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博 士 論 文

Effect of accelerometer-based feedback on physical activity in
hospitalized patients with ischemic stroke: a randomized
controlled trial

(加速度計を用いたフィードバックが入院中の脳梗塞患者の身体
活動量に与える影響：ランダム化比較試験)

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金居 督之

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Abstract

Objective: To evaluate the effect of accelerometer-based feedback on physical activity in hospitalized patients with ischemic stroke.

Design: Randomized controlled trial.

Setting: Acute care hospital.

Subjects: Fifty-five patients with ischemic stroke who could walk without assistance were randomly assigned to the intervention group (n=27) or the control group (n=28).

Interventions: At the baseline measurement, patients did not receive accelerometer-based feedback. At follow-up, a physical therapist provided instruction on accelerometer-based feedback, discussed physical activity targets, and encouraged the patients to walk more until discharge.

Main measures: The average daily number of steps taken was used as the index of daily hospitalized physical activity.

Results: The study sample consisted of 48 patients, of whom 23 patients comprised the intervention group and 25 patients comprised the control group. Although there were no significant differences in physical activity values between the two groups at the baseline measurement, the values in the intervention group at follow-up were significantly higher than those in the control group (5180.5 ± 2314.9 vs. 3113.6 ± 1150.9 steps/day, $P = 0.0003$). The effect size of physical activity values (Cohen's $d = 1.15$) at follow-up was large between the two groups.

Conclusions: Exercise training combined with accelerometer-based feedback effectively increased physical activity in hospitalized patients with ischemic stroke.

Keywords

Stroke, physical activity, promotion, accelerometer, feedback

Introduction

In stroke rehabilitation, early mobilization is beneficial for recovery of walking¹ and a favorable outcome.² However, timing of early mobilization is controversial.³⁻⁵

Increasing movement and activity from an early stage after stroke improves walking ability,⁶ functional outcome,^{7,8} and possibly the extent of recovery from stroke.

Increasing the amount of rehabilitation also improves activity,⁹ but therapy time is often limited in the acute phase. Thus, the patient is required to undertake an increase in activity by themselves. Few clinical data are reported about the promotion of physical activity during hospitalization, and the results were controversial.¹⁰⁻¹² Previously, we reported that accelerometer-based feedback increased physical activity and self-efficacy for physical activity in hospitalized patients with mild ischemic stroke.¹² In that study, patients monitored their activity and increased physical activity by themselves, and the study was of a pre-post design without a control group. Mansfield et al. reported that accelerometer feedback of walking activity combined with a goal setting process did not increase the amount of walking,¹⁰ and Dorsch et al. reported that the augmented feedback intervention was not associated with a greater amount of time spent walking.¹¹

In contrast, some studies reported that providing feedback from an accelerometer coupled with behavioral change techniques improved physical activity in elderly people,¹³ diabetes mellitus patients,¹⁴ and cardiac patients.^{15,16} Izawa et al. also reported in randomized controlled trials that accelerometer-based feedback may increase energy expenditure¹⁶ and self-efficacy for physical activity.¹⁵ Because increasing activity with these interventions was effective in patients with various diseases, a further trial of feedback from an accelerometer is justified for patients with stroke.

We hypothesized that exercise training combined with accelerometer-based feedback would increase hospitalized physical activity such as number of steps, energy expenditure and duration of activity time in patients with ischemic stroke. Therefore, we conducted a randomized controlled trial to evaluate the effect of accelerometer-based feedback on physical activity in hospitalized patients with ischemic stroke.

Methods

Study design and participants

This study was a prospective, single-blinded, randomized, controlled trial. Informed consent was obtained from each patient. The study was approved by the Itami Kousei Neurosurgical Hospital Research Ethics Committee (approval no. 20140002) and was registered in the UMIN Clinical Trials Registry, number UMIN000029120.

