Title
Early supported discharge by caregiver-mediated exercises and e-health support after stroke - a proof of concept trial

Cover title
Caregiver-mediated exercises with e-health support

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Abstract

Background and Purpose: This proof-of-concept trial investigated the effects of an 8-week program of caregiver-mediated exercises (CME) commenced in hospital combined with tele-rehabilitation services on patient self-reported mobility and caregiver burden.

Methods: 63 hospitalised stroke patients (mean age 68.7, 64% female) were randomly allocated to an 8-week CME program with e-health support, or usual care. Primary outcome was the Stroke Impact Scale (SIS) mobility domain. Secondary outcomes included length of stay (LOS), other SIS domains, readmissions, motor impairment, strength, walking ability, balance, mobility, (extended) activities of daily living, psychosocial functioning, self-efficacy, quality of life and fatigue. Additionally, caregiver's self-reported fatigue, symptoms of anxiety, self-efficacy and strain were assessed. Assessments were completed at baseline, 8 and 12 weeks.

Results: Intention-to-treat analysis showed no between-group difference in SIS-mobility (p=0.6), however carers reported less fatigue (4.6, CI95% 0.3-8.8, p=0.04), and higher self-efficacy (-3.3, CI95% -5.7--0.9, p=0.01) at week 12. Per protocol analysis, examining those who were discharged home with tele-rehabilitation, demonstrated a trend towards improved mobility (-9.8, CI95 % -20.1-0.4, p=0.06), significantly improved extended ADL scores at week 8 (-3.6, CI95% -6.3--0.8, p=0.01) and 12 (3.0, CI95% -5.8--0.3, p=0.03), a 9-day shorter LOS (p=0.046), and fewer readmissions over 12 months ($p<0.05$).

Conclusions: CME supported by tele-rehabilitation show promise to augment intensity of practice, resulting in improved patient extended ADL, reduced LOS with fewer readmissions post-stroke, and reduced levels of caregiver fatigue with increased feelings of self-efficacy. **The current findings justify a larger definite phase III randomized controlled trial**.

Clinical Trial Registration-URL: http://www.anzctr.org.au. Unique identifier: ACTRN12613000779774.

Introduction

Decreased mobility is one of the major concerns for patients who suffer a stroke.[1] Demand for stroke rehabilitation exceeds supply and as length of hospital stay is decreasing, new approaches to deliver rehabilitation are needed to improve health outcomes and promote independent living. Early Supported Discharge (ESD) and Home Rehabilitation services for patients who have suffered a stroke offer an approach to managing rising demand for hospital beds and appear to achieve comparable clinical outcomes to inpatient rehabilitation.[2, 3] Shorter lengths of stay however can mean less access to therapists, potentially less recovery and more burden to the caregiver and family, therefore novel, more efficient approaches to augment practice with less costs are needed.[4]

One way of increasing the intensity of exercise therapy is to actively involve family members in the rehabilitation process.[5, 6] Training caregivers as co-therapists enables them to assist with exercise delivery and increase practice intensity without increasing staff-time. However, studies examining caregiver-mediated rehabilitative exercise are scarce and the effects on patient and caregiver outcomes are under investigated.[6]

Next to caregiver-mediated exercises (CME) also tele-rehabilitation solutions allow patients to facilitate therapy and to augment practice at home after discharge. Tele-rehabilitation has been defined as the delivery of rehabilitation services using telecommunications technology.[7] Although there is emerging evidence to support the efficacy of tele-rehabilitation services at home, a recent Cochrane Review showed insufficient evidence to recommend a specified approach by lack of clinical trials.[8]

We hypothesized that an 8-week program of CME, commenced in hospital, supported by e-health and combined with tele-rehabilitation after discharge, results in improved self-reported mobility, reduced length of stay (LOS) without increased levels of strain of the caregiver when compared to usual care.

