Topics in Stroke Rehabilitation

Impact of mHealth technology on adherence to healthy PA after stroke: a randomized study

--Manuscript Draft--

Manuscript Number:	
Full Title:	Impact of mHealth technology on adherence to healthy PA after stroke: a randomized study
Article Type:	Original Article
Keywords:	stroke rehabilitation; sedentary behavior; physical activity; adherence; mHealth
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Abstract:	Background Physical activity (PA) is a key health behavior in people with stroke, including risk reduction of recurrent stroke. Despite the beneficial effects of PA, many community-dwelling stroke survivors are physically inactive. Information and communication technologies are emerging as a possible method to promote adherence to PA. Objective The aim of this study was to investigate the effectiveness of a smartphone activity App in improving levels of PA and reducing sedentary time. Methods This was a pilot randomized trial with a baseline and a 3-months follow-up assessment in an outpatient rehabilitation setting at a university hospital. Forty-one chronic stroke survivors were randomized into an intervention group (IG) n=24 and a control group (CG) n=17. Participants in the IG were engaged in the Multimodal Rehabilitation Program (MMRP) that consisted on the implementation of a mobile-health app, to supervise adherence to PA, and the participation of an 8-week rehabilitation program, two alternate days a week, in sessions of one hour (16 sessions in total) that included: aerobic, task-oriented, balance and stretching exercises. Participants also performed an ambulation program at home. The CG received a conventional rehabilitation program. Outcome variables were: adherence to PA activity, reported by community ambulation and sedentary behavior (walking and sitting time/day), walking speed (10-m walking test); walking endurance (6MWT); risk of falling (TUG); ADLs (Barthel); QoL (Eq-5D5L) and participant's self-reported satisfaction. Results

At the end of the intervention, community ambulation increased by an average of 38.95 (SD 20.37) minutes in the IG (p≤.05) and 9.47 (SD 12.11) minutes in the CG. Sitting time was reduced by 2.96 (SD 2.0) hours/day in the IG (p≤.05) and by 0.53 (SD 0.24) hours in the CG. Comfortable and fast walking speed, measured with the 10MWT, increased 0.21 (SD 0.07) and 0.27 (SD 1.3) meters/second respectively in the IG (p≤.05) and the CG increased 0.12 (SD 0.04) and 0.06 (SD 0.03) meters/second respectively. Risk of falling, measured with the TUG test, decreased by 3.46 seconds in the IG (p≤.05) and the CG increased 4.67 seconds. Participants in the IG achieved independence in ADLs (p=.009), and the CG remained mildly dependent. Regarding QoL, assessed with the EQ-5D-5L, there is a statistical improvement of self-perceived QoL in the IG (p<.001) and in the CG there were no changes in self-perceived QoL.

Conclusions

The results suggest that mHealth technology provides a novel way to promote adherence to home exercise programs post stroke. However, frequent support and guidance of caregiver is required to ensure the use of mobile devices.

Funding Information:	Departament de Salut, Generalitat de Catalunya (SLT006/17/)	Mrs. Montserrat Grau-Pellicer

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ABSTRACT

Background: Physical activity (PA) is a key health behavior in people with stroke, including risk reduction of recurrent stroke. Despite the beneficial effects of PA, many community-dwelling stroke survivors are physically inactive. Information and communication technologies are emerging as a possible method to promote adherence to PA.

Objective: The aim of this study was to investigate the effectiveness of a smartphone activity App in improving levels of PA and reducing sedentary time.

Methods: This was a pilot randomized trial with a baseline and a 3-months follow-up assessment in an outpatient rehabilitation setting at a university hospital. Forty-one chronic stroke survivors were randomized into an intervention group (IG) n=24 and a control group (CG) n=17. Participants in the IG were engaged in the Multimodal Rehabilitation Program (MMRP) that consisted on the implementation of a mobile-health app, to supervise adherence to PA, and the participation of an 8-week rehabilitation program, two alternate days a week, in sessions of one hour (16 sessions in total) that included: aerobic, task-oriented, balance and stretching exercises. Participants also performed an ambulation program at home. The CG received a conventional rehabilitation program. Outcome variables were: adherence to PA activity, reported by community ambulation and sedentary behavior (walking and sitting time/day), walking speed (10-m walking test); walking endurance (6MWT); risk of falling (TUG); ADLs (Barthel); QoL (Eq-5D5L) and participant's self-reported satisfaction.

Results: At the end of the intervention, community ambulation increased by an average of 38.95 (SD 20.37) minutes in the IG ($p \leq .05$) and 9.47 (SD 12.11) minutes in the CG. Sitting time was reduced by 2.96 (SD 2.0) hours/day in the IG ($p \leq .05$) and by 0.53 (SD 0.24) hours in the CG. Comfortable and fast walking speed, measured with the 10MWT, increased 0.21 (SD 0.07) and 0.27 (SD 1.3) meters/second respectively in the IG ($p \leq .05$) and the CG increased 0.12 (SD 0.04) and 0.06 (SD 0.03) meters/second respectively. Risk of falling, measured with the TUG test, decreased by 3.46 seconds in the IG ($p \leq .05$) and the CG increased 4.67 seconds. Participants in the IG achieved independence in ADLs ($p=.009$), and the CG remained mildly dependent. Regarding QoL, assessed with the EQ-5D-5L, there is a statistical improvement of self-perceived QoL in the IG ($p<.001$) and in the CG there were no changes in self-perceived QoL.

Conclusions: The results suggest that mHealth technology provides a novel way to promote adherence to home exercise programs post stroke. However, frequent support and guidance of caregiver is required to ensure the use of mobile devices.

Keywords: Stroke rehabilitation; sedentary behavior; physical activity; adherence; mHealth

Introduction

Stroke survivors usually complete a rehabilitation program adapted to their characteristics and needs with the aim to improve the motor control of the affected side of the body. These programs are completed in different areas, depending on the characteristics of every single person, their needs and the psycho-social support (inpatient, outpatient or home-based rehabilitation programs) with an intensity that depends on the exercise tolerance of each person[1]. Conventional rehabilitation programs focus on the subacute period and usually end when the person achieves basic activities of daily living (ADLs). Thus, conventional rehabilitation programs usually do not provide maintenance exercises to provide long term health gains. Recent evidence indicates that levels of community reintegration are low to moderate due to the fact that 70% of stroke survivors will regain ambulation sufficient for in-home mobility but they do not achieve community mobility (CM)[2], defined as "moving around in the community and using public or private transportation, such as driving, walking, cycling, or accessing and riding in buses, taxi cabs, or other transportation systems"[3]. Community reintegration an maintaining interpersonal relationships, which are major components of the participation domain in the International Classification of Functioning, Disability and Health (ICF) model, require essentially CM[4]. Therefore, independent community ambulation is a challenging rehabilitation goal[5].

People with stroke usually spend more time sitting and less time in activity than age-matched peers.[6] Reducing sitting time has demonstrated that leads to health benefits and clinically important reductions in cardiovascular risk in general population[7,8]. Physical activity (PA) is also a key health behavior for the management and maintenance of health in people with stroke[9], including risk reduction of recurrent stroke[10]. Recent studies recommend multimodal rehabilitation programs tailored to stroke survivors, with exercises addressed to improve aerobic condition, motor function, balance, coordination and independence in ADLs[11,12]. The practice of PA has been recognized as important for achieving higher levels of CM[2,13]. Walking is an effective, popular, and sustainable form of PA, which requires no special equipment, can be incorporated into everyday life[14], and is an acceptable form of activity in those most physically inactive. Despite the beneficial effects of PA, many community-dwelling stroke survivors are physically inactive[6]. Understanding common barriers to PA and creating strategies to overcome them may help to make PA as a key part of daily life. Some of the most common barriers include the severity of the residual impairment, co-morbidities, fatigue, lack of time, lack of motivation, lack of skills, lack of resources and transport problems[15]. Supervised exercise programs (for example pulmonary or cardiac rehabilitation programs) lasting for 4–6 weeks can be effective for participants to practice exercise in a safe and controlled environment[16]. However, adherence rates decline or cease after the completion of the program, along with the clinical gains obtained[17], highlighting the need for effective maintenance strategies. Programs of PA need active implementation strategies tailored to barriers and facilitators that prevent or promote successful implementation. Information and communication technologies (ICT), tracking devices and interactive elements such as pedometers, smartphone applications (Apps) and computer-based materials, adjusted to the individual needs of patients, have demonstrated to be successful in improving PA uptake in different chronic conditions[18] and in general population[8,19,20]. Apps on smartphones are programs that use data collected from a smartphone's inbuilt tools, such as the Global Positioning System (GPS), accelerometer, microphone, speaker, and camera, to measure health and fitness parameters (for example: activity/sedentary behavior, steps/day, walking distance or walking speed). The Apps can analyze these data and summarize them, as well as design individualized plans, provide feedback, personalized coaching, and motivation[21,22]. The use of this methodology is named mHealth technology [23–25] and is emerging as a possible method to provide customized activity goals and feedback to promote exercises in cancer survivors and in general population[19,20]. The impact of activity feedback on exercise adherence within stroke population is less clear. Most research related to lifestyle modification and management of chronic diseases has not focused in stroke patients. We aimed to evaluate the impact of a smartphone activity App on PA adherence in people following a stroke. The aim of this study was to investigate the potential effectiveness of a smartphone activity App in improving levels of PA, sedentary time, walking speed, health markers and well-being in people following stroke

Materials and methods

Study design

A pilot randomized trial was designed to evaluate the effectiveness of a mHealth app on PA adherence, after a post-stroke multimodal rehabilitation program (MMRP). Before enrollment, participants received a conventional rehabilitation program that included: trunk exercises, muscle strengthening, occupational therapy and gait training. Participants of both groups were evaluated at baseline (E1), and at three months (E2). The study conforms to the CONSORT statements

Participants

Figure 1 shows Consort Flow diagram of sample selection. Forty-one participants were recruited from Hospital-Consorci Sanitari de Terrassa (Barcelona, Spain). All of them had suffered a stroke one year ago and completed a conventional rehabilitation program. Inclusion criteria were: age≥18 years; diagnosis of ischemic or hemorrhagic stroke; functional ambulation classification (FAC) ≥3; Barthel Index ≥45. Exclusion criteria were: diagnosis of cognitive impairment (Mini Mental State Examination ≤24); unstable cardiovascular disease (acute heart failure, recent myocardial infarction, unstable angina, and uncontrolled arrhythmias)[26,27]; alcohol or other toxic substances abuse and decompensated psychiatric disorders that prevented from following a group session.

