



Effect of Remote Monitored Home-Based Exercise Therapy via Telerehabilitation on Balance of Patients with Stroke: A Randomized Controlled Trial

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Received: 8 Mar 2025

Accepted: 24 Jul 2025

Citation to this article

Forogh B, Atari A, Bagherzadeh Cham M, Janbazi L, Sajadi S. Effect of Remote Monitored Home-Based Exercise Therapy via Telerehabilitation on Balance of Patients with Stroke: A Randomized Controlled Trial. *J Iran Med Counc.* 2026;9(3):652-61.

Abstract

Background: Rehabilitation has positive physical effects on balance impairments after stroke. In recent years, special attention has been paid to telerehabilitation mainly due to difficulties in access to rehabilitation centers, and the cost of rehabilitation sessions. Preliminary results have shown the positive effects of telerehabilitation on balance of patients post stroke. The aim of this study was to evaluate the effect of remote monitored exercise programs via telerehabilitation compared with unmonitored home-based exercise programs on the balance of patients with late-sub acute and chronic stroke.

Methods: In this randomized clinical trial, 28 post stroke patients were randomly allocated to two groups. They received either 12 sessions of remote monitored home-based exercise programs via telerehabilitation or 12 sessions of the unmonitored home-based exercise programs over four weeks. The patients were evaluated using Berg Balance Scale (BBS) and Timed Up and Go (TUG) test before intervention, one month later, as well as one and three months after the end of the intervention.

Results: TUG test scores significantly improved only in the intervention group ($p=0.002$ vs. $p=0.37$), while BBS score significantly improved in both intervention and control groups ($p=0.001$, $p=0.02$, respectively). The effect of group-by-time interaction was not significant for either TUG [6.38 (-1.39, 14.15), $p=0.121$] or BBS [1.64 (-1.32, 4.60), $p=0.171$].

Conclusion: With the rehabilitation approach implemented in this study, unmonitored home-based exercise training is as effective as tele-monitored exercise programs on improving balance of late sub-acute and chronic stroke survivors.

Keywords: Exercise therapy, Remote rehabilitations, Rehabilitation, Stroke, Telerehabilitation

Introduction

Fall risk is recognized as a major health problem after stroke. Among all sensorimotor sequels of stroke, impaired postural control has probably the greatest effect on gait and activities of daily living independence (1). It has been reported that up to 73% of patients experienced a fall in the first 6 months after the discharge (2). Stroke rehabilitation is a process that starts soon after stroke and has positive physical effects on balance, mobility, and reduction of falls as well as mental effect in patients after stroke (3,4). Although post-stroke rehabilitation is widely used, the results could be affected by the patient adherence to the programs, difficulties in access to rehabilitation centers, and the cost of rehabilitation sessions (3). These facts have prompted efforts to improve strategies focusing on post-stroke exercise rehabilitation. Thus, in recent years, special attention has been paid to telerehabilitation. Telerehabilitation is one of the classifications of telehealth which provides distant rehabilitation services to the patients (5,6). Telehealth uses information and communication technologies to distribute health care services remotely. It has been used as a broader term and encompasses both clinical and non-clinical services (6). Telerehabilitation could generally lower the cost of rehabilitation as compared with the conventional in-person rehabilitation (7,8). It is very comforting (9) and can be accessible to more patients in remote and rural areas, patients in regions with limited healthcare facilities, and when physical attendance is impossible (7,8,10). Telerehabilitation can provide immediate rehabilitation services and continuity of care at home, which can make it useful for patients with stroke who need immediate and long-term rehabilitation services (10). The effectiveness of telerehabilitation has been demonstrated in various neurologic conditions, such as stroke (11-13), spinal cord injury (14,15), and multiple sclerosis (16). Telerehabilitation enables a safe balance as well as gait training at home for patients post stroke (17). The amount and intensity of exercise are crucial factors in achieving functional improvement, regardless of where the rehabilitation is performed (9,18). Data regarding the effect of telerehabilitation on stroke are inconsistent. Some previous systematic reviews could not reach a conclusion about the effect of telerehabilitation on

patients post stroke due to insufficient data (19,20). A systematic review by Knepley *et al* concluded that telerehabilitation is as effective as center-based rehabilitation in improving functional outcomes after stroke (12). However, a recent systematic review has suggested that telerehabilitation may be more effective than conventional rehabilitation in sitting and standing balance, as well as specific static postures after stroke (21).

On the other hand, more recently, a systematic review of nine trials suggested that equivalent doses of center-based exercises and home-based exercises have similar beneficial effects on walking speed and balance after stroke. The type and amount of supervision in home-based exercise programs were different among trials (9).