Study aims

In this proof-of-concept trial we aimed to investigate the effects of a well-defined and protocolled 8-week program of CME commenced in hospital combined with telehealth support on self-reported mobility. In addition we investigated the effects of the CME combined with telehealth support program on ADL, length of inpatient hospital stay and self-efficacy without increasing caregiver's burden.

Methods

Design

We undertook a pragmatic pilot study comparing conventional inpatient and home rehabilitation with a program which provided a caregiver-mediated exercise intervention to a patient and carer dyad supported by tele-rehabilitation after discharge. Hospital patients who had suffered a stroke were randomised to receive either: (a) the addition of the caregiver-mediated exercise program to usual rehabilitation care (b) usual rehabilitation care. Random allocation occurred after baseline assessment and outcomes were re-assessed at 8 and 12 weeks by an independent assessor blinded to allocation. Participants and treating physiotherapists could not be masked to intervention group allocation. The study protocol conforms to the ethical guidelines of the 1975 Declaration of Helsinki and was approved by the local health research ethics board of *Southern Adelaide Research Ethics Committee*. (Australian New Zealand Trials Registry number ACTRN12613000779774.

All eligible participants willing to take part in the study provided written informed consent and were assessed prior to randomisation. A statistician external to the study generated the random sequence in random blocks of 2 to 6 using a computer software programme and created sequentially numbered, sealed opaque envelopes, containing group allocation for participants. Group allocation was managed by a pharmacist external to the project. After completion of each baseline assessment the pharmacist received an email, then opened the envelope to reveal the group allocation, and by email informed the treating physiotherapist of the group allocation.

Participants and setting

Patients were recruited from the stroke units of two hospitals and the rehabilitation unit of another hospital, all in metropolitan Adelaide, Australia. Stroke was defined according to the WHO criteria.[9] Patients were eligible if they were: able to understand English; still in the early rehabilitation phase (24hrs-3 months post-stroke); able to appoint a caregiver who was willing to participate in the programme; able to follow instructions; experienced mobility problems due to stroke (FAC<5); had sufficient cognition to take part (defined as a Mini Mental State Examination (MMSE) score > 23 points and did not suffer from depression (Hospital Anxiety and Depression Scale (HADS) <11). Caregivers (partner, family member or volunteer) were eligible if they were: able to understand English; agreed to provide support to the patient; did not suffer from significant symptoms of depression (HADS<11); and were physically able to perform the exercises with the patient. Patient and/or caregivers reporting serious disabling comorbidity, which might interfere with participation, were excluded.

Five months into the trial inclusion criteria were adjusted as it was felt that potential patients were excluded due to too restrictive inclusion criteria. The MMSE cut-off score was lowered to 18 points (proxy consent was sought when necessary). In addition, the HADS was removed as a screening tool. A

significant proportion of individuals first approached experienced anxiety in response to the acute medical situation and this appeared to be restricting the inclusion of participants who were keen, willing and able to safely engage in the trial.

Intervention

The intervention comprised an 8-week caregiver-mediated training program with support using a customised exercise app loaded onto a tablet. More detailed information regarding the intervention itself is published in the protocol paper.[1] **In brief, while in hospital the patient and carer were provided with an iPad which was loaded with the caregiver-mediated exercise application with 37 standardized exercises aimed to improve gait and gait-related mobility, such as standing, turning or making transfers. The patient and their caregiver were asked to perform a selective set of exercises for 8 weeks, at least 5 times a week for 30 minutes and had a weekly evaluation session with the physiotherapist. In case discharge occurred earlier than the end date of the intervention period, the program continued at home with ongoing use of the exercise app, tele-rehabilitation services through a secure videoconferencing app using 3 and 4G (Vidyo) to provide access to the treating therapists, and weekly home visits. The decision to discharge patients from the wards to their homes was made at the twice weekly multidisciplinary case conferences attended by medical, nursing and allied health staff and made on the basis of clinical and psychosocial factors. Research clinicians did not attend these meetings.**

Additionally participants in the intervention group wore an activity monitor the *Fitbit Zip*™ (Fitbit, Inc., San Francisco, CA, USA) for the 8-week intervention period. The Fitbit is a portable lightweight clip-on activity monitor with the size of USB pendrive that monitors physical activity and was used to motivate

participants to increase physical activity through real-time feedback. Data was not collected for the purpose of analysis.

