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Feasibility, effectiveness and acceptability of two perturbation-based treadmill training protocols to improve reactive balance in fall-prone older adults (FEATURE): protocol for a pilot randomised controlled trial

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ABSTRACT

Introduction Perturbation-based balance training (PBT) targets the mechanism of falls (eg, slipping, tripping) to specifically train the recovery actions needed to avoid a fall. This task-specific training has shown great promise as an effective and efficient intervention for fall prevention in older adults. However, knowledge about the dose–response relationship of PBT, as well as its feasibility and acceptability in older adults with increased risk of falling is still limited. Thus, the aim of this study is to compare the effectiveness of two different treadmill PBT protocols for improving reactive balance control in fall-prone older adults, and to evaluate the feasibility and acceptability of these protocols.

Methods and analysis The study is designed as a pilot randomised controlled trial with a 6-week intervention and 6-week follow-up period. Thirty-six community-dwelling, fall-prone (Timed Up and Go >12 s, habitual gait speed <1.0 m/s and/or fall history) older adults will be randomised (1:1) to receive six (weeks 1–6) or two treadmill PBT sessions (weeks 1+6) plus four conventional treadmill training sessions (weeks 2–5). Training sessions are conducted 1×/week for 30 min. Each PBT will include 40 perturbations in anterior–posterior and mediolateral directions. Reactive balance after perturbations in standing (Stepping Threshold Test (STT)) and walking (Dynamic Stepping Threshold Test (DSTT)) will be assessed as the primary outcome for effectiveness. Secondary outcomes are spatiotemporal and kinematic parameters collected during STT, DSTT and PBT, maximum perturbation magnitude for each PBT session, static and dynamic balance, physical capacity, physical activity, concerns with falling and executive functions. Feasibility will be assessed via training adherence, drop-out rate, perturbations actually performed and adverse events; and acceptability via self-designed questionnaire and focus groups.

Ethics and dissemination The study has been approved by the Ethics Committee of the Medical Faculty Heidelberg (S-602/2022). Findings will be disseminated through publications in peer-reviewed journals and conference presentations.

Trial registration number DRKS00030805.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ A pilot randomised controlled trial to increase the knowledge about the feasibility, acceptability and dose–response relationship of perturbation-based balance training (PBT) on a treadmill in older adults.
⇒ Study population will include older adults at increased risk of falling.
⇒ Outcomes of the PBT protocols will be evaluated using a comprehensive and detailed assessment of various types of balance control abilities (static, dynamic, reactive).
⇒ Blinding of participants and trainers will not be possible, increasing the risk of bias.
⇒ Daily-life falls will not be assessed due to the pilot nature of the study.

INTRODUCTION

Falls and fall-related injuries are a major public health problem. About 30% of older adults experience a fall each year,[1–3] often associated with serious consequences such as hospitalisation, disability, institutionalisation and mortality.[4 5] Many older adults who have fallen also develop concerns with falling, which may lead to a vicious circle of activity avoidance, physical deconditioning and increased fall risk.[6–9] Falls also place a substantial economic burden on society. Fall-related medical costs account for about 1% of the total healthcare expenditures in high-income countries.[10] Due to the growing number of older adults, falls and fall-related medical costs are expected to increase in the future.[11] Thus, fall prevention in older adults is an urgent public health challenge.

Physical exercise is considered the most evidence-based intervention approach for

preventing falls and is a central component of recommendations for fall prevention worldwide.[11–13] The latest update of a 2019 Cochrane Review showed that exercise-based fall prevention programmes can reduce fall rates by 23% in older adults.[14] Most of these programmes included conventional balance, functional and strength exercises, performed multiple times a week over several months. The recently published World Falls Guidelines recommend exercise programmes for fall prevention in older adults that include balance and functional exercises, with sessions ≥3×/week and increasing intensity over ≥12 weeks.[11] The potential for large implementation and the scalability of such high-frequency and long-term exercise programmes may be limited, when considering that many older adults tend to lead physically inactive lifestyles.[15 16] In addition, two recent large-scale, pragmatic randomised controlled trials (RCTs) in community-dwelling older adults, conducted for the first time with sufficient statistical power (n>2000), found no significant benefit of such exercise-based fall prevention programmes in terms of fall rates and/or fall-related injuries.[17 18] Overall, there is still a need for novel concepts to increase the effectiveness and efficiency of fall prevention interventions.[19]

