Specific Training According to BaLance Evaluation (STABLE) Versus the Otago Exercise Program for Older Adults with Impaired Balance in Cross-sectoral Rehabilitation. A Double-blind Randomized Controlled Trial

Background

Falls among older adults are a major cross-sectoral challenge in healthcare (1-3). One in three adults over 65 falls at least once a year, and one third of these contact the healthcare system because of the fall (1, 4-10). In Denmark, the number of hip fractures after falls rose to nearly 7,500 in 2024 (11-13). Personal consequences include pain, fear of future falls and a sense of helplessness (14). Even without injury, a fall may lead to restriction of social and physical activity (15-17), which can cause functional decline, further falls and greater need for healthcare (18-21). The evidence for single falls-prevention interventions is weak, mainly because trials are unblinded and follow-up is short (10, 22).

Major risk factors for falls are neuropathy, neurological disease, cognitive impairment, medication side effects, gait abnormality and dizziness (23). Impaired balance increases the risk of falling by about 40% (24). There is strong evidence that balance training improves muscle strength and balance and reduces the total number of falls by more than 30% among community-dwelling older adults, but existing approaches have shown only small reductions in the number of older people who fall (25-29).

In Denmark, patients at risk of falling are assessed and rehabilitated through group training or individually supervised self-training in cross-sectoral pathways between hospital falls clinics and municipal rehabilitation units. Group training can improve balance (30, 31), and participants gain confidence in their balance (32). However, group exercises are not designed for independent practice and can therefore not be anchored in daily routines, so function may decline and fall risk may return after the group program ends (10).

Home-based self-training is more cost-effective than group training (33, 34), supports self-management (35-37) and provides tools for maintaining improvements after supervised training ends. The Otago Exercise Program (OEP) is the most established home-based falls-prevention program worldwide (38-41). Earlier studies showed that OEP improves strength and balance (42, 43), reduces fear of falling (44) and reduces the total number of falls by 35-42% among community-dwelling older adults (45, 46). However, OEP is only partly tailored to the individual, and recent studies have shown limited effects on balance and falls (47, 48). Patients with dizziness and impaired balance due to vestibular dysfunction are treated with vestibular rehabilitation (49-51), in which gaze stabilization exercises (GSE) are the central component (52-54). OEP supplemented with GSE can therefore be regarded as the current reference standard for standardized home-based balance training.

Specific Training According to BaLance Evaluation (STABLE) is a new approach to assessment and rehabilitation of balance, developed in collaboration between the participating clinics and municipal rehabilitation units. It

is centered on five simple clinical tests, each measuring a specific domain of balance (limits of stability, sensory orientation, reactive stepping, power and turning). Based on a patient-specific balance profile from the five test scores, the patient's goals and overall health condition, the clinician designs a home program of a few exercises, typically targeting the primary functional limitations at a suitable level of difficulty (55, 56). STABLE is described further at https://godbalance.dk/.

Clinically, patients appear motivated by the focused approach of STABLE and both want and adhere to home exercise to a much greater degree. In observational studies, the five STABLE tests were reliable and valid (56), and 40% fewer patients fell within six months after rehabilitation with STABLE (57). But because these findings come from a small cohort without a control group, it is unknown whether STABLE is more effective than the current standard of balance rehabilitation and should be preferred in cross-sectoral rehabilitation of older adults with impaired balance.

Objectives and hypotheses

Primary objective

To compare the effect of STABLE with OEP (supplemented with GSE in vestibular dysfunction) on falls in older adults with impaired balance in cross-sectoral rehabilitation.

Secondary objectives

To compare the two approaches on injurious falls, hospital admissions, mortality, balance, gait, patient-reported outcomes and adverse effects, and to explore patients' and physical therapists' experiences of using the two approaches in the cross-sectoral pathway.

Hypothesis

Participants instructed in STABLE achieve a greater effect than participants instructed in OEP with GSE on falls, quality of life, hospital contacts and mortality in the six months after the intervention, and on balance and mobility at the end of the intervention.

