

Technology-supported sitting balance therapy versus usual care in the chronic stage after stroke: A pilot randomized controlled trial

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Abstract

Insights in evidence on sitting balance and trunk rehabilitation have not resulted in specific device development. Hence, intensive one-by-one therapist-patient guidance is still required. We developed a novel rehabilitation prototype, specifically aimed at providing sitting balance therapy. In this study, we investigated if technology-supported sitting balance training was feasible and safe in chronic stroke patients and we evaluated whether clinical outcomes improved after a four-week programme when compared with usual care.

Methods. In this parallel-group, assessor-blinded, randomized controlled pilot trial, we divided first event chronic stroke participants randomly into two groups. The experimental group received usual care plus additional therapy supported by rehabilitation technology consisting of 12 sessions of 50 minutes of therapy in four weeks. The control group received usual care only. We assessed all participants twice pre-intervention and once post-intervention. Feasibility and safety were descriptively analysed. Between-group analysis evaluated the differences in changes in motor and functional outcomes.

Results. In total, 30 participants were recruited and 29 completed the trial (experimental group, n=14; control group, n=15). There were no between-group differences at baseline. Therapy was evaluated feasible by participants and therapist. There were no serious adverse events during sitting balance therapy. Changes in clinical outcomes from pre- to post-intervention demonstrated an increase in the experimental compared to the control group for trunk function; mean (standard deviation [SD]): 7.07 (1.69) versus 0.33 (2.35) points on trunk impairment scale ($p<.000$), maximum walking speed on 10-meter walk test (0.16 (0.16) m/s in the experimental group versus 0.06 (0.06) m/s in the control group; $p=.003$), and functional balance measured using Berg balance scale (median [interquartile range] 4.5 (5) points in the experimental group versus 0 (4) points in the control group ($p=.014$).

Conclusions. Technology-supported sitting balance training in persons with chronic stroke is feasible and safe. A four-week, 12-hour programme on top of usual care suggests beneficial effects for trunk function, maximum gait speed and functional balance.

Trial Registration: *ClinicalTrials.gov* identifier: **NCT04467554**,
<https://clinicaltrials.gov/ct2/show/NCT04467554>, date of Registration: **13 July 2020**.

Background

Stroke is an important cause of increasing disability-adjusted life-years (1), requiring rehabilitation. This is an intensive process with a multidisciplinary approach aiming to recover independence in activities of daily living (ADL) and to improve social interaction to an optimal level (2). Motor therapy being an important component of rehabilitation. The focus of therapy is often primarily aimed at the recovery of arm-hand function and gait. However, literature demonstrated convincingly that sitting balance is an important and significant predictor for functional recovery. Even in the chronic phase after a stroke there

is a persistent deficit in sitting balance and underlying, impaired trunk function (3,4). Furthermore, research indicates that intensifying general therapy improves activities of daily living (ADL)(5).

Nowadays there is a growing awareness that sitting balance and trunk function are essential in the rehabilitation process after stroke. Various studies focused on training trunk function, with participants not only trained in the acute or subacute phase (6–9), but also in the chronic phase (10,11,20–23,12–19). On average, the study population in the latter phase received 168 minutes of trunk therapy per week for 2 to 12 weeks. However, therapy offered in these trials was a labour-intensive approach. In addition, a structured implementation of motor learning principles (24) and literature findings would be beneficial for improving sitting balance and trunk function. Technology can facilitate this process by delivering an efficient method to offer intensive therapy, reducing the need for continuous input from a therapist. This could lead to a lower health care cost and an opportunity to increase therapy dose and intensity. Therefore, we developed a novel rehabilitation technology therapy concept, with sitting balance therapy offered on a newly developed device, called T-Chair. The T-Chair concept is explained further below.

In this study, we investigated the feasibility, safety, and potential effectiveness of technology-supported sitting balance therapy by use of T-Chair. Feasibility and safety are key aspects of technology development. Input from the target population is essential in patient-centred healthcare. Therefore, we conducted a monocentre pilot randomized controlled trial (RCT) with participants in the chronic phase after stroke with the primary objective to investigate feasibility and safety of sitting balance therapy enhanced with T-Chair. The second objective was to evaluate if utilizing technology-assisted therapy in addition to usual care improved sitting balance, trunk function, mobility, functional balance, strength and activities of daily living in participants post stroke, in comparison to usual care only.

Methods

The present study is an assessor-blinded monocentre parallel-group randomized controlled trial (*ClinicalTrials.gov identifier: NCT04467554*) that obtained ethical approval (Ethische Toestingscommissie Jessa Ziekenhuis, Belgian registration number; B2432020000014). To improve transparency we report this study according to the CONSORT guidelines for pilot or feasibility trial (25)

Recruitment, randomization and blinding

Participants were eligible when 1) suffering from first stroke, 2) more than six months ago, 3) 18 years or older, 4) had an impairment in trunk function (≤ 19 on trunk impairment scale (26)), 5) were able to maintain a seated position independently for more than 10 seconds, 6) were able to travel to the study location, 7) had no significant comorbidities other than stroke affected trunk function 8) having sufficient cognitive and language capacity to perform and understand study protocol participation, and 9) provided written informed consent. Participants were excluded if they did not meet the inclusion criteria.

Participants were recruited between July and November 2020. Leaflets and posters with study information and contact details were distributed in rehabilitation centres and at practices of

physiotherapy located near the study location. Written approval was given by the potential participant to be contacted by the investigator (signed informed consent for contact). One investigator contacted potential candidates for further explanation of the study. After confirming eligibility, a signed informed consent was obtained.

The study took place in a dedicated room in an outpatient centre in Belgium. For this study, we aimed to recruit 30 participants in the chronic phase after stroke. Because of the pilot design of this study a sample size calculation was not performed. However, according to previously conducted trials with similar design, and recommendations by Whitehead et al (27), a sample of 15 participants in each arm of the trial was considered in order to be able to answer the research question.

The principal investigator (GV) randomly allocated participants, after consent, to two different groups: the experimental group and the control group. The principal investigator (GV) used the coin flip randomization method (28) without having any contact with the therapist or participants. Allocation was concealed. The information concerning the group allocation was provided to the therapist (EV). Therapist (EV) and participants were aware of the allocated groupings. The assessor and data analyst (LT) was blinded throughout all the assessments (three measurement points) and analysis.

Interventions

Both groups received usual care comprising of physiotherapy and/or occupational therapy with strength exercises, conditional training, and task-oriented therapy. The usual care intensity was, on average, 3 sessions of 30 minutes to 2 hours therapy per week.

Control group

Participants in the control group received usual care only. No therapy time was spent on sitting balance therapy.

Experimental group

In the experimental group, participants received usual care plus additional technology-supported sitting balance therapy. The experimental therapy consisted of 12 one-hour individual sessions within four weeks at a ratio of three to four times per week. Each session consisted of 42 minutes of active sitting balance and trunk training and 8 minutes of cooling down in seated position. Time of intervention was monitored using a stopwatch and excluded all rest periods and set-up time. Sitting balance therapy was conducted in a seated position and consisted of predefined, standardised exercises including reaching training, lateral trunk lengthening and shortening, weight-shift training, pelvic tilt and training while sitting on an unstable surface. One therapist (EV) trained all participants. The therapist scored safety during and at the end of each training session. Participants rated tiredness of leg and trunk muscles after each session. When training was scored safe and tiredness was moderate, that is, scoring less than five out of ten points on a fatigue visual analogue scale, training difficulty was increased to the next level, according

to a standardised scheme. Additional file 1 supplies a detailed description of the exercises and cooling down of the first session of each week.