The declining ability to appropriately react to mechanical disturbances (perturbations) during walking, such as trips or slips, is one of the most important factors in the multifactorial aetiology of falls.[20–22] Conventional exercise-based fall prevention programmes address specific fall risk factors (eg, muscle weakness, balance and gait deficits), but often lack the task-specificity to train recovery actions required to prevent falling after perturbations. Perturbation-based balance training (PBT) is a novel type of task-specific intervention that directly addresses the fall-related context.[23] Trainees repeatedly experience externally applied mechanical perturbations under safe and controlled conditions to practice reactive balance control (ie, fast actions to regain postural stability).[23 24] Indeed, recent findings suggest that such task-specific training may be the most effective intervention for improving reactive balance control in older adults.[25] PBT may also hold great promise as a highly efficient fall prevention strategy in older adults, though current evidence is still not sufficient. While some studies found no fall-reducing effect of low-volume PBT,[26 27] other studies showed an impressive reduction in (trip-related) falls of about 50% over a 12-month follow-up period after just one and four PBT sessions, respectively.[28 29] This corresponds roughly to twice the effect of well-established fall prevention programmes,[14] while the training volume is significantly lower.

A recent review on PBTs in clinical practice highlighted that there is a clear need for studies on the dose–response relationship, especially for PBT protocols conducted on treadmills.[23] In addition, it was noted that PBT has so far been primarily studied in healthy community-dwelling older adults. Only few studies have demonstrated the effectiveness of PBT for improving reactive balance in older adults with increased risk of falling.[30–34] Thus, knowledge about the feasibility and effectiveness of PBT to improve reactive balance control and reduce fall risk in this population can still be increased.[23 25] Currently, there is also very little evidence on the acceptability of PBT in fall-prone older adults. However, the acceptability of training approaches is crucial, as even highly effective interventions are likely to fail if they are not accepted and adopted by the target group. To our knowledge, only one qualitative study has so far specifically evaluated the acceptability of a three-session PBT in such a population.[35] Different PBT protocols have not yet been compared for acceptability in fall-prone older adults.

The primary aim of this study is to compare the effectiveness of a six-session (6PBT) versus two-session PBT (2PBT) delivered on a treadmill for improving reactive balance control immediately and 6 weeks after a 6-week intervention period in fall-prone older adults, in order to gain insights into the dose–response relationship of PBT. The main hypothesis of this study is that the 6PBT results in significantly higher improvements in reactive balance control compared with the 2PBT. Secondary aims are to investigate the feasibility and acceptability of the PBT protocols.

METHODS AND ANALYSIS

Study design and setting

The FEATURE study is designed as a monocentric, parallel-group, randomised, controlled pilot trial with a 6-week intervention and follow-up period and three measurement time points (T1=before intervention, T2=after the 6-week intervention, T3=6 weeks after the end of intervention). Thirty-six participants will be recruited from the local geriatric rehabilitation sports club (REGE e.V., total club members: n=150) associated with the Agaplesion Bethanien Hospital (Heidelberg, Germany) and randomly assigned (1:1 ratio) to either the 6PBT or 2PBT intervention group. The study was preregistered at the German Clinical Trials Register (DRKS00030805) on 14 December 2022. The study started with participant recruitment in January 2023, and data collection is expected to be completed in November 2023. This study protocol is reported in accordance with the Standard Protocol Items: Recommendations for Interventional Trials guidelines.[36] Figure 1 contains a flow chart to describe the study design.

Recruitment and study population

Potential participants are recruited through direct contact during the regularly scheduled training sessions at the REGE e.V. Study personnel explain the background, content, procedures, and aims of the study, provide written information, respond to any open questions, screen for eligibility, and obtain written informed consent. Inclusion criteria were age ≥65 years, increased risk of falling (Timed Up and Go (TUG) >12 s, habitual gait speed <1.0 m/s and/or fall(s) in past 12 months),[37–43] and ability to walk ≥2 min without walking aid. Exclusion