Participants allocated to usual rehabilitation care received interdisciplinary rehabilitation following the standards outlined by the Australian clinical guidelines for stroke management (addressing mobility impairment, dysphagia or communication difficulties, upper limb activity, sensorimotor impairment, activities of daily living, cognition etc).[10]

Physiotherapists who delivered usual care did not provide the caregiver-mediated training program and physiotherapists who delivered the caregiver-mediated training program did not provide usual care to participants.

Outcome measures

Outcome measures have been detailed and fully referenced in a previously published protocol paper[1], so are reported in brief here. The primary outcome used to assess the effectiveness of the intervention 8 weeks after randomisation was the mobility part of the stroke specific self-reported health status measure of the Stroke Impact Scale (version 3.0).[11] Secondary measures included the other self-reported domains of the SIS, mobility, Rivermead Mobility Index (RMI); Barthel index (BI); Nottingham Extended ADL (NEADL); Timed Up and Go test (TUG); Modified Rankin Scale (MRS); Fugl Meyer (FM) lower extremity; Motricity Index (MI); Berg Balance Scale (BBS); length of stay (LOS); number of readmissions in the first 12 months post randomisation as well time from randomisation to first readmission.

Outcomes administered to measure the burden of patient and caregiver were: Hospital Anxiety and Depression Scale (HADS), General Self-Efficacy Scale (GSES), and Fatigue Severity Scale (FSS). The caregiver also completed the CarerQOL and the Expanded Caregiver strain index (CSI).

Length of stay was recorded at patient discharge and number of readmissions at 12 months. Patient and caregiver satisfaction with CME was measured at the end of the intervention period with a custom made questionnaire. The amount of (additional) practice performed by the participating dyads in both the intervention and control group was self-reported with a diary.

Statistical analysis

We anticipated a reduction of 5 points (11%, in favour of those patients who were allocated to the experimental group) and SD of 15 points in the self-reported mobility domain of the SIS version 3.0[12], corresponding to a Cohen's d of 0.3 (medium effect size). The ICC is set to be 0.8. We expected 28 patients to be required per arm of the trial, allowing for a 10% drop-out rate. A sample size of 62 stroke patients (31 per group) was required to provide 80% power to detect a significant between-group difference in the primary outcome measure, at the 5% level when tested two-tailed.

Data were analysed according to the intention-to-treat principle with the statistician masked to group allocation. The effect of the intervention was evaluated and tested by using linear mixed models with a time-by-treatment-group interaction term. Continuous mean scores were used for the linear mixed models. The covariates for the linear mixed models were group, time, time*group and baseline scores for the outcome variables. No other variables were included in the mixed model.[13, 14] We treated participants as a random effect (random intercept), and all other effects were fixed. Kaplan-Meier survival functions were used to compare the length from the randomization to the first readmission to the hospital using the

log-rank test. Post-hoc per-protocol analyses were performed by comparing those patients who received and completed the tele-rehabilitation intervention at home with controls, all of whom were discharged home within 8 weeks. One covariate was found to be unbalanced at baseline (time since stroke onset) and sensitivity analyses were performed to assess the impact. Multiple linear mixed model with and without the covariate were compared. A 2-sided p value of less than .05 was considered significant. Analyses were performed with SAS, version 9.3 (SAS institute, Cary NC, USA).

Results

Recruitment and participant characteristics

Recruitment commenced in July 2013 and ended when the recruitment target was reached in June 2014. The last follow-up assessment was completed in September 2014. **Participant flow and reasons for drop out are presented in the flow chart in Figure 1.** No adverse events were reported during the study.

