Original article:

Quality of Life and Activity of Daily living of Ischaemic Stroke Patients in North-Eastern of Peninsular Malaysia: The Effect of Bal-Ex Stroke Home Rehabilitation

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Abstract

Stroke is a leading cause of adult disability. Reduced stroke mortality leads to increasing need for rehabilitation services. Home-based stroke rehabilitation is an alternative to inpatient rehabilitation to help stroke survivors improve their functions. We assess the effect of Bal-ex stroke video module on the quality of life (QoL) and activity of daily living (ADL) of stroke patients. This study is an opened labelled randomised controlled trial (RCT) involving 80 patients with recent mild to moderate ischemic stroke. They were divided into control group and intervention group using randomisation of block of four. The intervention group received a Bal-ex stroke module and twice weekly outpatient follow-up at rehabilitation unit, University Hospital. The control group received only weekly outpatient therapy sessions. Both groups were assessed with Barthel Index (BI) for activity of ADL and at baseline, end of month 2 and month 4. The level of ADL total scores was analysed using a repeated measure ANOVA. 80 patients were recruited and all participants successfully completed the study. The majority of the participants were male (81.2%). Their average mean age was 59.78 (7.56) years old. There was no significant difference between QOL score of both groups at baseline assessment. Intervention group demonstrated a significantly greater mean in ADL, at 2 months [(66.00; 95% CI: 60.34, 71.66) vs. (42.25; 95% CI: 36.59, 47.91)]; and even at 4 months [(77.00; 95% CI: 72.42, 81.58) vs 61.38; 95% CI: 56.79, 65.96)] as compared to control group. Using Bal-Ex stroke home module in early ischaemic stroke can leads to better improvement of patients' quality of life than usual care.

Keywords; Activity of daily living, Bal-ex stroke, home rehabilitation, quality of life

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Introduction

More than half the patients who survive the first month after a stroke will require specialised rehabilitation.[1] Effective rehabilitation interventions that are initiated early after stroke onset can enhance the recovery process and minimise functional disability.[2] However, the effectiveness of rehabilitation interventions also relies on a multidisciplinary team approach and regular team meetings, as well as meetings with the patient, family and caregiver.[1]

Stroke rehabilitation can be administered as

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inpatient rehabilitation, at the patient's home or at an outpatient facility. Home-based rehabilitation (HBR) is defined as a 'rehabilitation programme provided in the patient's place of residence'.[2] HBR programmes provide the greatest flexibility in terms of the schedule, frequency and intensity of rehabilitation. They are most convenient for patients who are homebound because of lack of transportation or because they require only this therapy.[2]

In Malaysia, only a limited number of centres provide inpatient rehabilitation. Most patients who have had a stroke are discharged soon after they have been confirmed to be medically stable and have attended outpatient rehabilitation programmes. These outpatient programmes also have limited resources in terms of either a limited number of rehabilitation centres or insufficient physiotherapists trained in neurological rehabilitation.[3] The cost and time for travelling may also be contributing factors that have caused patients not to continue rehabilitation after being discharged from the hospital.[3] HBR is recommended as a safe programme that does not have negative impacts on the patients' independence and is not stressful for caregivers.[3] Thus, HBR,which does not require the presence of a physiotherapist, is a practical alternative to the current rehabilitation programme available in Malaysia. This has provided the justification for this study,which aimed to evaluate whether HBR using the Bal-ex module would improve the activities of daily living (ADL) and quality of life (QOL) of patients with stroke,without patients and their caregivers having to frequently attendroutine outpatient rehabilitation, which could be troublesome.

Methods

Study design and participants

This was a single-centre, parallel, open-label randomised control trial (RCT) study, with an allocation ratio of 1:1. Eighty participants recently diagnosed (less than 3 months) with mild to moderate ischaemic stroke (National Institutes of Health Stroke Scale <16) attended the rehabilitation centre at the University Tertiary Hospital in this region between May 2014 and April 2015. Those with severe speech disorders, hearing loss and any concurrent neurological disorder,for example, mental retardation, mental illness or epilepsy, were excluded. Eligibility criteria were maintained throughout the study.

After they provided consent, eligible participants were equally randomised in groups of four to either the intervention group (IG) or control group(CG). The allocation was concealed using a sealed envelope and the randomisation sequence was executed without any adaptation.