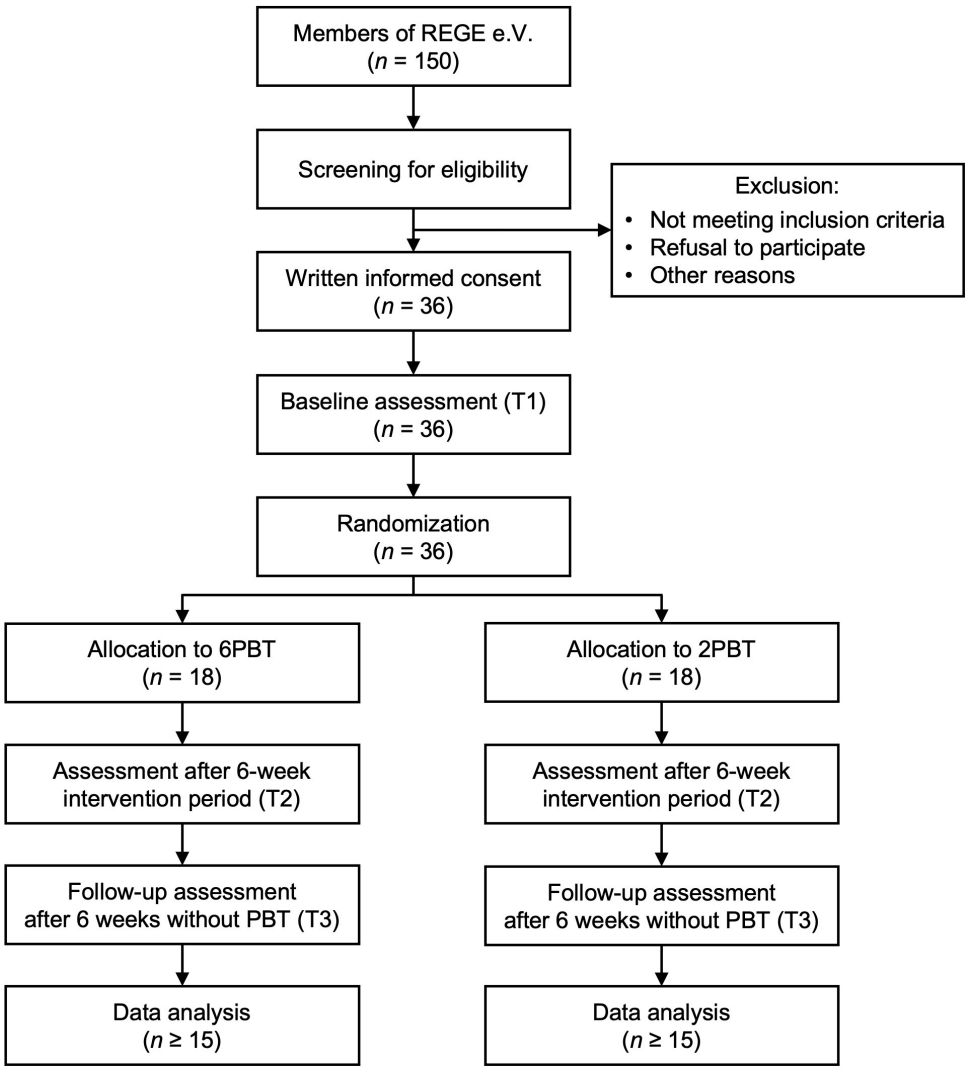

Figure 1 Flow chart of the recruitment, screening, allocation and assessment processes. REGE e.V., REhabilitation sports in GEriatrics; 6PBT, six-session perturbation-based balance training; 2PBT, two-session perturbation-based balance training (weeks 1+6) and four-session conventional treadmill training (weeks 2–5).

criteria are cognitive impairment (Mini-Mental State Examination <24 pt.)[44] or severe neurological, cardiovascular, metabolic or psychiatric disorders.

Randomisation and blinding

After the baseline assessment, participants will be randomly allocated to the 6PBT or 2PBT group using block randomisation with a 1:1 allocation ratio stratified by treadmill walking experience ('Do you exercise regularly on the treadmill during your REGE training session?' (yes vs no)) and habitual gait speed (≥1.0 m/s vs <1.0 m/s). Participants will be informed about the randomisation outcome by the study personnel at the phone call for scheduling the first training session. Outcome assessments will be conducted by assessors blinded to group allocation. Data that identify group allocation such as training adherence, number and maximum perturbation magnitude during PBT sessions, adverse events and dropout rates/reasons will be documented by the unblinded trainers.

Interventions

Both interventions (6PBT, 2PBT) are embedded in the participants' once-weekly, 90 min REGE training session, which consists of conventional strength, balance and functional exercises. Each PBT session lasts about 30 min and will be administered by an instructed trainer.

The 6PBT group will receive PBT once per week over the 6-week intervention period, while the 2PBT group will perform PBT only in weeks 1 and 6 with conventional treadmill training (cTT) in weeks 2–5.

All PBT sessions will be conducted on a perturbation treadmill (BalanceTutor, MediTouch, Netanya, Israel), which allows for anterior–posterior (AP) (acceleration or deceleration of the treadmill belt) or mediolateral (ML) (left or right displacement of the treadmill platform) perturbations with 30 different magnitudes that can be induced during standing or walking. Based on the centre of pressure (COP) data continuously recorded by the treadmill-integrated force plate, the initiation of

perturbations can be predefined to either the left or right leg swing phase under walking conditions. Participants are permanently secured by an overhead safety harness system to prevent a fall on the ground at any time.