Design and setting

Double-blind (participant and outcome assessor), two-arm, parallel-group, superiority randomized controlled trial with 1:1 allocation, with embedded qualitative studies of participants' and physical therapists' experiences. The trial is conducted at the falls and balance clinics of Herlev and Gentofte Hospital (HGH) and Rigshospitalet (RH), with follow-up in the hospitals or in the municipal rehabilitation centers of Rødovre, Herlev and Egedal. The flow of participants is shown in Figure 1.

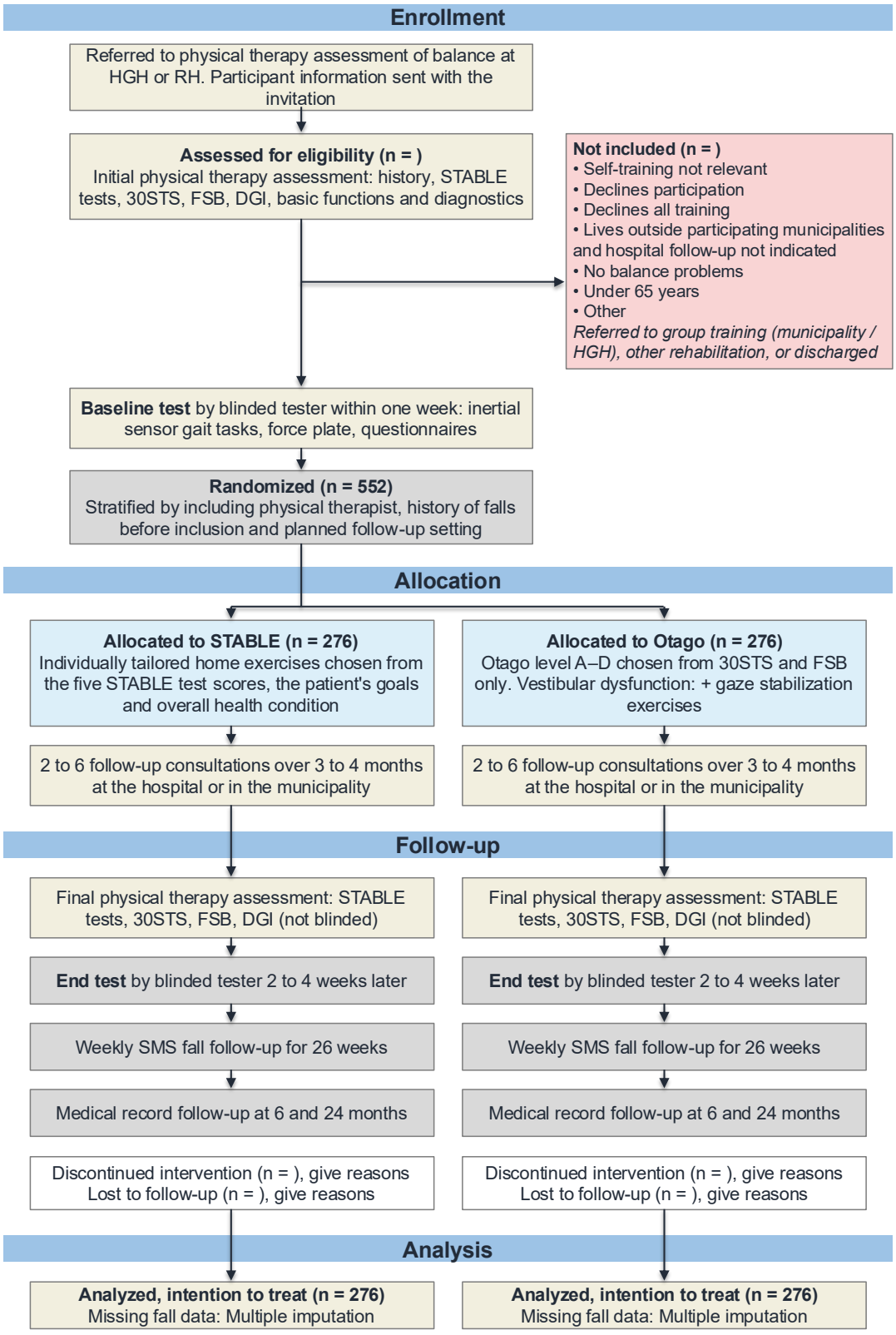


Figure 1. flow of participants

Participants and recruitment

Patients referred consecutively to physical therapy assessment at one of the participating clinics receive written participant information with the invitation (unless they have opted out of research invitations). Patients meeting the eligibility criteria at the physical therapy assessment are offered participation and give written informed consent.

Inclusion criteria	• Aged 65 years or older • Impaired balance • Judged able to carry out home-based self-training • Lives in a participating municipality (Rødovre, Herlev or Egedal), or the physical therapist judges that rehabilitation is best carried out with follow-up at the hospital
Exclusion criteria	• Significant cognitive or language limitations • Declines rehabilitation or participation

All referred patients are assessed with the five STABLE tests, 30-second chair stand test, 4-Stage Balance Test and the Dynamic Gait Index, basic mobility functions and relevant diagnostic assessments. The reason for non-inclusion (e.g. self-training not relevant, declines participation, declines all training, municipality not participating and hospital follow-up not indicated, no balance problems, under 65 years, assessing physical therapist is the blinded tester, referred for group-based vestibular rehabilitation, other) and the alternative referral are recorded to describe the screened population in the CONSORT flow diagram. Patients from non-participating municipalities are included when the physical therapist judges that rehabilitation is best carried out by follow-up physical therapy consultations at the hospital. Otherwise, they are referred to non-specific municipal rehabilitation and are not included.

Baseline assessment, randomization and allocation concealment

The baseline test is performed within one week after the physical therapy assessment and lasts about one hour. Gait is evaluated with an inertial sensor (Cometa WaveTrack) placed on the lower back. Standing balance, sit-to-stand power and forward reach are measured on a force plate (AMTI AccuSway). Standardized questionnaires are completed by interview. The date and time of the baseline and end tests are recorded.