Previous to enrollment, participants underwent a medical examination to ensure that there were no circumstances that prevented their participation in the program, following the guidance of the American College of Sports Medicine (ACSM) for patients with coronary heart disease[26] and the guidelines of the American Heart Association (AHA) for stroke survivors[27]. All experimental procedures were conducted according to the Declaration of Helsinki. The study was approved by the Ethics and Clinical Research Committee of Hospital-Consorci Sanitari de Terrassa. Written informed consent was obtained from each participant.

A computer-generated random sequence was generated in Microsoft Excel to allocate groups and generate numbers of which was then used to assign participants to intervention group (IG) or control group (CG).

Sample size calculation

The granmo sample calculator[28] was used to calculate the sample and applied a two independent means measurement. 21 subjects in the IG and 21 in the CG were needed, accepting an alpha risk of 0.05 and a beta risk lower than 0.2 in a bilateral contrast, assuming a SD of 29 and to detect a difference equal to or greater than 30 minutes/day community ambulation. A loss rate of 30% was estimated.

Procedure

Participants in the IG were engaged in the MMRP. It was conducted and delivered as a supervised program at the Rehabilitation Unit of the hospital (March to September 2018). It consisted of an 8-week intervention of two alternate days a week, in sessions of one hour (16 sessions in total). The intervention was performed in groups of 4–6 participants with a physical therapist who guided the session and consisted on:

1. The implementation of a digital platform based on two mHealth apps, Fitlab® Training and Fitlab® Test (www.HealthSportlab.com, Barcelona): 1) to supervise adherence to PA using the GPS and the accelerometer to monitor walking distance and walking speed; 2) to assess mood, effort, recovery, wellness and fatigue questionnaires; 3) to have bidirectional feedback: participants could visualize results and exchange messages with the researchers. Figure II.
2. A pedometer (model UW-100, UW-101® A&D®) to count steps/day.
3. A WhatsApp group was created with the aim to give motivation for active lifestyle, feedback to participants and to create a collective identity in the rehabilitation group[29].
4. Participation in an 8 week exercise program (2 days/wk, 1 hr/session) that consisted on: aerobic, task oriented training, balance and stretching exercises, as described previously[13]
5. A progressive daily ambulation program at home with the aim to reach PA levels recommended by the World Health Organization (WHO)[9] of 150 m/wk of moderate PA. The program was monitored with the app and the pedometer.
6. At the end of the intervention, participants were administered an ad hoc self-reported satisfaction questionnaire.

The CG received only the conventional rehabilitation program that included: trunk exercises, muscle strengthening, occupational therapy and gait training, as described previously.

Variables

The primary outcome measure was adherence to PA It was measured by:

1) Community ambulation time reported by participants
2) Sedentary behavior: sitting time reported by participants

Secondary outcome measures were:

1) Walking speed: 10 Meter Walking Test (10MWT). According to the Locomotor Experience Applied Post-stroke guidelines [30], the time that each participant takes to walk 10 meters at a comfortable pace and at their maximum speed was registered. Each measure was repeated twice and the average of the two distances was calculated in meters/second. Participants were categorized into: household ambulators (<0.4m/sec), limited community ambulation (0.4-0.8m/sec.) and community ambulators (>0.8m/sec.)[31]
2) Walking endurance: six-Minute Walking Test (6MWT). The 6MWT is an assessment of the distance walked over a period of six minutes and is considered a useful measure of walking capacity after a stroke[32]. It was validated as a submaximal oxygen consumption test for individuals with cardiac or pulmonary disease[33]. The test was standardized according to the American Thoracic Society Guidelines[34].
3) Functional mobility and risk of falling: Timed Up and Go Test (TUG). The TUG is an assessment of the time that takes when standing up from an armchair, walking straight for 3m, turning, walking back to the armchair and sitting down[35]. A cutoff value of 14s in the TUG distinguished between fallers and non-fallers[36]

4) Independence in basic ADLs: Barthel Index [37]. BI is composed of 10 items related to personal hygiene, eating, bladder and bowel control and walking capacity. Response ranges from independent activity, minimum assistance, intermediate assistance, maximum assistance and impossible to perform the activity. Participants were categorized into: moderately dependent (40-55/100), mildly dependent (≥60/100) and independent (100/100).
5) Self-perceived QoL: the EuroQol instrument (EQ-5D-5L). EQ-5D-5L is a generic health index related to QoL that has been validated for stroke survivors[38]. This instrument assesses whether patients achieve a level of functioning that allows them to realize life goals, which reflect a general well-being. It consists of two parts: 1) the descriptive system that evaluates five dimensions of the QoL: mobility, personal care, daily activities, pain/discomfort and anxiety/depression and 2) the visual analogue scale[39]
6) Participants' satisfaction: participants were administered an ad hoc satisfaction questionnaire. The objective was to assess their satisfaction with the rehabilitation program in relationship with the benefits obtained (use of app, improvement of physical condition, gait capacity, balance, expectations and self-efficacy).

Data analysis

Data analysis was performed using IBM SPSS Statistics ver. 21.0 (IBM Co., Armonk, NY, USA).. Comparisons between E1 and E2 as well as between IG (only those participants with high levels of mHealth adherence) and CG were performed with paired t-tests. Levene test was used to confirm the equality of variances. Statistical significance was set at $p<0.05$. The effect size was estimated using Cohen d for quantitative variables as follows: values up to d (.01) = very small, d (.2) = small, d (.5) = medium, d (.8) = large, d (1.2) = very large and d (2.0) = huge.[40,41].

Results

Characteristics of participants

From the 191 screened participants, 41 were recruited to the study; 24 in the IG and 17 in the CG (Figure 1). In the IG there were three lost at the end of the intervention (2 due to return to work and 1 due to familiar problems). In the CG there were four lost (2 not interested, 1 not located, 1 health problems). Finally, 34 participants completed the three-month assessment (IG n=21 and CG n=13). In the IG 10 participants used the app and participated in the exercise program. Furthermore, 11 participants only participated in the exercise program but couldn't use the app due to technical problems. Using gait speed to classify ambulation[31], in the IG, seven participants were classified as household ambulation (<0.4 m/s), three as limited community ambulation (0.4–0.8 m/s), and fourteen as full community ambulation (>0.8 m/s). In comparison, seven of the CG were classified as household ambulation, two as limited community ambulation, and eight as full community ambulation. Table I shows socio-demographic and clinical baseline characteristics of participants.

Outcome variables

Community ambulation and sedentary behavior

Table II shows pre-and post-treatment values for adherence to PA and sitting time in IG and CG. At the end of the intervention, community ambulation increased 38.95 (±20.37) minutes/day in the IG ($p \leq .05$) and 9.47 (±12.11) minutes/day in the CG. These results represent an increase of 105% in the IG and by 38% in the CG. Sitting time decreased by 2.96 (±2.0) hours/day in the IG ($p \leq .05$) and by 0.53 (±0.24) hours in the CG. These results represent a decrease of 30% in the IG and of 7% in the CG. The effect size of adherence to PA was moderate. The effect size in the reduction of sitting time was negative; this indicates the positive effect of the intervention.

To test the feasibility of ICT technologies to promote adherence to PA, rates of use and difficulties reported by participants were assessed. Figure III shows the rate of use of the app: 50% (n=10) of the participants were able to use the app. Technical problems were the main cause of the low rate of use: too challenging, problems with the internet connection or not appropriate mobile device. Then, we analyzed sensitivity of changes comparing the CG (n=13) with those participants in the IG who used the app (n=10). Results are shown in Table III. The increase of community ambulation was of 56.85 (± 52.81) minutes/day ($p \leq .05$) and sitting time decreased by 2.96 (± 2.07) hours/day ($p \leq .05$) in the group of participants in the IG who used the app. The effect size was higher than expected in community ambulation and very large in the reduction of sitting time. Figure IV shows levels of acceptance of the different parts of app used and the response was: 4.5% training (walking speed, walking distance and the GPS), 4.5% questionnaires (mood, effort, recovery, wellness and fatigue), 9.1% WhatsApp group, 54.5% the pedometer and 27.3% found more interesting the combination of the different parts of the app. Figure V shows participant's opinion of the different elements of the intervention: 27% considered more interesting the exercise program at the rehabilitation unit, 4.5% preferred the app and 68.2% found more interesting the use of both the app and the participation in the exercise program.

