⁻⁴ Annually medical costs related to falls are high and is estimated to account for ~1% of Danish total health expenditure (~€200 million in 2016).⁵ Fall-related medical costs are expected to grow as the older population will increase in numbers in the upcoming decades. Thus, effective fall prevention interventions are warranted to improve the well-being of older adults and reduce future medical expenses for society.⁶⁻⁹

A comprehensive systematic review from 2020, assessing 64 randomised controlled trials (RCTs), showed that general exercise decreased fall rates by 23%.¹⁰ This review, among others, have paved the road for conventional exercises such as balance training and strength training to become central aspects of fall preventive recommendation worldwide.^{8 11} While these conventional exercise regimens target specific fall risk factors, the

principle of task-specificity suggests approaches that directly address the fall-related context may provide better fall prevention.^{12 13} Perturbation-based balance training (PBT), in which participants are exposed to repeated slips and trips in a safe environment, could be one such approach. Among older adults, PBT has been shown to improve proactive and reactive dynamic stability resulting in a reduced risk of falling after a laboratory-induced slip and trip perturbation by 50%–100%.^{12 14–18} Additionally, two meta-analyses from 2015 and 2017, which assessed eight and four studies, showed that daily life fall rates decreased by 46% and 48% after PBT, respectively.^{19 20}

PBT adaptations have interestingly been observed after as little as a single session and appear to be maintained for up to 12 months.^{14 15 21–24} In contrast, conventional exercise regimes demands continuous weekly participation to preserve the fall preventive effect.²⁵ Furthermore, poor compliance with such exercise approaches is often reported, which inevitably causes meagre long-term prevention.^{26 27} The brevity of PBT reduce the reliance on continuous self-motivation and potentially promotes the older adults' willingness to conduct the necessary amount of training.¹² PBT may, therefore, emerge as an effective, sustainable and relatively inexpensive fall prevention intervention.

PBT has previously been performed using a variety of methods such as; (1) movable platforms,²⁸ (2) walkways with low friction platforms and/or trip boards^{14 16} and (3) treadmill that produces sudden accelerations.^{29–32} Among these, approaches that apply perturbations during walking are considered more task-specific as most falls occur during walking.^{33 34} Moreover, perturbations delivered on walkways are considered the most realistic; however, such setups is space-consuming, expensive and immobile. Treadmills, conversely, are less space-consuming, cheaper and more portable, enabling a more straightforward implementation into fall prevention and rehabilitation clinics.^{12 29 35 36} An additional benefit of treadmills is the perturbations' unpredictability, which enhances the reliance on reactive balance control strategies.²³ Studies have shown that treadmill-PBT improves proactive and reactive dynamic stability and decreases fall rates following laboratory-induced walkway perturbations.^{29 30 35 37 38} Nonetheless, the magnitude to which these adaptations translates to prevent daily life falls are still vastly unknown.³¹ Rosenblatt *et al* showed that four 1-hour sessions of trip treadmill-PBT decreased the rate of daily life trip-related falls by 46% (95% CI=3% to 70%) in 210 women aged 55 or more.³¹ The training did, however, not lead to any differences in overall fall rates.³¹ The treadmill-PBT protocol used by Rosenblatt *et al* only consisted of trip perturbations applied in a standing position, which might explain the absent fall preventive effect since people most often fall while moving.³¹ More recently,³² Lurie *et al* investigated, in a highly pragmatic RCT, the effects of adding treadmill-PBT using both trip and slip perturbations to usual multimodal exercise-based balance training at an outpatient physical

therapy clinic.³² While the number of injurious falls was decreased after 3 months, no differences in daily life fall rates were found among the 506 older adults.³² However, the pragmatic nature of the study by Lurie *et al* prevents a standardised dose and intensity of the treadmill-PBT protocol limiting the ability to draw conclusions.³² Thus, the current literature limitations highlight the need for large-scale RCTs using treadmill-PBT in multiple directions (slips and trips) and with recommended training doses to elucidate the effects on daily life falls in older adults.^{23 39}

Our primary objective of this parallel-group RCT will therefore be to determine the effects of treadmill-PBT on fall rates in community-dwelling older adults aged 65 or older, compared with treadmill walking without perturbations. Second, we aim to evaluate the effects on physical, cognitive and social-psychological fall-related risk factors and the intervention's health economic impact.