We enrolled consecutive patients in the acute phase of ischemic stroke who were admitted to Itami Kousei Neurosurgical Hospital less than 48 h from stroke onset and who underwent rehabilitation from April 2016 to March 2017. Patient inclusion criteria included fulfillment of both criteria: magnetic resonance or computerized tomographic imaging showing an acute ischemic stroke and patients who could walk without assistance or gait aid within 1 week of admission. Exclusion criteria were as follows: patients with aphasia, visual field defect, or dementia (Mini-Mental State Examination score¹⁷ < 23) as evaluated by the primary physician; age > 80 years old; premorbid modified Rankin Scale score¹⁸ > 2 due to a history of musculoskeletal disease; severe cardiopulmonary disease or psychiatric disease based on the patient's medical record as evaluated by a physical therapist; and patient refusal to participate in the study.

The study sample size was determined as $n = 26$ per group based on the effect size of our previous pilot study¹² ($r = 0.87$) (two-tailed type 1 error 0.05; type 2 error 80%), which evaluated the effect of the accelerometer-based feedback on physical activity. An independent person who was not involved in enrollment or outcome assessment performed the randomization using a computer-generated 1:1 allocation sequence and permuted block size of 2. Participants were randomly assigned to the intervention group or the control group by this independent person. The sequence was concealed until intervention. This study did not blind physical therapists as to which patients were in the intervention group or control group.

We evaluated several patient characteristics: age, sex, body mass index, subtypes of stroke according to the Trial of ORG 10172 in Acute Stroke Treatment (TOAST) classification of subtypes of acute ischemic stroke,¹⁹ stroke side, National Institutes of Stroke Scale (NIHSS),²⁰ comorbidities, medications and duration of intravenous drip. Patients were assessed on the basis of previous exercise habits, walking speed test and Berg balance scale²¹ by a physical therapist at patient enrollment. Previous exercise habits were assessed using the stages of exercise behavior change.²² We considered the

patient's previous exercise habits as the preparation, action and maintenance stages of exercise behavior change. Walking speed was calculated as the result of a 10-m walking test.²³ Speed was derived from timing the patient's walking over 10-m with a stopwatch. Measurements were taken over the middle 10-m of a 14-m walkway. Patients were instructed to walk at a comfortable speed. Afterwards, walking speed was calculated as 10 m/time required in sec. We calculated the time between admission and study enrollment, the time between admission and discontinuance of the intravenous drip, the average duration of supervised rehabilitation time per day over the study period and the length of hospital stay based on the patients' medical records.

Physical activity and rehabilitation program

After enrollment, all patients wore an accelerometer on their waist belt 24 h/day until discharge except when bathing. The average daily number of steps taken was used as the index of daily hospitalized physical activity. This was measured by a Fitbit One (Fitbit Inc., San Francisco, CA) three-dimensional accelerometer that calculates steps taken, floors climbed, distance traveled, calories burned and sleep quality. It has been used for stroke patients,^{12,24,25} and the accuracy of Fitbit models has been shown in stroke patients (Fitbit Ultra)²⁶ and in community-dwelling older adults (Fitbit One).²⁷ At discharge, the Fitbit One was returned to us.

All patients underwent 40–120 min of a supervised rehabilitation program 5–6 times a week. The program consisted of physical therapy and occupational therapy and was mainly composed of body stretches, body weight resistance exercise, aerobic exercise and a cool-down period. Additionally, patients who needed to improve their balance, walking ability or activities of daily living skills received specific exercise instruction. Body weight resistance exercise comprised upper extremity exercises (shoulder flexion and abduction from anatomic position) and lower extremity exercises (squats and calf raises). Exercise intensity during aerobic exercise was 40–60% of maximum predicted heart rate or at an intensity of 11–13 (per the Borg 6–20 scale²⁸) with cycle ergometer exercise.

Intervention

After enrollment, the first two days were used for the baseline measurement of physical activity. Patients in both groups underwent only the supervised rehabilitation program as mentioned above and did not receive any feedback. After baseline measurement, patients in the intervention group were instructed in the use of accelerometer-based feedback to promote hospitalized physical activity in addition to participating in the supervised rehabilitation program.