Walking speed, walking endurance and risk of falling

Comfortable and fast walking speed, measured with the 10MWT, increased 0.21 (±.07) and 0.27 (±1.3) meters/second respectively in the IG ($p \leq .05$). The CG increased 0.12 (±.04) ($p \leq .05$) and 0.06 (±.03) meters/second (ns). (Table II). The effect size was very high. Participants in the IG who used the app increased .49 (± .06) and .67 (± .18) meters/second ($p \leq .002$) in comfortable and fast walking speed respectively. The effect size was very large (Table III).

Walking endurance, measured with the 6MWT, increased 47.62 m. (±12.37) in the IG ($p \leq .05$) and 19.79 m. (±9.19) in the CG (ns) (Table II). The effect size was large. Participants in the IG who used the app increased 142.28 (±1.11) meters ($p \leq .004$) in comfortable and fast walking speed respectively. The effect size was very large (Table III).

Functional mobility and risk of falling was measured with the TUG test. A cutoff value of 14s in the TUG distinguished between fallers and non-fallers[36]. Participants in the study (IG and CG) were considered as fallers. At the end of the intervention, the TUG decreased by 3.46 seconds in the IG ($p \leq .05$) and could be considered as non-fallers; the CG increased 4.67 seconds in the TUG and remained considered as fallers (Table II). The effect size was negative; this indicates the positive effect of the intervention. Participants in the IG who used the app decreased 14.83 (±19.82) seconds ($p \leq .057$). The effect size was large (Table III).

Activities of daily living

ADLs were measured with the Barthel Index. At baseline, participants in the IG and in the CG were mildly dependent. At the end of the intervention participants in the IG were independent and participants in the CG remained mildly dependent. (Table II). The effect size was large.

Self-perceived quality of life

Quality of life was assessed with the EQ-5D-5L. At baseline, participants in the IG and in the CG perceived limitations that affected mildly-moderately their QoL. At the end of the intervention the limitations perceived by the IG affected mildly their QoL. In the CG there were no changes in self-perceived QoL. (Table II). The effect size was negative; this indicates the positive effect of the intervention.

Participants' satisfaction

Figure VI shows participants' satisfaction with the following items: physical condition, gait capacity, balance, participation in the rehabilitation program, own effort and QoL. They also were asked if they would recommend the participation in the rehabilitation program. There were no adverse events during the intervention.

Discussion

The aim of the present study was to evaluate the impact of a mHealth App on PA adherence in stroke survivors. The results demonstrate that there was a clinically significant increase in adherence to community ambulation (minutes/day) by 105% and a statistically significant reduction of sitting time (minutes/day) by 30% in the IG. Community ambulation in the CG increased by 38% and we interpret it as the natural process of recovery of the stroke. On the other hand, CG decreased sedentary behavior only by 5%. There is evidence that stroke survivors, compared to general population, have increased levels of sedentary behavior[6] and is necessary to explore effective adherence strategies of rehabilitation and PA programs[42]. These results confirm the findings of a recent meta-analysis which reports that the use of mobile devices is effective on increasing PA in stroke survivors[43]. Considering the improvements of the participants in the IG who used the app, the results are extremely positive. These results were maintained during three months, but there were no long term assessments. Duncan reported a rapid decline in 3-9 month adherence of a web- and mobile phone-based intervention to promote PA and healthy eating in middle-aged males[44]. As concluded Zhou in a recent systematic review, the effectiveness of mobile devices depends on its long-term application and we agree that it would be interesting to evaluate long term adherence on the use of mobile applications and rehabilitation programs for stroke survivors[45].

In the present study we would like to outline the difficulty in recruitment of participants similar to other studies[46]. Comparing with general population[47], our participants described more difficulties on the use of smartphones and the Apps. The Main difficulties were due to technical problems (internet connection, not proper device or too complicated procedures for a regular use) similar to other studies[48]. The most accepted device was the pedometer, due to the easiness of use. Participants valued positively the combination of an 8 week MMRP at the rehabilitation unit with the digital platform based on the app and the pedometer. Participants perceived the use of the app as a bit challenging. They evaluated positively the assistance at the rehabilitation unit, because they could be supervised in the use of the app and they also were encouraged to PA (the exercise program at the rehabilitation unit and the guided progressive ambulation program at home). The WhatsApp group encouraged participants to adhere to the program and to the use of the app, as they received feedback from the professionals and from the fellows. This increased self-confidence. The question regarding whether mHealth technology in rehabilitation will help adherence to healthy PA after stroke remains to be answered. Nevertheless, Ozdalga et al.[25], in a systematic review concluded that patients who were unable to attend traditional hospital-based rehabilitation were monitored in real time through their smartphones connected via Bluetooth, while they exercised in their own neighborhoods. In a cardiac rehabilitation program, information obtained from the smartphones allowed clinicians to track their patients' heart rates, locations, altitudes, and walking speed; then, this information was used to create custom exercise regimens, leading to improved post-intervention 6-minute walk tests similar to our results[48]. Another study demonstrated the smartphone's potential to monitor the activity level of patients who have recently had a stroke[49]. We agree with Ozdalga et al. who concluded that mHealth has a very bright future in stroke rehabilitation, while doctors, engineers, and others alike continue to collaborate to contribute to this dynamic field[25]. The aim will be to design apps tailored to stroke survirvors characteristics, specially cognitive and physical impairments.

Walking speed is a powerful measure of health that can predict risk of falling and mortality[50]; it is often used as an overall measure of walking capacity and preparedness for safe community mobility[31] A proper gait speed is essential to achieve functional outdoors ambulation[51]. Gait speed measured with the 10MWT is a common outcome measure in stroke rehabilitation[52]. Improvements in walking speed correlate with improved function and quality of life (QoL)[53]. People who walk faster improve their ambulation function and tend to be able to walk in the community[54]. The improvement in gait speed relates to a faster and higher gait quality and, therefore, a more effective walking capacity[11]. Fulk et al.[52] estimated that a change in gait speed ≥ 0.175 m/s was a meaningful improvement in walking ability in people with stroke undergoing outpatient rehabilitation. Tilson et al.[55] considered that an improvement in walking speed of 0.16m/s can be interpreted as a clinically relevant change in stroke rehabilitation. Participants in the IG achieved an increment in comfortable and fast walking speed of 0.21/0.27 m/sec respectively. These results are similar to another study with a similar rehabilitation intervention in which participants did not use the app, but they were phoned monthly during six months after the intervention with the aim to promote adherence to an ambulation program at home[11]. But if we consider the improvements of the participants in the IG who used the app, the results are much better. In the CG there was no improvement and there was observed a trend towards diminishing walking speed.

Walking endurance was assessed with 6MWT which correlates with both aerobic capacity and muscle strength[56]. The 6MWT has been used in individuals undergoing rehabilitation poststroke[32]. Participants in the study gained a statistically significant increment in the 6MWT at the end of the intervention and it was observed a trend towards continuing increasing walking distance. In the control group there was a non-significant improvement and there was observed a trend towards diminishing walking distance in the 6MWT. We interpret the improvement of walking distance in the 6MWT, because of the use of the ICT facilitated adherence to the rehabilitation program.

Functional mobility and risk of falling was assessed with the TUG test which was developed primarily to evaluate basic functional mobility in frail elderly persons[57] and it has been recommended for persons with chronic stroke[35]. Participants in the study (IG and CG) were considered as fallers. At the end of the intervention and at three months the IG improved in the TUG test and participants could be considered as non-fallers. The CG worsened in the TUG test and they remained considered as fallers. Similar improvements were found in ADLs, assessed with the Barthel Index. Before intervention, participants in the study (IG and CG) were mildly dependent. At the end of the intervention, participants in the IG were independent for ADLs. The control group remained mildly dependent. These results coincide with other studies including similar multimodal interventions performed in an outpatient rehabilitation unit[58].

We consider that community mobility, functional mobility and independence on ADLs are mediated by improvements of walking speed, walking endurance and adherence to the rehabilitation program[13]. After conventional stroke rehabilitation programs, it is usually observed a trend towards diminishing long term adherence to PA[59]. The implementation of novel strategies to promote adherence (Apps, pedometers and the WhatsApp group) has facilitated self-efficacy and adherence to the ambulation program and therefore to community ambulation. Overall it has promoted an improvement of self-perceived QoL and satisfaction with the rehabilitation program. Nevertheless, we would highlight the difficulty perceived by the participants on using the ICTs (mHealth) and the importance of supervision during the use of technological devices. Stroke survivors, in general, are less familiar to the use of smartphone technology. It is necessary to develop evidence-based technologies adapted to stroke survivors to facilitate engagement and to provide long term assessments to evaluate benefits[60,61].

Limitations

Studying rehabilitation interventions in stroke survivors is difficult due to the high comorbidity and the need of third parties to participate in the programs. It caused difficulties in recruitment and a high rate of losses.

There were no long term assessments and we don’t know if the adherence was maintained after the three months of assessment.

We used a sample of convenience for stroke and control participants which may reduce the generalizability of results.

Conclusions

The mHealth technology is increasingly accessible and provides a novel way to provide home exercise programs post stroke with a number of benefits. However, frequent support and guidance of researchers and careers are required to ensure completeness of clinical assessment data and protocol adherence. This technology can be widely used for stroke survivors with the support of formal or informal caregivers. In terms of efficiency it can reduce socio-sanitary costs.