[insert Figure 1 here]

Table 1 shows the participant characteristics at baseline. Participants had an average age of 68.7 years (SD 15.4), and 64% were male. The average MMSE score was 26.2 (SD 2.8). On average patients lived 38 km away from the hospital. There was a significant difference between the groups at baseline for number of days from stroke to moment of baseline assessment. As a consequence, days from stroke was included as one of the covariates in the sensitivity analyses.

[insert Table 1 here]

Intention-to-treat analyses

Supplemental Table I shows the baseline, week 8, and week 12 scores for the primary and secondary outcome measures for the intervention and control groups, presenting both analyses according to intention-to-treat and per protocol principles.

[refer to Supplemental Table I here]

There was no between-group difference in primary measure of outcome SIS-mobility (p=0.6) at 8 weeks. Intention-to-treat analyses showed a difference between groups in the memory domain of the SIS at 12 weeks which favored the intervention group (-11.2, 95% CI, -18.2 to -4.3, p = 0.0018). However the control group performed significantly better on the strength domain of the SIS (8.2, 95% CI 0.8 to 15.5, p = 0.0299) and the TUG (-8.0, 95% CI -15.3 to -0.8, p = 0.0307) at week 12. There were no between-group differences in LOS.

Carers in the intervention group reported higher self-efficacy assessed with the General Self-Efficacy Scale (-3.3, CI 95% -5.7 to -0.9, p = 0.0078) and less fatigue on the Fatigue Severity Scale (4.6, CI 95% 0.3 to 8.8, p = 0.0369) at week 12.

Per protocol analyses

Twenty out of 31 patients in the intervention group received the tele-rehabilitation at home. Seven patients remained in hospital for the full length of the intervention period, one patient did not have tele-rehabilitation facilities due to a nursing home placement, one patient deceased due to illness unrelated to the intervention and two withdrew from the intervention because they felt generally overwhelmed during the rehabilitation process and did not longer wish to participate in additional research intervention, however agreed to participate in the assessments. We performed a per protocol analyses to examine the individuals who received the tele-rehabilitation component of the intervention at home with additional support from videoconferencing. In these analyses the 11 who had only received the intervention whilst in hospital were excluded.

Those who had received the intervention program at home demonstrated a trend towards improved mobility in the primary outcome measure, the SIS mobility domain (-9.8, CI95% -20.1 to 0.4, p = 0.06) at week 8, however this did not reach significance. In the secondary outcomes, the SIS "communication" domain showed significant better outcomes at week 8 (-7.7, CI 95% -14.0 to -1.3, p = 0.0179) and 12 (-7.3, CI 95% -13.6 to -1.0, p = 0.0246), and the "memory" domain at week 12 (-15.4, 95% CI (-23.5 to -7.3, p = 0.0003). A significant shorter inpatient stay (from randomization to discharge) was noted in the experimental group with a median of 11 days compared with median 20 days in the control group (p = 0.0464) (see Figure 2).

[insert Figure 2 here]

There were also significant between-group differences in favor of the intervention group for the Nottingham Extended ADL index at week 8 (-3.6, CI 95% -6.3 to -0.8, p = 0.0118) and 12 (3.0, CI 95%

-5.8 to -0.3, p = 0.0319). At week 12, the caregivers in the intervention group reported significantly higher self-efficacy measured with the General Self-Efficacy Scale (-3.9, CI 95% -6.7 to 0.0, p = 0.0072). There was a trend towards improved fatigue (4.8, CI 95% -0.1 to 9.8, p = 0.0543), and anxiety and depression (2.9, CI 95% -0.1 to 5.8, p = 0.0555), however these differences were not statistically significant.

No between-group differences were observed in the number of patients who were readmitted. **The average number of days in hospital during the 12 months post-randomization follow up was non-significantly lower (p = 0.0767) in the intervention group (mean 0.7, 95% CI: 0-1.5) than in the control group (mean 8.1, 95%CI: 0-16.3)** (see Table 2).