METHODS

Study design and setting

The effects of treadmill-PBT will be investigated in a parallel-group randomised controlled superiority trial with a 1:1 allocation ratio (see [figure 1](#)). The study will be performed as a collaboration between Aalborg University Hospital, Aalborg University and Aalborg Municipality, Denmark. All interventional and testing activities will be conducted in a laboratory placed at Aalborg University. This study protocol follows the Standard Protocol Items: Recommendations for Interventional Trials guidelines,⁴⁰ and has been registered on ClinicalTrials.gov.

Participants

We aim to recruit 140 community-dwelling older adults (70 in each group) living in and around Aalborg via advertisements in local and national newspapers, radio and television spots and snowball sampling. Participants are included if they are (1) ≥65 years old, (2) community-dwelling and (3) able to walk without a walking aid. Participants will be excluded if they (1) have 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 (eg, Parkinson's disease), (2) have an unstable medical condition that would prevent safe participation, (3) have a severe cognitive impairment (a score <8 in The Short Orientation–Memory–Concentration Test)⁴¹ and (4) are currently participating in another fall prevention trial.

Potential participants will receive written information about the study followed by verbal information from a research staff member over the phone. During the phone call, the research staff will also screen for eligibility, obtain verbal consent and arrange an initial session appointment.

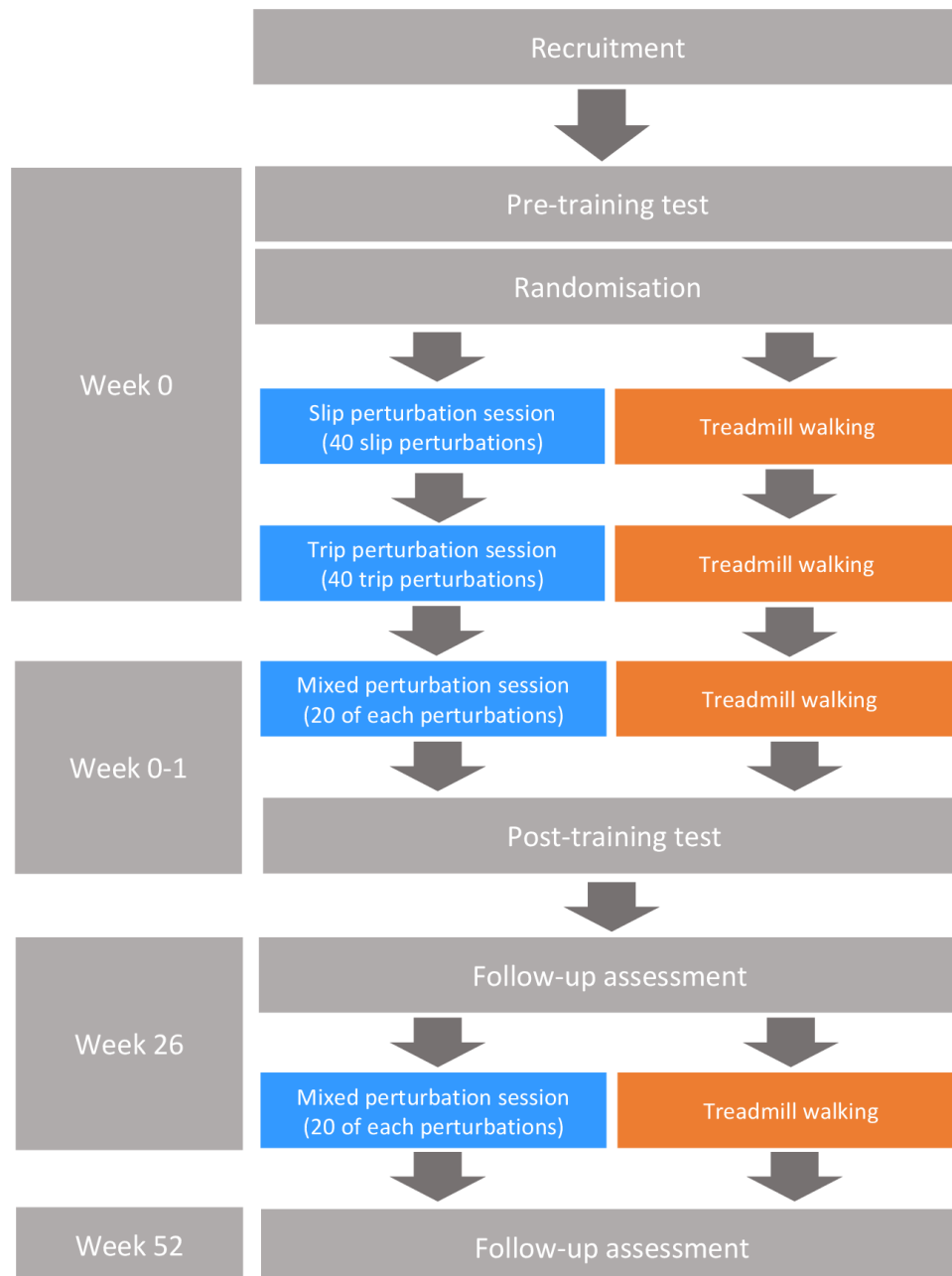


Figure 1 Illustration of the study flow. Blue squares indicate the study flow of the treadmill-perturbation-based balance training group, while the orange squares illustrate the study flow of the treadmill walking group.

Randomisation




After the pre-training tests, participants will be randomly allocated to either the treadmill-PBT or treadmill walking group using a randomisation module in REDCap (Research Electronic Data Capture; V.9.5.6). Permuted block randomisation will be used to produce similar group sizes, and random block sizes (two, four, six or eight) will ensure that allocation concealment is maintained. The allocation sequence will be generated by a research staff member not involved in enrolling or assigning participants to groups. A timeline for enrolment, intervention and assessment of the participants is presented in [table 1](#).