After the baseline test, participants are randomized 1:1 to STABLE or OEP. Randomization is stratified by (1) the including physical therapist who performed the initial assessment and starts the training, (2) history of falls before inclusion (yes/no) and (3) planned follow-up setting (hospital or municipality). The planned follow-up setting is a stratification factor because physical therapists at the hospital are generally more experienced with the STABLE approach than those in the municipalities. Within each stratum, allocation follows randomly permuted blocks of 4 and 6. The allocation table was generated in R by an unblinded colleague using a secret seed and uploaded to REDCap. The seed and table are stored inaccessibly to blinded staff.

Randomization is performed automatically in REDCap when the physical therapy assessment form is saved with confirmed inclusion and all stratification variables completed, so no blinded person handles the randomization. REDCap then sends the allocation by e-mail to the including physical therapist. The allocation field is on a separate REDCap instrument to which blinded users have no access.

Blinding

Participants are informed only that two types of balance training are compared and are therefore blind to which effect is expected in their group. Baseline and end tests (inertial sensor, force plate and questionnaires) are performed by a tester who is blinded to allocation. Participants are asked not to mention their training type at the end test, and any accidental unblinding of the tester is recorded with date. If a tester has included a participant (and therefore knows the allocation), the participant's end test is performed by another blinded tester. The scores of the STABLE tests, 30-second chair stand test, 4-Stage Balance Test, the Dynamic Gait Index and basic mobility functions at the final physical therapy assessment are collected by the treating physical therapist who cannot be blinded. Data analysis is performed blinded to allocation (groups coded) until the primary analysis is completed.

Interventions

At the physical therapy consultation following inclusion, exercises are instructed according to allocation:

- **STABLE:** exercises are selected and instructed based on the five STABLE test scores, the patient's goals and overall health condition.
- **OEP:** the participant is instructed at the OEP level judged relevant from the 30-second chair stand test and the 4-Stage Balance Test. Participants with vestibular dysfunction are additionally instructed in gaze stabilization exercises.