In both intervention groups, the first PBT session will start with a 5 min treadmill walk at 50% of the habitual overground walking speed (measured as part of the 10 m gait analysis at T1) without any perturbations to familiarise participants with treadmill walking.[45] Then, the treadmill speed will gradually be increased and decreased to determine the individual upper and lower boundaries of comfortable walking speed for each participant. The average speed of these boundaries will be defined as the comfortable walking speed and be used in all PBT and cTT sessions over the entire intervention period.[46]

Perturbation magnitudes in the first PBT session will be selected according to the individual reactive balance control abilities measured by the Dynamic Stepping Threshold Test (DSTT) at T1. Initial perturbation magnitude for AP and ML perturbations, respectively, is chosen to be one level lower than that achieved at T1 (eg, T1: DSTT level 2 ≙magnitude 10 → PBT session 1: magnitude 5 ≙DSTT level 1), with the lowest perturbation magnitude of 3. Perturbation magnitudes will then successively be increased within the PBT session and over the intervention period (see below). Maximum applied magnitudes for AP and ML perturbations of each PBT session will be recorded and serve as a starting point in the subsequent PBT sessions. Detailed descriptions of the 6PBT and 2PBT are provided in the Template for Intervention Description and Replication (see online supplemental appendix 1).[47]

Protocol of the perturbation-based treadmill training

The PBT protocol was designed based on the recently published study protocol by Nørgaard *et al*.[46] Each PBT session lasts about 30 min including preparations (putting on/off harness system), warm-up, breaks and cool-down. Details of the training protocol of a PBT session is shown in table 1.

The warm-up consists of 3 min unperturbated walking on the treadmill, followed by five blocks of perturbated walking (8.5–14.5 min), 2 min recovery breaks after each perturbation block and a 3 min cool-down of unperturbated treadmill walking.

Each PBT session includes 5 blocks with 8 perturbations each (40 perturbations in total). Blocks 1 and 2 contain perturbations in AP direction, blocks 3 and 4 perturbations in ML direction, and block 5 perturbations in both AP and ML directions.

Time intervals between each perturbation are randomised and set in the BalanceTutor software to range from about 10 to 20 s (block 1+2), 15 to 25 s (block 3+4) or 10 to 25 s (block 5), considering the duration for automated detection of the specific gait swing phase for perturbation timing (max. duration ~3 s). The intervals in-between ML perturbations are longer because the return time of the treadmill platform to the initial position after these perturbations takes longer than the acceleration or deceleration of the treadmill belt (AP perturbations). Each AP and ML perturbation will be induced at the swing phase of the left and right leg, respectively, resulting in four different types of perturbations in both AP and ML directions (ie, eight different perturbations in total). In blocks 1–4, each of the following four types of perturbations are performed twice and in randomised order: (1) perturbation direction 1 (forward (AP) or left (ML))+perturbation initiation on left leg swing phase, (2) perturbation direction 1 (forward (AP) or left (ML))+perturbation initiation on right leg swing phase, (3) perturbation direction 2 (backward (AP) or right (ML))+perturbation initiation on left leg swing phase and (4) perturbation direction 2 (backward (AP) or right (ML))+perturbation initiation on right leg swing phase. In block 5, all eight types of perturbations are performed once in random order.

Within the 2 min break after each block, the trainer assesses the participants' self-perceived difficulty and anxiety on a 5-point Likert scale to specifically tailor the intensity of PBT to the individual participant (see

Table 1 Training protocol of a PBT session

Block		Perturbation				
No	Duration	Direction	Repetitions	Intensity*	Time interval†	Break
1	~1.5–2 min	AP (forward/backward)‡	8 (2×4 types)	2–3	10–20 s	2 min
2	~1.5–2 min	AP (forward/backward)‡	8 (2×4 types)	3–4	10–20 s	2 min
3	~2–3.5 min	ML (left/right)‡	8 (2×4/types)	2–3	15–25 s	2 min
4	~2–3.5 min	ML (left/right)‡	8 (2×4 types)	3–4	15–25 s	2 min
5	~1.5–3.5 min	AP (forward/backward)‡ ML (left/right)‡	8 (1×8 types)	3–4	10–25 s	2 min

*Intensity determined by the trainers according to the participants' self-perceived difficulty and anxiety on a 5-point Likert scale.
†Time interval between perturbations (randomised within given interval).
‡Direction of perturbations in randomised order.
AP, anterior–posterior; ML, mediolateral; PBT, perturbation-based balance training.