T-Chair

T-chair seating and gaming

Therapy in the experimental group occurred on a novel rehabilitation technology prototype, called T-Chair (Figure 1). T-Chair is an instrumented chair that provided visual feedback. This prototype is specifically developed to train sitting balance. The seating provided a stable and unstable surface and allows for movements of the seating surface in the anterior-posterior and lateral direction(29). In the seating, 64 sensors (FlexiForce A401 force sensors, Tekscan, United States) permanently measures patient's responses to external stimuli, such as movements of centre of pressure. The T-Chair provided visual feedback of range of motion of forward, backwards and lateral movements during therapy. The T-chair included specifically designed gaming to stimulate and activate participants. The goal of the game (boat game, Figure 2) was to keep balance and improve range of motion during weight shifts according to targets visualised on the screen. To maintain safety, T-Chair is equipped with a safety belt and two emergency stop buttons. The therapist continuously supervised participants during this pilot trial.

Figure 2 Screenshots of boat game exercise: boat game (left) the participant has to navigate the boat through weight distribution to the left to catch the arrows and then move the boat at the port. Boat game (right), the participant is on the left side of the canal, against the bank, and by weight distribution, the participant can move the boat to the right where a new target is located.

T-chair mechanical properties

The rotational axis of the T-Chair seat is placed approximately 30 cm above the seat level height. The chair has following characteristics regarding range of motion (ROM): forward and backwards movements of 10° (71 mm) each and sideways bending of approximately 10° (73 mm). The seating can be positioned at a horizontal plane or at a stable inclined plane of maximally 10°. The chair has a height of 50 cm, a width of 55 cm and a depth of 90 cm. T-Chair development is based on structured input from participants and clinical experts. A previous study evaluated usability of this training prototype and feedback by therapists and participants after stroke led to further improvements (30).

T-chair features and electronical properties

The training prototype contains emergency stop buttons. During an emergency situation the button can be pushed by the participant as well as the therapist. All actions are immediately interrupted, making it possible to move the seat manually to all directions, choose to return to the starting position of the training prototype or to remove the participant from the seat without further movement of the T-Chair. The

main voltage remains active on the prototype during this emergency action. All parts of T-Chair continue to be powered to prevent a new potentially unsafe situation.

A PC application is used together with the chair. The training protocols of the application can be applied to the chair via an RFID badge (USB Desktop reader evohfv2, idtronic, Germany). In the training protocol the therapist can choose an exercise, adapt the duration of the exercise, the direction and the number of repetitions and synchronise it with the badge. Before starting the therapy, the chair homes to the starting position followed by placing the badge on the badge reader (NiniX Technologies, Belgium) located on the T-Chair. The T-Chair has five controllers (Figure 3) each with their own software, 1) the master controller is the main controller of the T-Chair and communicates with the touch display-, motion-, game- and sensor controller, 2) the motion controller calculates the center of gravity, the acceleration and controls the drives of the motors, 3) the game controller provides all needed range of motion and sway measurements, trainings and exercises (= protocols) and also provides the ability to play games on the T-Chair, 4) the sensor controller controls all sensors that are embedded in the seat of the T-Chair. It sends its data to the motion controller for processing and 5) the touch-display controller provides all the needed features for the therapist to interface with the T-Chair.

Assessments

Descriptive baseline characteristics and testing time points

Baseline data such as age, type and location of stroke, comorbidities, dominant hand, educational level and gender were collected. Participants were screened for neglect (star cancellation (31)), cognition (Montreal cognitive assessment (32)) and level of depression (patient health questionnaire (33)). Testing was performed three times for all participants. Two time points pre-intervention, with an interval of 2 weeks, established baseline (baseline and pre time point). This evaluated stability in our outcomes in the chronic stage. The third time point was post-intervention, i.e., four weeks after pre-intervention. All outcomes were assessed using clinical measurement tools or questionnaires.

Feasibility

The primary aim of this study was to examine feasibility of the intervention. We evaluated feasibility in terms of recruitment and retention, participation, adherence, acceptability and enjoyment, safety and adverse events, and device development or modification suggestions after each therapy session in the experimental group.

The number of contacted and eligible participants characterized recruitment and retention. We defined recruitment rate as the number of participants in the trial divided by the number of contacted participants. Retention is the number of recruited participants that completed all 12-therapy sessions divided by the total numbers of trial participants that entered the trial.

The Pittsburgh rehabilitation participation scale (34) assessed participation. The therapist judged participation on a six-point Likert scale, ranging from poor to excellent participation. Adherence was evaluated using the Clinician Rating of Compliance Scale (35)(36). This is a seven-point ordinal scale that assesses the level of adherence of the participant. A score lower than five is defined as non-adherent. A score of six stands for moderate participation with some knowledge and interest, no prompting required and a score of seven represents active participation and the participant shows responsibility for the therapy regimen. Participants scored level of enjoyment during the therapy by means of the physical activity enjoyment scale (37). This scale contains 18 items, each with a seven-point Likert scale, with a range of 18-126. In this scale the maximal score of 126 represents total enjoyment. Also, all interferences of the therapist to pursue the safety of the participants were noted after each therapy session. The therapist asked for fatigue using Visual Analog Fatigue Scale, ranging from zero to ten (38). A score of zero stands for none fatigue and a score of ten for worst possible fatigue. Level of fatigue was asked for leg, trunk and general. Borg Rating of Perceived Exertion (39) evaluates fatigue and exertion. The scale ranges from zero to 20. A score of six represents no exertion and a score of 20 maximal exertion. Feedback from the participants and therapist to improve the prototype and protocol were noted after intervention by a questionnaire containing 16 questions with three open questions and 13 categorical questions on a five- and seven-point Likert scale (Additional file 2). This questionnaire was only administered after the last therapy session and asks, among other things, whether therapy with the prototype has an additional benefit for rehabilitation and whether it was easy to use.

At the last assessment session all participants completed the Self-Reported Patient Global Impression of Change (40), which evaluated participants' believe in improvement and rate the change as for instance 'very much improved' to 'no change' to 'very much worse'.

Clinical outcome

At all-time points an experienced, blind assessor (LT) conducted all the assessments.

We investigated trunk function using the Trunk Impairment Scale (TIS) (26) and sitting stability using the Modified Functional Reaching Test (41). For this task a participant sat on a stable surface next to a measuring tape on a wall, leaning on against the wall was not allowed. The participant was instructed to reach as far as he/she can with their non-affected hand, without losing stability, towards four directions: forwards, to the affected side, to the less affected side and backwards. The distance measured in each direction was recorded in centimeters (cm).

Gait was assessed on different levels; gait capacity, gait speed and endurance. The Functional Ambulation Categories (42) (FAC) examined walking capacity. This scale is a 6-point ordinal scale which scores level of independent walking. Ten Meter Walk Test (43) measured comfortable and maximum gait speed. The two-minute walk test scored gait endurance. The Fugl-Meyer Lower Extremity assessment (44) evaluated selective movements of the lower extremities. The Berg Balance Scale (45) scored functional balance. The Functional Independence Measure (46) and the Modified Barthel Index (47) measured the level of independence in activities of daily living.