IG

The IG underwent a HBR programmeusing a Bal-ex module (a combination of a digital video disc (DVD) with a pictographic manual) and outpatient follow-up twice amonth at the rehabilitation unit of the HUSM. The frequency and types of therapy were recorded in the diary provided at the back of the manual. Patients were required to performthe exercises ten times for each step, at least two times per day. During the visit, they performed exercises similar to theCG,depending on their disabilities. The patients and their caregivers were taught individually by physiotherapists and hands-on Bal-ex exercises were shown depending on each patient's disability andthesteps needed during each visit.

CG

Patients in the CG underwent their weekly outpatient follow-ups at the rehabilitation unit of the HUSM. They were individually taughtthe hands-on exercises tobe performed as rehabilitation therapy at home. Although the frequency of therapy performedat home was not recorded, patients and their caregivers weretaught how to perform home exercises during every visit and were advised to do so at home.

Research tools

1. Bal-ex module

The Bal-ex module is a self-instructional 40-min audiovisual DVD of standardised rehabilitation procedures and a pictographic manual produced by local researchers.[4] This module consists of 56 movements divided into seven different stages for patients who have had a stroke. This module is a combination of a prayer's movements, Bobath techniquesand customised Cawthorne–Cooksey techniques. It involves orderly audiovisual physical movements to assist caregivers and patients to perform exercises at home. It consists of passive, active and resistance exercise and ADL, including eating activities, putting on and taking off trousers and a shirt and activity during

'solah'. Bal-ex stroke exercises can be performed in an orderly and systematic manner according to the patient's capability. The movements are done step-by-step from stages1 to 7. Each movement is advised to be performed 10 times and repeated 2–3 times daily by patients or assisted by the caregiver. After patients have successfully completed a movement, they may proceed to the next movement in the sequence. The seven stages of movement include the patient's position; activities while in a prone position–body and hand movements, leg movements and lifting the hip in a prone position while both knees are bent; patient transferring technique and self-grooming activity; activities while sitting–exercise movements and daily routine activities; activities while standing; walking exercises and stairs exercises.

2. Barthel index (BI)

All patients were assessed on the BI for ADL at baseline and the second and fourth months. The BI has ten items of basic activities, including feeding, bathing, grooming, dressing, bowels, bladder, toilet use, chair/bed transfers, mobility and stairs. The total score ranges from 0 to 100, with 100 representing complete independence and 0, complete dependence. The 10-item scale, scoring 0 to 100 with 5-point increments, has been used in several multi-centre stroke trials and in the absence of any clearly superior 'Barthel', it seems reasonable that this should become the uniform stroke trial BI.[5]

The criteria for classifying patients with a favourable outcome varied substantially from trial to trial. Granger et al.found that 60 was a pivotal score at which patients move from assisted independence to dependence.[6] Therefore, the BI scoring used for this study was >60 for independent patients and <60 for dependent patients.

3. Stroke-Specific Quality of Life (SS-QOL) Questionnaire

The SS-QOL is a single stroke-outcome measure that aims to efficiently assess the various domains important in determining stroke-specific HRQOL across the spectrum of stroke symptoms and severity. This self-administered SS-QQL questionnaire consist of 49 items,with 12 domains: energy, family roles, language, mobility, mood, personality, self-care, social roles, thinking, upper extremity function, vision and work/productivity. Each item is ranked on a 5-point Likert scale: (1) the amountof help required to do specific tasks, ranging from no help to total help;(2) the amountof trouble experienced when attempting tasks, ranging from unable to do a taskto no trouble at all and (3)the degreeof agreement with statements regarding their functioning, ranging from strongly agree to strongly disagree. The point of reference for all items was the previous week. The highest score indicates better function and QOL.[7]

Among patients, the SS-QOL questionnaire appears to be a valid tool to measure mild to moderate deficits resulting from a stroke.[8] The minimum score is 49 points and the maximum is245 points;the higher the points obtained,the better the patient's QOL. The cut-off point of 60% from 245 points (≥147) was used to determine good QOL.[9] These disease-specific HRQOL measures are more sensitive to meaningful changes in post-stroke HRQOL and may aid in identifying specific aspects of post-stroke function that clinicians and 'trialists'can target to improve patients' HRQOL after stroke.[10]

Sample size

The sample size calculation was based on the comparison effect of the Bal-ex module on the changes of ADL and QOLscores between the IG and CG among patients with ischaemic stroke using powerand sample size calculation software for comparing two mean scores, as recommended by Gbiri et al.[11] The required sample size was determined to be 40 patients per group after considering the probability of a 20% dropout rate.

