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RESEARCH PAPER



## “Stay balanced” – effectiveness of evidence-based balance training for older adults transferred into a physical therapy primary care setting – a pilot study

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### ABSTRACT

**Purpose:** To evaluate the effects of the Stay Balanced program when this is transferred into a clinical setting regarding balance, gait speed, leg muscle strength, concerns about falling, and physical activity.

**Method:** Implementation pilot study with a pre-post intervention design. Fifteen older adults, 75–91 years of age, participated in a progressive balance training program with a focus on divided attention. The balance training was performed in group sessions twice a week for 10 weeks at a primary care physical therapy clinic. Training efficacy was evaluated after completion of training as well as after 3 months using the Mini-Balance Evaluation Systems Test (Mini-BESTest), 10-meter walk test, 30-s chair stand test, Fall Efficacy Scale-International (FES-I), and steps/day.

**Results:** Significant improvements were shown at the 10-week follow up for balance, gait speed, leg muscle strength, and concerns about falling ( $p < 0.008$ ). At the 3-month follow-up balance, leg muscle strength and concerns about falling showed persistent improvement compared to baseline ( $p < 0.045$ ). No significant differences were found for physical activity.

**Conclusions:** This study confirms the results of our previous randomized controlled trials (RCTs), and suggests that the Stay Balanced program can be transferred to clinical physiotherapy practice. The program was appreciated by the participants and proved to be safe, effective, and feasible in primary care.

### ARTICLE HISTORY

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### KEYWORDS

Implementation; older adults; balance; fear of falling; training; clinical practice

### ► IMPLICATION FOR REHABILITATION



- The Stay Balance program can easily be transferred to clinical practice without losing the effectiveness of the intervention in older adults with balance problems.
- The program was appreciated by the participants and proved to be safe, effective, and feasible when executed in primary care.
- Stay Balance program is an individually adjusted and progressive group balance training including exercises with divided attention that can easily be transferred to tasks in daily life.

## Introduction

Physical therapy practice should be informed by evidence gained through systematic research, such as randomized controlled trials (RCT) [1]. However, demonstration of significant effects in an RCT does not guarantee that the intervention will be effective in clinical settings. The generalizability may be limited due to recruitment procedures resulting in samples that are not representative for the intended target population. Furthermore, research trials are often conducted in a controlled research setting, with participants and trial leaders who may be more motivated than patients and physical therapists in general practice. These factors, together with other practical and structural circumstances, may result in physical therapy interventions in clinical practice that are substantially different from what was originally developed and evaluated in research, and

their effectiveness will depend on which components are modified and how this is done. To be able to consistently deliver best practice to our patients, it is necessary to carry out research on implementation and follow the process of adaptation and modifications of the program when it is transferred.

*Stay Balanced* [2] is a balance training program developed based on the theoretical background that balance control is dependent on several physiological systems and the fact that balance control is challenged in situations that require divided attention. *Stay Balanced* has been evaluated in two RCTs including community-dwelling older adults with and without osteoporosis [3–10]. It has been shown to reduce the fear of falling and increase walking speed, physical function, and habitual physical activity [3–6, 9], factors that are crucial for preventing falls. It is important to transfer this knowledge into routine clinical practice,

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thus evaluating research-based knowledge under more realistic conditions in a clinical setting. The primary care setting is well suited for the *Stay balanced* program, as primary care physical therapists can identify patients at risk of falling and tailor individual treatment plans including balance training. Therefore, the aim of this study was to evaluate the effects of the *Stay Balanced* program on balance, gait speed, leg muscle strength, fear of falling, and physical activity when the program is transferred into a physical therapy primary care setting.

## Methods

This was an implementation pilot study evaluating a balance training program, *Stay Balanced*, for older adults delivered in clinical practice with a pre-post intervention design with additional follow-up. The *Stay Balanced* program has previously been shown to be effective in research settings [3–10].