Table 2 Five-point Likert scale for self-perceived difficulty and anxiety to determine the intensity after a perturbation block with eight perturbations[48 49]

Item	Rating				
Difficulty	Easy (1)	Fairly easy (2)	Challenging (3)	Very challenging (4)	Too hard (5)
Anxiety	Not at all (1)	Just a little (2)	Mildly (3)	Moderately (4)	Extremely (5)

table 2).[48 49] The intensity of the blocks is chosen to be the average score of ratings for perceived difficulty and anxiety between 2 and 3 points (block 1+3) or 3 and 4 points (block 2, 4+5). Based on this rating score, perturbation magnitudes will be individually and successively adjusted over the five blocks of one training session as well as over the entire intervention period. Perturbation magnitudes will only be increased if the participant does not fall into the harness system during any of the perturbations in the previous block and if the participant agrees to it.[46]

The predefined six PBT protocols (session 1–6) are provided in online supplemental appendix 2, containing information about the five blocks à 8 perturbations and their direction, initiation timing and time interval (all randomised).

Conventional treadmill training

The cTT will be conducted on the medical treadmill pluto med (h/p/cosmos sports & medical gmbh, Nussdorf-Traunstein, Germany) regularly used in the REGE e.V. The cTT sessions last also about 30 min in total, divided into five blocks à 3 min each, and 2 min breaks between each block, matching the total duration spent on the treadmill by the 6PBT group. Participants are also secured during cTT by a harness system and supervised by instructed trainers.

Measurements

All primary and secondary outcomes, screening parameters, and descriptive variables and their measurement time points are listed in table 3. They include sociodemographics, physical characteristics, health status, treadmill experience, cognitive functioning, psychological status, reactive balance control, static and dynamic balance, physical capacity, feasibility and acceptability.

Primary outcomes

The primary outcome measure is the Stepping Threshold Test (STT),[50] which assesses reactive balance control while standing. In the STT, the participant stands on the perturbation treadmill with closed feet, instructed to react to unannounced surface perturbations (forward, backward, left, right) with as few compensatory steps as possible. The test consists of six levels with increasing perturbation magnitudes where each level contains four unannounced perturbations, one in each direction and in random order. Intervals between perturbations are also randomised and range from 10 to 19.5 s.[50] Reactive balance control is assessed by determining the single-step and multiple-step thresholds for each perturbation direction, which are defined as the levels at which a participant requires one step or multiple steps (≥2) to regain balance.[50] If a stepping threshold is not reached, the threshold value is set one level above the highest executed level. All levels of the eight single-step and multiple-step thresholds (2 thresholds×4 directions) will be summed to an STT total score, ranging from 8 to 56 points, with higher scores indicating better reactive balance control.[50] For familiarisation with the perturbation treadmill, participants will walk 6 min on the treadmill with 50% of their habitual overground walking speed (assessed as part of the 10 m gait analysis at T1) prior to the STT.[45] Only one AP (forward) and one ML (right) perturbation with a very low magnitude (3) will be induced while standing during this familiarisation phase.[50 51]

A modified STT while walking (DSTT) will be used as the second primary outcome measure to assess reactive balance control. Participants will walk on the perturbation treadmill with 70% of their habitual overground walking speed (assessed within the 10 m gait analysis at T1) and receive unannounced perturbations in different directions. The test protocol is oriented on that of the STT and includes five levels with perturbation magnitudes increasing in steps of 5 (level 1: perturbation magnitude=5 → level 5=perturbation magnitude 25).[50] Each level contains the eight different perturbations described above (4 directions×2 swing phases), which are performed once per level in random order and with random time intervals in-between. Time intervals are set between 7 and 16 s, such that the actual interval including the automatic swing phase detection ranges from about 10 to 19.5 s as in the STT. Detailed information on the DSTT protocol is provided in online supplemental appendix 3. In total, participants complete a maximum of 40 perturbations with the instruction to respond to unannounced perturbations and return to normal walking as fast as possible. The DSTT (and the STT) is stopped immediately in case of a fall or excessive anxiety of the participant, which prevents increasing the perturbation magnitude. For each of the five levels, a subscore is calculated as follows: level number×number of successfully completed perturbation (eg, level 2×4 perturbations=8 pt.). Each level subscore is summed up to yield a DSTT total score ranging from 0 to 120 points.

Both the STT and DSTT on the treadmill are recorded by two cameras (HERO9 Black, GoPro, San Mateo, California, USA) positioned at about 35° frontolateral to the participant and recording at a frame rate of 60 Hz. For STT scoring based on the single-step and multiple-step thresholds, two blinded assessors will subsequently

Table 3 Overview of screening instruments, and descriptive measures, and outcome measures over the course of the study