Compliance with Ethical Standards

Trial resgistration:

ClinicalTrials.gov identifier: NCT03507894.

Funding

This study was funded by the 2018 PERIS grant (Strategic Plan of health research and innovation) by the Catalan Government. MGP has received Fellowships from the Catalan Department of Health.

Conflict of Interest

The authors declare no conflict of interest.

Ethical Approval

All procedures performed were in accordance with the ethical standards of the institutional research committee and with the 1964 Helsinki Declaration. All participants provided written informed consent for the study.

The study was registered with ClinicalTrials.gov Identifier: NCT03507894.

Informed Consent

Informed consent was obtained from all individual participants included in the study.

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Title: *Impact of mHealth technology on adherence to healthy PA after stroke: a randomized study.*

ABSTRACT

Background: Physical activity (PA) is a key health behavior in people with stroke, including risk reduction of recurrent stroke. Despite the beneficial effects of PA, many community-dwelling stroke survivors are physically inactive. Information and communication technologies are emerging as a possible method to promote adherence to PA.

Objective: The aim of this study was to investigate the effectiveness of a smartphone activity App in improving levels of PA and reducing sedentary time.

Methods: This was a pilot randomized trial with a baseline and a 3-months follow-up assessment in an outpatient rehabilitation setting at a university hospital. Forty-one chronic stroke survivors were randomized into an intervention group (IG) n=24 and a control group (CG) n=17. Participants in the IG were engaged in the Multimodal Rehabilitation Program (MMRP) that consisted on the implementation of a mobile-health app, to supervise adherence to PA, and the participation of an 8-week rehabilitation program, two alternate days a week, in sessions of one hour (16 sessions in total) that included: aerobic, task-oriented, balance and stretching exercises. Participants also performed an ambulation program at home. The CG received a conventional rehabilitation program. Outcome variables were: adherence to PA activity, reported by community ambulation and sedentary behavior (walking and sitting time/day), walking speed (10-m walking test); walking endurance (6MWT); risk of falling (TUG); ADLs (Barthel); QoL (Eq-5D5L) and participant's self-reported satisfaction.

Results: At the end of the intervention, community ambulation increased by an average of 38.95 (SD 20.37) minutes in the IG ($p \leq .05$) and 9.47 (SD 12.11) minutes in the CG. Sitting time was reduced by 2.96 (SD 2.0) hours/day in the IG ($p \leq .05$) and by 0.53 (SD 0.24) hours in the CG. Comfortable and fast walking speed, measured with the 10MWT, increased 0.21 (SD 0.07) and 0.27 (SD 1.3) meters/second respectively in the IG ($p \leq .05$) and the CG increased 0.12 (SD 0.04) and 0.06 (SD 0.03) meters/second respectively. Risk of falling, measured with the TUG test, decreased by 3.46 seconds in the IG ($p \leq .05$) and the CG increased 4.67 seconds. Participants in the IG achieved independence in ADLs ($p=.009$), and the CG remained mildly dependent. Regarding QoL, assessed with the EQ-5D-5L, there is a statistical improvement of self-perceived QoL in the IG ($p<.001$) and in the CG there were no changes in self-perceived QoL.

Conclusions: The results suggest that mHealth technology provides a novel way to promote adherence to home exercise programs post stroke. However, frequent support and guidance of caregiver is required to ensure the use of mobile devices.

Keywords: Stroke rehabilitation; sedentary behavior; physical activity; adherence; mHealth

Introduction

Stroke survivors usually complete a rehabilitation program adapted to their characteristics and needs with the aim to improve the motor control of the affected side of the body. These programs are completed in different areas, depending on the characteristics of every single person, their needs and the psycho-social support (inpatient, outpatient or home-based rehabilitation programs) with an intensity that depends on the exercise tolerance of each person[1]. Conventional rehabilitation programs focus on the subacute period and usually end when the person achieves basic activities of daily living (ADLs). Thus, conventional rehabilitation programs usually do not provide maintenance exercises to provide long term health gains. Recent evidence indicates that levels of community reintegration are low to moderate due to the fact that 70% of stroke survivors will regain ambulation sufficient for in-home mobility but they do not achieve community mobility (CM)[2], defined as "moving around in the community and using public or private transportation, such as driving, walking, cycling, or accessing and riding in buses, taxi cabs, or other transportation systems"[3]. Community reintegration an maintaining interpersonal relationships, which are major components of the participation domain in the International Classification of Functioning, Disability and Health (ICF) model, require essentially CM[4]. Therefore, independent community ambulation is a challenging rehabilitation goal[5].

People with stroke usually spend more time sitting and less time in activity than age-matched peers.[6] Reducing sitting time has demonstrated that leads to health benefits and clinically important reductions in cardiovascular risk in general population[7,8]. Physical activity (PA) is also a key health behavior for the management and maintenance of health in people with stroke[9], including risk reduction of recurrent stroke[10]. Recent studies recommend multimodal rehabilitation programs tailored to stroke survivors, with exercises addressed to improve aerobic condition, motor function, balance, coordination and independence in ADLs[11,12]. The practice of PA has been recognized as important for achieving higher levels of CM[2,13]. Walking is an effective, popular, and sustainable form of PA, which requires no special equipment, can be incorporated into everyday life[14], and is an acceptable form of activity in those most physically inactive. Despite the beneficial effects of PA, many community-dwelling stroke survivors are physically inactive[6]. Understanding common barriers to PA and creating strategies to overcome them may help to make PA as a key part of daily life. Some of the most common barriers include the severity of the residual impairment, co-morbidities, fatigue, lack of time, lack of motivation, lack of skills, lack of resources and transport problems[15]. Supervised exercise programs (for example pulmonary or cardiac rehabilitation programs) lasting for 4–6 weeks can be effective for participants to practice exercise in a safe and controlled environment[16]. However, adherence rates decline or cease after the completion of the program, along with the clinical gains obtained[17], highlighting the need for effective maintenance strategies. Programs of PA need active implementation strategies tailored to barriers and facilitators that prevent or promote successful implementation. Information and communication technologies (ICT), tracking devices and interactive elements such as pedometers, smartphone applications (Apps) and computer-based materials, adjusted to the individual needs of patients, have demonstrated to be successful in improving PA uptake in different chronic conditions[18] and in general population[8,19,20]. Apps on smartphones are programs that use data collected from a smartphone's inbuilt tools, such as the Global Positioning System (GPS), accelerometer, microphone, speaker, and camera, to measure health and fitness parameters (for example: activity/sedentary behavior, steps/day, walking distance or walking speed). The Apps can analyze these data and summarize them, as well as design individualized plans, provide feedback, personalized coaching, and motivation[21,22]. The use of this methodology is named mHealth technology [23–25] and is emerging as a possible method to provide customized activity goals and feedback to promote exercises in cancer survivors and in general population[19,20]. The impact of activity feedback on exercise adherence within stroke population is less clear. Most research related to lifestyle modification and management of chronic diseases has not focused in stroke patients. We aimed to evaluate the impact of a smartphone activity App on PA adherence in people following a stroke. The aim of this study was to investigate the potential effectiveness of a smartphone activity App in improving levels of PA, sedentary time, walking speed, health markers and well-being in people following stroke

Materials and methods

Study design

A pilot randomized trial was designed to evaluate the effectiveness of a mHealth app on PA adherence, after a post-stroke multimodal rehabilitation program (MMRP). Before enrollment, participants received a conventional rehabilitation program that included: trunk exercises, muscle strengthening, occupational therapy and gait training. Participants of both groups were evaluated at baseline (E1), and at three months (E2). The study conforms to the CONSORT statements

Participants

Figure 1 shows Consort Flow diagram of sample selection. Forty-one participants were recruited from Hospital X. All of them had suffered a stroke one year ago and completed a conventional rehabilitation program. Inclusion criteria were: age≥18 years; diagnosis of ischemic or hemorrhagic stroke; functional ambulation classification (FAC) ≥3; Barthel Index ≥45. Exclusion criteria were: diagnosis of cognitive impairment (Mini Mental State Examination ≤24); unstable cardiovascular disease (acute heart failure, recent myocardial infarction, unstable angina, and uncontrolled arrhythmias)[26,27]; alcohol or other toxic substances abuse and decompensated psychiatric disorders that prevented from following a group session.

Previous to enrollment, participants underwent a medical examination to ensure that there were no circumstances that prevented their participation in the program, following the guidance of the American College of Sports Medicine (ACSM) for patients with coronary heart disease[26] and the guidelines of the American Heart Association (AHA) for stroke survivors[27]. All experimental procedures were conducted according to the Declaration of Helsinki. The study was approved by the Ethics and Clinical Research Committee of Hospital-X. Written informed consent was obtained from each participant.

A computer-generated random sequence was generated in Microsoft Excel to allocate groups and generate numbers of which was then used to assign participants to intervention group (IG) or control group (CG).

Sample size calculation

The granmo sample calculator[28] was used to calculate the sample and applied a two independent means measurement. 21 subjects in the IG and 21 in the CG were needed, accepting an alpha risk of 0.05 and a beta risk lower than 0.2 in a bilateral contrast, assuming a SD of 29 and to detect a difference equal to or greater than 30 minutes/day community ambulation. A loss rate of 30% was estimated.