## Intervention

The balance training followed the *Stay Balanced* program and was conducted at a physical therapy practice in a primary care unit in Stockholm County. The balance training was delivered in group sessions lasting 45 min per session, twice a week for 10 weeks. Two physical therapists led the training sessions following a written protocol; i.e. a user manual (*Stay Balanced*®) [2]. The training session began with a short warm up followed by exercises sitting on a ball and exercises in standing and walking with and without divided attention (dual and multi-tasking). Even though the training was performed as group sessions, the exercises were individually adjusted for each participant, with the aim of challenging their balance control throughout the training period. For a detailed description, see Halvarsson et al. [2]. At the beginning and end of the training period, the participants were trained in the balance control system and how to improve and maintain their balance, as well as the importance of muscle strength and physical activity. During the training period, the participants were instructed to take daily walks for at least 30 min and perform additional home exercises for 10 min, focusing on balance and leg muscle strength.

## Recruitment

Participants were recruited by advertisement in local food stores, through senior associations and from waiting lists in physical therapy primary care. To be included, participants had to be 65 years or over, able to walk indoors without aid, have a self-reported fear of falling and impaired balance. Participants were excluded if they had a disease or an impairment that would interfere with participation in the balance training program, such as severely reduced vision, a fracture within the last 6 months, impaired cognition, or other severe health conditions with symptoms that might influence their participating in the program. This was assessed by the recruiting physical therapist on a case-by-case basis. Two balance training groups were evaluated in this study, with eight participants recruited to each group.

## Data collection

After the potential participant had reported an interest in participating in the study, a telephone interview was carried out to ensure that they fulfilled the inclusion criteria and in order to collect demographic data.

Physical function data (balance performance, walking speed, leg muscle strength) were collected at the primary care unit by a

physical therapist at baseline, after the 10-week training period, and at follow-up, 3 months after the training period. Data on concerns about falling were collected through a self-report questionnaire at baseline, after the 10-week training period, and at follow-up, 3 months after the training period. Objective physical activity data were collected at baseline, one week before the training period, and one week after the 10-week training period.

## Assessments of outcome variables

### Mini-Balance Evaluation Systems Test (Mini-BESTest)

The Mini-Balance Evaluation Systems Test (Mini-BESTest) was used to assess balance performance [11, 12]. The test evaluates four dimensions of balance: anticipatory postural adjustments, balance reactions, sensory integration, and dynamic walk. It consists of 14 items which are rated on a three-point scale (0 = severe, 1 = moderate, and 2 = normal) with a maximum score of 28.

### 10-meter walking test

Preferred and fast walking speed were assessed with the 10-meter walking test [13]. The participant was instructed to walk between two taped lines on the floor and started walking two meters before the first line. Time was measured while the participant walked the 10-metre distance. The test has been shown to be reliable and valid for assessing older adults' walking speed [13].

### The 30 s chair stand test

Leg muscle strength was assessed with the 30-s chair stand test [14]. A 43 cm-high chair was used and the participant was instructed to rise to a full standing position and then sit down again, without using their arms, as many times as possible in 30 s. The test has been shown to be valid and reliable for assessing leg muscle strength in older adults [14].

### Falls Efficacy Scale-International (FES-I)

Fall Efficacy Scale-International (FES-I) was used to assess concerns about falling. The questionnaire includes 16 items, and the participant rated the perceived level of concern about falling in 16 daily activities on a four graded scale ranging from "not at all" to "very concerned." The total score ranges from 16 to 64 points, and higher values indicate more concern about falling. The questionnaire has been shown to have good reliability and validity [15, 16]. The FES-I questionnaires were mailed to the participants.

### Pedometer steps

To objectively assess habitual physical activity, number of steps per day was monitored using pedometers (KEEP walking Yamax LS2000 pedometer, Yamax Corporation, Japan) worn for seven days. The participants were asked to put on the pedometer when they got dressed in the morning and wear it until they went to bed at night. Number of steps per day and wear time were noted on a log sheet every night. The pedometers were handed out by the physical therapist after the physical function assessments, and returned by mail together with the log sheet in a prepaid envelope. The outcome variable was the mean number of steps per day.