Regardless of group, participants are offered 2 to 6 follow-up physical therapy consultations over 3 to 4 months, in which exercises are adjusted. At the final physical therapy assessment, the test procedure from the initial physical therapy assessment is repeated (STABLE tests, 30-second chair stand test, 4-Stage Balance Test, Dynamic Gait Index, basic mobility functions), and the number of follow-up consultations, exercise focus, weekly exercise frequency and duration, and adherence are recorded.

Participants included at RH receive all follow-up consultations at the hospital. Participants living in a participating municipality are instructed at the hospital in exercises according to allocation and followed up in their municipal rehabilitation center, where the final physical therapy assessment is also performed. The participant's rehabilitation plan and secure e-mail are used to exchange study data between hospital and municipality.

End test and follow-up

Two to four weeks after the final physical therapy assessment (at the hospital or in the municipality), the end test is performed with the same procedures as the baseline test by a blinded tester.

For 26 weeks after the end test, participants receive an automatic weekly SMS with a short questionnaire: "Have you fallen since you last answered this questionnaire?", the number of falls (1 to 10, or more than 10), the reason for the fall (including loss of consciousness), circumstances, injury (including fracture), whether they were examined, and hospital admission. A test SMS is sent at the end test to check that the participant can open the questionnaire, but it is not part of the outcome. Participants who stop answering the questionnaire for more than three consecutive weeks are flagged by an alert in REDCap and then contacted by the principal investigator.

Participants who cannot receive SMS themselves use, in order of priority: (1) SMS to a relative's mobile phone with the relative's consent, or (2) a paper version of the questionnaire, on which falls are recorded with the date, returned in a prepaid envelope after 6 months, combined with a telephone call at 6 months. The method is recorded for each participant.

Six months and again two years after the end test, the number of hospital admissions (all-cause and fall-related), diagnoses, rehabilitation courses and vital status with date of death are recorded from the medical records of all participants, together with the date of the record review.

Dropout. If a participant withdraws from the intervention or the end test, the date and reason are recorded (cannot or no longer wants training, wants the other allocation, worsening of existing or new problems, transport problems, moved, logistical error, declines test, cannot be contacted, death, or other reason). Participants who stop answering the SMS questionnaire are identified from the SMS data. Medical record follow-up continues for all randomized participants unless consent is withdrawn.

Outcomes

Time points: Baseline = test within one week after the initial physical therapy assessment. End of treatment (EoT) = end test 2 to 4 weeks after the final physical therapy assessment, approximately 3 to 5 months after baseline. Fall follow-up runs weekly for 26 weeks after EoT.

Primary outcome

Title	Description	Time frame
Proportion of participants who fall at least once	A fall is defined as an unexpected event in which the participant comes to rest on the ground, floor or lower level, regardless of cause or consequence. Recorded with a weekly SMS questionnaire ("Have you fallen since you last answered this questionnaire?"). Each answer covers all weeks from the previous answer. A fall-related hospital admission in the medical record also counts as a fall. Participants are classified as non-fallers only if all answers are "no", week 26 is answered and no fall-related admission is recorded. Others with incomplete data are imputed. The test SMS sent at the end-of-treatment test does not count. Participants who cannot receive SMS report falls via a relative's phone, or via a paper fall diary returned by post supplemented by a telephone call at 6 months.	Weekly for 26 weeks after the end-of-treatment test