Statistical analyses

Data entry and statistical analyses were performed using IBM Statistics SPSS software version 22.0. Age was presented as the mean score and standard deviation (*SD*) and sex was presented as the frequency (*n*) and percentage (%). Characteristics of the study participants in the IG and CG were compared using the independent sample *t*-test for age and the *chi-squared* test for sex. An alpha value of 0.05 was used as the cut-off level for significance. Comparisons of ADL and QOL between the IG and CG based on time (time-treatment interaction) were made using repeated-measures analysis of variance. The overall time–treatment interaction was assessed using Wilk's lambdatest statistic and the *F*-value. The overall time–treatment interaction was statistically significant when the *F*-statistic was smaller than the critical alpha value of 0.05. At each time level (baseline, month2 and month4), the differencesin ADL and QOL between

the two groups werestatistically significant when the 95% confidence interval (CI) of the CG did not overlap with the 95% CI of the IG.

Results

A total of 164 patients who had a stroke were screened at the rehabilitation unit of the HUSM during the recruitment period. Eighty patients who met the inclusion criteria consented to participate in the study. Forty patients were randomised to each group. No adverse events were reported during the study period. The randomisation flowchart is shown in Figure 1.

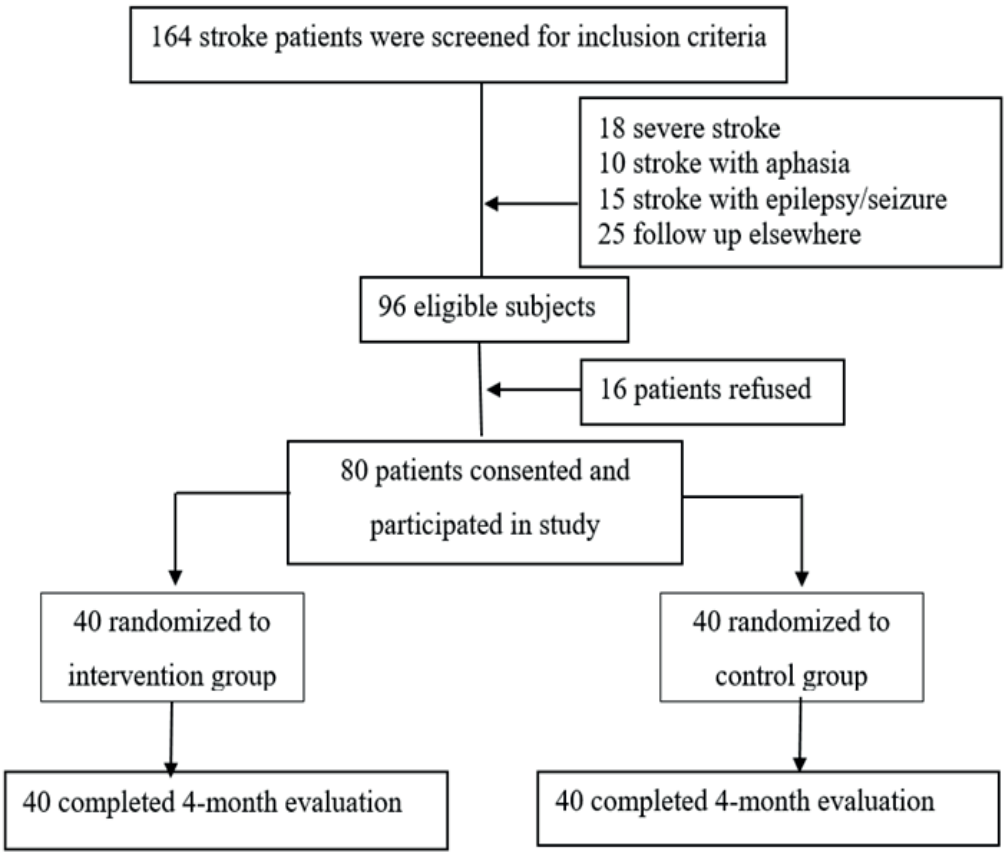

Figure 1: Consort flow chart of the study

Characteristicsof participants

Of the 80 participants included, all completed the study, yielding a 100% response rate. The majority of participants were male (81.2%), with a mean age of 59.78 (*SD*7.56) years. The comparison of age and sex between bothgroups showed that there was no statistically significant difference (Table 1). Throughout the study, no harmful or unintended effects were reported in both groups.