It is hypothesized that monitored home exercise training *via* telerehabilitation could improve the balance and functional mobility of patients post stroke. However, there is a lack of data regarding monitored exercise training *via* telerehabilitation as compared with the effect of unmonitored home-based exercise training on the balance and mobility of patients post stroke. Accordingly, the aim of this study was to examine the effects of 12 sessions of remote monitored exercise programs *via* telerehabilitation (videoconference) over four weeks compared with 12 sessions of unmonitored home-based exercise programs on balance of late sub-acute and chronic stroke survivors over four weeks.

Materials and Methods

Study design and settings

This parallel single-blind randomized controlled trial was carried out at physical medicine and rehabilitation departments of two university hospitals during 2020-21. Only the person who was responsible for data analysis was blinded to the groups. The study was performed in accordance with the Declaration of Helsinki, and the study protocol was approved by the local ethics committee. The study was conducted during the COVID-19 pandemic when patients were unable to attend in in-person rehabilitation. A written informed consent was obtained from all the patients at the beginning of the study. Details and limitations of the interventions were explained to the patients. The participants were assured regarding the confidentiality,

Table 1. Progressive exercise training protocol for patients during 12 sessions

Sitting position	Standing position
Push-up, marching, knee extension and flexion, ankle exercises, hip external rotation stretching, calf stretching, shifting weight forward, backward, and lateral, sitting to standing in different speeds, reaching forward and diagonal to pick up objects in different height (seated in hard and soft surface).	Double leg standing in hard surface, standing in a soft surface, heel rise, cross-over steps, tandem standing, walking forward, walking with an object in hands, side walking, reaching forward and diagonal to pick up objects in different height (standing in hard and soft surface), walking and kicking a ball, walking around obstacles, single leg standing, tandem walking, perturbed walking, step-ups, backward walking. (All progressed from supported to unsupported position, from eyes open to eyes closed)

security and integrity of their clinical data. The study was registered in the Iranian Registry of Clinical Trials under number IRCT20201204049596N1.

Participants

The study participants were recruited *via* phone calls to patients identified through the medical records of two university hospitals. The study inclusion criteria were as follows: patients aged over 45 with ischemic or hemorrhagic stroke in the area of the middle cerebral artery proved by brain MRI or CT scan who had hemiplegia for at least three months, those who were not willing to participate in in-person rehabilitation, having passed at least one month since the last session of their previous rehabilitation programs, having the ability to execute a three-step command, having decreased balance and walking ability, being able to walk with or without support, being in Function Ambulatory Categories (FAC) II–IV, having access to the Internet and communication applications, and the presence of one of the family members next to the patient in all the training sessions. The study exclusion criteria included paraplegia, damaged cerebellum or brainstem, any other neurological diseases such as neuropathy, orthopedic problems such as pain, significantly decreased joint range of motion and moderate-to-severe hip or knee osteoarthritis, significant cognitive problems such as memory loss, attention deficit, disorientation and communication disorders, mental illnesses such as major depression, psychosis and bipolar disorder, or any underlying diseases that would prevent patients from exercising.

Intervention

Twenty-eight patients were randomly allocated to either intervention group or control group in a

1:1 ratio using a computer-generated number. The patients were given group assignments in sealed opaque envelopes. Random sequence generation and allocation concealment were made by an independent researcher. During the first visit, the demographic information of the patients in both groups was recorded. The process of the study was explained to the patients in the intervention group plus their families, and made sure that patients or their families had access to the Internet and knew how to contact the therapist. An exercise-training video was sent to the patients or their caregivers *via* mobile communication applications. The video clip consisted of progressive individualized static and dynamic exercise programs including stretching, balance, strengthening, and task-oriented exercises of lower limbs. The exercises were introduced in order of difficulty in sitting and standing positions over 12 sessions (Table 1). Each exercise could be progressed based on the patient's capacity from 2 to 3 sets of 10-15 repetitions with about 2-4 *min* break in between. Patients in the intervention group were asked to do the exercises 12 sessions, each for 45 *min*, three times a week over four weeks. The exact time of the sessions was scheduled for the patient, with each session monitored through video call or videoconference. In each session, the patients were monitored and provided with supervision, encouragement, and feedback on the amount and correct implementation of exercises. During the video call, the patients could also communicate with their therapist, ask questions, and give their opinions. The intervention protocol was constant during the study; however, an individualized progression and modification of exercises were imposed according to the patients' conditions and capacity.