The accelerometer-based feedback used in this study was previously described by Kanai et al.¹² and Izawa et al.^{15,16} During the intervention, all patients in the intervention group were asked by a physical therapist to record physical activity measured with the accelerometer on an exercise calendar. Our goal for this intervention was to promote physical activity in the patient by the physical therapist to greater than that currently performed during the baseline period. The accelerometer-based feedback used in this study was based on the self-efficacy theory of Bandura,²⁹ which posits that the performance of a specific behavior is strongly influenced by the confidence of individuals in their ability to perform that behavior. To enhance self-efficacy, the patients determined their physical activity target including steps per day or objective activity and long-term goals based on the therapist's advice. However, this target was initially set at a low and feasible level. For example, the physical therapist asked the patient to walk 100–500 steps more than the previous day. Patients were allowed to confirm their number of steps in real time so that they could attain their target steps. If the patient attained the target of physical activity, the physical therapist praised the patient. If the patient could not attain the target of physical activity, the physical therapist discussed a modified physical activity target with the patient by viewing the feedback log. Thus, with this intervention, the patients were expected to maintain physical activity behavior and to adopt other positive health behaviors. Although patients in the control group also continued to undergo the supervised rehabilitation program, they were not instructed on methods to confirm their number of steps or to promote physical activity. At discharge, a physical therapist provided them with report about the daily number of steps taken while hospitalized.

Outcome measures

The main outcome was physical activity values derived from the average number of steps. Secondary outcomes were exercise energy expenditure, duration of activity time and self-efficacy for physical activity. These outcomes were calculated or evaluated both at baseline measurement and at follow-up. We confirmed the number of steps, exercise energy expenditure and duration of activity time by downloading data files to Fitbit online dashboard software.³⁰ To download these outcomes, we needed to input each patient's setup parameters such as age, sex, height and weight in the device software. Duration of activity time (min/day) was calculated for each intensity (light: 1–3 metabolic equivalents [METs]), moderate: 3–6 METs and vigorous: > 6 METs).²⁴ Self-efficacy for physical activity, which was originally devised for patients with myocardial infarction,³¹ measures self-confidence for the performance of a given activity or task and represents an individual's perceptions or beliefs about how capable he or she is of performing that specific activity or task.^{29,32} The self-efficacy for physical activity score was measured with the Japanese version, whose reliability has been validated.³² The measure consists of four subscales: the domains of walking, stair climbing, weight lifting and push off. We evaluated the domain of walking, which we used as the index of self-efficacy for physical activity in this study. Subscale scores range from 0 to 100, with lower scores indicating a poor level of self-efficacy for physical activity and higher scores indicating better levels. The self-efficacy for physical activity score was measured at the baseline measurement and again at end of the follow-up. These outcomes were evaluated by a physical therapist who was aware of the exposure status of the study participants.

Statistical analysis

Results are expressed as mean \pm SD and count rate (%). We defined physical activity at baseline measurement as day 2 after enrollment because the patients did not wear an accelerometer for 24 h on day 1. We further defined physical activity at follow-up as the average number of steps per day taken from day 3 after enrollment to the day prior to hospital discharge. The average values of exercise energy expenditure and duration of activity time were calculated the same way. An independent *t*-test and χ^2 test were used to compare patient characteristics between groups. Two-way repeated measures analysis

of variance was used to compare outcomes. The within-participants factor was term (baseline vs. follow-up), and the between-participants factor was group (intervention group vs. control group). An independent person blinded to group allocation conducted these analyses. A P value of <0.05 was considered to indicate statistical significance. Statistical analyses were performed with IBM SPSS 24 statistical software (IBM SPSS Japan, Inc., Tokyo, Japan). Additionally, effect size (Cohen's d) was calculated using data at baseline measurement and intervention period. Values for Cohen's d of 0.2, 0.5 and 0.8 were interpreted as small, moderate and large, respectively.

