
Balance exercise program reduced falls in people with multiple sclerosis – a single group pretest posttest trial


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None declared

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# Balance exercise program reduced falls in people with multiple sclerosis –a single group pretest posttest trial

**Abstract**

**Objective:** To evaluate the effects of a balance exercise program on falls in people with mild-to-moderate multiple sclerosis (MS).

**Design:** Multi-center, single-blinded single group pretest posttest trial..

**Setting:** Seven rehabilitation units within five county councils.

**Participants:** Community-dwelling adults with MS (N=32) able to walk 100 meters but unable to maintain 30-second tandem stance with arms alongside the body.

**Intervention:** Seven weeks of twice-weekly physiotherapist-led 60-minute sessions of group-based balance exercise targeting core stability, dual tasking, and sensory strategies (CoDuSe).

**Main outcome measures:** Primary outcomes: number of prospectively-reported falls and proportion of participants classified as fallers during 7 pre-intervention weeks, intervention period, and 7 post-intervention weeks. Secondary outcomes: balance performance on the Berg Balance Scale, Four Square Step Test, Sit-to-Stand Test, Timed Up and Go test (alone and with cognitive component), and Functional Gait Assessment Scale; perceived limitations in walking on the 12-item MS Walking Scale; and balance confidence on the Activities-specific Balance Confidence Scale rated 7 weeks before intervention directly after intervention, and 7 weeks later.

**Results:** Number of falls (166 to 43; $p \leq 0.001$) and proportion of fallers (17/32 to 10/32; $p \leq 0.039$) decreased significantly between the pre-intervention and post-intervention periods. Balance performance improved significantly. No significant differences were detected for perceived limitations in walking, balance confidence, the Timed Up and Go test, or Sit-to-Stand Test.

**Conclusions:** The CoDuSe program reduced falls and proportion of fallers and improved balance performance in people with mild-to-moderate MS, but did not significantly alter perceived limitations in walking and balance confidence.

**Key words:** multiple sclerosis, exercise, postural balance, accidental falls, walking

**List of abbreviations**

| | |
|---|---|
| ABC | Activities-specific Balance Confidence Scale |
| CI | confidence interval |
| IQR | interquartile range |
| MS | multiple sclerosis |
| MSWS-12 | 12-item MS Walking Scale |
| PwMS | people with multiple sclerosis |
| RCT | randomized controlled trial |
| TUG | Timed Up and Go |
| TUG$^{cognitive}$ | Timed Up and Go cognitive |

Imbalance and its association with risk for falls in people with multiple sclerosis (MS) is well recognized [1-12]. Several interacting factors are associated with fall risk in people with MS (PwMS). Dual tasking is frequently impaired [13], and there is some evidence supporting that dual tasking; divided attention or being distracted are causative of falls [8,14-16]. Impairments in sensory qualities are common and often present at onset of disease [17], though there is conflicting evidence on whether this leads to an increased risk of falling [8,18]. Increased postural sway in standing has been reported to be associated with fall risk [18]. In addition, trunk control contributing to balance is often decreased in PwMS [19].

A systematic literature review on the effects of physiotherapy interventions on balance in MS revealed that there is a lack of intervention studies evaluating balance performance, and thus there is a knowledge gap that needs to be addressed [20]. Studies investigating interventions aimed at reducing falls in PwMS are also sparse. In one pilot study, 44 PwMS were randomized to two intervention groups and a control group. The interventions consisted of 12 sessions of individual balance exercise sessions aiming to improve i) motor and sensory strategies, or ii) motor strategy only, while the control group received treatment not specifically aimed at improving balance [21]. Fall frequency was reduced post-intervention in comparison with that reported retrospectively one month prior to intervention. Both intervention groups showed significant improvements on the Berg Balance Scale, with a larger improvement in the combined exercise group compared to the motor-only group. Another randomized controlled trial (RCT) investigated a 10-session circuit exercise program focusing on balance and strength for PwMS using walking aids, which significantly reduced the number of falls and number of fallers [22]. However, data on falls were collected retrospectively. A single-group crossover study showed that six weeks of twice-weekly sessions of visuo-proprioceptive exercises reduced the risk of falls, defined as the percentage of time using hand support to avoid falls in double-leg and single leg stance in a laboratory setting [23].