Patients in the control group received an educational written exercise program describing the same

Table 2. Participant's demographics and baseline evaluations

Characteristic		Intervention N=14	control N=14	p-value
Sex	Male, N(%)	8(57)	6(43)	0.70
	Female, N(%)	6(43)	8(57)	
Age (year), mean (SD)		63.28(9.69)	63.28(8.06)	0.38
Weight (kg), mean (SD)		75.64(14.91)	72.21(12.22)	0.29
Height (cm), mean (SD)		168.71	165.50	0.30
Disease duration (months) (SD)		29.00(28.47)	29.92(30.70)	0.59
FAC, mean (SD)		3.35(0.84)	3.28(0.82)	0.88
Type of stroke	Ischemic, N(%)	12(86)	11(79)	>0.99
	Hemorrhagic, N(%)	2(14)	3(21)	
Comorbidities	Asthma, N(%)	1(6)	0	>0.99
	Hypertension, N(%)	8(47)	6(38)	0.70
	Diabetes mellitus, N(%)	7(41)	7(44)	1.00
	Pulmonary embolism, N(%)	1(6)	0	>0.99
	Heart arrhythmia, N(%)	0	2(12)	0.41
	Mitral valve stenosis, N(%)	0	1(6)	>0.99
BBS, mean (SD)		38.50(11.01)	39.14(7.61)	0.17
TUG, mean (SD)		51.56(44.66)	45.71(42.61)	0.85

N: Number; SD: Standard Deviation; FAC: Functional Ambulatory Categories; BBS: Berg Balance Scale; TUG: Timed Up and Go test.

exercises and rules as the intervention group. They were also asked to do the exercises in 45-min sessions three times a week at home for 12 sessions over four weeks. To address safety concerns, an informed family member or a caregiver was also asked to be present next to the patient in all the sessions. A physical medicine and rehabilitation resident taught exercise programs to the patients and supervised the telerehabilitation sessions, as well. The patients were asked to inform the therapist if the patients received any other treatment or rehabilitation during the study.

Outcome measures

Berg Balance Scale (BBS) and Timed Up and Go (TUG) were used to assess the patients' balance and evaluate balance as well as functional mobility, respectively.

BBS is a valid and reliable instrument for measuring balance (22). It consists of 14 items scored from 0 to 4. The total score varies between 0 and 56. Higher scores indicate better ability to balance.

The TUG test is a reliable and valid test first developed in 1991 for quantifying functional mobility and balance (23). In this test, patients sit on a standard armchair (approximately 46 cm height) and lean back. As soon as patients hear the starting sound, they get up, walk three meters with the maximum possible speed, turn, and walk back to the chair and sit down. The total time was measured and recorded by the therapist. During the test, the patients were not encouraged so that the manner of performing the activities would not change. The patients in both groups were evaluated before intervention, at the end of the last treatment session (after one month), and one and three months after the end of the intervention. The patients were taught and asked to do each activity before initiating the assessment tests. The evaluation of both the patients and video calls were performed by a single physical medicine and rehabilitation resident.

Statistical analysis

The data were analyzed using SPSS version 24.

Central indicators (the mean) and dispersion (standard deviation and range of changes) were used to report the quantitative variables, while frequency and percentage were employed to report qualitative variables. The Kolmogorov-Smirnov test (KS) revealed a normal distribution of the data, thus parametric tests were used. T-test and Chi-square tests were used to compare baseline values between the two groups. Repeated measures analysis was applied to assess the main as well as interaction effect of time and group. Greenhouse-Geisser estimates of sphericity were used to correct degrees of freedom when Mauchly's test was significant. The statistical analysis was performed according to the intention-to-treat principle. The Last Observation Carried Forward (LOCF) method was used to replace missing data. A p-value <0.05 was considered as the significant threshold.

Results

Of the 46 patients assessed, 28 patients (14 females, 14 males) ageing 45-75 years met eligibility and

consented to participate in the study. They were randomized into either intervention group or control group (14 patients in each group). In the control group, six patients did not participate in the second and third follow-ups, hence the intention to treat method was used to analyze the data.

Table 2 reports the demographic data of all the patients. Statistical analysis indicated that baseline data were not significantly different between the two groups (p-value>0.05).

The time-group interaction effect on BBS (df=1.17, F=1.95, p-value=0.171) and TUG (df=1.34, F=2.43, p-value=0.12) was not significant (Table 3).

Post-hoc comparison showed that BBS and TUG significantly improved at all follow-ups vs. baseline in the intervention group. In the control group, no significant difference was observed in TUG score between different time periods and BBS significantly improved only at the last session of exercise program and three months later (Table 4).