Time–intervention interaction effect on patients' ADL

The *P*-value for the *F*-statistic for the time–intervention interaction was smaller than the critical alpha value of 0.05 (Wilk's lambda$F$ (2, 77) = 20.35, P<0.001). The null hypothesis that the average ADL between groups was the same for all time periods was rejected and the time–intervention interaction was significant.

At baseline, there was no significant difference in the mean ADL between the CG and IG. At months 2 and 4, patients in the IG had significantly higher ADL scores than patients in the CG (Table 2). The

Table 1: Comparison of sociodemographic characteristics between control and intervention group

Variables	Control group (n=40)	Intervention group (n=40)	Mean diff (95% CI)	P-value
Age, Mean (SD)	58.63 (6.66)	60.93 (8.29)	-2.30 (-5.65, 1.05)	0.175
Sex, n(%)				
Male	33 (50.8)	32 (49.2)		0.775
Female	7 (46.7)	8 (53.3)		

There was no significant difference in sociodemographic data between the groups.

estimated marginal mean ADL for patients in both groups is shown in Figure 2.

Table 2: Differences of ADL between control and intervention group based on time.

Time	Group	Mean ADL (95% CI)	F-statistics (df)	P-value
Baseline	Control	32.88 (28.50, 37.25)		
	Intervention	29.13 (36.59, 47.91)		
Month 2	Control	42.25 (36.59, 47.91)		
	Intervention	66.00 (60.34, 71.66)	20.35 (2, 77)	<0.001
Month 4	Control	61.38 (56.79, 65.96)		
	Intervention	77.00 (72.42, 81.58)		

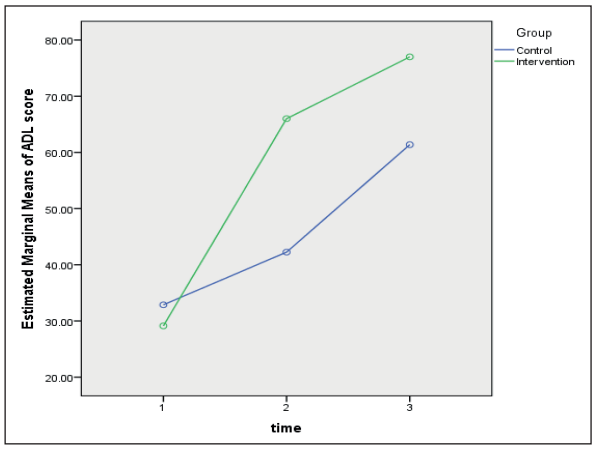

Figure 2: Profile plot showing estimated marginal mean of ADL for patients in control and intervention group based on time.

Time–intervention interaction effect on patients' QOL

The *P*-value for the *F*-statistic for the time–treatment interaction was smaller than the critical alpha value of 0.05 (Wilk's lambda $F(2, 77) = 32.48$, $P<0.001$). The null hypothesis that the average QOL between groups was the same for all time periods was rejected and the time–treatment interaction was significant. At baseline, there was no significant difference in the mean QOL between the CG and IG. At months 2 and 4, patients in the IG had significantly higher QOL scores than patients in the IG (Table 3). The estimated marginal mean QOL for patients in both groups is shown in Figure 3.

Table 3: Differences of QOL between control and intervention group based on time

Time	Group	Mean QOL (95% CI)	F-statistics (df)	P-value
Baseline	Control	80.73 (74.66, 86.79)		
	Intervention	87.70 (81.64, 93.77)		
Month 2	Control	110.78 (103.81, 117.74)		
	Intervention	143.15 (136.18, 150.12)		
Month 4	Control	143.45 (137.10, 149.80)	32.48 (2, 77)	<0.001
	Intervention	161.28 (154.93, 167.62)		

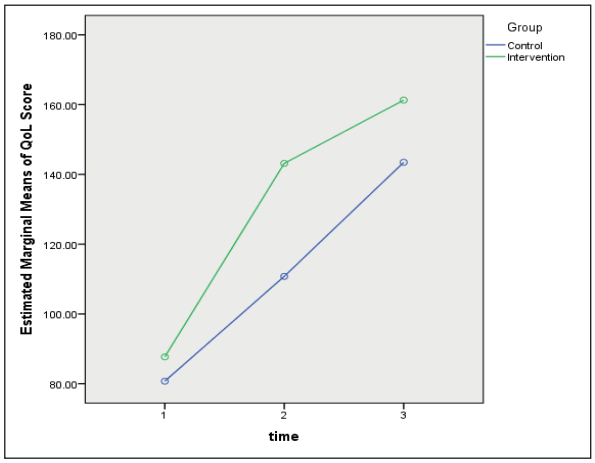

Figure 3: Profile plot showing estimated marginal mean of QOL for patients in control and intervention group based on time.