## Data analyses

Analyses were conducted on a per protocol basis, and non-parametric statistics were used due to the small sample size [17]. Descriptive data are presented as medians, minimum (min.), maximum (max.), number of (*n*), and percentage (%). Differences

**Table 1.** Baseline characteristics of the participants included who completed the balance training ( $n = 15$ ).

Variable	
Age, median (min-max)	81.5 (75–91)
Gender (female/male), $n$	11/4
Body Mass Index, median (min-max)	24.7 (18.7–30.1)
Household status (living alone/together), $n$	2/13
Type of residence (house/apartment), $n$	3/12
Need of support from home care services or relative, $n$	3
Experienced a fall during the past year, $n$	10
Fear of falling (Not at all, a little, quite a bit, a lot), $n$	0/5/7/3
Number of prescribed medications, median (min-max)	3 (0–12)
Use walking aid outdoors, $n$	6
Level of physical activity <sup>a</sup> (1/2/3/4/5), $n$	0/3/2/10/0

<sup>a</sup>According to Frändin-Grimby activity scale (60).

**Table 2.** Median and minimum and maximum (min-max) of balance performance (the Mini BESTest), preferred and fast walking speed (10-meter walk test), leg muscle strength (chair stand test), concerns about falling (FES-I), and habitual physical activity (steps/day) at baseline, after 10 weeks of balance training and at 3-month follow-up. The Wilcoxon Signed-Rank test was used to analyze differences between baseline and follow-ups. Significance level was set to  $p \leq 0.05$ .

	Baseline $n = 15$	10-weeks follow-up $n = 15$	3-months follow-up $n = 14$	$p$ -Value and effect size					
				Baseline – 10-weeks	10-weeks – 3-months	Baseline – 3-months			
Balance performance	Median (min-max)								
Mini BESTest	17 (13–25)	24 (19–28)	22 (17–27)	<b>0.001</b>	0.62	<b>0.040</b>	0.39	0.001	0.60
Walking speed m/s									
10-m walk, preferred	1.0 (0.6–1.3)	1.1 (0.7–1.4)	1.0 (0.7–1.5)	<b>0.007</b>	0.49	0.188	0.25	0.111	0.30
10-m walk, fast	1.3 (0.7–1.7)	1.4 (1.0–2.0)	1.3 (0.8–2.1)	<b>0.002</b>	0.57	<b>0.009</b>	0.50	0.151	0.27
Leg muscle strength									
Chair stand test	10 (0–14)	11 (5–22)	12 (1–24)	<b>0.002</b>	0.55	0.427	0.15	<b>0.045</b>	0.38
Concerns about falling									
FES-I	31 (20–52)	26 (21–43)	28.5 (18–42)	<b>0.008</b>	0.49	0.944	0.13	<b>0.028</b>	0.42
Physical activity									
Steps/day	3731 (486–7895)	3854 (273–8559)		0.691	0.12				

Bold values indicate significant values.

before and after the intervention were assessed using the Wilcoxon Signed-Rank test with a significance level set to  $p < 0.05$ . Non-parametric effect sizes were calculated based on the  $z$  values obtained from the Wilcoxon Signed-Rank test (effect size =  $z/\sqrt{n}$ ). Effect sizes were categorized as follows: small effect = 0.1; medium effect = 0.3; and large effect = 0.5 [18]. All calculations were performed in IBM SPSS version 24.0 (Armonk, NY).

### Ethics

The study followed the principles of the Declaration of Helsinki, and was approved by the Local Ethics Committee in Stockholm, Sweden (Dnr 2016/415 – 31). All participants gave their written informed consent. ClinicalTrials.gov Identifier: NCT02909374.

### Results

In total, 16 older adults (12 women) between 75 and 91 years (mean age 82) were included in the study. One participant (female, 79 years) dropped out after two training sessions for medical reasons. Baseline characteristics of the 15 participants who completed the balance training are shown in Table 1. The most common diseases were hypertension and pain in the lower extremities due to arthritis. Three participants used a cane and three used a walker when walking outdoors. The majority were regularly physically active with walks and gardening. All participants were afraid of falling and a majority had fallen during the last year.