A history of falls is associated with a poor sense of coherence as well as concerns about and fear of falling [24-26]. As many as 93% of community-dwelling PwMS aged 21 to 73 years reported fear of falling as measured by the Falls Efficacy Scale – International, and 57% fell at least once during a six-month follow-up [27]. Beside the risk of injury when falling [7,28-30], concerns about falling can lead to restrictions in activities [25,26] although no association was found between falling history and the level of physical activity measured as steps per day [31]. Confidence in ability to maintain balance during activity is lower in those experiencing multiple falls compared to non-fallers [32].

To summarize, there are few studies evaluating balance exercise programs in PwMS where falls have been used as an outcome. More importantly, data on falls have only been collected retrospectively, introducing the risk of recall bias. Hence, the aim of the present study was to evaluate the effects of a seven-week twice-weekly group exercise program (CoDuSe) on prospectively reported falls, balance performance, balance confidence, and perceived limitations in walking among PwMS. The specific hypotheses were that participation would i) decrease the number of falls and proportion of fallers from a pre-intervention period to a post-intervention period, ii) improve performance on clinically-administered balance measures and self-rated walking and balance-related measures between a pre-intervention test occasion and a test directly after the intervention period, and iii) show continued benefits in that the improvement would be maintained at a follow-up seven weeks after completion of the intervention.

## METHODS

The study sample was derived from a RCT investigating balance exercise, in which the participants were randomized to either an early start or a late start of the intervention (Clinical Trials ID: NCT01582126). The present study focused on falls and analyzed data for those starting the intervention late, enabling a prospective data collection on falls during seven-week periods not only during and after the intervention, but also before intervention. Adults diagnosed with MS by a neurologist, and living within the recruitment area of the centers, were consecutively invited to participate. Eligible for inclusion were PwMS who were i) able to walk 100 meters, ii) able to get up from the floor with minor support, and iii) unable to maintain tandem stance for 30 seconds with arms alongside the body. Exclusion criteria were major cognitive or linguistic difficulties, or other diseases or conditions preventing participation in the intervention or data collection, established by clinical judgment by the respective physiotherapist Data were collected between August 2012 and June 2013. The allocation from the RCT remained concealed throughout the study, assuring blinding of the data collectors. The study had an experimental design with repeated test occasions (Figure 1). The study was approved by the regional ethics committee (2012/117) and conducted according to the Declaration of Helsinki.

*Intervention development*

Development of the program began with a scrutiny of the scientific literature for evidence regarding exercise interventions aimed at reducing imbalance in PwMS. Based on the findings, it was determined that the program should incorporate core stability, dual tasking, and activities involving altering sensory conditions. Next came an interactive process in which the program components were presented to physiotherapists interested in participating in the project. All physiotherapists involved had clinical experience of treating PwMS, and the majority had previous experience of leading balance exercise groups. In a day-long session, the exercises were tested practically and discussed in depth with the physiotherapists. The discussion included time to be spent on each component in the exercise program, safety aspects, group size, verbal and hands-on instructions, and how the exercises could be individualized and progressed. The length of each session and the intensity and duration of the exercise program were defined in congruence with previous research and clinical experience among the physiotherapists. Practical issues were also considered, such as the possibility and likelihood of an out-patient investing time and effort into participating in the exercise program, and the feasibility of delivering the program to actual patients. A preliminary program was constructed, and the physiotherapists had further opportunity to practice the exercises themselves. A second meeting was held where the physiotherapists were able to reflect and comment once more before the final version of the program was confirmed. Once consensus was reached, a manual was printed with description of the exercises in text and illustrations including progression of the exercises. The manual was accessible at each site during the intervention period, and the primary investigators were available for discussion and advice throughout the study period. The balance exercise program was delivered by physiotherapists involved in the intervention development.