Secondary outcomes

Title	Description	Time frame
Number of falls	Total number of falls reported in the weekly SMS (1 to 10, or more than 10, per answer), at least the number of fall-related admissions in the medical record, analyzed as a rate per week covered.	26 weeks after the end-of-treatment test
Number of falls with loss of consciousness	Self-reported in the weekly SMS questionnaire (reason for falling).	26 weeks after the end-of-treatment test
Number of falls with fracture	Self-reported in the weekly SMS questionnaire.	26 weeks after the end-of-treatment test
Hospital admissions	Number of all-cause and fall-related hospital admissions, from medical records.	6 and 24 months after the end-of-treatment test
Mortality	Vital status and date of death, from medical records.	6 and 24 months after the end-of-treatment test
Rehabilitation courses	Number of subsequent rehabilitation courses, from medical records.	6 and 24 months after the end-of-treatment test
Gait performance and movement quality	Seven walking tasks measured with an inertial sensor (Cometa WaveTrack) on the lower back: Timed Up and Go, 3-meter walk, line walking, foam walking with eyes open and closed, figure-of-eight walk and walking over an obstacle. Outcomes: task duration (s), log dimensionless jerk (LDLJ-A), spectral arc length (SPARC), root mean square acceleration (anteroposterior, mediolateral, vertical) and turning velocity. Fastest trial of two per task.	Baseline and end of treatment
Postural sway	Modified Clinical Test of Sensory Interaction on Balance (firm and foam surface, eyes open and closed, 40 s each) on a force plate (AMTI AccuSway). Centre of pressure (COP) sway measures (e.g. RMS, velocity, sway area) from the middle 30 s, and loss of balance.	Baseline and end of treatment
Sit-to-stand power	Peak power during a fast sit-to-stand on the force plate (body weight × vertical displacement / time). Best of 2 trials.	Baseline and end of treatment
Forward reach (limits of stability)	Maximal anterior COP displacement during forward reach on the force plate, expressed as a percentage of the distance from the posterior edge of the medial malleolus to the tip of the big toe. Best of 2 trials.	Baseline and end of treatment
STABLE test scores	Scores on the five STABLE tests (Mreach, TRIB, RFSST, ASTS, TAT). Not blinded at the final physical therapy assessment. Assessment not blinded.	Initial physical therapy assessment and final physical therapy assessment

Dynamic Gait Index (DGI)	Score 0 to 24, higher is better. Not blinded at the final physical therapy assessment. Assessment not blinded.	Initial physical therapy assessment and final physical therapy assessment
4-Stage Balance Test (FSB)	Score 0 to 40, higher is better. Not blinded at the final physical therapy assessment. Assessment not blinded.	Initial physical therapy assessment and final physical therapy assessment
30-second chair stand test (30STS)	Score 0 and above, higher is better. Not blinded at the final physical therapy assessment. Assessment not blinded.	Initial physical therapy assessment and final physical therapy assessment
Fear of falling	Falls Efficacy Scale-International (FES-I), 16 to 64, higher is more concern.	Baseline and end of treatment
Dizziness handicap	Dizziness Handicap Inventory (DHI), 0 to 100, higher is more handicap.	Baseline and end of treatment
Physical activity	Physical Activity Scale for the Elderly (PASE).	Baseline and end of treatment
Health-related quality of life	EQ-5D-5L index and EQ VAS.	Baseline and end of treatment
Patient-reported global change and tailoring	Perceived overall change in balance and/or dizziness, perceived tailoring of home exercises and continuity between assessment and exercises (5-point scales).	End of treatment

Other pre-specified outcomes

Title	Description	Time frame
Adverse effects during exercise	Frequency, intensity and duration of pain and dizziness during home exercise, falls during exercise, and worsening or new health problems during the training period	End of treatment
Exercise adherence	Self-reported adherence to home exercise (4-point scale), number of exercise sessions per week and duration.	Final physical therapy assessment
Physical therapists' use of test results	Questions answered by the municipal physical therapist at the final assessment of each participant: "Did you use the test results to select or adjust exercises?" (5-point Likert scale).	Final physical therapy assessment

Statistical methods

Fall classification

Only SMS weeks 1 to 26 count. Each answer covers all weeks from the previous answer, so the number of weeks covered equals the last week answered. A participant is classified as a faller if at least one SMS answer is "yes" or the medical record shows at least one fall-related admission within 6 months (the medical record overrules SMS). A participant is a non-faller if all answers are "no", week 26 is answered and there is no fall-related admission. All other participants (missing answers at the end, dropout, death) have unknown status and are handled by multiple imputation, with the number of fall-free weeks covered as a predictor.