Interventions

Before the first training session, all participants will walk for 5 min at 50% of their overground walking speed to familiarise themselves with the treadmill.⁴² The preferred treadmill walking speed will then be determined by gradually increasing and decreasing the treadmill speed to identify the participant's upper and lower boundaries of comfortable walking. The mean velocity of these boundaries will be defined as the preferred walking speed.^{43 44} The preferred walking speed found during the first training session will be used for all training sessions.

A thorough description of the treadmill-PBT and treadmill walking intervention, following the Template for

Table 1 Schedule for enrolment, intervention and assessment

Study period						
Time point	Enrolment	Pre-training	Intervention	Post-training	26-week follow-up	52-week follow-up
	-T1	T0	T1	T2	T3	T4
Enrolment:						
Eligibility screening	X					
Informed written consent		X				
Randomised allocation		X				
Intervention:						
Treadmill-PBT						
Walking training						
Assessments:						
Falls						
Physical		X		X	X	X
Cognitive		X		X	X	X
Social-psychological		X		X	X	X
Neurophysiological		X		X	X	
Descriptive		X				

PBT, perturbation-based balance training.

Intervention Description and Replication guidelines, is provided in online supplemental material 1.⁴⁰ Participants in both the treadmill-PBT and treadmill walking group will be encouraged to continue their regular activity schedule during the trial period.

Treadmill-PBT

The treadmill-PBT group will be assigned to four training sessions in total. The two initial training sessions will be performed on the same day, separated by an approximate 5 min break, and will consist of only slip (first session) and trip (second session) perturbations. These sessions, with predictable perturbation types, are planned to enhance the participant's confidence and decrease anxiety associated with training.^{14 45} The third session is performed a week later and will consist of randomly ordered slip and trip perturbations, which have been shown to maximise the training effects.^{46 47} Lastly, the fourth session will be similar to the third session but performed at week 26 and will serve as a booster training, which previously has been shown to sustain training effects for longer.⁴⁸ An overview of the study flow is provided in [figure 1](#).