Procedure

Participants in the IG were engaged in the MMRP. It was conducted and delivered as a supervised program at the Rehabilitation Unit of the hospital (March to September 2018). It consisted of an 8-week intervention of two alternate days a week, in sessions of one hour (16 sessions in total). The intervention was performed in groups of 4–6 participants with a physical therapist who guided the session and consisted on:

1. The implementation of a digital platform based on two mHealth apps, Fitlab® Training and Fitlab® Test (www.HealthSportlab.com, Barcelona): 1) to supervise adherence to PA using the GPS and the accelerometer to monitor walking distance and walking speed; 2) to assess mood, effort, recovery, wellness and fatigue questionnaires; 3) to have bidirectional feedback: participants could visualize results and exchange messages with the researchers. Figure II.
2. A pedometer (model UW-100, UW-101® A&D®) to count steps/day.
3. A WhatsApp group was created with the aim to give motivation for active lifestyle, feedback to participants and to create a collective identity in the rehabilitation group[29].
4. Participation in an 8 week exercise program (2 days/wk, 1 hr/session) that consisted on: aerobic, task oriented training, balance and stretching exercises, as described previously[13]
5. A progressive daily ambulation program at home with the aim to reach PA levels recommended by the World Health Organization (WHO)[9] of 150 m/wk of moderate PA. The program was monitored with the app and the pedometer.

6. At the end of the intervention, participants were administered an ad hoc self-reported satisfaction questionnaire.

The CG received only the conventional rehabilitation program that included: trunk exercises, muscle strengthening, occupational therapy and gait training, as described previously.

Variables

The primary outcome measure was adherence to PA It was measured by:

1) Community ambulation time reported by participants
2) Sedentary behavior: sitting time reported by participants

Secondary outcome measures were:

1) Walking speed: 10 Meter Walking Test (10MWT). According to the Locomotor Experience Applied Post-stroke guidelines [30], the time that each participant takes to walk 10 meters at a comfortable pace and at their maximum speed was registered. Each measure was repeated twice and the average of the two distances was calculated in meters/second. Participants were categorized into: household ambulators (<0.4m/sec), limited community ambulation (0.4-0.8m/sec.) and community ambulators (>0.8m/sec.)[31]
2) Walking endurance: six-Minute Walking Test (6MWT). The 6MWT is an assessment of the distance walked over a period of six minutes and is considered a useful measure of walking capacity after a stroke[32]. It was validated as a submaximal oxygen consumption test for individuals with cardiac or pulmonary disease[33]. The test was standardized according to the American Thoracic Society Guidelines[34].
3) Functional mobility and risk of falling: Timed Up and Go Test (TUG). The TUG is an assessment of the time that takes when standing up from an armchair, walking straight for 3m, turning, walking back to the armchair and sitting down[35]. A cutoff value of 14s in the TUG distinguished between fallers and non-fallers[36]
4) Independence in basic ADLs: Barthel Index [37]. BI is composed of 10 items related to personal hygiene, eating, bladder and bowel control and walking capacity. Response ranges from independent activity, minimum assistance, intermediate assistance, maximum assistance and impossible to perform the activity. Participants were categorized into: moderately dependent (40-55/100), mildly dependent (≥60/100) and independent (100/100).
5) Self-perceived QoL: the EuroQol instrument (EQ-5D-5L). EQ-5D-5L is a generic health index related to QoL that has been validated for stroke survivors[38]. This instrument assesses whether patients achieve a level of functioning that allows them to realize life goals, which reflect a general well-being. It consists of two parts: 1) the descriptive system that evaluates five

dimensions of the QoL: mobility, personal care, daily activities, pain/discomfort and anxiety/depression and 2) the visual analogue scale[39]

6) Participants' satisfaction: participants were administered an ad hoc satisfaction questionnaire. The objective was to assess their satisfaction with the rehabilitation program in relationship with the benefits obtained (use of app, improvement of physical condition, gait capacity, balance, expectations and self-efficacy).

Data analysis

Data analysis was performed using IBM SPSS Statistics ver. 21.0 (IBM Co., Armonk, NY, USA).. Comparisons between E1 and E2 as well as between IG (only those participants with high levels of mHealth adherence) and CG were performed with paired t-tests. Levene test was used to confirm the equality of variances. Statistical significance was set at $p<0.05$. The effect size was estimated using Cohen d for quantitative variables as follows: values up to d (.01) = very small, d (.2) = small, d (.5) = medium, d (.8) = large, d (1.2) = very large and d (2.0) = huge.[40,41].

Results

Characteristics of participants

From the 191 screened participants, 41 were recruited to the study; 24 in the IG and 17 in the CG (Figure 1). In the IG there were three lost at the end of the intervention (2 due to return to work and 1 due to familiar problems). In the CG there were four lost (2 not interested, 1 not located, 1 health problems). Finally, 34 participants completed the three-month assessment (IG n=21 and CG n=13). In the IG 10 participants used the app and participated in the exercise program. Furthermore, 11 participants only participated in the exercise program but couldn't use the app due to technical problems. Using gait speed to classify ambulation[31], in the IG, seven participants were classified as household ambulation (<0.4 m/s), three as limited community ambulation (0.4–0.8 m/s), and fourteen as full community ambulation (>0.8 m/s). In comparison, seven of the CG were classified as household ambulation, two as limited community ambulation, and eight as full community ambulation. Table I shows socio-demographic and clinical baseline characteristics of participants.

Outcome variables

Community ambulation and sedentary behavior

Table II shows pre-and post-treatment values for adherence to PA and sitting time in IG and CG. At the end of the intervention, community ambulation increased 38.95 (±20.37) minutes/day in the IG ($p\leq.05$) and 9.47 (±12.11) minutes/day in the CG. These results represent an increase of 105% in the IG and by 38% in the CG. Sitting time decreased by 2.96 (±2.0) hours/day in the IG ($p\leq.05$) and by 0.53 (±0.24) hours in the CG. These results represent a decrease of 30% in the IG and of 7% in the CG. The effect size of adherence to PA was moderate. The effect size in the reduction of sitting time was negative; this indicates the positive effect of the intervention.

To test the feasibility of ICT technologies to promote adherence to PA, rates of use and difficulties reported by participants were assessed. Figure III shows the rate of use of the app: 50% (n=10) of the participants were able to use the app. Technical problems were the main cause of the low rate of use: too challenging, problems with the internet connection or not appropriate mobile device. Then, we analyzed sensitivity of changes comparing the CG (n=13) with those participants in the IG who used the app (n=10). Results are shown in Table III. The increase of community ambulation was of 56.85 (± 52.81) minutes/day ($p \leq .05$) and sitting time decreased by 2.96 (± 2.07) hours/day ($p \leq .05$) in the group of participants in the IG who used the app. The effect size was higher than expected in community ambulation and very large in the reduction of sitting time. Figure IV shows levels of acceptance of the different parts of app used and the response was: 4.5% training (walking speed, walking distance and the GPS), 4.5% questionnaires (mood, effort, recovery, wellness and fatigue), 9.1% WhatsApp group, 54.5% the pedometer and 27.3% found more interesting the combination of the different parts of the app. Figure V shows participant's opinion of the different elements of the intervention: 27% considered more interesting the exercise program at the rehabilitation unit, 4.5% preferred the app and 68.2% found more interesting the use of both the app and the participation in the exercise program.

Walking speed, walking endurance and risk of falling

Comfortable and fast walking speed, measured with the 10MWT, increased 0.21 (±.07) and 0.27 (±1.3) meters/second respectively in the IG ($p \leq .05$). The CG increased 0.12 (±.04) ($p \leq .05$) and 0.06 (±.03) meters/second (ns). (Table II). The effect size was very high. Participants in the IG who used the app increased .49 (± .06) and .67 (± .18) meters/second ($p \leq .002$) in comfortable and fast walking speed respectively. The effect size was very large (Table III).

Walking endurance, measured with the 6MWT, increased 47.62 m. (±12.37) in the IG ($p \leq .05$) and 19.79 m. (±9.19) in the CG (ns) (Table II). The effect size was large. Participants in the IG who used the app increased 142.28 (±1.11) meters ($p \leq .004$) in comfortable and fast walking speed respectively. The effect size was very large (Table III).

Functional mobility and risk of falling was measured with the TUG test. A cutoff value of 14s in the TUG distinguished between fallers and non-fallers[36]. Participants in the study (IG and CG) were considered as fallers. At the end of the intervention, the TUG decreased by 3.46 seconds in the IG ($p \leq .05$) and could be considered as non-fallers; the CG increased 4.67 seconds in the TUG and remained considered as fallers (Table II). The effect size was negative; this indicates the positive effect of the intervention. Participants in the IG who used the app decreased 14.83 (±19.82) seconds ($p \leq .057$). The effect size was large (Table III).

Activities of daily living

ADLs were measured with the Barthel Index. At baseline, participants in the IG and in the CG were mildly dependent. At the end of the intervention participants in the IG were independent and participants in the CG remained mildly dependent. (Table II). The effect size was large.

Self-perceived quality of life

Quality of life was assessed with the EQ-5D-5L. At baseline, participants in the IG and in the CG perceived limitations that affected mildly-moderately their QoL. At the end of the intervention the limitations perceived by the IG affected mildly their QoL. In the CG there were no changes in self-perceived QoL. (Table II). The effect size was negative; this indicates the positive effect of the intervention.

Participants' satisfaction

Figure VI shows participants' satisfaction with the following items: physical condition, gait capacity, balance, participation in the rehabilitation program, own effort and QoL. They also were asked if they would recommend the participation in the rehabilitation program. There were no adverse events during the intervention.