We measured trunk and leg strength in Newton with a hand-held dynamometer (MicroFet 2, Hoggan Health Industries Inc., USA) of trunk extensors, flexors and lateral flexors, hip extensors, flexors, abductors and adductors, knee extensors and flexors and ankle plantar and dorsal flexors. This protocol was based on previous trials (48–50) and adapted to reduce compensations.

Tone of different muscle groups was evaluated using the Modified Ashworth Scale (51); elbow flexors and extensors, hip flexors and adductors, knee flexors and extensors, and ankle plantar flexors. We composed a total score for the affected and the non-affected side.

For all clinical scales, a higher score represents a better outcome, except for the Modified Ashworth Scale.

All participants received a calendar to note the number of falls and their accompanied circumstances, to monitor their usual care and included sporting activities.

Statistical analysis

The feasibility and safety results are presented descriptively as distribution of response frequencies to the questionnaires and scales.

Regarding changes in clinical outcomes, we evaluated normality of pre-intervention evaluations using the Shapiro-Wilk test and visual inspection of Q-Q plots because of the sample size. Change scores and their variability (pre-intervention minus baseline and post minus pre-intervention) in both groups were calculated, both mean and standard deviation or median and interquartile range, depending on whether data was normally distributed or not. Differences between groups were then analysed using parametric one-way analysis of variance or non-parametric Mann-Whitney test with a two-sided p -value <0.05 . If data of change scores were normally distributed, we applied parametric testing, in the other case non-parametric analysis. Analyses were conducted with IBM SPSS Statistics for Windows, version 27 (IBM Corp., Armonk, N.Y., USA). Analyses was by intention-to-treat and included all randomized participants in the groups to which they were assigned. Dropouts were included if there was a post intervention assessment independent of the number of treatments the participants received. This is an exploratory pilot study, hence we did not conduct a multiple testing correction for incorporating multiple variables.

Results

Feasibility and safety

Recruitment and retention and baseline characteristics

In total, 41 participants were contacted and were assessed for eligibility. Four did not meet the inclusion criteria and seven decided not to participate. The Covid-19 pandemic situation and travel from home to study location were the main reasons. In total, 30 participants were recruited for this trial (experimental group, $n = 15$; control group, $n = 15$). With 30 participants recruited to the trial, the recruitment rate is

30/41=73%. One participant (3.30%) of the experimental group dropped out (1/30=3.30%). This person had a back injury due to heavy lifting, not related to the study and was unable to continue the protocol and post-intervention evaluation. The other participants in the experimental group were able to complete all 12 intervention sessions (100%). Retention for this study in the experimental group was high with 14 participants completing all treatment sessions and the final assessment (93%=14/15) and 29 completed all test points (97%=29/30). Figure 3 presents the flow diagram of this study. Table 1 presents the patient characteristics for both groups and shows that there were no significant differences between groups at baseline.

Participation and adherence

Participation scores were high during T-Chair training. All participants scored 'very good' for their participation during the therapy with eight participants (53%) receiving an excellent (maximum) score. Only one participant was evaluated to participate fair to good during some of the 12 sessions.

Adherence scored also high, the median score was 7 out of 7, which represents active participation and the participant shows responsibility for the therapy regimen.

Enjoyment

On average, participants enjoyed the therapy (range 72-123). Five participants had an average score below 100 out of 126, seven scores between 100 and 125 and 2 had average scores higher than 120 for enjoyment.

Safety and adverse events

The therapist evaluated safety and recorded adverse events. During and after therapy a limited number of therapy-related adverse events occurred. One participant fell once during the cooling down therapy in the first therapy week, the participant did not wear the safety belt but had no injury. Three times, different participants indicated muscle soreness after therapy (shoulder, hip, and back region).

Fatigue (general, and of the leg and trunk) was acceptable, considering the intensive therapy provided. On a score of 30, the mean score was between 5 and 21, which means that participants were mildly to very fatigued. A similar result was noted with the Borg score with a mean score per participant across sessions from 10 to 13.5 out of 20, indicating therapy was fairly light to somewhat hard.

Impression of change

In the experimental group, two participants indicated their global perceived condition "very much improved", six "much improved", three "minimally improved" and three "no change". In the control group, one participant rated the overall change of condition as "much improved", five as "minimally improved", six as "no change" and three as "minimally worse".

Participant experience

In the Patient Experience Questionnaire (Additional file 2) all participants in the experimental group scored that the prototype could bring benefit, they all scored neutral or agreed that it was easy to use and agreed that it was enjoyable and felt good to practise with the prototype. Five participants thought that the explanation of the prototype was sufficient and five thought it could be better. Nine participants indicated that therapy with the prototype improved sitting balance, five were neutral. Three persons would not use the prototype or were neutral if it was free of charge and all the others would use the prototype. The most important aspects of the training, as indicated by the participants, were that it was fun to use, it focused on improvement and that throughout the four weeks, and the benefits were evident. As limiting factors, the participants indicated that when the prototype malfunctioned, this was hampering the therapy, that they thought the seat did not slide properly, that the seat height should be adjustable, that feedback could be sent to the participant by e-mail, that it is too difficult to use with one hand and that there should be more variation in gaming applications. Each participant indicated that, overall, it meets his or her needs.

Clinical outcomes

At baseline no important differences between groups were present between the two baseline time points apart from walking speed ($p < .004$). For trunk function (Trunk Impairment Scale, $p < .000$), maximum gait speed (10-Meter Walk Test, $p < .027$) and functional balance (Berg Balance Score, $p < .014$) significant pre- to post-intervention differences between groups in favour for the experimental group were detected compared to the control group (Figures 5-7, Table 2). Overall, improvements were larger in most of the variables in the experimental compared to the control group (Table 2). There was no significant difference between groups in hours of usual care received during the four-week intervention period (Table 1, $p = .89$). There were no differences in change from pre- to post-intervention between groups for strength and tone measures (Additional file 3).

Discussion

This study demonstrated that technology-supported sitting balance therapy was feasible and safe and, when provided in addition to usual care in the chronic stage after stroke, improved trunk function, gait and functional balance for community-dwelling stroke survivors.

Generally, T-Chair was found feasible and safe for sitting balance training. Improvements in gaming applications could be achieved by including a greater variety of games that are targeted specifically to patients after a stroke. Regarding feedback, a standardized report could be generated and send to the patients' end device via Email or an integrated app. Further improvements regarding accessibility for one-hand use, adequacy of challenges, less technical hampering and resources required for independent training are desired and will become implemented. There were no serious adverse events or other safety issues. The purpose of the T-chair is to enable intensive independent training. The T-Chair will allow to achieve this purpose after implementation of the information and feedback that has emerged from this

study. Patients with a high level of functioning and in the late phase after stroke highly enjoyed this technology-supported sitting balance therapy.

Our study suggests a positive effect for trunk function, which is the primary focus of the T-Chair. The experimental group improved 7 points out of a total score of 23 (31%) on TIS, while the control group improved 0.33 points (1.4%). This improvement in favour of the experimental group is clinically relevant. For the TIS, the clinical meaningful difference is 3.5 points in the chronic phase after stroke (52). The mean improvement in the experimental group is well above this cut-off. In fact, out of our 14 experimental participants, all surpassed this threshold, in compared with only one participant in the control group. This supports our rationale that T-Chair, which is specifically designed to train sitting balance and trunk function improves what it trains.