Each training session will have a duration of approximately 20 min, and consist of 40 perturbations delivered bilaterally with 20 perturbations to each leg in random order on a computer-controlled treadmill moving uniformly (Split 70/157/ASK; Woodway, Weil am Rhein, Germany). To further enhance the unpredictability of the perturbations, the duration (10–50 steps) between each perturbation will be random. Before the first perturbation, participants will be shown a video of both the slip and trip perturbation to minimise potential anxiety

associated with the situation. An overhead harness safety system will secure the participants and prevent them from falling to the ground during training.

The slip perturbations are induced by a quick forward acceleration at heel strike (0% of the gait cycle), causing a reversal in the direction of the treadmill, resulting in a backward loss of balance. The trip perturbations are caused by a slight deceleration followed by a large backward acceleration of the treadmill during the mid-swing phase (~80% of the gait cycle), causing a forward loss of balance. The perturbation intensity for each of the training sessions will be adjusted to the participants preferred walking speed and will be divided into five levels with progressively longer perturbation durations (slips) or greater accelerations (trips) (see [table 2](#)). The protocol is split into 11 blocks of two to four perturbations arranged in a progressive ascending-mixed-intensity manner (see [figure 2](#)).^{30 49} The ascending phase serves as a warm-up and to increase the training's tolerability, while the mixed phase facilitates over-learning to maximise the training effects.⁴⁹ After each block, the participants will rate their perceived difficulty and anxiety on a Visual Analogue Scale from 1 to 5. For the intensity to be increased, the following three criteria have to be met: (1) the combined perceived difficulty and anxiety score have to be 4 or less, (2) the participant did not fall during any of the perturbations in the block prior and (3) the participants accepted to increase the intensity. If any of these criteria are not met, the intensity remains unaltered.

Table 2 Schematic presentations of the intensity levels in the slip perturbation protocol (A) and the trip perturbation protocol (B)

(A) Slip perturbation protocol

Walking speed	Belt acceleration	Level 1 slip duration	Level 2 slip duration	Level 3 slip duration	Level 4 slip duration	Level 5 slip duration
≥1.2 m/s	−6 m/s ²	0.35 s	0.40 s	0.45 s	0.50 s	0.55 s
<1.2 to 1.0 m/s	−6 m/s ²	0.30 s	0.35 s	0.40 s	0.45 s	0.50 s
<1.0 to 0.8 m/s	−5 m/s ²	0.25 s	0.30 s	0.35 s	0.40 s	0.45 s
<0.8 m/s	−5 m/s ²	0.20 s	0.25 s	0.30 s	0.35 s	0.40 s

(B) Trip perturbation protocol

Walking speed	Level 1 trip acceleration	Level 2 trip acceleration	Level 3 trip acceleration	Level 4 trip acceleration	Level 5 trip acceleration
≥1.2 m/s	7 m/s ²	8 m/s ²	9 m/s ²	10 m/s ²	11 m/s ²
<1.2 to 1.0 m/s	6 m/s ²	7 m/s ²	8 m/s ²	9 m/s ²	10 m/s ²
<1.0 to 0.8 m/s	5 m/s ²	6 m/s ²	7 m/s ²	8 m/s ²	9 m/s ²
<0.8 m/s	4 m/s ²	5 m/s ²	6 m/s ²	7 m/s ²	8 m/s ²

Treadmill walking

Participants allocated to the treadmill walking group will undergo four training sessions arranged similar to the treadmill-PBT group. Each training session consists of 20 min of treadmill walking, matching the duration spent on the treadmill by the treadmill-PBT group.

Outcomes

The participants' descriptive data will be collected following recommendations on conducting and reporting trials in older adults during the pre-training tests.⁵⁰ Descriptive data include height, weight, sex, physical and cognitive function, medication usage, Tilburg Frailty Indicator, highest education level, living arrangements, fall history including associated injuries, Vulnerable Elders Survey-13 (everyday activity functionality), physical activity levels and home care usage. Information will be collected through a combination of self-reporting, measurements, questionnaires and medical/municipality records (see table 3).