Results

Participant flow through the present study is shown in Figure 1. In total, 55 patients met the criteria and were randomly assigned to either the intervention group ($n = 27$) or the control group ($n = 28$). However, 7 patients dropped out. Therefore, the study sample consisted of 48 patients, of whom 23 patients comprised the intervention group and 25 patients comprised the control group.

Clinical characteristics of the patients are shown in Table 1. There were no significant differences between the two groups. Most patients were discharged within 2 weeks of admission.

Differences in physical activity and self-efficacy for physical activity score between the baseline measurement and follow-up in the two groups are shown in Table 2. There were significant term by group interactions for physical activity values derived from the number of steps detected. Physical activity values in the intervention group at follow-up were significantly higher than those in the control group. There were also significant term by group interactions for exercise energy expenditure and light activity time detected. Exercise energy expenditure and light and moderate activity time at follow-up were significantly higher in the intervention group than those in the control group. In the comparison between terms, all outcomes at follow-up were significantly higher than those at the baseline measurement in the intervention group. However, physical activity values, moderate activity time, vigorous activity time and self-efficacy for physical activity score at follow-up were significantly higher than those at the baseline measurement in the control group.

Discussion

The results of the present study indicated that the accelerometer-based feedback may increase physical activity, exercise energy expenditure and the duration of activity time in hospitalized patients with ischemic stroke.

The number of steps taken at follow-up in the intervention group was about 2500 steps higher than that at the baseline measurement. In our previous study, promotion of physical activity was mainly attained by the promotion of unsupervised physical activity.¹² Although we did not analyze unsupervised physical activity in the present study, the supervised rehabilitation program was the same for each group, and the average duration of the program was not different between the groups. Thus, the increase in unsupervised physical activity might be mainly attributed to the promotion of physical activity. To promote physical activity, two previous studies conducted randomized controlled trials during inpatient stroke rehabilitation to determine the effect of accelerometer-based feedback by therapists.^{10,11} The results of these studies indicated that accelerometer-based feedback did not promote increases in physical activity or daily walking time in the hospitalized patients. However, there were discrepancies between their interventions and that of the present study. First, these two studies included the subacute phase of stroke, and time between enrollment or the number of days monitored varied with each patient. Second, although we encouraged the patients to confirm their number of steps and record daily physical activity on an exercise calendar, patients in these other studies might have received accelerometer-based feedback passively. Third, the patients determined their own physical activity target. Self-monitoring of progress and goal setting are important sources of self-motivation.³³ Mansfield et al.¹⁰ also set a walking-related goal; however, the patients' physical activity target in the present study was initially set at a low level and was accomplishable. To promote walking, Bird et al. reported in a systematic review that behavior change techniques such as "prompt self-monitoring of behavior" and "prompt intention formation" were coded in more than half of the intervention studies.³⁴ In the present study, we considered these components and incorporated them to promote physical activity. Therefore, the patients in the intervention group may have been active and had

enhanced confidence for the promotion of physical activity.

The self-efficacy for physical activity score measured at follow-up was significantly higher than that at the baseline measurement in the intervention group, which concurred with the findings reported by Kanai et al.¹² and Izawa et al.¹⁵ However, the self-efficacy for physical activity score also increased in the control group at follow-up, and there were no significant differences in the score between the groups. Thus, improvement in the self-efficacy for physical activity score did not mediate the promotion of physical activity in the present study. Because the Japanese version of the self-efficacy for physical activity measure was originally developed for cardiac patients,³² this measure might not be sensitive for patients with stroke. Although we evaluated previous exercise habits in both groups, we could not assess the type or intensity of exercise. These factors might affect the variability of the self-efficacy for physical activity scores within the domain of walking. Izawa et al.¹⁵ showed that accelerometer-based feedback improved self-efficacy for physical activity in cardiac patients after discharge and improved the rate of exercise maintenance compared to controls. Therefore, further study is needed to clarify the effect of accelerometer-based feedback on self-efficacy for physical activity and exercise maintenance in patients with ischemic stroke after discharge.