Results also show that additional sitting balance therapy has a positive effect on maximum gait speed and functional balance. The clinical meaningful difference for gait speed ranges from 0.13 (53) to 0.19 m/s (54). The mean improvement of 0.16 m/s in the experimental group therefore represents a clinically relevant improvement. However, our two baseline measures indicate variability in assessment of gait speed, hence we should be careful with interpreting our mean pre to post intervention change scores. We found a significant difference between the two groups for functional balance. The Berg balance scale addresses many functions that are not directly targeted with the T-Chair therapy i.e. balance during 360° turn or stepping in standing position. The clinical meaningful difference for the Berg balance score is 12.5 points (55). In this study, the median change score in the experimental group is about 4.5 points (in the control group zero). This is below the threshold but still a significant difference in comparison to the control group. Furthermore, in a systematic review (56) examining the effect of exercise therapy on balance in the chronic stage after stroke, the pooled effect of 28 studies (N=985) of balance training on Berg Balance Scale showed an improvement with a mean difference of 2.2 points (95% CI, 1.26-3.17; $p < 0.01$). Our study demonstrates a median improvement above the upper 95% confidence interval limit, suggesting that additional sitting balance therapy provides improvement in the domain of functional daily life standing balance activities.

Additional therapy was offered to the experimental group. The effect of the additional therapy on trunk function is similar to previous results. In the trial by An et al (13) for instance, participants also received additional trunk training in the chronic phase. The intensity in this study was lower, with six hours of therapy in total, compared to 12 hours in our study. An et al not only looked at the effect of training on trunk function, but also on gait and balance. They also concluded that trunk therapy had a positive effect on trunk, gait, and balance. In the literature, additional trunk therapy has been investigated by using technology with feedback. In the most recent study (57), participants in the experimental group received 7.5 hours additional canoe-based training with Wii Sports Resort game (Nintendo®, Kyoto, Japan). The researchers demonstrated a significant post-intervention improvement in reaching towards the affected side. In our study, reaching showed no between-group effect. Studies incorporating technology should focus on the application of rehabilitation-specific technology, as participants require a dedicated therapy approach and not mainstream gaming as this can be challenging and too difficult for a large group of

participants. This finding is confirmed by a systematic review pooling 22 studies (58), where the effects of training with virtual reality technology developed for patients with a stroke (SVR) showed larger effects on body function and activities than training with nonspecific technology compared to control therapy. This is an important value of T-Chair, as it is designed specifically for the large group of patients in need of sitting balance therapy.

Functional performance, measured by means of the Barthel Index or the Functional Independence Measure, is not commonly used as an outcome measure to evaluate the effect of trunk training. Out of six studies, three (16,59,60) found a significant difference between groups and three (17,61,62) did not find a difference. In our study, we did not see a significant effect of therapy. This can be explained by the fact that at baseline both groups had a high level of independence in daily activity as measured with Barthel Index and that in the previous studies effect on functional performance was evaluated in the earlier rehabilitation phase, where independence in daily life is more affected. Currently, a Cochrane review and meta-analysis is performed addressing treatment effects of sitting balance training on functional performance (63). This will shed light on the possibility of trunk therapy on improving functional independence but should be investigated as well in a future trial.

Based on the results of this study, we estimate a sample size for a further study (with a longer follow-up period and active control intervention) in G*power 3 (64). We selected the a-priori calculation, t-test for test family and the means, difference between two independent means as statistical test. Sample size calculation was based on the evaluated post-intervention score of the outcome of TIS and its standard deviation of both groups. Based on the effect size of 1.54 in this pilot study we would have to include 10 participants in each group to have a power of 90%, with a two-tailed significance level of 0.05. We obtained this sample size in this pilot trial. However, we expect the effect size to be smaller when an active control therapy is offered.

Other clinical outcomes, such as strength and reaching, showed only small improvements in the experimental group and between-group comparisons were not significant. This may be related to the limited sample size, the duration of our therapy protocol, and the fact that our sample was already achieving a high functional status. Nevertheless, when providing therapy, we should consider (functional) goal specific therapy, based on patient's defined aim. Therapy should focus on training different components of this aim along with the final aim itself. Thus, sitting balance and trunk therapy should be considered as one part of an integrated approach to functional rehabilitation. However, with T-Chair we propose a rehabilitation device that allows patients to train independently, thereby reducing the need for continuous therapist supervision and allowing for a potentially in a cost-effective way and greater rehabilitation intensity. This integrative aspect will be key in future, larger studies.

There are a few limitations concerning our study. As in many clinical rehabilitation trials, only the assessor was blinded. The quality of the research will increase if both the therapist and the participant are blinded. An active intervention in the control group has the advantage that the limitation of additional versus no additional therapy is reduced. An alternative is to conduct a trial where active trunk training in

the control group is compared with technology-supported trunk training to determine the effect of the added technology. For this feasibility study, it was decided not to perform a follow-up measurement. As a result, we do not know whether the effects of therapy are maintained. Therefore this should be included in a larger study. It is clear, by noting the Barthel Index scores, that the majority of the participants had already a good too high level of independence in daily life. This limits the generalizability of our findings. The COVID-19 pandemic has affected usual care. Some usual care was paused, and perhaps more variability in usual care happened. Still, there was no between-group difference for hours of usual care. The protocol described that we were going to conduct the 10-meter walk tests on a sensor mat, but due to technical reasons this data was not usable. For the future, it is important to develop a phase III study in which intensive training takes place for a longer period, with a larger sample size and whereby an attempt is made to blind both the therapist, assessor and patient and both groups receive additional active training with usual care controlled as much as possible.

The strength of this study is the design. A homogeneous population, with no significant differences from baseline was included. It is also positive that there has been a lot of input and user involvement from the target population, which is essential to be able to offer patient-centred care. Recommendations for further development have been formulated from this feasibility study. In addition, the effect of the training on various outcome measures was investigated. Additional T-Chair therapy suggests a positive effect on clinical outcome, which warrants the further development of technology-supported sitting balance therapy.

Conclusion

Technology-supported sitting balance therapy, which was specifically developed and based on literature, demonstrated a positive effect on trunk function, gait speed and functional balance in the chronic phase after stroke for people with a high level of ADL independence. Therapy was feasible and safe, and well-accepted by the study population and clinically meaningful. In the future, it is therefore useful to further develop this technology and therapy programme, so that the final device consists of a broad variety of exercises. There is a need to investigate this device in a large-scale study, where both groups receive an active additional therapy.

Contribution of the Paper:

- To inform that 12 hours of technology-supported sitting balance therapy can improve trunk function, gait speed and functional balance in patients in the chronic phase after stroke.
- To highlight that specific-developed technology benefits rehabilitation outcome in people in the late phase after the stroke event.