The adherence rate for training sessions, was 94% (85–100%). At the 10-week follow-up, significant improvements were found regarding balance performance, preferred and fast walking speed,

leg muscle strength, and concerns about falling. There were no significant differences in habitual physical activity.

One participant dropped out at the 3-month follow-up due to hospitalization. At the 3-month follow-up, all variables had deteriorated except for leg muscle strength compare to the 10-week follow-up.

When comparing differences from baseline to 3-month follow-up, physical function had improved on all outcomes except for walking speed. There were significant improvements in balance performance (Mini-BESTest, 5 points), leg muscle strength (30-s chair stand test,  $n = 2$ ), and concerns about falling (FES-I, 2.5 points). See Table 2 and Figures 1 and 2.

No adverse events were reported from the training sessions.

### Discussion

Physical therapy research needs to direct more attention and resources to the implementation of programs shown to be effective in the research setting. In addition, programs that are implemented in daily clinical practice need to be evaluated in order to ensure they are still producing beneficial patient outcomes.

The “Stay Balanced” training program was designed and developed based on well-established principles of exercise and on the knowledge that balance control relies on the interaction of several physiological systems, as well as interaction with environmental factors and the performed task [2]. It includes exercise with dual- and multi-task performance, i.e., performance when a person’s attention is divided between a motor and a cognitive task, a natural component of daily activities that may increase the risk of falling in older adults [11]. For more detailed description of the programme, see methodological article published in 2015 [2].

In previous research, the program has been found to be feasible and effective to improve important aspect for balance performance as well as beneficial transfer effects to everyday life, seen as increased physical activity and improved activities of daily living [3–10].

This pilot study was the first attempt to transfer *Stay Balanced* into clinical practice. We found that the program can easily be transferred without losing the effectiveness of the intervention in

older adults with balance problems. The results showed that the program was effective and significantly improved balance performance, walking speed, leg muscle strength, and concerns about falling directly after 10 weeks of balance training. At follow-up, 3 months after the training was completed, balance performance, leg muscle strength, and concerns about falling were still significantly improved compared to baseline values. These findings are in accordance with previous RCTs evaluating balance training for older adults. For example, Halvarsson et al. [5] found similar improvements regarding concerns about falling and walking speed in older women with osteoporosis, and Conradsson et al. [19] found similar results for balance performance in older adults with Parkinson's disease. Nonetheless, demonstration of significant effects in controlled research settings does not guarantee that the intervention will prove to be effective in clinical practice settings.

In the present study, the median pre-post change in balance performance assessed by the Mini BESTest was 7 points (from 17 to 24 points). With a minimal clinically important difference (MCID) for the Mini BESTest of 4 points [20], this is a clinically relevant change for older adults. In people with Parkinson's disease and stroke, the Mini BESTest is found to predict future falls with cut off values of 17.5 points and 19.0 points, respectively. [21]. Although findings are promising, further research will show whether fall risk was actually reduced.

Even though gait training is not the primary focus in the *Stay Balanced* program, preferred walking speed pre-post increased from 1.0 m/s to 1.1 m/s, and the fast speed from 1.3 m/s to 1.4 m/s, which is of clinical relevance with a MCID for walking speed ranging 0.10–0.20 m/s [22]. Low walking speed has been shown to be associated with increased fall risk [23] and also with poor health and survival [24]. An average walking speed over 1.0 m/s indicates a healthy aging mean, while a walking speed below 0.6 m/s indicates poorer health and physical function. To be able to increase the walking speed is an important safety precaution in function in everyday life. For example, the required speed for crossing a signal-controlled transition range from 1.0 to 1.4 m/s. However, at follow-up at 3 months after the training, the effect had disappeared, which shows the importance of maintaining training in order to gain a long-lasting effect.