		SC	T1	INT	T2	T3
	Sociodemographics					
SP, DV	Age, gender	X				
DV	Marital status, years of education		X			
	Physical characteristics					
DV	Height, weight, body mass index, handedness		X			
	Medical information					
DV	Chronic diseases		X			
SP, DV	Self-reported falls in the past 12 months	X				
	Health status					
DV	EQ-5D Visual Analogue Scale[77]		X			
DV	Frailty phenotype (weight loss, exhaustion, physical activity (Minnesota Leisure Time Activities Questionnaire), slow gait speed, muscle weakness)[78]		X			
	Treadmill experience					
DV	'Do you walk regularly on the treadmill during the REGE training?'		X			
	Cognitive functioning					
SP, DV	Global cognitive status: Mini-Mental State Examination[44]	X				
SO	Executive functions: Trail Making Test A+B[61]		X		X	X
	Psychological status					
DV	5-Item Geriatric Depression Scale[79]		X			
DV	Exhaustion 'Do you feel full of energy?' (single question of the Geriatric Depression Scale)[80]		X			
SO	Concerns with falling: Short Falls Efficacy Scale-International[60]		X		X	X
SO	5-point Likert scale (difficulty: 1='easy' to 5='too hard'; anxiety: 1='not at all' to 5='extremely')[48 49]		X	X	X	X
	Reactive balance control					
PO	Stepping Threshold Test[50]		X		X	X
PO	Dynamic Stepping Threshold Test		X		X	X
SO	Spatio-temporal, kinematic and stability parameters while (Dynamic) Stepping Threshold Test and perturbation-based balance training (video-based motion capture, IMU and COP data)		X	X	X	X
SO	Maximum perturbation magnitude			X		
	Static+dynamic balance					
SO	Four-Square Step Test[55]		X		X	X

Continued

Table 3 Continued

		SC	T1	INT	T2	T3
SO	Brief Balance Evaluation Systems Test[54]		X		X	X
	Physical capacity					
SO	Instrumented 10 m gait analysis (Mobility Lab)[56]		X		X	X
SO	2 min Walk Test[57]		X		X	X
SO	Short Physical Performance Battery[58]		X		X	X
SP, SO	Timed Up and Go[59]	X			X	X
SP	Walking ability without walking aid ≥2 min	X				
DV	Handgrip strength (Jamar dynamometer)*		X			
	Physical activity					
SO	Sensor-based physical activity (eg, body postures,(in-)active states, walking activity) for 5 days (ActiGraph GT9X Link)		X		X	X
	Feasibility					
SO	Training adherence, drop-out rate/reason during intervention period, number of perturbations, adverse events/reactions			X		
	Acceptability					
SO	Self-designed questionnaire based on theoretical framework of acceptability[62]				X	
SO	Focus groups with (A) participants and (B) trainers				X	

*As part of the assessment of the Fried frailty phenotype.
COP, centre of pressure; DV, descriptive variable; EQ-5D, European Quality of Life-5 Dimensions; IMU, inertial measurement unit; PO, primary outcome; REGE, REhabilitation sports in GEriatrics; SC, screening; SO, secondary outcome; SP, screening parameter; T1, before intervention; T2, after 6 week intervention; T3, 6 weeks after intervention end.

review the videos in slow motion afterwards and indicate the number of compensatory steps to regain balance (no step, single step or multiple steps).[50 52]

Secondary outcomes

Spatio-temporal and kinematic parameters (eg, stride length and duration, step width; saggital ankle, hip and knee angle, and centre-of-mass movements) as well as dynamic stability (margin of stability) will be collected while standing and walking on the treadmill, both under perturbated (STT, DSTT) and unperturbated (for comparison) conditions. These variables will be extracted from GoPro video recordings using markerless motion capture software (eg, Free Motion Capture Project (FreeMoCap)),[53] two synchronised inertial measurement units (IMUs) (3DTutor, MediTouch, Netanya, Israel) worn on the left and right ankle, and the COP data collected by the treadmill-integrated force plate. IMU and COP data will also be collected during each PBT session, as will the maximum perturbation magnitude successfully completed by participants. This documentation allows an evaluation of the adaptation processes of the reactive stepping responses within each single session and over the entire intervention period (dose–response relationship).

Dynamic and static balance will be assessed by the Brief Balance Evaluation Systems Test and Four-Square Step Test.[54 55]

Physical capacity will be measured via an instrumented 10 m gait analysis (Mobility Lab, APDM, Portland, Oregon, USA)[56] and the 2 min Walk Test,[57] Short Physical Performance Battery[58] and TUG.[59]

Physical activity will be recorded over 5 days using a wrist-worn, small (35×35×10 mm), lightweight (14 g), waterproof activity sensor (GT9X Link, ActiGraph Corp, Pensacola, Florida, USA).

Concerns with falling will be assessed by the short version of the Falls Efficacy Scale-International.[60] Participants' self-perceived difficulty and anxiety on the perturbation treadmill will be recorded directly after completing the STT and DSTT.[48 49]

Executive functions will be tested using the Trail Making Test (parts A+B).[61]

Feasibility of the PBT will be assessed via the adherence rate to the scheduled PBT sessions, drop-out rate/reasons during the intervention period, number of perturbations actually performed and adverse events/reactions during PBT sessions and the study period.