List Of Abbreviations

SD= Standard deviation

IQR= Interquartile range

n=number

N=Total number

TIS= Trunk impairment scale 1.0

CI= Confidential interval

RCT= Randomized controlled trial

phq-9= patient health questionnaire

MoCa= Montreal cognitive assessment

FAC= functional ambulation categories

cm= centimetre

ROM= range of motion

Declarations

- Ethics approval and consent to participate: Ethische Toestingscommissie Jessa Ziekenhuis, Belgian registration number; B2432020000014, all participants have signed an informed consent.
- Consent for publication: Not applicable
- Availability of data and materials: All data generated or analysed during this study are included in this published article.
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- Authors' contributions: LT designed the study project, performed data analysis, wrote the protocol and manuscript, finalised the training programme, recruited and assessed the subjects and was

consulted on the clinical aspect of the prototype. GV was the principal investigator, designed the study project, performed data analysis, wrote the protocol and manuscript and was consulted on the clinical aspect of the prototype. EV finalised the training programme and performed the therapy. RL was consulted on the design of the study and helped write the manuscript. EW finalised the training programme and was consulted on the clinical aspect of the prototype. JK was consulted on the clinical aspect of the prototype and study protocol. CB was consulted on the clinical aspect and mechanical aspect of the prototype and study protocol. PB was consulted on the mechanical aspect of the prototype. DB supervised the project and was consulted on the mechanical aspect of the chair. TN supervised the technological aspects of the project. YA supervised the technological aspects of the project. HH supervised the technological aspects of the project. All authors read and approved the submitted version.

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Table

Table 1 baseline characteristics of both groups

| | Experimental group | | Control group | | |
|--|--------------------|-------|---------------|-------|-----------------------------|
| | N=15 | | N=15 | | p-value between group ANOVA |
| Age (mean ± SD) | 54.20 | 11.46 | 49.07 | 13.99 | .28 |
| Sex | | | | | |
| Female (n) | | 7 | | 8 | |
| Male (n) | | 8 | | 7 | |
| Type of stroke | | | | | .72 |
| Ischemic (n) | | 7 | | 10 | |
| Haemorrhagic (n) | | 7 | | 5 | |
| Hemiplegic side | | | | | .48 |
| Left (n) | | 8 | | 5 | |
| Right (n) | | 6 | | 10 | |
| Dominant side | | | | | .33 |
| Left (n) | | 2 | | 1 | |
| Right (n) | | 12 | | 13 | |
| Bilateral (n) | | | | 1 | |
| Time since stroke in days (mean ± SD) | 1913 | 2834 | 1177 | 1375 | .39 |
| PHQ-9 [0-27] (mean ± SD) | 6.47 | 3.46 | 3.87 | 4.31 | .08 |
| Laterality index Star Cancellation [0-1] (mean ± SD) | 0.48 | 0.07 | .50 | .01 | .33 |
| MoCa [0-30] (mean ± SD) | 25.67 | 4.37 | 26.33 | 2.35 | .61 |
| Fall ratio last month (n) (mean+ range) | 0.29 | 0-1 | .07 | 0-1 | .13 |
| 2-Minute Walk Test in meter (mean ± SD) | 104.05 | 53.54 | 104.86 | 48.86 | .97 |
| Functional Ambulation Category | | | | | .33 |
| 0 (n) | | 1 | | 1 | |
| 1 (n) | | 0 | | 0 | |
| 2 (n) | | 0 | | 2 | |
| 3 (n) | | 4 | | 4 | |

| | | | | | |
|--|-------|-------|-------|-------|------|
| 4 (n) | | 5 | | 8 | |
| 5 (n) | | 4 | | 0 | |
| 10-Meter Walk Test, comfortable speed in m/s (mean ± SD) | 0.76 | 0.32 | .81 | 0.35 | .68 |
| 10-Meter Walk Test, maximum speed in m/s (mean ± SD) | 1.08 | 0.49 | 1.12 | 0.56 | .82 |
| Trunk Impairment Scale [0-23] (mean ± SD) | 11.80 | 3.10 | 12.40 | 3.60 | .63 |
| Fugl-Meyer of Lower Extremities [0-34] (median ± IQR) | 24.00 | 17 | 24.00 | 8 | .84 |
| Forward Reach in cm (mean ± SD) | 37.42 | 6.14 | 41.06 | 7.8 | .17 |
| Reach to the affected side in cm (mean ± SD) | 23.25 | 7.24 | 25.58 | 4.27 | .29 |
| Reach to the less affected side in cm (median ± IQR) | 28.25 | 11.50 | 28.75 | 5.00 | .39 |
| Backwards Reach in cm (mean ± SD) | 39.18 | 10.21 | 39.81 | 7.11 | .85 |
| Berg Balance Scale [0-56] (median ± IQR) | 50 | 14 | 50 | 9 | 1.00 |
| Functional Independence Measure | | | | | |
| - Cognition [5-35] (mean ± SD) | 28.27 | 5.86 | 31.47 | 3.83 | .09 |
| - Motor [13-91] (median ± IQR) | 80 | 18 | 81 | 10 | .87 |
| - Total [18-126] (median ± IQR) | 107 | 9 | 112 | 21 | .43 |
| Modified Barthel Index [0-20] (median ± IQR) | 18 | 4 | 19 | 3 | .49 |
| Total rehabilitation time in hours (mean ± SD) | 14.43 | 15.24 | 15.23 | 13.84 | .89 |

SD= Standard deviation, IQR= Interquartile range, n=number, N=Total number, cm= centimetre, m=meter, s=seconds, MoCa= Montreal cognitive assessment, PhQ-9= patient health questionnaire