The participants improved their leg muscle strength by rising twice in the chair stands test. In a study by Wright et al. [25], the cut off for chair stands test was set to  $\geq 2.0$ . Previous studies have found that muscle weakness in lower extremities can contribute to an increased risk of falling and therefore it is of importance to perform regular muscle training [26]. Yet, performing muscle training alone is not enough to reduce the risk of falling. Interventions

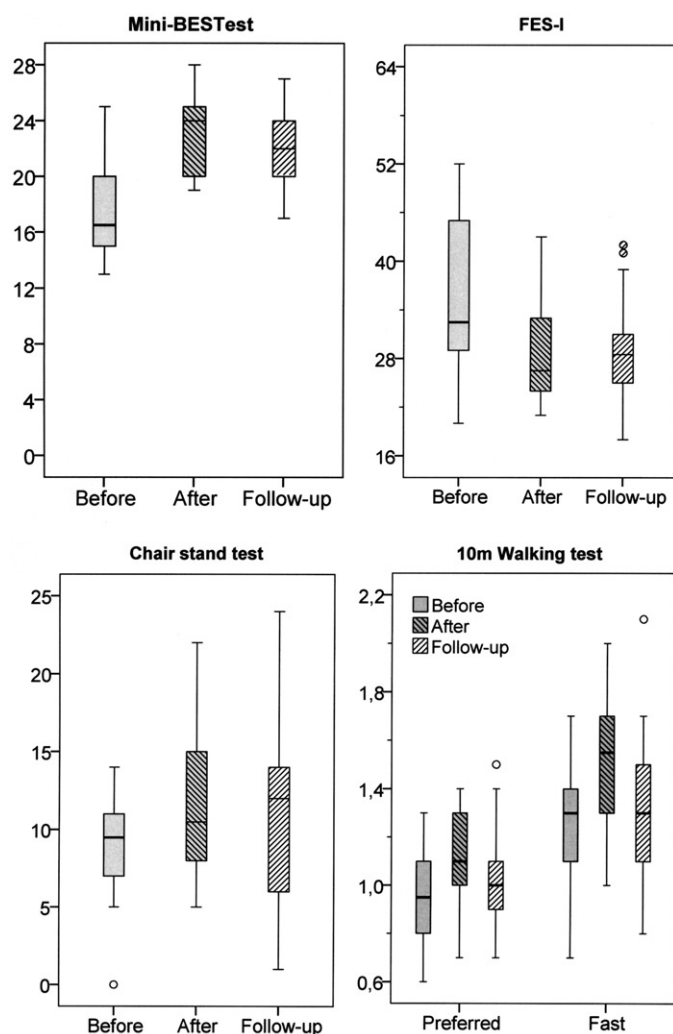


Figure 1. Mini-BESTest, FES-I, Chair stand test, and 10-meter Walking test illustrated with box plot, at Before (baseline) and After (10 weeks) and Follow-up (3 months). The box plots represent median, quartiles, min-max, and outliers.

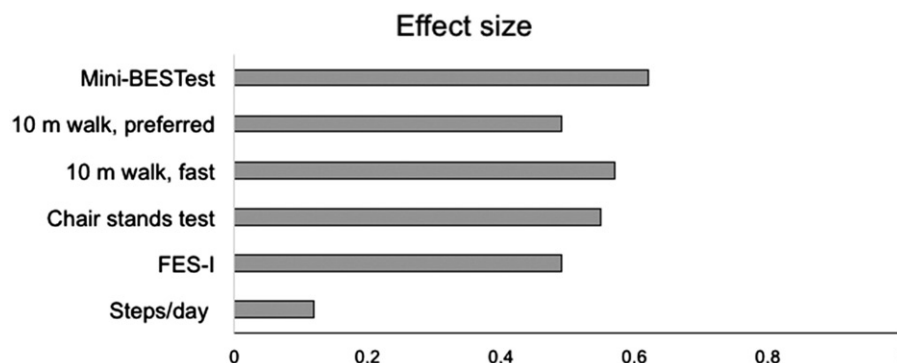


Figure 2. Effect size between baseline and 10 weeks follow-up. Effect sizes were categorized as follows: small effect = 0.1; medium effect = 0.3; and large effect = 0.5 [18].



should include both muscle strengthening exercises and balance training [27] as in the present study, where balance training exercises such as launches, stepping up and down, and walking on different surfaces were strengthening the lower extremity muscles. Even the core stabilization musculature is significant for balance performance [28], and many of the exercises in the balance training program target the core stabilization, for example, those conducted while sitting on a ball. Post training the participants had reduced their concerns about falling by five points (from 31 to 26) assessed with FES-I, which is considered to be a relevant change at group level [29]. This is in accordance with findings in other balance training studies [3, 5].