Acceptability of the PBT will be evaluated after the end of the intervention period (T2) using a self-designed questionnaire (see online supplemental appendix 4). This questionnaire is guided by the theoretical framework of acceptability (TFA) of Sekhon *et al*,[62] in which acceptability is considered to be a multifaceted construct consisting of seven dimensions: (1) affective attitude, (2) burden, (3) ethicality, (4) intervention coherence, (5) opportunity cost, (6) perceived effectiveness and (7) self-efficacy. For each of these dimensions, the questionnaire contains one item rated on a 5-point Likert scale (1='strongly disagree' to 5='strongly agree'). The ratings of the individual items are summed up to a total score ranging from 7 (=lowest acceptability) to 35 points (highest acceptability). In addition, a qualitative assessment of acceptability of the PBT will also be conducted through focus group interviews with (A) 4–6 participants of each intervention group and (B) all trainers at T2. Trained facilitators will guide semi-structered interviews, also based on the TFA and audiorecorded with consent. Audiorecordings will be transcribed verbatim and analysed using MAXQDA software, V.2020 (VERBI Software, Berlin, Germany).

Safety and harms

Participants will permanently wear a harness system fixed to a safety bar during the STT, DSTT and PBT sessions to protect them from falling. The length of the harness lanyard will be adjusted with a 15 cm distance between the participant's knees and the floor. A safety check will be conducted with a full body relief into the harness system before each session. Training intensity and perturbation magnitudes will be individually adjusted to the participants' abilities and self-perceived difficulty and anxiety. Participant will be encouraged to report all adverse events and reactions throughout the study by being asked about them at the study visits.

Sample size

Sample size was calculated based on recommendations for pilot RCTs.[63] Assuming a moderate effect size (0.5) for the differences between the two groups, with a statistical power (1–β) of 0.90 and a two-sided significance level (α) of 0.05, a sample size of 15 participants per group are recommended.[63] Based on previous RCTs conducted by the research group in the same setting (REGE e.V.) and with a comparable study population,[64 65] an expected dropout rate of 15% increased the sample size per group to n=18 (total: n=36).

Data collection and management

Data collection will be done by assessors that received extensive training in all aspects of the measurements to ensure the highest possible standardisation and data quality. Paper documents will be collected in a study file archiving and supervised by the principal study investigator. All electronic devices used to collect and/or extract data (eg, Mobility Lab, BalanceTutor, project computers) are password protected, with access to study data restricted to participating study personnel. Audiorecordings of the focus group interviews will be deleted after transcription verification, and participant-identifiable information will be removed from digital transcript files. All data collected is entered into a digital dataset in pseudonomised form directly after the assessments. The final dataset will be password protected and accessible only to the study personnel directly involved in the data analysis.

Statistical analysis

Descriptive data will be presented as means and standard deviations, medians and interquartile ranges, or numbers and percentages. Group differences (6PBT vs 2PBT) in baseline variables, feasibility and acceptability will be analysed by using χ^2 tests or Fisher's exact tests, Mann-Whitney U tests, or *t*-tests for independent samples. Two-way (group×time) repeated-measures analyses of variance will be used to analyse differences between intervention groups over time. In case of between-group differences at baseline, analyses of covariance will be conducted with the relevant baseline variables taken into account as covariates. All main analyses will be conducted according to intention-to-treat principle, with all participants randomised after baseline assessment, and regardless of subsequent training adherence. Participants who withdrew or dropped out are requested to participate in follow-up assessments. If more than 5% of the data is missing, multiple imputation will be performed using multivariate imputation by chained equations with predictive mean matching as an imputation method, assuming that data is missing at random. Complete-case analyses will also be conducted to investigate the robustness of the findings. Statistical significance will be set at $p<0.05$. IBM SPSS V.29.0 will be used for statistical analysis (IBM).

Patient and public involvement

Participants or the public were not involved in the design, nor will they be involved in the conduct, reporting or dissemination plans of this research. Different dimensions of participants' acceptability of the PBT (affective attitude, burden, ethicality, coherence of the intervention, opportunity cost, perceived effectiveness, self-efficacy) will be assessed via questionnaire and in focus group interviews after the intervention period.

Ethics and dissemination

The study protocol has been approved by the Ethics Committee of the Medical Faculty Heidelberg (approval # S-602/2022). All procedures in this study involving human participants are in accordance with the 1964 Declaration of Helsinki and its later amendments. Written informed consent for study participation is obtained from all participants prior to study inclusion, and separate written informed content will be obtained for participation in and audio recording of the focus group interviews from participants and trainers. Findings will be disseminated through publications in peer-reviewed journals and presentations at scientific conferences.