Table 3. Between-groups comparisons of outcome measures during the study

Outcome	Before intervention	First follow-up	Second follow-up	Third follow-up	Total change (95%CI)
BBS					
Intervention, mean (SD)	38.50(11.01)	43.42(10.61)	44.14(10.76)	43.71(11.38)	5.21 (2.42, 8.85)
Control, mean (SD)	39.14(7.61)	41.85(6.01)	42.35(5.95)	42.71(6.34)	3.57 (0.30, 6.83)
Comparison of groups, MD (95% CI)	-0.64 (-7.99, 6.71)	1.57 (-5.13, 8.27)	1.79 (-4.96, 8.54)	1 (-6.16, 8.15)	1.64 (-4.60, 1.32)
p-value	0.859	0.634	0.590	0.776	0.171
TUG					
Intervention, mean (SD)	51.56(44.66)	41.10(42.90)	38.73(42.55)	39.65(43.67)	-11.91 (-20.02,-3.79)
Control, mean (SD)	45.71(42.61)	40.35(39.16)	40.06(39.33)	40.18(39.02)	-5.53 (-13.64,2.58)
Comparison of groups, MD (95% CI)	5.85 (-28.06,39.76)	0.75 (-31.32,66)	-1.33 (-33.16,30.50)	-0.53 (-32.70,31.64)	-6.38 (-14.15,1.39)
p-value	0.726	0.962	0.932	0.973	0.121

BBS: Berg Balance Scale; TUG: Timed Up and Go test; SD: Standard Deviation; MD: Mean Difference; First follow-up: at the end of training sessions; Second follow-up: after one month; Third follow-up: after three months.

Table 4. Within-group comparisons of outcome measures during the study

Outcome	Baseline vs. 1 st follow-up	Baseline vs. 2 nd follow-up	Baseline vs. 3 rd follow-up
BBS, mean difference (SE)			
Intervention group	4.92(0.87)	5.64(1.12)	5.21(1.14)
p-value	<0.001	<0.001	0.001
Control group	2.71(0.87)	3.21(1.12)	3.57(1.14)
p-value	0.02	0.052	0.02
TUG, mean difference (SE)			
Intervention group	-10.45(2.66)	-12.82(2.75)	-11.91(2.84)
p-value	0.001	0.002	0.007
Control group	-5.36(2.66)	-5.65(2.75)	-5.53(2.84)
p-value	0.32	0.30	0.37

BBS: Berg Balance Scale; TUG: Timed Up and Go test; SE: Standard Error; 1st follow-up: at the end of training sessions; 2nd follow-up: after one month; 3rd follow-up: after three months.

Discussion

In the present study, the effect of remote monitored exercise programs was evaluated through telerehabilitation on the balance of 28 hemiplegic patients with late sub-acute or chronic stroke compared to unmonitored home-based exercise programs. Due to the emergence of COVID-19, the participants of this study were patients with late sub-acute or chronic stroke who were identified through the medical records of two university hospitals and recruited by phone call. Thus, the patients in the control group were taught and received written exercise programs to do them correctly at home without monitoring. The participants of both groups had previously undergone rehabilitation programs. According to the results of this study, both remote monitored and unmonitored exercises significantly improved BBS score during the study. TUG score significantly improved in the intervention group, while the improvement of TUG was not significant in the control group. Meanwhile, it should be noted that minimal detectable change (MDC) TUG was estimated to be 7.84 for patients with chronic stroke (24). The mean difference of TUG was 11.91 points in the intervention group vs. 5.53 points in the control group in present study. However, there were no significant differences between the groups in terms of either BBS or TUG. In addition, BBS improvement in the control group

and lack of significant differences between the groups in outcome measures might be partly since patients in the control group had a high adherence to their exercise programs, particularly when they were not able to attend in in-person rehabilitation due to COVID-19 pandemic. In addition, follow-ups of the patients in control group might play an incentive role in adherence to the programs. As with the results, previous studies have suggested that unsupervised home-based exercises are as effective as supervised programs on balance and functional recovery (25,26). A systematic review of nine trials demonstrated high-quality evidence that equivalent doses of home-based exercises and center-based exercises provide similar benefits on walking speed plus balance after stroke. The amount and type of supervision varied among trials (9). In the current study, unlike the mentioned studies, home-based exercises were compared with remote exercise training not with center-based rehabilitation.