Discussion

The aim of the present study was to evaluate the impact of a mHealth App on PA adherence in stroke survivors. The results demonstrate that there was a clinically significant increase in adherence to community ambulation (minutes/day) by 105% and a statistically significant reduction of sitting time (minutes/day) by 30% in the IG. Community ambulation in the CG increased by 38% and we interpret it as the natural process of recovery of the stroke. On the other hand, CG decreased sedentary behavior only by 5%. There is evidence that stroke survivors, compared to general population, have increased levels of sedentary behavior[6] and is necessary to explore effective adherence strategies of rehabilitation and PA programs[42]. These results confirm the findings of a recent meta-analysis which reports that the use of mobile devices is effective on increasing PA in stroke survivors[43]. Considering the improvements of the participants in the IG who used the app, the results are extremely positive. These results were maintained during three months, but there were no long term assessments. Duncan reported a rapid decline in 3-9 month adherence of a web- and mobile phone-based intervention to promote PA and healthy eating in middle-aged males[44]. As concluded Zhou in a recent systematic review, the effectiveness of mobile devices depends on its long-term application and we agree that it would be interesting to evaluate long term adherence on the use of mobile applications and rehabilitation programs for stroke survivors[45].

In the present study we would like to outline the difficulty in recruitment of participants similar to other studies[46]. Comparing with general population[47], our participants described more difficulties on the use of smartphones and the Apps. The Main difficulties were due to technical problems (internet connection, not proper device or too complicated procedures for a regular use) similar to other studies[48]. The most accepted device was the pedometer, due to the easiness of use. Participants valued positively the combination of an 8 week MMRP at the rehabilitation unit with the digital platform based on the app and the pedometer. Participants perceived the use of the app as a bit challenging. They evaluated positively the assistance at the rehabilitation unit, because they could be supervised in the use of the app and they also were encouraged to PA (the exercise program at the rehabilitation unit and the guided progressive ambulation program at home). The WhatsApp group encouraged participants to adhere to the program and to the use of the app, as they received feedback from the professionals and from the fellows. This increased self-confidence. The question regarding whether mHealth technology in rehabilitation will help adherence to healthy PA after stroke remains to be answered. Nevertheless, Ozdalga et al.[25], in a systematic review concluded that patients who were unable to attend traditional hospital-based rehabilitation were monitored in real time through their smartphones connected via Bluetooth, while they exercised in their own neighborhoods. In a cardiac rehabilitation program, information obtained from the smartphones allowed clinicians to track their patients' heart rates, locations, altitudes, and walking speed; then, this information was used to create custom exercise regimens, leading to improved post-intervention 6-minute walk tests similar to our results[48]. Another study demonstrated the smartphone's potential to monitor the activity level of patients who have recently had a stroke[49]. We agree with Ozdalga et al. who concluded that mHealth has a very bright future in stroke rehabilitation, while doctors, engineers, and others alike continue to collaborate to contribute to this dynamic field[25]. The aim will be to design apps tailored to stroke survirvors characteristics, specially cognitive and physical impairments.

Walking speed is a powerful measure of health that can predict risk of falling and mortality[50]; it is often used as an overall measure of walking capacity and preparedness for safe community mobility[31] A proper gait speed is essential to achieve functional outdoors ambulation[51]. Gait speed measured with the 10MWT is a common outcome measure in stroke rehabilitation[52]. Improvements in walking speed correlate with improved function and quality of life (QoL)[53]. People who walk faster improve their ambulation function and tend to be able to walk in the community[54]. The improvement in gait speed relates to a faster and higher gait quality and, therefore, a more effective walking capacity[11]. Fulk et al.[52] estimated that a change in gait speed ≥ 0.175 m/s was a meaningful improvement in walking ability in people with stroke undergoing outpatient rehabilitation. Tilson et al.[55] considered that an improvement in walking speed of 0.16m/s can be interpreted as a clinically relevant change in stroke rehabilitation. Participants in the IG achieved an increment in comfortable and fast walking speed of 0.21/0.27 m/sec respectively. These results are similar to another study with a similar rehabilitation intervention in which participants did not use the app, but they were phoned monthly during six months after the intervention with the aim to promote adherence to an ambulation program at home[11]. But if we consider the improvements of the participants in the IG who used the app, the results are much better. In the CG there was no improvement and there was observed a trend towards diminishing walking speed.

Walking endurance was assessed with 6MWT which correlates with both aerobic capacity and muscle strength[56]. The 6MWT has been used in individuals undergoing rehabilitation poststroke[32]. Participants in the study gained a statistically significant increment in the 6MWT at the end of the intervention and it was observed a trend towards continuing increasing walking distance. In the control group there was a non-significant improvement and there was observed a trend towards diminishing walking distance in the 6MWT. We interpret the improvement of walking distance in the 6MWT, because of the use of the ICT facilitated adherence to the rehabilitation program.

Functional mobility and risk of falling was assessed with the TUG test which was developed primarily to evaluate basic functional mobility in frail elderly persons[57] and it has been recommended for persons with chronic stroke[35]. Participants in the study (IG and CG) were considered as fallers. At the end of the intervention and at three months the IG improved in the TUG test and participants could be considered as non-fallers. The CG worsened in the TUG test and they remained considered as fallers. Similar improvements were found in ADLs, assessed with the Barthel Index. Before intervention, participants in the study (IG and CG) were mildly dependent. At the end of the intervention, participants in the IG were independent for ADLs. The control group remained mildly dependent. These results coincide with other studies including similar multimodal interventions performed in an outpatient rehabilitation unit[58].

We consider that community mobility, functional mobility and independence on ADLs are mediated by improvements of walking speed, walking endurance and adherence to the rehabilitation program[13]. After conventional stroke rehabilitation programs, it is usually observed a trend towards diminishing long term adherence to PA[59]. The implementation of novel strategies to promote adherence (Apps, pedometers and the WhatsApp group) has facilitated self-efficacy and adherence to the ambulation program and therefore to community ambulation. Overall it has promoted an improvement of self-perceived QoL and satisfaction with the rehabilitation program. Nevertheless, we would highlight the difficulty perceived by the participants on using the ICTs (mHealth) and the importance of supervision during the use of technological devices. Stroke survivors, in general, are less familiar to the use of smartphone technology. It is necessary to develop evidence-based technologies adapted to stroke survivors to facilitate engagement and to provide long term assessments to evaluate benefits[60,61].

Limitations

Studying rehabilitation interventions in stroke survivors is difficult due to the high comorbidity and the need of third parties to participate in the programs. It caused difficulties in recruitment and a high rate of losses.

There were no long term assessments and we don’t know if the adherence was maintained after the three months of assessment.

We used a sample of convenience for stroke and control participants which may reduce the generalizability of results.

Conclusions

The mHealth technology is increasingly accessible and provides a novel way to provide home exercise programs post stroke with a number of benefits. However, frequent support and guidance of researchers and careers are required to ensure completeness of clinical assessment data and protocol adherence. This technology can be widely used for stroke survivors with the support of formal or informal caregivers. In terms of efficiency it can reduce socio-sanitary costs.

Compliance with Ethical Standards

Trial resgistration:

ClinicalTrials.gov identifier: NCT03507894.

Funding

This study was funded by the 2018 PERIS grant (Strategic Plan of health research and innovation) by the Catalan Government. MGP has received Fellowships from the Catalan Department of Health.

Conflict of Interest

The authors declare no conflict of interest.

Ethical Approval

All procedures performed were in accordance with the ethical standards of the institutional research committee and with the 1964 Helsinki Declaration. All participants provided written informed consent for the study.

The study was registered with ClinicalTrials.gov Identifier: NCT03507894.

Informed Consent

Informed consent was obtained from all individual participants included in the study.