DISCUSSION

Falls and their negative consequences present a significant burden to the public healthcare system. The inability to recover balance after slips or trips during walking is the most common mechanism of falls in daily life.[66 67] PBT seems to be a promising, task-specific and efficient intervention approach to improve this reactive balance ability. As such, emerging evidence indicates its effectiveness also in older adults with increased risk of falling.[30–34] However, there is an urgent need for studies evaluating dose-response relationship, feasibility and acceptability in this population.[23 35] This pilot study is intended to help fill this research gap and provide more knowledge for clinical recommendations of PBT.

Technologies that enable the application of unpredictable mechanical disturbances of different magnitude, direction and/or type under safe and controlled conditions have been recommended as optimal for training reactive balance control.[23] In line with these recommendations, we integrate the BalanceTutor to deliver PBT, allowing for unannounced perturbations of a wide range of magnitudes (1–30), in four different directions (forward, backward, left, right), and at different initiation timings (left+right leg swing phase), while participants are permanently secured with an overhead safety harness.

PBT is a highly challenging intervention method that pushes participants to the limits of stability and can be associated with more anxiety than traditional exercises.[68 69] Anxiety can negatively affect reactive balance control and cause high drop-out rates.[70–72] Hence, it should be minimised to achieve better training outcomes and prevent dropouts.[23] We will use a rating scale to continuously monitor participants' level of difficulty and anxiety after each block of an PBT session and to individually adjust the perturbation magnitude to participants so that the PBT is still perceived as challenging but not overwhelming or too anxious. To our knowledge, this is the first study to use participants' self-perceived difficulty and anxiety levels for training progression of PBT in fall-prone older adults.

Previous studies on PBT investigated different training dosages, ranging from single to multiple PBT sessions (for review, see McCrum *et al*[23]). The optimal dosage for improving reactive balance control and reducing fall risk remains, however, still to be determined. Our findings will provide useful insights into the dose–response relationship of PBT by (1) comparing the effectiveness and short-term retention of two specific training protocols (6PBT vs 2PBT) and (2) continously monitoring reactive balance control based on the spatiotemporal, kinematic and dynamic stability parameters and maximum perturbation magnitudes documented from each training session. This provides insight into potential differences of two PBT with distinct training doses regarding the adaptations over the intervention period and those for retention, and may allow us to identify a potential plateau in the specific effects of PBT on reactive balance control.

To date, there is still very little knowledge about the acceptability of PBT in older adults with increased risk of falling, with only one qualitative study showing that a three-session PBT is acceptable in older adults with a history of falls.[35] The use of our acceptability questionnaire and the conduct of the focus groups, both guided by the TFA[62] allow the quantitative and qualitative assessment of multiple facets to the acceptability of the PBT

and extend current knowledge for PBT protocols with different training doses.

Reactive balance is still under-represented in the clinical assessment of older adults, despite its importance in the aetiology of falls. Individual tools such as the Brief Balance Evaluation Systems Test[54] or the Performance-Oriented Mobility Assessment[73] only contain a few items on reactive balance and do not specifically address motor responses on unexpected loss of balance. We thus defined the recently developed and validated STT as a primary outcome measure, which is not yet widely established but may represent a potential step towards a more specific tool for clinical assessment of reactive balance responses to unexpected postural disturbances.[50] As the STT measures reactive balance while standing and there is currently no validated clinical tool to assess reactive balance while walking and thus the task-specific effects of our PBT, the DSTT was designed as a modified version of the STT, but ist psychometric properties are not yet known. There is still a great need for the development and validation of easy-to-implement tools to assess such dynamic reactive balance responses in the clinical context.

Potential transfer effects of the PBT will be investigated for a number of secondary outcomes (eg, dynamic/static balance, concerns with falling, physical activity). Given the high task specificity of PBT for reactive balance control, it is assumed that the potential benefit to balance ability will decrease for less dynamic or static balance tasks.[74 75] A potential transfer effect on concerns with falling might be obtained by participants recognising their improved ability to successfully manage fall-critical situations. In turn, this higher self-efficacy could also lead to a reduction in activity avoidance and an increase in physical activity in everyday life.[76]

This pilot study is limited in that trainers and participants are not blinded to the group allocation due to the nature of the study. Another limitation is that the effectiveness of PBT in reducing real-life falls will not be evaluated. However, our findings may inform future large-scale RCT that is sufficiently powered to examine such fall-related outcomes. The study is also not designed to examine the impact of different perturbation directions, but may show how perturbation magnitudes and associated self-perceived difficulty and anxiety will progress across different perturbation directions. Further, a self-designed, non-validated questionnaire is used to assess the participants' acceptance of the PBT. However, the design of the questionnaire items was based on an established, multiconstruct TFA of healthcare interventions.[62]

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