The effects of telerehabilitation on balance and mobility of stroke survivors have been compared with those of conventional rehabilitation in previous studies. In a study conducted by Lin *et al*, 24 patients who experienced stroke over at least the previous six months were recruited and divided into telerehabilitation (*via* video conferencing system) and conventional therapy groups. Similar to the present

study, their participants received 12 sessions exercise programs for four weeks. In agreement with the current study's results, the changes in the BBS and Barthel Index scores were significant in both groups, but there was no significant difference between the two groups (27). Another study compared the effect of telerehabilitation with balance training using a standing frame and with conventional therapy in patients with subacute stroke (28). Their study had several differences from the present one. First, they compared telerehabilitation with conventional rehabilitation and with standing frames. Moreover, the telerehabilitation was performed *via* virtual reality-supported balance training in their study. In addition, all the participants were sub-acute stroke patients and the duration of programs was 20 sessions over 4 weeks. However, they achieved similar results. The results revealed that the BBS, TUG, and 10-meter walk test improved in each group, but there was no significant difference between the groups (28). Similarly, a recent study concluded that telerehabilitation was as effective as conventional balance training in patients with chronic stroke (29). Despite the similar results, their study also differed from the current study in terms of the method of telerehabilitation, duration of rehabilitation (20 training sessions) and control group. They used a Kinect-based rapid movement training platform system for telerehabilitation.

Similarly, Chen *et al* failed to find the superiority of telerehabilitation over conventional rehabilitation. Similar to the present study, they performed 12 sessions of rehabilitation over 4 weeks but unlike the present study, they compared telerehabilitation with face-to-face rehabilitation (30). Furthermore, they performed telerehabilitation using exergames. No significant differences were observed between the two groups in terms of the measured indices including TUG, BBS, and modified fall efficacy scale.

Several studies evaluated the additive effect of telerehabilitation on conventional rehabilitation. A recent RCT on patients with chronic stroke found that core stabilizing exercise guided by a telerehabilitation app, combined with conventional physiotherapy, could improve trunk function and sitting balance but not standing balance than

conventional physiotherapy alone (10). Burgos *et al* demonstrated that exergames telerehabilitation system in addition to conventional physiotherapy could have greater effect on BBS compared with conventional therapy (31).

Consistent with the results of current study, most of the previous studies reported that telerehabilitation was as effective as conventional rehabilitation on balance and mobility of patients post stroke. However, a recent meta-analysis of nine RCTs concluded that telerehabilitation might be more effective in static balance abilities, while conventional rehabilitation was superior in reactive balance and locomotion (25). However, some discrepancies in the results of previous studies might be due to the differences in patients, exercise programs, as well as method and equipment of telerehabilitation.

Although conventional rehabilitation has been compared with either telerehabilitation or unsupervised home-based exercise program in previous studies, to the best of authors' knowledge, this was the first study to compare the remote monitored exercise programs *via* telerehabilitation with unmonitored home-based exercise programs on the balance and mobility of patients with late sub-acute and chronic stroke.

In this study, no significant between-groups differences were observed in BBS and TUG. This result should be considered in the light of several limitations. First, six patients in the control group dropped out of the study in the second and third follow-ups. Nevertheless, it does not seem to have had much effect on the overall results of this study since no patients withdrew at the first follow-up (at the end of the last session of exercises). Another limitation of this study may be related to the ceiling effect of BBS, rendering it less useful for detecting the differences between two groups of the participants. Limited duration of intervention and follow-up, non-blinding of outcome assessor as well as employing limited number of outcome measures were other limitations of this study. Further, the adherence of the patients of control group to their exercise program was not measured. It is therefore recommended that further studies with an extended duration of exercise program and follow-up and larger sample size should be conducted. Employing

various clinical outcome measures in conjunction with technology-based assessment tools should be another consideration for future studies. In addition, comparison of different types of telerehabilitation, could be of benefit in understanding the best telerehabilitation protocol.

Conclusion

With the rehabilitation approach implemented in this study, unmonitored home-based exercise training is as effective as tele-monitored home-based exercise training on improving the balance of late sub-acute and chronic stroke survivors.

Ethical approval

The study was registered in the Iranian Registry of

ClinicalTrialsundernumberIRCT20201204049596N1.

Funding

This research was supported by a grant from Iran University of Medical Sciences (Grant number: 21564).

Acknowledgement

The study was performed in accordance with the Declaration of Helsinki, and the study protocol was approved by the local ethics committee (Ethics approval number: IR.IUMS.FMD.REC.1399.434).

Conflict of Interest

There was no conflict of interest in this manuscript.

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