*Intervention description*

The exercise program was given twice weekly for seven weeks in groups of four to seven people. Each session lasted for 60 minutes, and started with 20 minutes of selected core stability exercises inspired by those described by Freeman et al. (*Core Stability Exercise Program* *www.mstrust.org.uk*). The physiotherapists initially explained and demonstrated the core muscles and the core stability exercise technique. After training core stability, the participants were encouraged to maintain their focus on core stability when performing the remaining tasks, which covered dual tasking and different sensory conditions (for more details, see Appendix; the program is available at request to anette.forsberg@orebroll.se). Examples of sensory strategies were using an uneven, soft, or moving surface and/or withdrawing visual input. Each session allowed for approximately five minutes of stretching and/or relaxing at the end. All participants were provided with a printout of the program after the study period.

*Primary outcome measure*

Data on self-reported falls (in- and outdoors) were collected prospectively during three seven-week periods A fall was defined as “an unexpected contact of any part of the body with the ground or lower level due to loss of balance” [33], and a faller was defined as a person reporting one or more falls during a seven-week period. The physiotherapists instructed the participants how to fill in the fall diaries. The diaries consisted of six sheets (two for each seven-week period) where number of falls (0 = no falls) was to be recorded for each day during the study period. The diaries were handed out together with pre-paid envelopes, and filled in during a pre-intervention period (A), during the intervention (period B), and during a post-intervention period (C) (Figure 1). The diaries were either sent to the primary investigator every 3-4 weeks or handed to a physiotherapist. Reminding or clarifying phone calls were made by the primary investigator if needed. Participants that returned fall diaries for the whole study period (21 weeks) were included in the analysis.

*Secondary outcome measures*

Data on the secondary outcomes were collected at inclusion ($T_0$), immediately after completing the CoDuSe program ($T_1$), and 7 weeks after completion of the program ($T_2$). Balance was measured using the Berg Balance Scale, the Four Square Step Test, the Sit-to-Stand Test, the Timed Up and Go test both alone (TUG) and with cognitive component ($TUG^{cognitive}$) , the Functional Gait Assessment, the 12-item MS Walking Scale (MSWS-12), and the Activities-specific Balance Confidence Scale (ABC).

The Berg Balance Scale is a well-known measure of static and dynamic balance including 14 items giving a maximum score of 56[34]. It is valid [35] and reliable for PwMS [36,37] .

The Sit-to-Stand Test measures functional muscle strength in the lower extremities while performing a basic transfer [38], and has been related to muscle strength as well as balance in PwMS [39]. The present study measured the time taken for 10 repeated sit-to-stands from a standard chair with arm support.

The Four Square Step Test requires the participant to step over 2.5 cm high sticks placed in a cross formation, first clockwise and then counterclockwise, forward, sideways, and then sideways again [40]. The test is valid for PwMS [41], and has excellent interrater [40] and test-retest reliability [41]. The mean time to complete two attempts was used in further analyses.

The TUG test is a well-established test to measure basic mobility skills [42]. Time is registered for a sequence where a person rises from a chair, walks 3 meters, turns around, walks back, and sits down again. The test is valid for PwMS [35] and has excellent test-retest reliability [36]. The time for one attempt at forced speed was used.

The TUG$^{cognitive}$ test measures a multitask condition in which participants are asked to subtract in steps of three from a randomized number between 20 and 100 while performing the TUG test [43]. It's predictive validity has been estimated [8], and it has good face validity.

The Functional Gait Assessment consists of ten items covering walking at normal speed, with altering speed, with vertical and horizontal head turns, with eyes closed, over obstacles, in tandem, backwards, and up a flight of stairs. Items are scored 0-3, with lower scores indicating greater impairment. It is a valid measure of dynamic balance and gait for ambulatory PwMS[44].