[insert Table 2 here]

A sensitivity analysis controlling for a between-group difference at baseline in number of days between stroke and randomisation was performed and revealed no differences in results.

While the data collected from the self-reported calendars revealed that those in the intervention group performed more exercises with a carer (p < 0.001), there was no statistically significant difference in the therapy time that the 'usual care' group received from a therapist (p=0.7220) or in their recorded independent practice time (0.6014). The intervention group reported approximately 1000 minutes of total extra therapy time over the 8-week period, which is about 2 hours a week (Table 3).

[insert Table 3 here]

Discussion

To our knowledge, this is the first trial to investigate the effects of a combined e-health program of CME with tele-rehabilitation support on self-reported mobility in patients who have recently suffered a stroke. Those who received the intervention reported an additional 1000 minutes of exercise practice, but this did not directly translate into an improvement in our primary outcome of self-reported mobility following the stroke impact scale. Despite the neutral results in this proof of concept trial, **based on the per protocol analysis,** a 9-day shorter inpatient stay was observed in the intervention group, and significant clinically meaningful improvements of 3 to 4 points favoring the intervention were found in terms of extended-ADLs post-intervention and at follow-up**. Intention-to-treat analyses,** importantly, showed that the program significantly improved carer well-being in terms of fatigue and self-efficacy at 12 weeks. The program was well tolerated and acceptable to patients as well as carers and the intervention group spent on average fewer days than control group in hospital over the following 12 months suggesting resource savings were associated with the approach. No adverse events were reported, suggesting that CME with e-health support is a safe way to augment intensity of practice at home.

Significant improvements in caregiver self-efficacy and fatigue were observed in week 12, but not in week 8, in **both the intention-to-treat and per protocol analyses**. Our work suggests that it is important to already involve caregivers in the inpatient phase, but that the intervention takes some time to impact caregiver's outcomes. Galvin et al.[15] previously found favorable effects of family mediated exercises on functional outcome in stroke patients and on perceived strain by caregivers. Both patients and caregivers showed physical and psychological benefits as a result of the program. Other work has suggested that the involvement of family members and caregivers in rehabilitation can reduce fears that

caregivers may have about their ability to cope at home.[16, 17] Increased pleasure, mood and self-esteem have also been reported in a previous trial examining dyadic exercise for people with dementia living at home[18], suggesting that the impact of structured patient-carer interactions extends beyond patient benefits alone.

Only 13% of the screened admissions to the stroke and rehabilitation units were found to be eligible. While 21% were not acute strokes, a large number of patients did not have mobility problems appropriate for the intervention and 10% were unable or unwilling to identify a carer to assist them. However, 68% of those eligible consented to take part in the trial suggesting that patients and their caregivers are open to joint interventions early after a stroke. Common reasons for not consenting were feeling overwhelmed, and finding it "too much", however many families welcomed a structured approach to their involvement in post-stroke recovery and this may not be specific to the proposed CME program.

Study strengths include a pragmatic intervention design in busy acute stroke and rehabilitation wards, and an individually tailored intervention with a purposefully designed exercise app. A limitation is the small sample size, however, a small proof of concept trials are designed to demonstrate feasibility and to detect an efficacy signal in a small group of patients. This neutral phase II trial provides sufficient evidence for a multicentre phase IV trial in which cost-effectiveness is investigated. Participants recorded any therapy and (self) training sessions in a diary (minutes of exercise) which might provide important information for potential dose-matching in later phase work.