Figures

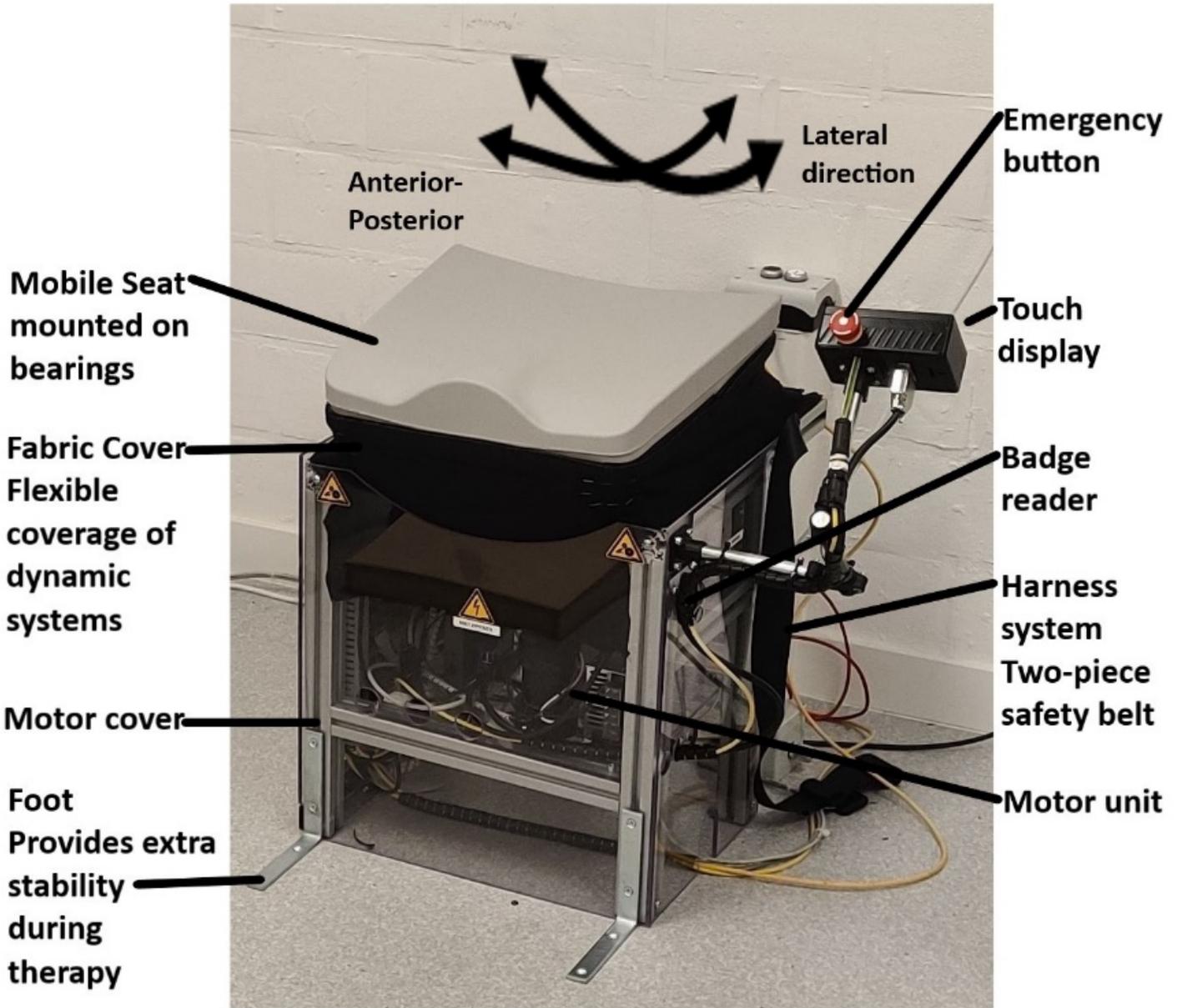


Figure 1

T-Chair prototype and main components.



Figure 2

Screenshots of boat game exercise: boat game (left) the participant has to navigate the boat through weight distribution to the left to catch the arrows and then move the boat at the port. Boat game (right), the participant is on the left side of the canal, against the bank, and by weight distribution, the participant can move the boat to the right where a new target is located.

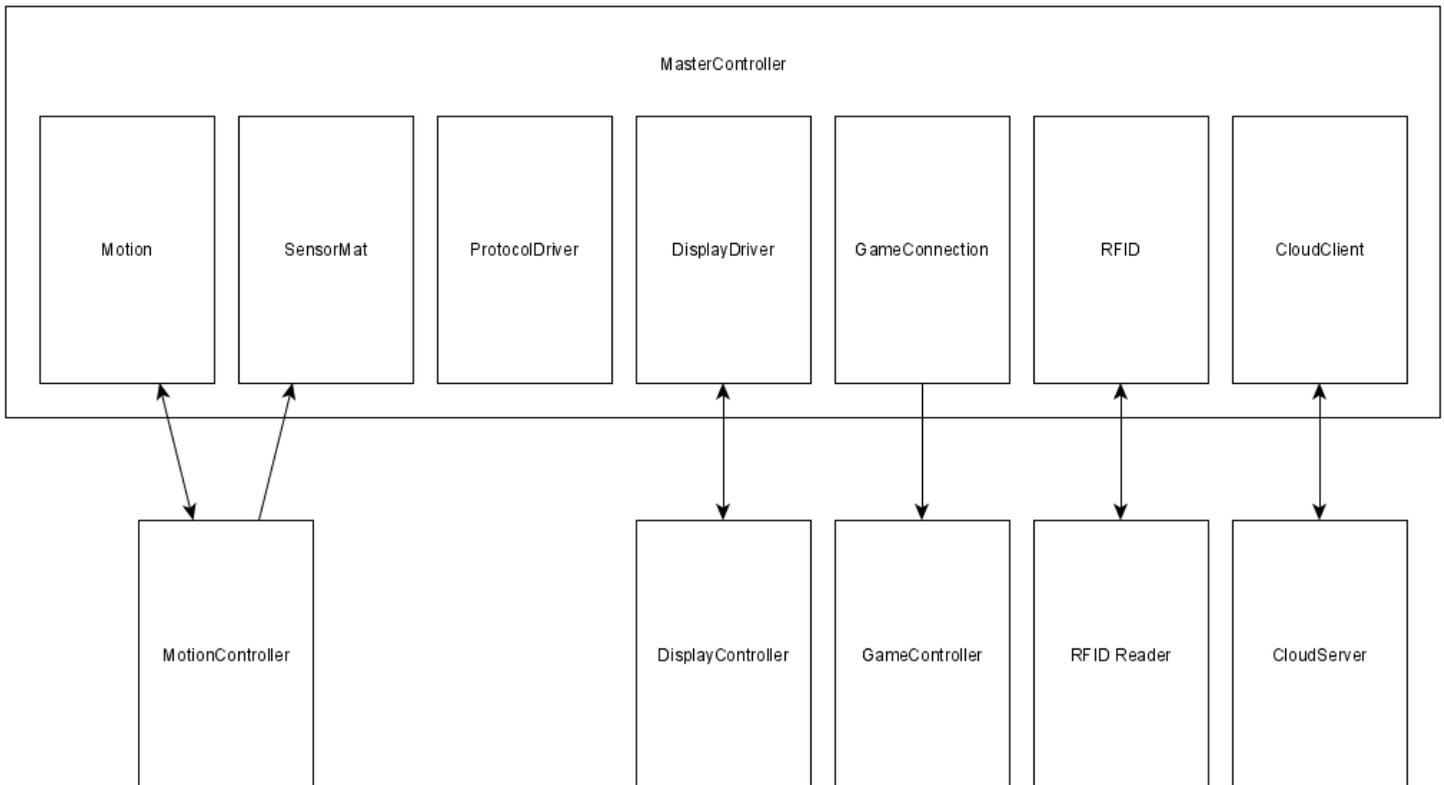


Figure 3

Diagram of the control architecture.