Several studies reported on energy expenditure or physical activity level among stroke patients during hospitalization.^{24,35,36} In the present study, the accelerometer-based feedback might not only be effective in increasing the number of steps taken but also in increasing energy expenditure on exercise or duration of activity time. Because the patients in the intervention group walked to attain their target level of physical activity, the more physical activity was promoted, the greater was the energy expenditure on exercise and the METs increased. Lacroix et al.³⁶ reported that active energy expenditure was 91 kcal among patients hospitalized in a rehabilitation unit and 221 kcal among patients who reached the recommendation that at least 30 minutes of physical activity be performed per day. Because that study measured active energy expenditure only during the daytime, we could not unconditionally compare energy expenditure and duration of activity time. Although accelerometer-based feedback increased the duration of activity time, only about 10 minutes of moderate to vigorous

physical activity was performed per day in the intervention group at follow-up. Tudor-Locke et al. suggested that 30 minutes of moderate to vigorous physical activity be recommended for older adults and/or special populations living with disability.³⁷ Patients in the present study could not achieve this recommend level, which was also not achievable by stroke patients in a hospital rehabilitation unit^{35,36} or by community-dwelling stroke patients.^{38,39} Thus, we might need to consider incorporating moderate to vigorous physical activity into our rehabilitation program and to emphasize the importance of this activity during hospitalization so that the patients will continue to be physically active after discharge.

There are several limitations in this study. First, it was conducted at a single center, and the sample population was small. We calculated sample size before the study and included $n > 26$ patients per group, but 7 patients dropped out of the study. Even so, our analysis yielded statistically significant findings indicating that the effect size may be large. Second, we included only patients who could walk without assistance. Thus, we do not know if accelerometer-based feedback would promote activity in patients with moderate to severe stroke. A previous study suggested that patients with moderate to severe stroke tend to remain inactive during the first 14 days of acute stroke unit care.⁴⁰ Further study will be necessary to establish a method to promote physical activity or decrease sedentary behavior in these patients. Third, we did not conduct functional tests such as walking speed and the Berg balance scale at discharge. Improvements in these aspects might possibly contribute to changes in the patients' physical activity. Finally, because the measurement of physical activity was performed only during hospitalization, we do not know whether the effect of physical activity promotion will continue over time and influence the long-term prognosis. Several studies showed that hospitalized physical activity has effects on readmission⁴¹ and mortality.⁴² Therefore, additional study is needed to determine whether the benefits of accelerometer-based feedback will continue over time.

An important clinical implication of this study is that the physical activity of hospitalized patients with stroke could be increased with simple methods through appropriate feedback and goal setting. Because physical inactivity during hospitalization is associated with poor functional outcome,⁷ physical therapists need to consider these

interventions in the practice of rehabilitation to make the best of limited therapy time.

Clinical messages

- Exercise training combined with accelerometer-based feedback and goal setting may be an effective method to increase physical activity in hospitalized patients with ischemic stroke.
- The present study can contribute to the development of methods to promote physical activity in hospitalized patients with stroke.

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Conflict of interest

The Authors declare that there is no conflict of interest.