Self-perceived limitation in walking was measured by using the MSWS-12 [45], a valid [45-48] and reliable [45,46] scale for PwMS. Finally, balance confidence was evaluated using the ABC [49], which consists of 16 balance-demanding activities. The ABC is considered valid for PwMS [32,35], and discriminates between multiple fallers and non-fallers as well as between users and non-users of walking aids [32]. The sum score ranges between 0 (no confidence) and 100 (completely confident).

The MS Impact scale was filled in at study start to describe the disease impact on daily functioning [50]. It is a 29-item self-report measure with 20 items associated with a physical scale and 9 items with a psychological scale. Each item is scored on a scale ranging from 1 (not at all) to 5 (extremely). A score (0-100) is calculated for each subscale [physical (sum score – 20/80 x 100; psychological (sum score – 9/36 x 100]. High scores indicate greater impact.

*Statistical methods*

Descriptive statistics were calculated for demographic data. McNemar's test was used to assess differences in proportions of fallers, and the Wilcoxon signed-rank test was used for differences in number of falls, for the respective periods. The Friedman test was used to assess differences between test occasions where the data were ordinal and/or deviated from a normal distribution (Shapiro-Wilk test). Where significant differences were detected, the Wilcoxon signed-rank test was used to detect where the differences occurred. A Bonferroni adjustment was then calculated using the significance level (0.05) divided by the number of tests run (15) = 0.0033. If the p-values were larger than 0.0033, the results were considered not statistically significant. For normally distributed data, one-way repeated-measures ANOVA with a Greenhouse-Geisser correction was used to calculate overall differences between related means with Bonferroni correction for multiple comparisons. Version 17.0 of the SPSS software package was used for the statistical analyses.

## RESULTS

Thirty-two participants (26 females) with a mean age of 56 years (SD 11.3) completed the intervention and had complete fall diaries, and 29 of them also attended all test occasions (Figure 1). Eleven had a relapsing-remitting MS, 16 a secondary, and five a primary progressive MS. Mean duration since MS diagnosis was 15.6 years (SD 12.2). Six used a walking aid indoors and 21 outdoors. The physiological impact of MS was mild (MSIS-29 mean 45.3; SD 18.5; range 7.5-75) as was the psychological impact (MSIS-29 mean 37.1; SD 22.9; range 0-88.9) [51]. The median intervention attendance rate was 12 of 14 sessions [25-75% Inter quartile range (IQR) 9.2 – 13]. Five persons never attended the exercise group, and two persons attended only once; all seven were excluded. Reasons for drop-out were lack of time (n=4) and illness (n=3).

[Figure 1]

*Fall reduction*

Prior to the intervention, 53% of those with complete falls data were classified as fallers and 44% of the total sample were classified as multiple fallers (78% of the fallers). A reduction of falls was reported between the pre-intervention period (A) and both period B and C (Table 1). The number of falls reported during period C was 123 less than that during period A. The fallers fell 1-33 times in period A and 1-13 times in period C. Ten or more falls were reported by seven participants in period A, three participants in period B, and only one participant in period C.

*Proportion of fallers*

The proportion of fallers was significantly lower in period C (Table 1). Eighteen participants reported no falls or only one fall during period A, while the corresponding numbers in later periods were 20 during period B and 25 during period C.

There were significant improvements in balance on the Berg Balance scale, Four Square Step test, $TUG^{cognitive}$ test, and Functional Gait Assessment when comparing tests i) pre-intervention and directly after the intervention was completed and ii) pre- intervention and at 7 weeks post-intervention (Table 2). There were no differences between these test occasions for MSWS-12 ($p<0.26$), the ABC ($p<0.14$), the TUG test ($p=0.035$), or the Sit-to-Stand test ($p=0.73$).

Adverse effects and treatment complications were systematically measured by the physiotherapists in charge of the intervention. Two participants fell while performing more challenging standing and walking activities on their own initiative. There were no injuries.