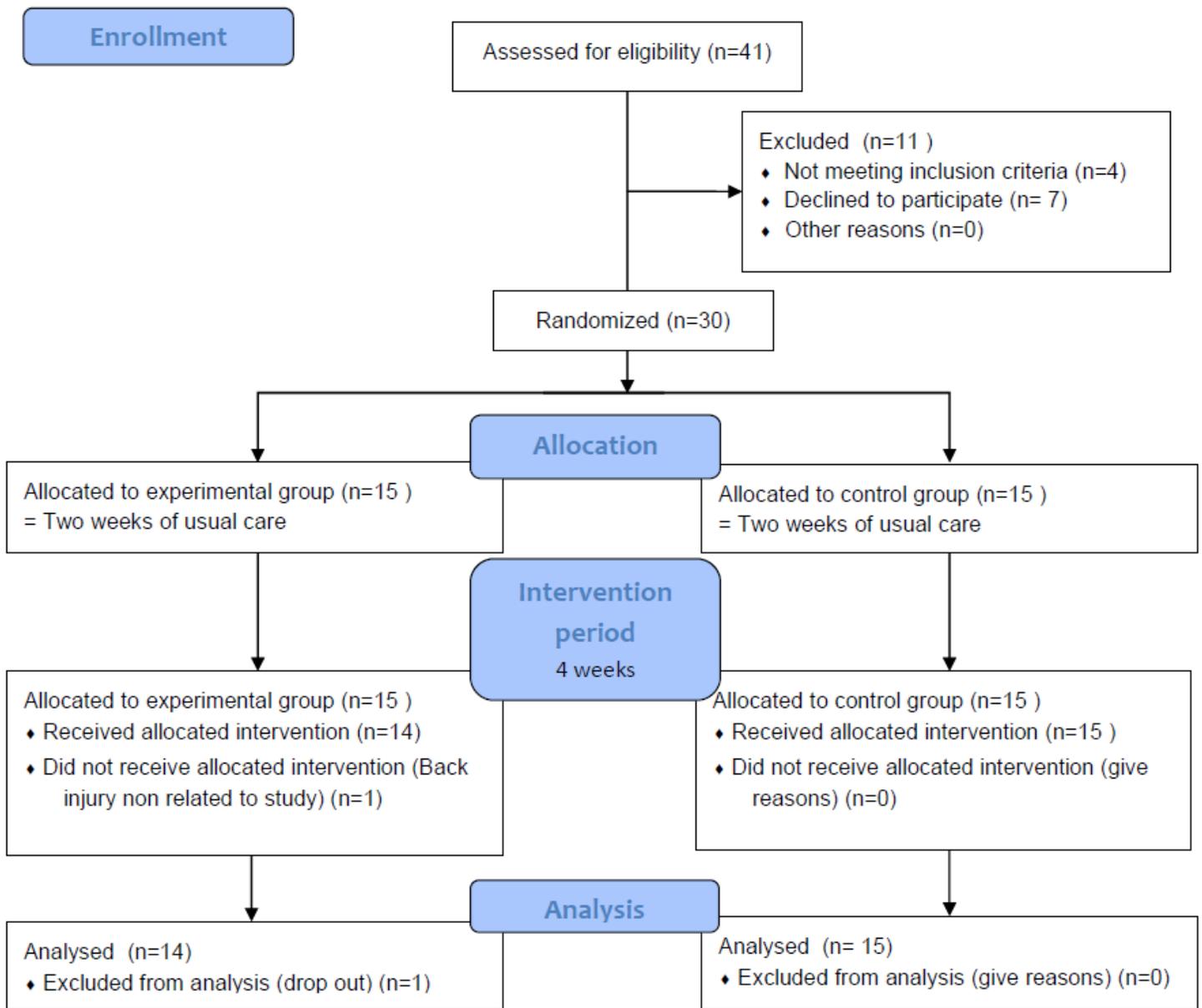


Figure 4

CONSORT flow diagram outlining the distribution of the study participants.

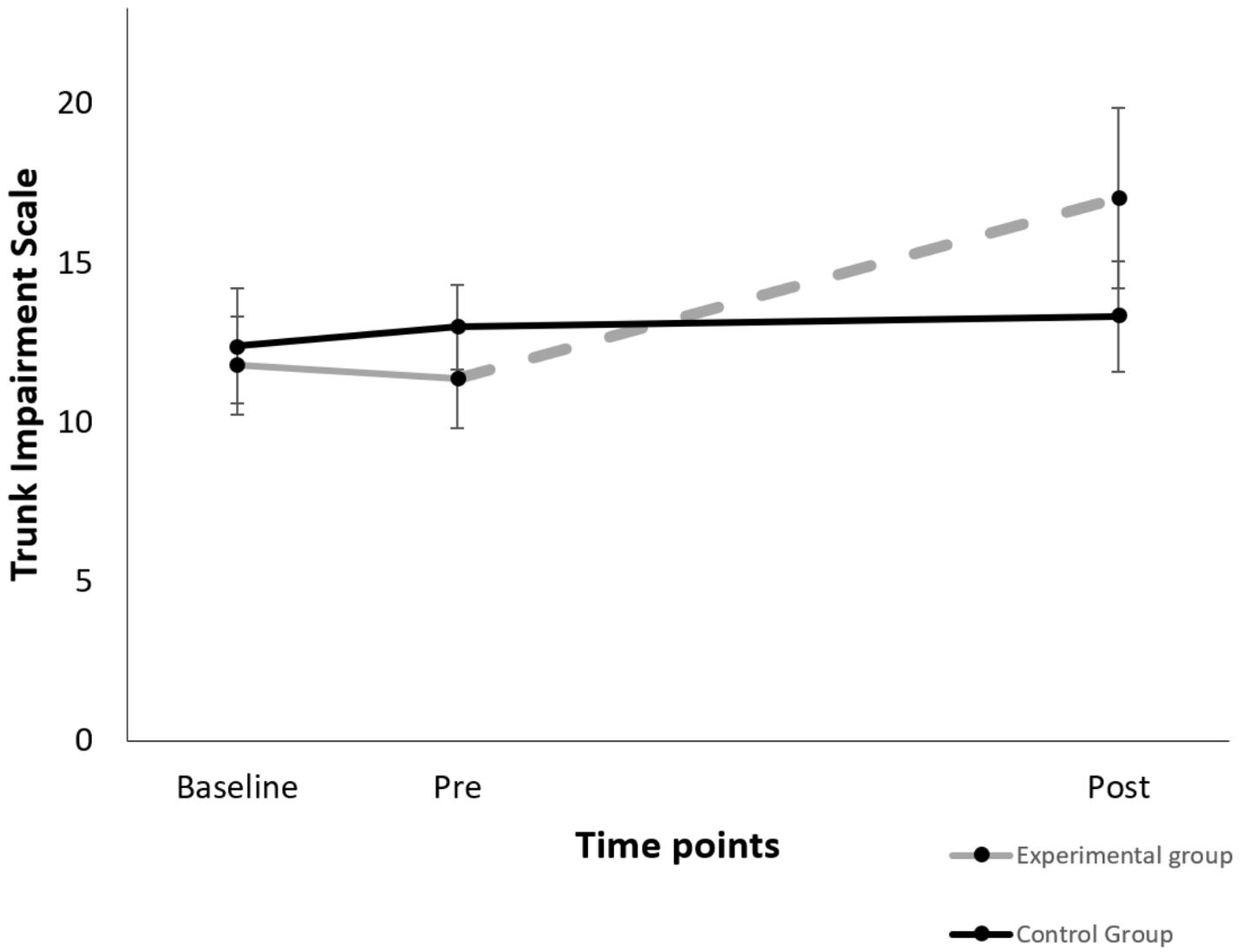


Figure 5

Total TIS score over time (Mean and Standard deviation).