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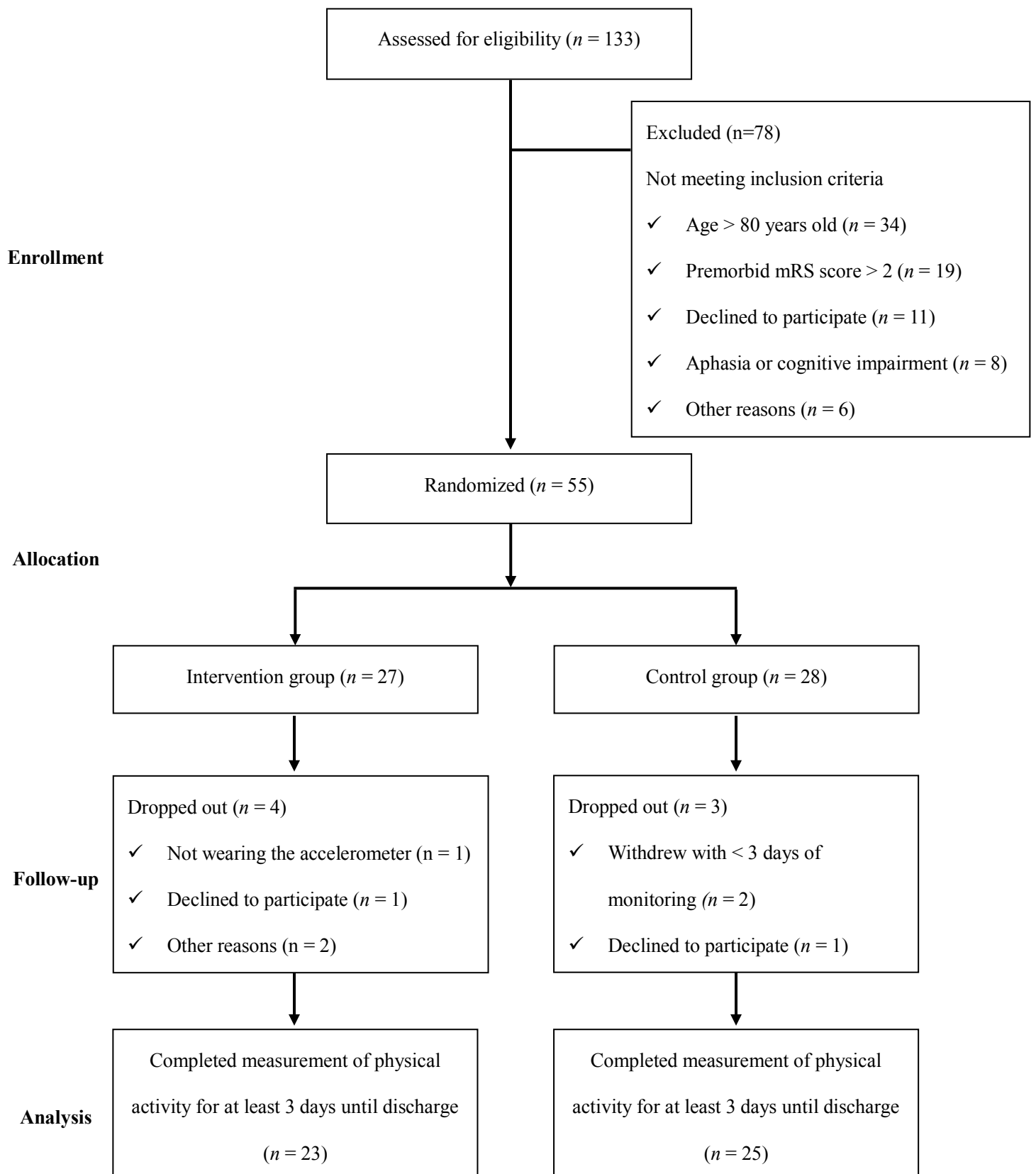


Figure 1. Participant flow in the study. mRS: modified Rankin Scale.

Table 1. Clinical characteristics.