Primary outcome

The primary outcome is daily life fall rate (falls per person-year). Daily life falls will be assessed continuously throughout a 52-week period using fall calendars

as recommended by ProFaNE.⁵¹ The fall calendars are designed for daily recordings and monthly returns by mail in prestamped envelopes. A fall is defined as 'an unexpected event in which the participant comes to rest on the ground, floor or lower-level'.⁵¹ When a fall has occurred, a research staff member blinded to group allocation will call the participant. During this phone interview, information about the fall's circumstances and consequences (eg, fall-related injuries) will be obtained. If a fall calendar is not returned within 14 days from the deadline, participants will be contacted to acquire the missing information.

Secondary outcomes

The secondary outcomes include other fall metrics, physical, cognitive and social-psychological measures, which will elucidate the effects of the treadmill-PBT intervention on important fall risk factors. An overview of the tests and timing of the assessments can be seen in table 3.

Secondary fall and fall-related injury metrics will also be collected via the aforementioned fall calendars. The fall metrics include (1) the number of participants with at least one fall and (2) the time to first fall. Fall-related injury metrics include (1) the number of fracture events

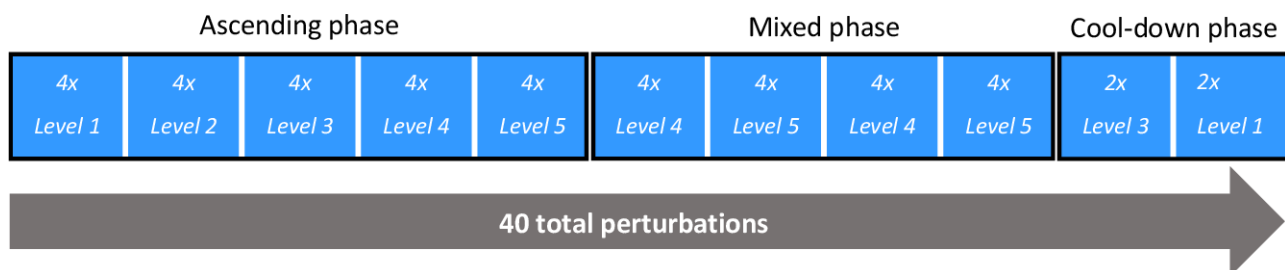


Figure 2 The sequential arrangement of perturbation intensity levels in the training protocol. The protocol is arranged in three phases: (1) an ascending phase in which the intensity of the perturbations progressively increases, (2) a mixed phase where the perturbation intensity varies between level 4 and 5 and (3) a cool-down phase at which the perturbation intensity decreases.

Table 3 Assessment of outcomes across the study timeline

Fall assessments					
	Pre-training (T0)	Post-training (T2)	26-week follow-up (T3)	52-week follow-up (T4)	Continuous assessment (T0–T4)
Falls*					X
Fall-related injuries†					X
Fall-related use of healthcare services†					X
Laboratory-induced falls†	X	X	X	X	
Physical and cognitive assessments					
	Pre-training	Post-training	26-week follow-up	52-week follow-up	Continuous assessment
Single-task and dual-task gait patterns‡	X	X	X	X	
Single-task and dual-task balance‡	X	X	X	X	
Choice stepping reaction test‡	X	X	X	X	
The Short Physical Performance Battery†	X	X	X	X	
The Short Orientation–Memory–Concentration Test†	X	X	X	X	
The Trail-Making-Test Part A and B†	X	X	X	X	
Questionnaire-based assessments					
	Pre-training	Post-training	26-week follow-up	52-week follow-up	Continuous assessment
EQ-5D-5L‡	X	X	X	X	X
The Short Falls Efficacy Scale†	X	X	X	X	
The Tilburg Frailty Index‡	X				
Vulnerable Elders Survey-13‡	X				
The Physical Activity Enjoyment Scale†		X			
Others					
	Pre-training	Post-training	26-week follow-up	52-week follow-up	Continuous assessment
Anthropometric data‡	X				
Charlson Comorbidity Index‡	X				
Adverse events†	X	X	X	X	X
Intervention and healthcare costs (economic evaluation)†					X

*Fall rate (fall per person-year) is the primary outcome.