## DISCUSSION

This study, using prospectively reported falls, shows that the CoDuSe program can reduce falls in people with mild to moderate MS. These findings are important, particularly given the commonness of falls that may lead to injuries [7,16,29,30]. The results are in line with previously published research [21,23,52] providing evidence that targeted physiotherapy interventions can positively affect falls in PwMS [19,21,49]. The CoDuSe program also produced improvements in balance performance and the results were maintained at the seven-week follow-up. The conservative statistical approach, with correction for multiple comparisons, strengthens the likelihood that the results are valid.

Still, the intervention did not alter balance confidence. One possible explanation for this could be that the intervention was held indoors in a safe and supervised environment, while falls in everyday life occur in a number of different settings, including outdoors [8]. Another explanation could be that the intervention period was insufficiently long for the participants to become more confident in performing activities. There is conflicting evidence on the ability of the ABC to capture changes produced by an intervention [21,53]. Modification of existing scales to better address the MS population may be necessary to capture changes produced by interventions such as the Falls Efficacy Scale-International [27]. Finally, filling in a fall diary may have increased their awareness of the risk of falling.

The program was strongly inspired by the scientific work of others [21,23,54], and seems sufficient in terms of content, intensity, and duration for the purposes of fall reduction and balance performance improvement. Two additional advantages are that it was developed using the clinical experience of physiotherapists specializing in neurorehabilitation, and that it uses a standardized manual. Practicing together further enhanced the coherence of how the intervention should be administered. Using small groups made it possible for the physiotherapists to adjust the level of difficulty and to individually instruct each participant. The use of group interventions is time-saving compared to individual sessions. For practical and safety reasons, it was not possible to include persons with more severe imbalance. However, it should be possible to use the same program for more severely affected patients, in individual sessions or in smaller groups.

*Study limitations*

A limitation of the present study is the lack of control group. A one-group repeated measures study design was used to report the collected data for the group that started late in the RCT. Another limitation is the reliance on self-reported data for falls. Monitoring falls using equipment such as wearable sensors could give more reliable data. Furthermore, interventions that demand active involvement over time introduce some selection bias. Only those able to commit to taking part in an exercise program will accept the invitation to participate, and so the results cannot be generalized to all PwMS. The drop-out rate was higher than expected, but this was primarily due to practical reasons unrelated to the intervention; specifically, not being able to participate on the days when the groups were held. The combined strain of travelling to the physiotherapist and participating in the exercise program was too much effort for some. It was considered unethical to include participants that would not be able to fully understand the study information and important that patient-reported outcome measures could be included. The respective physiotherapist clinically judged whether a potential participant would fulfill these criteria. A systematic evaluation of cognitive dysfunction would enable evaluation on how cognitive dysfunction affects the reporting of falls or adherence to balance exercise programs.

A strength of the study is that the data collectors were blinded to whether or not the participants were in the intervention group at the time of measurement. The fact that the intervention program and manual were developed in collaboration with participating physiotherapists is likely to have increased its implementation as intended. Similarly, the interaction between the study physiotherapists in determining the final study protocol is considered to increase the transferability and implementation into clinical practice. The use of falls as an outcome measure is highly relevant. We suggest falls as a patient-related outcome and balance performance scales as proxy measures for imbalance. Future research should evaluate balance interventions which also include outdoor activities and activities performed in the participants' home environment, as well as interventions specifically aimed at improving balance confidence. Prospective collection of data on falls is recommended, as it reduces the risk of recall bias [8,33].

## Conclusions

Seven weeks of twice-weekly group balance exercises using the CoDuSe program can reduce the number of falls and fallers as well as improve balance performance, but changes in perceived limitation in walking or balance confidence were not captured.

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*Figure and table legends*

**Figure 1** *Flowchart of study participants and measurements*

**Table 1** Comparisons of frequencies for fallers and falls between periods A (pre-intervention), B (during intervention), and C (post-intervention), n= 32.