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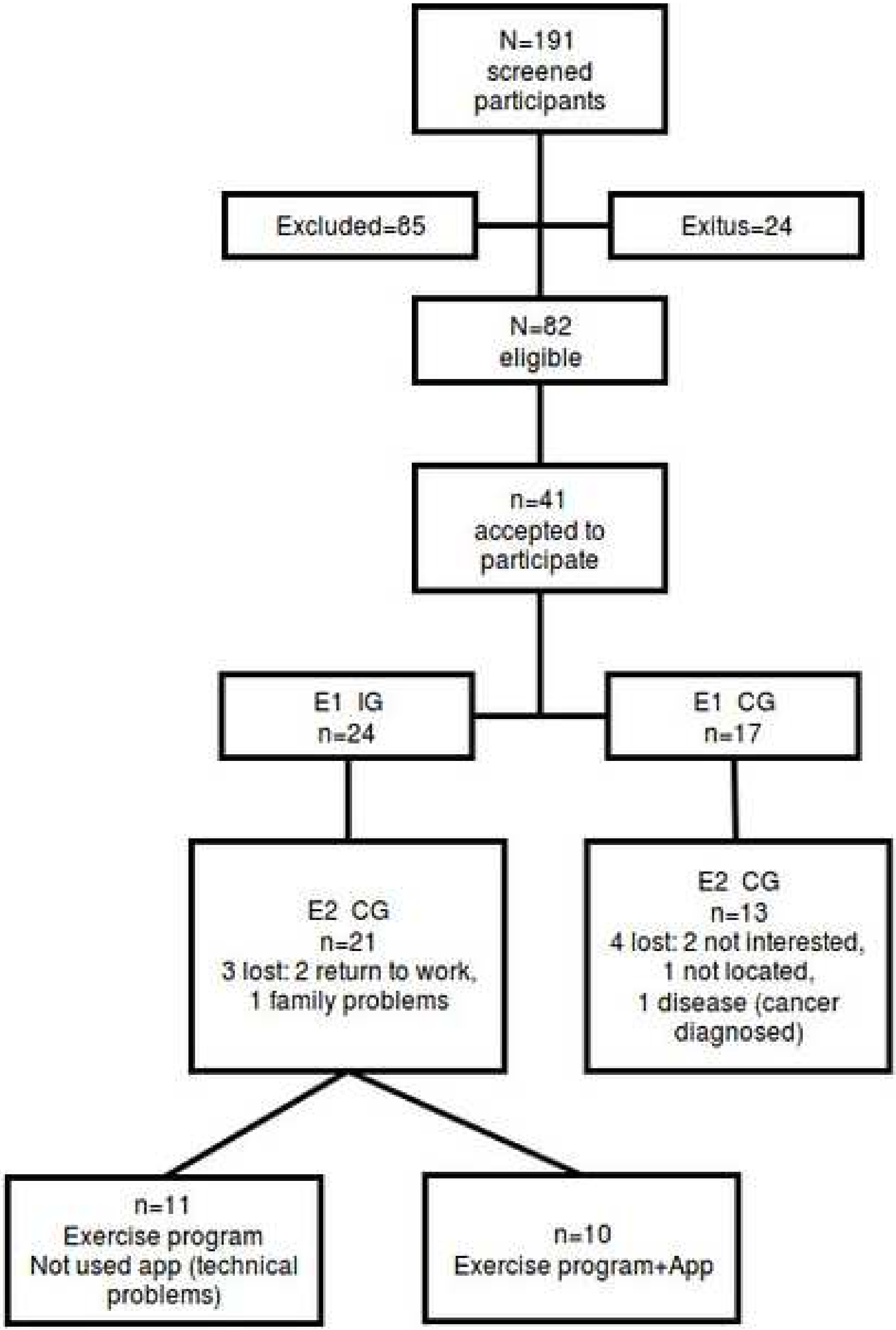
Figure I



E: evaluation; IG: intervention group; CG: control group

Figure 1. Consort Flow diagram of sample selection.

Figure II

A. Fitlab® app

B. Participant's route

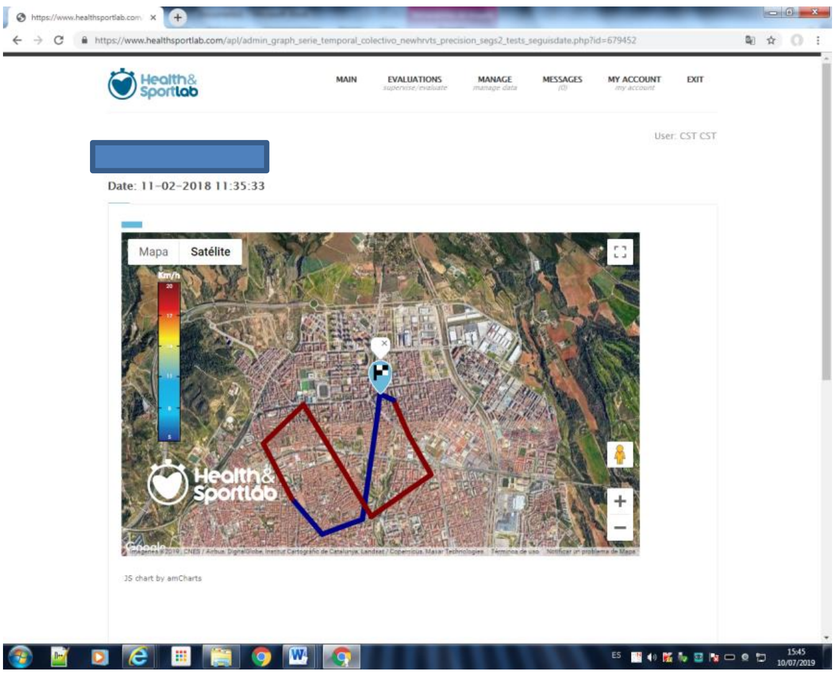


Figure 2. Fitlab® Training and Fitlab® Test.

Figure III

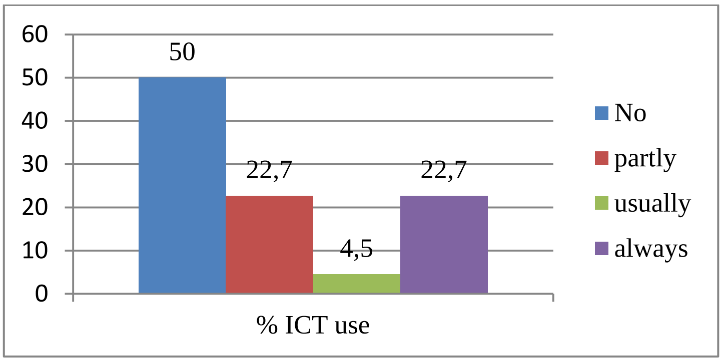


Figure III Rate of use of app

Figure IV

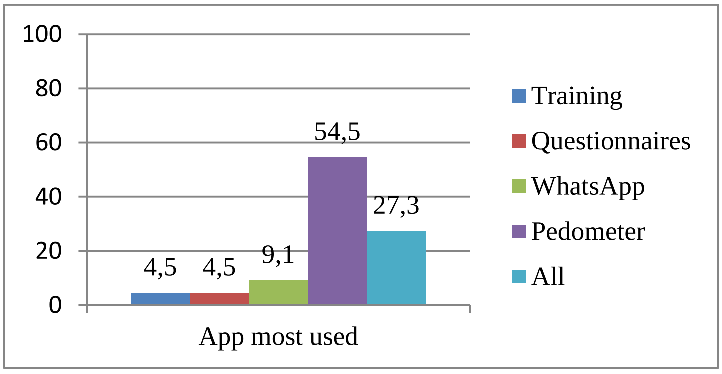


Figure IV Levels of acceptance of app

Figure V

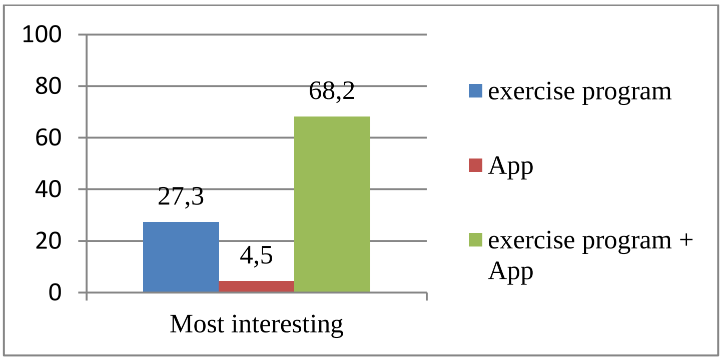


Figure V Participant's opinion of the different elements of the intervention

Figure VI

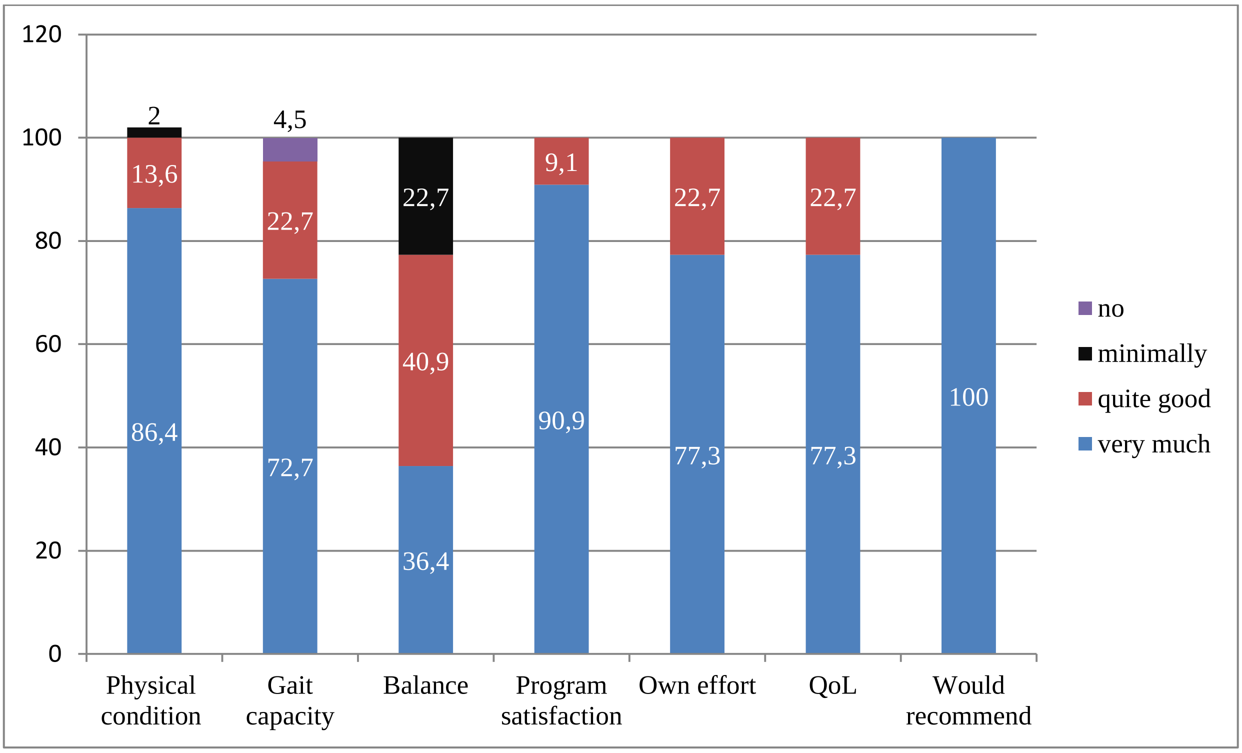


Figure VI Participants satisfaction with improvement

Table I Socio-demographic and clinical baseline characteristics of participants.