†Secondary outcome.

‡Descriptive data.

EQ-5D-5L, EuroQol 5-dimensions 5-levels.

per person-year, (2) the number of participants with at least one fracture, (3) the number of other injuries (eg, sprains, bruises and head injuries) per-person year, (4) the number of participants with at least one other injury and (5) the number of fall-related hospital contacts and general practitioner visits. Moreover, at the four testing sessions, a level 1 slip and trip perturbation will be induced to investigate the participants' reactive balance adaptations. The slip and trip perturbations will be recorded in slow motion, and a research staff member, blinded for group allocation, will review the videos to determine if

the participant falls or not. It will be deemed a fall if the safety harness unambiguously supports the participant. If the participant does not fall, the number of compensatory steps to regain balance will be assessed.

An unblinded research staff member will conduct the physical assessments that include single-task and dual-task gait patterns, single-task and dual-task static balance, stepping reactions and lower extremity performance. These assessments have been selected because they are identified as risk factors for falls.^{52–55} To assess gait patterns, the participants will be asked to walk 8 metres at their habitual

pace six times. First, the participants will be instructed to walk for three trials as a single task. They will then be instructed to walk three trials while counting backwards in intervals of three from a random three-digit number as a dual-task.^{56 57} Participants will not be instructed to prioritise gait over cognitive tasks or vice versa as this provides the best representation of what happens naturally.⁵⁸ The middle 6 metres will be timed and recorded following the recommendations for gait assessments.⁵⁸ Gait speed will be used for further analysis. Balance will be assessed on a Wii Balance Board (WBB) using the FysioMeter software (FysioMeter, V.1.2.1.4, Denmark).^{59 60} Prior research has shown that WBB provides valid and reliable assessments of the centre of pressure displacements in older adults.⁶¹ Participants will be instructed to stand as still as possible for 30 s during three single-task and three dual-task trials. The dual-task involves naming items from the grocery store, and the participants will not be given instructions to prioritise either the balance or cognitive task. The area and speed of the centre of pressure displacements will be used for further analysis.⁵⁹ Stepping reactions will be assessed using a choice stepping reaction test on a WBB using the FysioMeter software.^{53 62} The WBB has previously shown valid and reliable recordings of stepping reaction time in older adults.⁶² During the choice stepping reaction test, participants will be asked to react as fast as possible to visual clues given on a computer screen by tapping the foot on the correct side of the WBB. The visual clues are provided as a green indicator at a random time (between 1 and 4 s) and side (left or right). Seven recordings will be made, and the reaction time from the first six (three from each side) will be used for further analysis.⁶² Lastly, The Short Physical Performance Battery, which has been shown to validly and reliably determine older adults' lower extremity performance and frailty, will be used.^{55 63} The Short Physical Performance Battery consists of three elements; balance with three different foot positions, two 4-metre walks and five chair-stands. Each element will be scored based on the performance and the score will be used for further analysis.

Executive function is identified as a cognitive fall-related risk factor and will be assessed using the Trail-Making-Test Part A and B.^{56 64 65} Part A involves sequentially connecting 25 randomly arranged numbers (1-2-3-...-25) with pencil lines, while Part B encompasses sequentially connecting 25 randomly placed numbers and letters (1-A-2-B-...-12-L) in an alternating manner.⁶⁴ The difference in time-to-complete Part A and B (B-A) will be used in the current study, as this index has been suggested to quantify executive function the best.^{65 66} Moreover, the participants' global cognitive function will be evaluated using The Short Orientation–Memory–Concentration Test.⁶⁷

Danish-translated questionnaires will assess social–psychological factors. Health-related quality of life will be quantified using the EuroQoL 5-dimensions 5-levels (EQ-5D-5L),⁶⁸ fear of falling will be assessed using The Short Falls Efficacy Scale International⁶⁹ and the

enjoyment of the interventions will be determined by the Physical Activity Enjoyment Scale.⁷⁰ The score derived from these questionnaires will be used for further analysis.