The present study shows some limitations. First, not all participants began the program while still in an inpatient facility, however 11 people did not undertake the program at home for various reasons. **Per protocol analysis** showed that when patients start exercising with their carers whilst still an inpatient a lower number of readmissions occur at 12 months. This group was also more likely to accrue benefits in

extended ADLs. Second, the present study did not provide definitive measures of effectiveness and the addition of more robust measures such as objective portable activity monitors to validly record real-world physical activity should be considered. Third, participants were aware of their group allocation which may have introduced a bias to the self-report measures. However, the neutral effects on the primary measurement of outcome SIS-mobility domain suggest that the bias is limited. Patients in both the control and intervention groups completed daily exercise diaries. Patients in the control group reported exercising with a caregiver for 5 minutes per day (versus 20 minutes in the intervention group) supporting the hypothesis that intensity of practice is a main driver for observed improvements in extended ADLs and suggesting that "exercise contamination" in the control group was minimal. **Last, although no adverse events were reported, this study was not designed or powered to detect adverse events.**

The exercises were progressive in nature and task specific, as per prevailing guidelines[19], and patients wore a Fitbit that gave feedback on daily physical activity. We assume that together this package is responsible for the observed effects in ADL. Mean change scores in a range of 2.4 to 6.1 points on the total NEADL have found to be indicative of patients who show a clinically important difference.[20] This suggests that the observed intervention gains in level of ADL performance may qualify as clinically meaningful.

This study was performed in Australia, a country where many people live long distances away from rehabilitation hospitals. The caregiver-mediated e-health intervention is aimed at reducing the need to visit outpatient facilities and face-to-face contact with a therapist. This raises the question if the same study paradigm would lead to similar results in other cultures, or whether cross cultural differences between western countries require modification of the carer-mediated exercise model. **To obtain insights into determinants of participation in tele-rehabilitation interventions and investigate cross**

cultural differences with respect to ability to recruit patients and effects of therapies, the presented caregiver-mediated e-health intervention is currently also being evaluated in the Netherlands.[1]

Conclusions

With the current emphasis on shorter hospital stays, caregivers will play an increasingly important role in the care and continued rehabilitation of patients after stroke. This study has shown that a caregiver-mediated exercise intervention supported by tele-rehabilitation is feasible and may offer an approach not only to improve patient independence, but also caregiver outcomes, by providing continuing support. **However, the current proof of concept trial justifies a larger (multicenter) definitive phase III randomized controlled trial, to evaluate the effectiveness and cost-effectiveness trial with an economic evaluation.** The effects on health-related quality of life can then be studied next to direct and indirect costs savings in terms of reduced LOS and prevention of readmissions of stroke patients. In addition, budget impact analysis can be done to study the impact on national health care budgets. We suggest that future studies assess the feasibility of caregiver-mediated exercise intervention supported by tele-rehabilitation in other post-discharge settings such as nursing homes and we belief that the beneficial effects of CME are also applicable for other patients with an acquired brain injury such as patients with a traumatic brain injuries.

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Conflict of interest

The authors declare that there are no conflicts of interest.

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Figure Legends

Figure 1 Consort Diagram

Figure 2 Probability from randomization to final discharge

Table 1 Participant characteristics

Demographic	Control N=32	Intervention N=31	Intervention per-protocol N= 20
Sex			
Male, n(%)	21(65.6)	19(61.3)	14(70.0)
Female, n(%)	11(34.4)	12(38.7)	6(30.0)
Age(years)			
Mean(SD)	70.1(12.4)	64.5(18.5)	64.7(19.5)
Median(IQR)	69.5(14.5)	67(19.0)	67(20)
Minimum	42	19	19
Maximum	94	92	92
Marital Status			
Married, n(%)	23(71.9)	23(79.3)	15(79.0)
Divorced, n(%)	2(6.3)	1(3.5)	0(0.0)
Widowed, n(%)	4(12.5)	2(6.9)	1(5.26)
Single, n(%)	1(3.1)	1(3.5)	1(5.26)
Defactor, n(%)	1(3.1)	0(0.0)	0(0.0)
Other, n(%)	1(3.1)	1(3.5)	1(5.26)
Unknown, n(%)	0(0.0)	1(3.5)	1(5.26)
Living arrangement			
Alone, n(%)	6(18.8)	4(13.3)	2(10.0)
With spouse/partner only, n(%)	19(59.4)	20(66.7)	15(75.0)