**Table 2** Post hoc analysis comparing the secondary outcome measures at the different test occasions, n=29.

**Table 1** Comparisons of frequencies for fallers and falls between periods A (pre-intervention), B (during intervention), and C (post-intervention), n= 32.

| | **Period A**<br>Weeks 1-7 | **Period B**<br>Weeks 8-14 | **B *vs.* A**<br>P-value | **Period C**<br>Weeks 15-21 | **C *vs.* A**<br>P-value |
|---|---|---|---|---|---|
| Fallers | 17 (53%) | 17 (53%) | 1.000 (n.s.) | 10 (31%) | <0.039 |
| Falls | 166 | 85 | <0.027 | 43 | <0.001 |

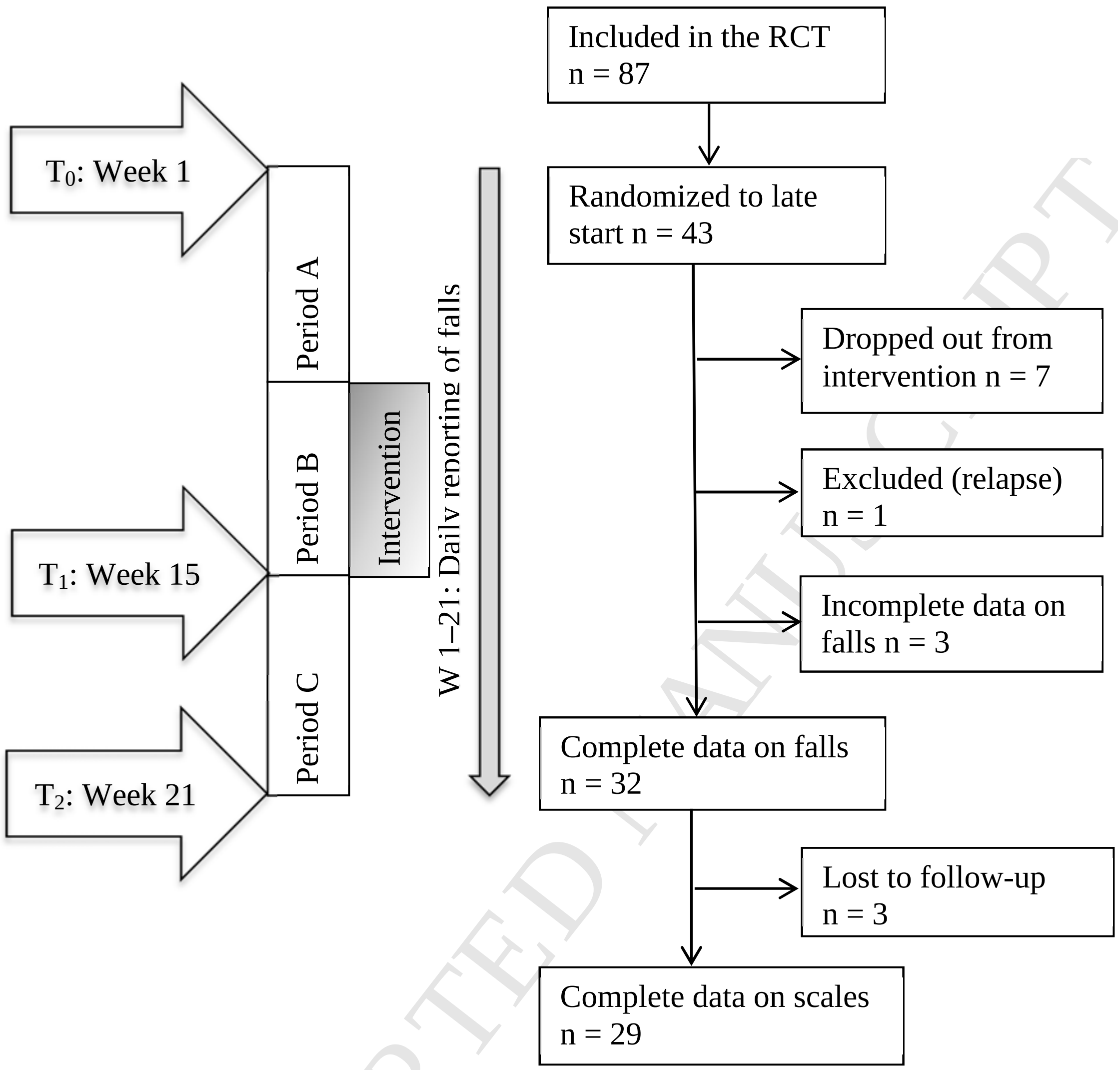
**Table 2** Post hoc analysis comparing the secondary outcome measures at the different test occasions, n=29.