Economic evaluation

An economic evaluation of the treadmill-PBT intervention will be conducted as both a cost-effectiveness analysis (CEA) and cost-utility analysis (CUA) following the guidelines for conducting and reporting economic evaluation of fall prevention strategies.⁷¹ In the CEA, the outcome measure will be the difference in the number of falls during the 52-week follow-up period. The outcome measure in the CUA will be quality-adjusted life years (QALY) gained quantified using the utility weight of the EQ-5D-5L.⁷² Cost data will prospectively be collected regarding the training programme (staff salaries and expenses, administration, equipment, rental of premises and overhead) and fall-related healthcare resources (hospital admissions, emergency department visits, general practitioner visits, home-care, rehabilitation and nursing home admissions).

Harms

Participants will be encouraged to report any minor or major adverse event during the testing procedure or the intervention. Furthermore, anxiety related to the treadmill-PBT intervention will continuously be assessed during the training sessions.

Data management

All data will be collected and managed using the secure, web-based software platform REDCap hosted at The Region of Northern Denmark.^{73 74} The data collection forms in REDCap ensure strong data integrity by applying functions that check for mandatory information, data ranges and alerts whenever data violates specific limits.⁷⁴ Paper documents, such as written consent forms, will be stored in a locked cabinet in an area of limited access.

Sample size estimation

The sample size calculation was conducted in G*power (V.3.1.9.4, University of Kiel, Kiel, Germany) using a Poisson regression model. The calculation was made with certain assumptions (80% power, 5% significance level, 50% difference in fall rate (favouring the PBT) and 20% dropout rate) and an expected average fall rate of 0.85.⁷⁵ The sample size calculation estimated an required sample size of 70 participants in each group.

Statistical methods

All statistical analyses will be conducted using the intention-to-treat principle. A per-protocol analysis will also be performed, including only participants who complete 75% of the training sessions. The statistical analyses will be conducted by an external statistician. The level of significance will be set at 5% ($p < 0.05$).

Descriptive data will be presented as mean and SD, median and IQR or number and percentage, where appropriate. Group differences in baseline values will

be compared using unpaired t-tests for continuous variables, Fisher's exact test for binary variables and Poisson's regression for count variables.

Primary outcome

The primary outcome, daily life fall rate (count variable), will be analysed using a Poisson's regression with, if necessary, bootstrapping to account for the often-observed overdispersion in fall rate data.⁷⁶ Sensitivity analysis will be made in which we adjust for confounders, including age, sex and previous falls.

Secondary outcomes

Besides the secondary fall metrics, the secondary outcomes will be analysed as differences in means from the pre-training test to the post-training test, the 26-week and the 52-week follow-up, respectively. Dichotomous outcomes will be analysed using Fisher's exact test. Count outcomes will be analysed using Poisson's regression with bootstrapping if data are overdispersed. Continuous outcomes will be analysed using a 2 (group) × 4 (time) analysis of variance, with repeated measures on the second factor (time). If continuous variables violate the assumption of normal distribution, log-transformation will be performed and, if necessary, bootstrapping. Sensitivity analyses adjusting for age, sex and previous falls will be conducted for all the secondary outcomes.

In the economic evaluation group differences in falls and QALYs are divided by the group-difference in costs to determine the incremental cost-effectiveness ratio of the CEA and CUA's. The 95% CI will be estimated with bootstrapping, and the result of the economic analysis will be presented on a cost-effectiveness plane. To systematically account for the economic evaluation's uncertainties, sensitivity analyses using the one-way scenario method will be conducted. Additionally, probabilistic sensitivity analysis by making 10 000 computer-based Monte-Carlo simulations will be performed and presented on a cost-effectiveness acceptability curve to guide the decision-making process.