Contrary to our expectations and the results of our earlier studies [9], no differences were found in the number of steps per day after the intervention or at the 3 months follow-up. It might be expected that better balance performance, improved walking speed, and increased muscle strength would have beneficial effects on the participants' physical activity level. One explanation for the lack of improvement in the number of steps per day could be that the intervention was not primarily aimed at increasing physical activity level. Physical activity is a complex behavior, and to achieve changes in physical activity pattern, more support regarding habitual physical activity may be required, such as reinforcement with personalized behavior change counseling or physical activity on prescription. A majority of the participants (60%) walked fewer than 5000 steps per day, which is considered to be a very low level associated with a higher prevalence of cardiovascular risk factors, obesity and depression, and lower HRQoL [10, 30, 31]. Only two participants achieved at least 7000 steps per day, which is the recommended level for older adults. Unfortunately, due to logistical reasons, we were not able to assess physical activity at the 3-month follow-up. It would have been of interest to evaluate physical activity in the longer term, since changes in physical activity behavior are complex and often need continuous support and encouragement.

A Cochrane review from 2012 [32] states that balance training programs conducted three times per week over 3 months were the most efficient in improving balance performance. This can be hard to achieve in a clinical setting due to practical issues, such as a lack of training facilities or available staff, health care financial systems, or participant commitment. It is, therefore, very promising that, even though the program was modified due to clinical issues and in this way only performed twice per week over 10 weeks, significant positive effects were found.

A limitation in the present study is the recruitment process, which may have resulted in participants who were more motivated and positive to the intervention than typical primary care patients. In addition, the majority of the participants were female (73%), which could limit the generalization of the results to a larger population. The study was designed to suit a clinical context, resulting in the same person performing the baseline and follow-up testing as well as the intervention. This could have an impact on the internal validity of the results of the study. Still, the main aim of this pilot study was to translate the balance training from a scientific setting into a clinical setting, and this is how the clinical context is structured. The lack of a control group may also be considered as a limitation. However, we have already found from previous RCTs [3–6, 9, 33] that this balance training program is effective in improving balance performance and reducing concerns about falling. Research should now focus on the implementation of the *Stay Balanced* program into the clinical context on a broader basis. It may even be considered to be unethical not to give all eligible participants the opportunity to take part in an

evidence-based training regime that have proved to be very positive.

Among the strengths of this study are the high attendance rate in the training sessions, the low dropout rate, no reported adverse events, and a successful first attempt to transfer the *Stay Balanced* program from a controlled research setting to clinical practice.

Even though physical therapy practice should be informed by evidence gained through systematic research, a large amount of existing scientific knowledge remains unused in practice [1, 34]. In the literature, there are many studies reporting on the efficacy of certain treatments, methods or training programs, which may often have taken years for the researchers to develop, but few of the researchers take their results further into clinical practice and, if so, it may take years for them to come into daily use. This gap between best evidence and common practice means that possible gains are not achieved as quickly as one would have hoped for [35], and it is of great importance to get these discoveries accepted in practice so that they actually improve our patients' health and health-related quality of life [34].

Several considerations need to be taken when implementing a physical therapy intervention and transferring it from a controlled research setting to clinical practice: effectiveness, the resources required, appropriateness to practice context, and overall cost [34]. Future larger studies are needed to further evaluate and understand the effectiveness, fidelity, feasibility, and acceptability of the *Stay Balanced* program in primary care, as well as in senior housing and nursing homes.

## Conclusions

The *Stay Balanced* program was shown to be effective when transferred to a clinical setting. Ten weeks of balance training improved balance, gait speed, leg strength, and fear of falling. As for physical activity, no significant differences were found. The program was appreciated by the participants and proved to be safe and feasible in a primary care setting.

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