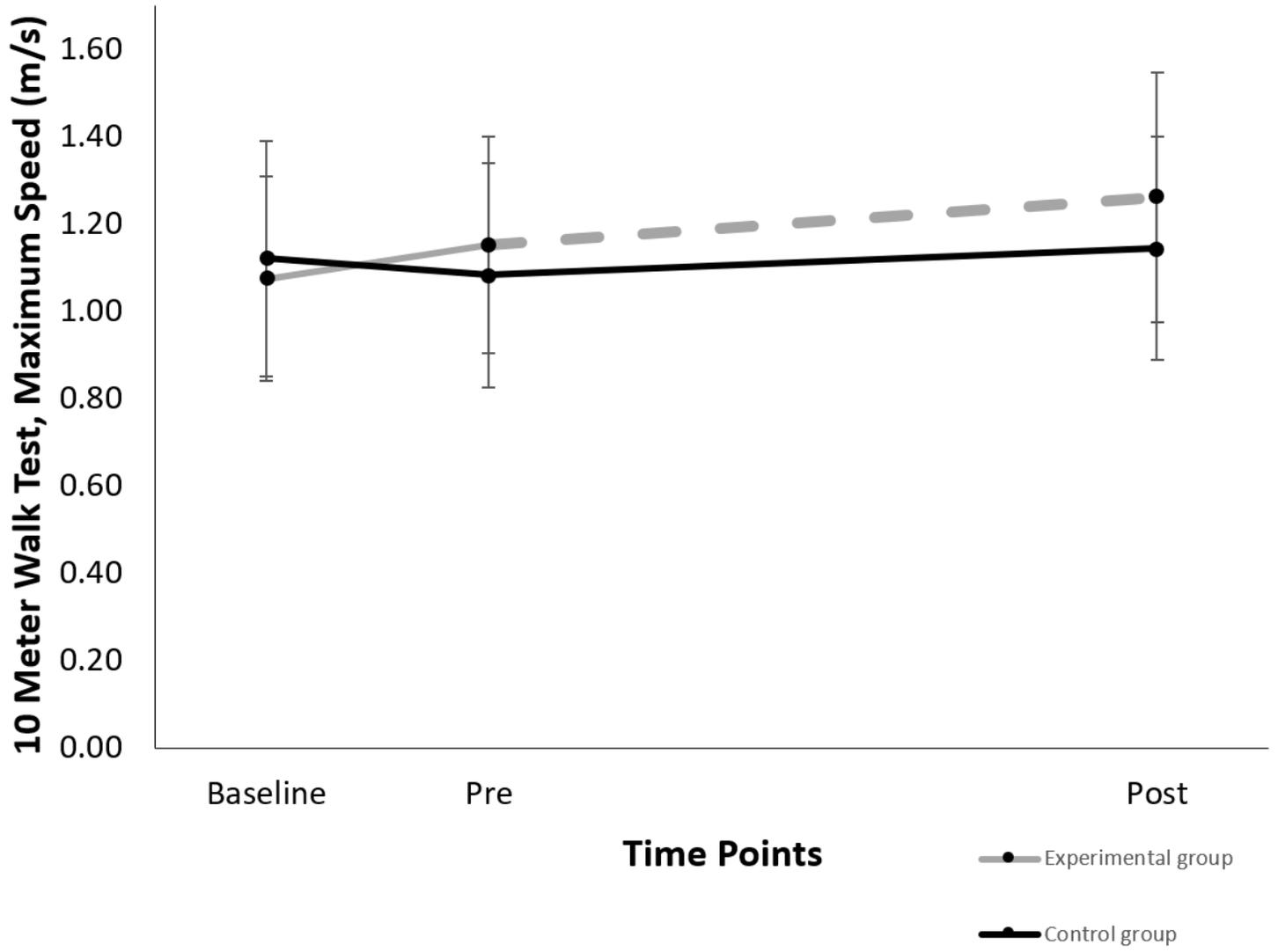


Figure 6

Maximum gait speed over time (Mean and Standard deviation).

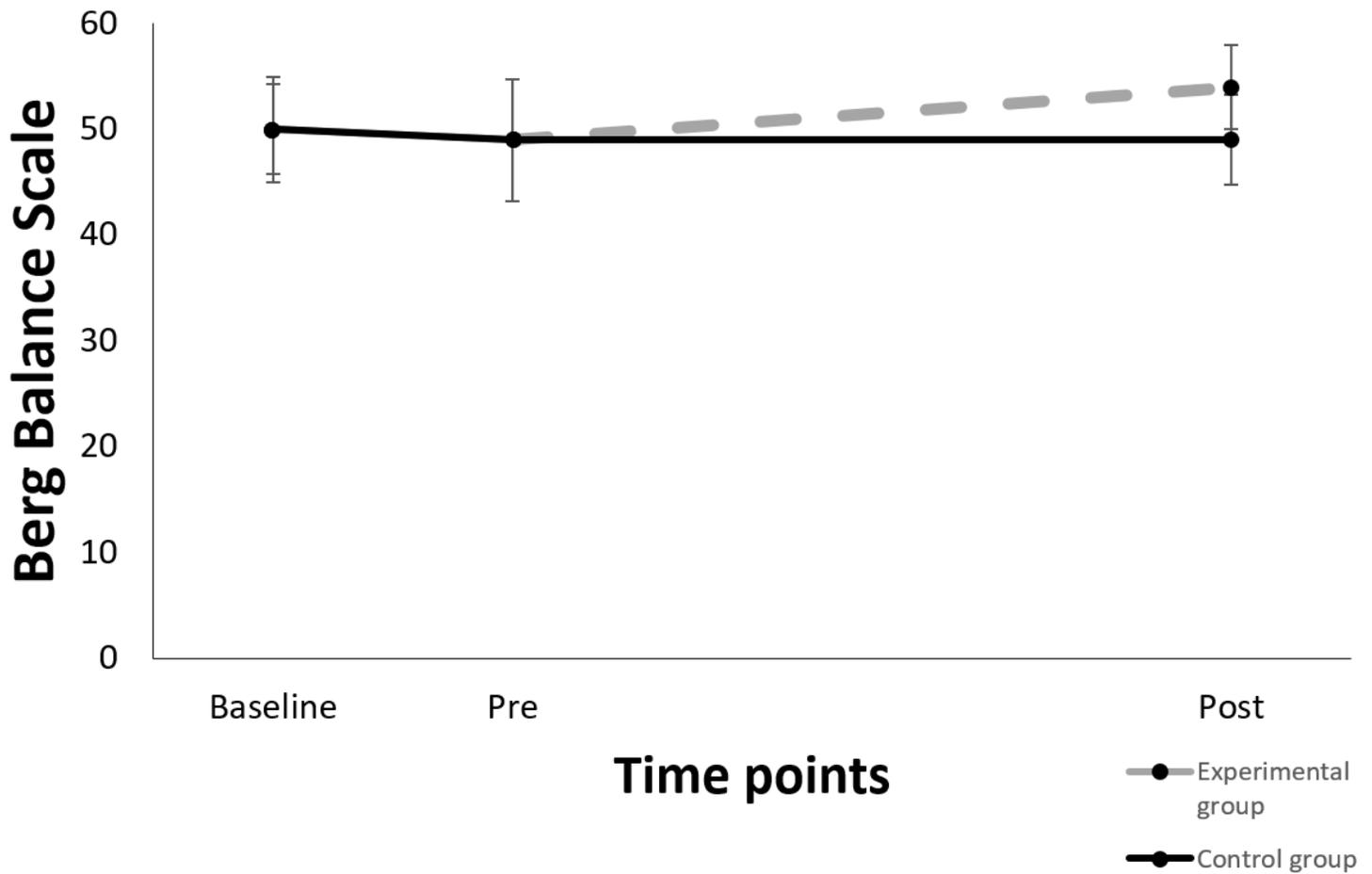


Figure 7

Functional balance over time (Median and Interquartile range).

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