PUBLIC AND PATIENT INVOLVEMENT

Before recruitment began, pilot trials were conducted on community-dwelling older adults to evaluate the training protocol; however, none of the feedback insinuated any changes to the protocol. The public has been involved in the recruitment process through public service mentions in national television news, local radio and web articles. Neither the public nor patients will be involved in conducting or measuring outcomes. The patients will not assess the burden of the intervention. Written reports of the results will be sent by email to the participants of the trial.

DISCUSSION

The population of older adults at high risk of falling is expected to increase in the coming decades, highlighting the need for effective fall prevention strategies.⁶ Physical exercise is currently considered an effective method to decrease fall rates; yet, conventional exercise approaches have issues with a high degree of attrition, limiting the long-term prophylactic effect.^{26 27 75 77 78} In contrast, PBT has previously shown a vaccination-like effect as even small dosages have been shown to decrease daily life fall rates by ~50%.^{14 23 39} Thus, current pieces of evidence indicates that such training could be an effective, inexpensive and sustainable fall prevention strategy.

In this RCT, we seek to evaluate a four-session treadmill-PBT intervention's effectiveness in reducing the daily life fall rate among older adults aged 65 years or older. The current study's secondary outcomes will also enlighten the effects on well-known fall-related physical and cognitive risk factors. Furthermore, fear of falling and health-related quality of life assessments will elucidate additional transfer effects of treadmill-PBT to other important factors. We believe this study has the potential to decrease the number of daily life falls and fall-related injuries and improve crucial social-psychological factors among older adults. Improvements in any of these parameters offer valuable insights into the beneficial effects of treadmill-PBT targeting older adults. This study will also attempt to address the subsequent implementation as the economic analysis evaluates the intervention's cost-effectiveness and -utility. The recruited older participants are expected to be relatively healthy, motivated and community-dwelling; thus, the results will mainly apply to this population.

Recruitment of participants is expected to begin in April 2021, and the results are expected to be accessible in late 2022.

ETHICS AND DISSEMINATION

The protocol has been approved by The North Denmark Region Committee on Health Research Ethics (N-20200089) and the Danish Data Protection Agency (2021-014). Serious adverse events will be reported within 2 weeks with comments on the participants' safety and potential consequences for the trial. Such events will be reviewed by The North Denmark Region Committee on Health Research Ethics independent from the trial investigators. Additional adverse events will be collected and reported to the local ethics committee annually. The trial participants will be covered by the Danish Act on the Right to Complain and Receive Compensation in health-care. Furthermore, each participant will provide written informed consent before the commencement of any study activities (online supplemental material 2).

Regardless of the outcome, the results will be disseminated in relevant peer-reviewed scientific journals and at national and international conferences. To facilitate the subsequent implementation of treadmill-PBT at

fall clinics, the results will be presented to the decision-makers across the country's municipalities and hospitals. Press releases in layman's terms will be administrated to local and national newspapers, radio and television stations to address the general public, including the use of social media.

Authorship will be determined following the Vancouver Convention. All authors will have provided substantial intellectual contributions to the development of the protocol, the conduct of the study and/or the manuscript. The authors have approved the final manuscript and agree to be accountable for the work.

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Contributors Author contributions are described using the CRediT taxonomy.

JEN: conceptualisation, methodology, developing the formal analysis plan, project administration, software, supervision, visualisation and writing the original draft.

SA: conceptualisation, funding acquisition and reviewing/editing the draft. JR: conceptualisation, methodology, visualisation and reviewing/editing the draft. JA: methodology, visualisation and reviewing/editing the draft. AdSCO: methodology, visualisation and reviewing/editing the draft. AJTS: conceptualisation, methodology, software, resources, supervision, visualisation and reviewing/editing the draft.

MBD: conceptualisation, methodology, visualisation and reviewing/editing the draft. MGJ has been involved in conceptualisation, methodology, developing the formal analysis plan, funding acquisition, supervision, visualisation and reviewing/editing the draft.

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