	Intervention group (n = 23)	Control group (n = 25)	t or χ^2 value	P value
Age (years)	66.8 (10.0)	62.9 (9.1)	1.43	0.160
Sex (male), n (%)	15 (65.2)	13 (52.0)	0.86	0.353
Body mass index (kg/m ²)	24.0 (3.5)	22.9 (3.1)	1.18	0.243
TOAST classification of subtypes of acute ischemic stroke, n (%)			1.77	0.621
Large-artery atherosclerosis	6 (26.1)	4 (16.0)		
Cardioembolism	1 (4.3)	2 (8.0)		
Small-vessel occlusion	16 (69.6)	18 (72.0)		
Undetermined	0 (0)	1 (4.0)		
Stroke side (left /right /bilateral)	13 /9 /1	14 / 11/ 0	1.13	0.268
NIHSS (score)	0.9 (0.8)	1.0 (1.0)	-0.65	0.517
Comorbidity, n (%)				
Hypertension	14 (60.9)	14 (56.0)	0.12	0.732
Diabetes mellitus	3 (13.0)	6 (24.0)	0.94	0.331
Medication, n (%)				
Antiplatelet	20 (87.0)	19 (76.0)	0.94	0.331
Anticoagulant	4 (17.4)	7 (28.0)	0.76	0.382
Angiotensin receptor blocker	3 (13.0)	2 (8.0)	0.33	0.568
Calcium channel blocker	8 (34.8)	7 (28.0)	0.26	0.613
β -blocker	1 (4.3)	2 (8.0)	0.27	0.602
Statin	8 (34.8)	8 (32.0)	0.04	0.838
Previous exercise habits, n (%)	19 (82.6)	21 (84.0)	0.17	0.897
Walking speed (m/sec)	1.1 (0.2)	1.1 (0.3)	-0.05	0.961
Berg balance scale (score)	54.1 (2.1)	54.7 (1.7)	-0.96	0.325
Time between admission and	3.6 (1.4)	3.8 (1.5)	-0.55	0.584

study enrollment (days)				
Time between admission and finish intravenous drip (days)	7.3 (2.7)	6.7 (2.3)	0.81	0.423
Average duration of supervised rehabilitation time (min/day)	76.9 (26.9)	76.5 (20.6)	0.06	0.951
Length of hospital stay (days)	12.2 (2.8)	11.4 (3.9)	0.87	0.392

NIHSS: National Institutes of Health Stroke Scale; TOAST: Trial of ORG 10172 in Acute Stroke Treatment.

Mean (\pm SD) or ordinal variables and counts (%) for categorical variables,

Table 2. Physical activity and self-efficacy between groups.

	Intervention group	Control group	<i>P</i> value	Effect	Interaction	
	(<i>n</i> = 23)	(<i>n</i> = 25)		size (<i>d</i>)	<i>F</i>	<i>P</i>
					value	value
Number of steps (/day)					17.49	<0.001
Baseline	2726.8 (1931.3)	2405.0 (1435.5)	0.519	0.19		
Follow-up	5180.5 (2314.9) ^c	3113.6 (1150.9) ^b	0.0003	1.15		
Exercise energy expenditure (kcal)					14.88	<0.001
Baseline	288.8 (212.2)	268.0 (135.2)	0.685	0.12		
Follow-up	420.0 (268.3) ^c	295.7 (109.9)	0.038	0.62		
Duration of activity (min/day)						
Light activity					13.85	0.001
Baseline	101.0 (59.2)	110.2 (51.3)	0.564	0.17		
Follow-up	139.5 (52.0) ^c	113.7 (35.1)	0.048	0.59		
Moderate activity					3.42	0.071
Baseline	1.7 (6.4)	0.6 (2.1)	0.425	0.23		
Follow-up	7.1 (9.4) ^b	2.7 (3.8) ^a	0.036	0.63		
Vigorous activity					2.30	0.136
Baseline	1.5 (7.1)	0	0.302			
Follow-up	3.4 (8.2) ^a	0.8 (1.5) ^a	0.127	0.45		
Self-efficacy for physical activity (score)					0.13	0.718
Baseline	56.6 (30.5)	60.3 (25.4)	0.700	0.13		
Follow-up	66.8 (24.9) ^a	68.4 (22.4) ^a	0.809	0.07		

Light activity: 1-3 metabolic equivalents; Moderate activity: 3-6 metabolic equivalents;

Vigorous activity: > 6 metabolic equivalents.

Mean (\pm SD).

^a $P < 0.05$ (vs. Baseline), ^b $P < 0.01$ (vs. Baseline), ^c $P < 0.001$ (vs. Baseline).