Primary analysis

Intention-to-treat analysis with multiple imputation. Logistic regression with allocation group, the stratification factors including physical therapist and history of falls before inclusion, sex and rehabilitation location (five sites: two hospitals and three municipalities) as fixed effects. The third stratification factor, planned follow-up setting (hospital or municipality), is accounted for by rehabilitation location, because each location is either a hospital or a municipality, and it is therefore not entered as a separate term. Results are reported as odds ratio (OR), absolute risk reduction (ARR) and number needed to treat (NNT = 1/ARR) with 95% confidence intervals.

Missing fall status is assumed missing at random and imputed by multiple imputation by chained equations (50 imputed datasets) using logistic regression, including allocation group, all covariates of the primary model, the number of fall-free weeks covered, fall-reporting method and baseline balance; results are combined using Rubin’s rules.

Secondary analysis

Count outcomes: Poisson or negative binomial regression with the number of weeks covered as offset, reported as incidence rate ratio (IRR). Continuous outcomes: Linear regression adjusted for the baseline value, reported as mean difference and effect size (Cohen's d). Time to first fall: Kaplan-Meier curves and Cox proportional hazards regression, reported as hazard ratio (HR). Time is counted in weeks from the end-of-treatment test, or the planned date if the test is not performed, and participants without a fall are censored at the last week covered or at week 26. The same covariates as in the primary analysis are used. Normality is assessed on residuals.

Baseline characteristics are presented by group with standardized mean differences (SMD) instead of p-values, and $|SMD| \geq 0.1$ is flagged.

Sensitivity analyses

Include the primary model with an added random intercept for treating physical therapist, to account for variation between municipal physical therapists within the same location (for participants followed up at the hospital, the treating physical therapist is already accounted for as the including physical therapist), analyses of SMS-reported falls only, complete cases only and by fall-reporting method (own SMS, relative's SMS or paper), best-/worst-case analyses (all participants with unknown status classified as fallers in one group and non-fallers in the other, and vice versa) and a tipping-point analysis in which the imputed fall probability is shifted by a range of values separately in each group to identify the departure from missing at random that

would change the conclusion, and subgroup analyses by adherence, comorbidity, previous falls, baseline balance, medication (FRIDs) and cognition.

Per-protocol analysis

All primary and secondary outcomes are also analyzed in a per-protocol population, using the same models, covariates and multiple imputation procedure as in the intention-to-treat analysis. The per-protocol population includes participants who carried out the allocated home exercise program as instructed, defined as exercise adherence at the end test of “did all exercises as instructed” or “did some exercises as instructed”. Participants are excluded if they discontinued the intervention, including participants who after randomization were judged by the physical therapist to be unable to carry out the home exercise program, did other exercises than instructed or did no exercises, or received the exercise program of the other allocation. The number of excluded participants and the reasons are reported by group. Because the per-protocol population is not protected by randomization, this analysis is supplementary, and conclusions are based on the intention-to-treat analysis.

An exploratory analysis adds a random slope for allocation group by treating physical therapist, to explore whether the treatment effect varies between physical therapists.

A detailed statistical analysis plan, including handling of non-convergence in the sensitivity analysis with a random intercept, merging of small locations and the imputation model, will be finalized and published before unblinding.

Sample size

Existing training approaches reduce the absolute proportion of people who fall by about 7.2% from a fall risk of 48% in the control group (31). In our earlier cohort study, we found a 44% reduction in the proportion of people who fell (61). Because that study had few participants and a high dropout rate (25%), a more conservative estimate of a 22% reduction is used. With a 48% baseline fall risk, the expected incidence of fallers is 40.8% in the OEP group and 26.0% in the STABLE group. Using a two-sided z-test for two independent proportions (40.8% vs 26.0%, absolute difference 14.8 percentage points), $\alpha = 0.05$ and power = 0.90 (62), $n = (z_{1-}\alpha/_2 + z_{1-}\beta)^2 \times (p_1(1 - p_1) + p_2(1 - p_2)) / (p_1 - p_2)^2$, with $z_{1-}\alpha/_2 = 1.96$ and $z_{1-}\beta = 1.28$, approximately 207 participants completing the study are required per group (207 per group gives a power of 0.898). Allowing for 25% dropout (207 / 0.75), 276 participants are included per group, 552 in total.