| **Outcome measure** | **Time point** | **Median (IQR)** | **Paired test** | **P-value** |
|---|---|---|---|---|
| Berg Balance Scale (0-56) | $T_0$ | 48 (43-53) | T0-T1<br>T0-T2 | 0.000*<br>0.001* |
| | $T_1$ | 53 (48-55.5) | T1-T2 | 0.517 |
| | $T_2$ | 54 (47-56) | | |
| Four Square Step Test (sec) | $T_0$ | 16.26 (13.46-21.49) | T0-T1<br>T0-T2 | 0.000*<br>0.000* |
| | $T_1$ | 14.16 (11.48-18-87) | T1-T2 | 0.476 |
| | $T_2$ | 13.06 (11.41-17.62) | | |
| TUG test (sec) | $T_0$ | 12.69 (10.32-19.22) | T0-T1<br>T1-T2 | 0.035<br>0.074 |
| | $T_1$ | 11.43 (9.42-15.46) | T1-T2 | 0.658 |
| | $T_2$ | 11.93 (9.42-17.70) | | |
| $TUG^{cognitive}$ test (sec) | $T_0$ | 15.78 (11.89-26.22) | T0-T1<br>T1-T2 | 0.002*<br>0.001* |
| | $T_1$ | 13.40 (11.16-20.92) | T1-T2 | 0.320 |
| | $T_2$ | 13.97 (10.73-21.95) | | |
| Functional Gait Assessment (0-30) | $T_0$ | 16 (12-19.5) | T0-T1<br>T0-T2 | 0.000*<br>0.000* |
| | $T_1$ | 18 (13-21.5) | T1-T2 | 0.144 |
| | $T_2$ | 19 (15-23) | | |

$T_0$: prior to intervention; $T_1$: directly after intervention period; $T_2$: at seven-week follow-up.

* Significance remained after Bonferroni correction

Figure 1




*Flowchart of study participants and measurements*

## Appendix 1

**Examples of core stability exercises**

*In supine position* (knees bent): engaging the core muscles, alternately sliding one heel forward to straighten the leg, alternately lifting one foot off the floor and bringing the knee over the hip, single leg drop out, lifting both legs towards the trunk and back, stretching one leg with foot off the floor, bridging by lifting the bottom and spine off the mat, bridging on gym ball, and knee rolling on gym ball.

*Lying on one's side:* bent leg side lifts and straight leg side lift.

*On all fours:* finding a neutral position, weight shifting forwards, "walking" forwards with the hands, leaning forward in kneeling position with elbows on gym ball, sliding one foot in a straight line away and back from the body, straight leg lift off the floor, diagonally straight arm and leg lift, and side lift.

*Standing:* bending forward.

**Examples of dual tasking**

*Juggling a balloon:* on one's own or with a partner, while transferring from sitting to standing or while walking, and using one's hands or a racket.

*Holding a tray with small balls on top:* while transferring, walking, or stepping over obstacles.

*Carrying shopping bags:* while walking or stepping over obstacles.

*Picking up items from the floor.*

*Walking:* while turning one's head, backwards, while counting or reciting the days of the week in reverse order, taking long steps, taking step combinations in different directions.