With spouse/partner and others, n(%)	5(15.6)	3(10.0)	1(5.0)
With child (not spouse/partner), n(%)	2(6.3)	1(3.3)	0(0.0)
With parent(s) or guardians(s), n(%)	0(0.0)	1(3.3)	1(5.0)
With sibling(s), n(%)	0(0.0)	1(3.3)	1(5.0)
Exercise partner			
Child, n(%)	8(25.0)	8(25.8)	2(10.0)
Friend, n(%)	0(0.0)	1(3.2)	1(5.0)
Parent, n(%)	1(3.1)	2(6.5)	2(10.0)
Partner, n(%)	23(71.9)	20(64.5)	15(75.0)
No. Days from stroke to randomization			
Mean(SD)	13.9(7.9)	22.4(13.3)	20(11.5)
Median(IQR)	12.0(9.5)	20.0(19)	18(17.5)
Minimum	5	4	4
Maximum	40	59	43
Stroke type			
Haemorrhagic	4(12.5)	4(12.9)	3(1.50)
Ischemic	28(87.5)	26(83.9)	16(80.0)
Haemorrhagic and Ischemic	0(0.0)	1(3.2)	1(5.0)
Mini Mental State score (MMSE)			
Mean (SD)	26.5(3.0)	25.8(2.6)	25.9((2.5)
Median (IQR)	28.0(5)	26.0(4)	26.5(2)

*P values were calculated by Chi-square /Fisher exact test, t-test and Mann-Whitney test. There were no statistical different between two groups except No. Days from stroke to randomization

Table 2 Length of stay in hospitals after randomization and hospital use after discharge

Variable	ITT			Per-protocol		
	Control (N=32)	Intervention (N=31)	P value	Control (N=32)	Intervention (N=20)	P value
Length of hospital stays between randomization to final discharge (median days,95% CI)	20 (9-26)	16 (8-24)	0.9508	20 (9-26)	11 (4-18)	0.0464
Length of hospital stays between randomization to final discharge (mean days, 95% CI)	24.7(14.9-34.5)	25.6 (16.4-34.9)	0.8891	24.7 (14.9-34.5)	12.8 (7.6-18.0)	0.0326
Number of patients who were readmitted during one year follow up period (n, %)	8 (25)	7 (22.6)	0.8217	8 (25)	4 (20.0)	0.6772
Total number of days in hospital from randomization to one year follow up period (mean, 95% CI)	8.1 (0-16.3)	4.7 (0-9.7)	0.4769	8.1 (0-16.3)	0.7 (0-1.5)	0.0767
Total number of days in hospital	0 (0-112)	0 (0-61)	0.5712	0 (0-112)	0 (0-7)	0.3666

from randomization to one year follow up period (median, range)	

P values were calculated from log-rank test (time to events), Chi-square (n, %), t test (mean, SD) and Mann-Withney test (median, range)

Table 3 Intervention and Control Therapy

	Intervention mean(SD)	Control mean(SD)	P value
Self-reported Therapy Time (mins per day)			
During the therapy sessions	135.8 (191.4)	116.8 (202.3)	0.722
Independent	29.0 (35.0)	28.6 (32.1)	0.9676
With nurse	1.8 (3.2)	6.7 (8.4)	0.0062
With carer	19.8 (13.8)	5.1 (6.8)	<0.0001
Total	186.2 (189.5)	157.9 (208.7)	0.6014
Number of home visits	7.3 (1.0)		
Home visit therapy time	237.5 (64.7)		
Total home visit travel time	238.6 (234.0)		
Tele-rehabilitation (n=20)			
Total number of video calls	3 (1-6)		
Total video call therapy time	45.0 (27.2)		