	Intervention Group n=24		**Control Group n=17**		
Characteristics	**Mean (±SD) Percentage (%)**	**Range**	**Mean (±SD) Percentage (%)**	**Range**	**P**
Age	62.96 (±11.87)	33-89	68.53 (±11.53)	41-83	.155
Sex					.756
Male	13 (54.2%)		8 (47.1%)		
Female	11 (45.8%)		9 (52.9%)		
Civil status					.441
Married	14 (58.2%)		13 (76.5%)		
Widow	7 (29%)		2 (11.8%)		
Divorced	2 (8.3%)		2 (11.8%)		
Single	1 (4.2%)				
Employment Situation			12 (70.6%)		.736
Retired	15 (62.5%)		3 (17.6%)		
Sick leave	3 (12.5%)		1 (5.9%)		
Permanent disability	4 (16.7%)		1 (5.9%)		
Working	1 (4.2%)				
Unemployed	1 (4.2%)				
Oxford Stroke Classification					.441
PACS	6 (25%)		8 (47.1%)		
LACS	12 (50%)		5 (29.4%)		
TACS	1 (4.2%)		2 (11.8%)		
POCS	2 (8.3%)		1 (5.9%)		
Hemorrhagic	3 (12.5%)		1 (5.9%)		
Previous Stroke/TIA	11 (45.8%)		9 (52.9%)		.756
Time since stroke (months)	18.92 (±27.60)	1-96	20.85 (±59.74)	1-252	.890
Affected side					
Right	12 (50%)		10 (58.8%)		.458
Left	10 (41.7%)		7 (41.2%)		
Ataxia	2 (8.3%)		0 (0%)		
Functional Ambulation capacity					
Household ambulation	7 (29%)		7 (41.2%)		.889
Limited CA	3 (12.5%)		2 (11.8%)		
Community ambulation	14 (58.2%)		8 (47.1%)		
			15 (88.2%)		
Risk of falling (Downton)	17 (70.8%)		7 (41.2%)		.350
Previous falls	14 (58.3%)				.174

n: sample; SD: standard deviation; PACS: partial anterior circulation syndrome; LACS: lacunar syndrome; TACS: total anterior circulation syndrome; POCS: posterior circulation syndrome; TIA: transient ischemic sStroke; RHB: rehabilitation; CA: community ambulation; SBP: systolic blood pressure; DBP: diastolic blood pressure; HR: heart rate; min: minutes; Kg: kilograms; cm: centimeters; BMI: body mass index; WHI: waist hip iIndex MS: metabolic syndrome;

	Intervention Group n=24		Control Group n=17		
Characteristics	**Mean (±SD) Percentage (%)**	**Range**	**Mean (±SD) Percentage (%)**	**Range**	**P**
RHB program	9 (37.5%)		5 (29.4%)		.645
Hospital (acute phase)					
Inpatient	8 (33.3%)		4 (23.5%)		
Outpatient	6 (25%)		6 (35.3%)		
High intensity	1 (4.2%)		2 (11.8%)		
Cardiovascular Risk					
Hypertension	19 (79.2%)		13 (76.5%)		.565
Diabetes	11 (45.8%)		7 (41.2%)		.510
Cholesterol	21 (87.5%)		13 (76.5%)		.304
Smoking	6 (25%)		3 (17.6%)		.435
Alcohol consumer	4 (16.7%)		1 (5.9%)		.298
SBP mm/Hg	137.92 (±22.79)	98-164	143.12 (±14.68)	107-173	.380
DBP mm/Hg	81.92 (±10.59)	59-98	81.18 (±14.92)	58-113	.853
HR (beats/min)	74.33 (±12.19)	51-105	70.82 (±9.63)	54-90	.330
Weight (Kg)	79.82 (±13.86)	60.6-101.50	75.95 (±12.74)	55.5-95.5	.368
Height (cm)	161.52 (±8.55)	145-177.50	159.52 (±8.32)	148-176	.461
Abdominal girth (cm)	106.62 (±10.23)	85-126	106.12 (±10.52)	93-127	.878
BMI (weight/talla²)	30.76 (±5.50)	24.60-43	30.14 (±3.99)	24.30-37.60	.334
WHI	0.92 (±.07)	.80-1.03	0.92 (±.05)	0.82-1	.988
SM criteria	17 (70.8%)		17 (70.8%)		
Comorbidities					
Charlson Index	4.58 (±1.17)	1-8	5.59 (±2.15)	2-10	.105

n: sample; SD: Standard Deviation; PACS: Partial Anterior Circulation Syndrome; LACS: Lacunar Syndrome; TACS: Total Anterior Circulation Syndrome; POCS: Posterior Circulation Syndrome; TIA: Transient Ischemic Stroke; RHB: rehabilitation; SBP: systolic blood pressure; DBP: diastolic blood pressure; HR: Heart Rate; min: minutes; Kg: kilograms; cm: centimeters; BMI: Body Mass Index; WHI: Waist Hip Index MS: Metabolic Syndrome;

Table II

Table II. Changes in functional outcome measures and self-perceived QoL at three months of the MMRP

	IG (n=21)				CG (n=13)				
	E1	E2	score	*p*-value	E1	E2	score	*p*-value	Cohen´s d
Community ambulation min./day	36.93 ±50.33	75.88 ±70.70	38.95 ±20.37	.034*	24.53 ±18.96	34.00 ±31.07	9.47 ±12.11	.259	.76
Sitting time hours/day	7.31 ±5.25	4.35 ±3.18	-2.96 ±2.079	.015*	10.38 ±5.66	9.85 ±5.90	-.53 ±.24	.697	-1.16
10MWT comfort (m/sec.)	.82 ±.26	1.03 ±.33	.21 ±.07	.000*	.57 ±.25	.69 ±.29	.12 ±.04	.043*	1.09
10MWT fast (m/sec.)	1.06 ±.35	1.33 ±.48	.27 ±.13	.000*	.79 ±.38	.85 ±.35	.06 ±.03	.200	1.14
6MWT (m.)	300.48 ±99.99	348.10 ±112.35	47.62 ±12.369	.001*	218.83 ±112.99	238.62 ±103.80	19.79 ±9.19	.281	1.01
TUG (sec.)	15.39 ±6.37	11.93 ±7.09	-3.46 ±.72	.000*	19.75 ±9.17	24.42 ±22.97	4.67 ±13.8	.272	-0.73
Barthel	89.05 ±13.93	95.71 ±9.52	6.66 ±4.41	.009*	75.69 ±23.84	84.62 ±14.20	8.93 ±9.64	.224	0.91
EQ-5D-5L	12.62 ±3.78	8.43 ±2.83	-4.19 ±.95	.000*	13.85 ±3.10	12.54 ±3.71	-1.31 ±.61	.098	-1.24

IG: intervention group; CG: control group; E: evaluation; score: changes in the score from before rehabilitation program to 3 months follow-up; 10MWT comfort: ten meter walking test at comfortable speed; 10MWT fast: ten meter walking test at fast speed; m/sec: meters/second; 6MWT: six minute walking test; m: meters; TUG: Timed up and Go test; sec: seconds; p: ≤ 0.05 (T-Test)

Table III

Table III. Changes in functional outcome measures and self-perceived QoL at three months of the MMRP between IG users of the app and CG

	IG (n=10)	CG (n=13)	score	*p*-value	Cohen´s d
Community ambulation min./day	90.85 ±83.88	34 ±31.07	56.85 ±52.81	.034*	2.58
Sitting time hours/day	4.40 ±2.22	9.84 ±5.89	-5.44 ±3.67	.012*	1.22
10MWT comfort (m/sec.)	1.18 ±..35	.69 ±..29	.49 ±.06	.002*	1.25
10MWT fast (m/sec.)	1.52 ±..53	.85 ±..35	.67 ±..18	.002*	1.49
6MWT (m.)	380.90 ±102.69	238.62 ±103.806	142.28 ±1.116	.004*	1.37
TUG (sec.)	9.59±3.15	24.42 ±22.97	-14.83 ±.19.82	.057	.90
Barthel	97.50 ±5.40	84.62 ±14.21	12.88 ±8.81	.013*	1.19
EQ-5D-5L	8 ±1.82	12.54 ±3.71	-4.54 ±1.89	.002*	1.55

IG: intervention group users of the app; CG: control group; score: differences between IG and CG at 3 months follow-up; 10MWT comfort: ten meter walking test at comfortable speed; 10MWT fast: ten meter walking test at fast speed; m/sec: meters/second; 6MWT: six minute walking test; m: meters;TUG: Timed up and Go test; sec: seconds; p: ≤0.05 (T-Test).