Qualitative studies

Participants

After the end test, individual semi-structured interviews explore participants' experiences of training with STABLE and OEP in the cross-sectoral context, focusing on understanding and use of the assessment and test results, and motivation for self-training during and after the supervised period. Initially 5 to 7 participants from each group are included, or until data saturation (60).

Physical therapists

After data collection, individual semi-structured interviews with participating physical therapists explore understanding of patient problems through the rehabilitation plan, clinical use of STABLE and OEP

(advantages, disadvantages and barriers) and patients' expressed experiences of the two approaches (who can use what).

Interviews are transcribed and analyzed with reflexive thematic analysis as an iterative process in which meaningful units are identified, coded and developed into themes reflecting the respondents' experiences (58-60).

Data management

Data are collected in REDCap (Capital Region of Denmark) with SMS delivery via CPsms (Compaya). Balance profiles with metadata are completed in a standardized spreadsheet and imported into REDCap. Inertial sensor and force plate recordings are processed with standardized R scripts and imported into REDCap. Data are stored on secure regional drives. A data processing agreement with CPsms is in place.

Ethics

Balance training is the only known effective treatment for impaired balance. OEP is an evidence-based and widely used intervention, and STABLE currently forms the basis of the physical therapy offered at the participating clinics. All participants are therefore expected to obtain a meaningful therapeutic benefit regardless of allocation. Balance training has not been associated with serious risks in clinical trials (22, 31) or in clinical practice. Participants are instructed in correct performance of exercises at a safe level of difficulty, so dizziness and muscle soreness are minimal and transient and the risk of falling during training is minimal. Participants receive at least the treatment they would have received outside the study.

The study is approved by The Scientific Ethics Committee of the Capital Region of Denmark (H-26038898), and data protection approval has been obtained (Reference p-2026-21537, Research Legal Office, Capital Region of Denmark). Written informed consent is obtained from all participants.

Patient and public involvement

Patient involvement is a core element of STABLE: the patient's goals and experiences are used together with the balance profile and overall health condition to compose the individual exercise program (55). Participants' perspectives are evaluated quantitatively through patient-reported outcomes, adverse effects and adherence, and qualitatively in the interview study.

Dissemination

Results will be published in at least five peer-reviewed papers and presented at national and international conferences, internally at the hospitals and in the collaborating municipalities, and in the regional health councils. A summary of each participant's intervention and results is sent to the general practitioner after the end test. Results will also form an essential part of clinical courses in STABLE.

Organization and timeline

Herlev and Gentofte Hospital	Principal Investigator, physical therapist, PhD Kasper Søndergaard; Professor Carsten Bogh Juhl; Professor Jesper Ryg; Senior researcher Anders Møllesøe Vinther. *Steering group:* Head therapist Rikke Sigvardt Saugsted.
Rigshospitalet	Professor Måns Magnusson; Professor Stefania Serafin. *Steering group*: Chief physician Mads Klokker.
Municipalities	Clinical development physical therapists: Herlev: Charlotte Greve Sommer; Egedal: Lone Kanstrup Eriksen; Rødovre: Henriette Worsøe Bjerrum. *Steering group:* Head therapist Linda Hergott Andersen
General practice	GP Rasmus Hjardem-Hansen
Timeline	2026: Procedures, systems, permissions and training. Nov 2026 to 2028: inclusion and intervention (2 years). Follow-up: 26 weeks of SMS after each end test and medical records at 6 and 24 months. Analysis and publication from 2029.

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