Discussion

In recent years, home rehabilitation in patients who have had a stroke has been increasingly used to improve their ability to perform ADL and to prevent the loss of motor function. This study provides important information onthe effectiveness of an early home rehabilitation intervention in patients with ischaemic stroke as

other studies,[5,13-15] although the latter used different approaches for HBR programmes.

Sociodemographic data

Overall, 80 subjects were enrolled in this study. There was no dropout in this study probably because the participants who attended the rehabilitation unit did not have any problem to attend the follow-up, lived near the hospital, had a good support system and were themselves willing to participate in this study. From the data, both groups had a majority of male participants. The mean age of the CG and IG was comparable with that in other studies.[5,13-14] We did not divide the mean age according to sex differences because of the small percentage of female participants that might have contributed to bias. Globally, men have higher age-specific stroke rates than women and are more likely to have their first-ever stroke at a younger age.[15]

Effect of Bal-Ex module on ADL

From the baseline data, the results showed no significant difference of the mean ADL score between the CG and IG. The mean ADL score showed that patients in both groups were dependent in their ADL, which was ≤60 at baseline. Most previous studies had findings similar to our study, which showed low ADL scores at baseline. This is because most participants in these studies had recently had a stroke and had not yet started their physiotherapy as outpatients.

Similar baseline mean scores were also found in studies conducted by Chaiyawat et al., Elena Sirbu et al.and Redzuan et al.[5,13-14] However, Duncan et al. had a higher mean BI score at baseline, at 82.5, leaving little range for improvement after the intervention.[16] The patients recruited in this study had completed inpatient rehabilitation before the intervention, which may contribute to the higher baseline BI score. A lower mean baseline BI score for ADL seems to yieldhigher chances for improvement after the intervention.

The results showed statistically significant improvements in the ADL score regardless of time compared to the CG. In the IG, the resultsshowed early accelerated improvement of the ADL score from baseline to month 2 compared to the CG. The mean BI score showed that ADL in both groups changedto independent (BI score >60) after 4 months of rehabilitation. However,themean ADL score was higher in the IG (77.00 vs. 61.38). This result demonstrated that individuals with stroke could gain benefitsfrom home rehabilitation programmesin motor functions and ADL beyond those that occurwith usual care.

The outcomes of the BI for ADL among patients who have had a stroke are similar with different interventions. Duncan et al.demonstrated that the RCT of a post-stroke home-based exercise programmeis feasible.[16] This programmeinvolved patients who had mild to moderate stroke within 30–90 days after astroke and who had completed acute rehabilitation. The IG received a therapist-supervised home-based exercise programmethree times per week for 8 weeks. From the intervention, neurological impairments and lower extremity function showed the greatest improvements. However, the effects of the intervention on ADL were equivocal in both groups,with the mean BI score at baseline for these individuals beinghigher (82.5), leaving little range for improvement even after 12 weeks of intervention.[16]That HBR study differed from our study in that those patients had regular home visitsby the physiotherapist and their study participants underwentinpatient rehabilitation before the intervention, even though their stroke severity was similar to our participants.

In Thailand, Chaiyawat et al. used a similar method, combining an individual's exercise programmeprovided by a physical therapist once a month for 6 months and standard materials on an audiovisual CD of rehabilitation procedures. The BI also improved in both groups, but was significantly better for the IG, with 97.2(2.8) vs. CG 76.4(9.4), $P<0.001$.[14] Similar findings werereported by Elena Sirbu et al., in which the intervention provided significantly better outcomes in ADL, as well as motor and balance functions. However, their study used a small number of participants (14 patients who had a stroke) and did not use audiovisualexercises for home rehabilitation.[13]

A localstudy by Redzuan et al. also combined home rehabilitation with a DVDcontaining therapy techniques.[5] They conducted twice-monthly follow-ups for 44 patients with stroke for 3months and measured their primary outcome

using the modifiedBI. Both groups had significant increases in the MBI score (P<0.001);however, there were no significant differences with regard to the number of patients with improved MBI scores.[5] All thesestudies suggest an early home rehabilitation programmein the first few months after an ischaemic stroke as it leads to more rapid improvements in function and reduces disability compared to usual care.

Effect of Bal-Ex module on QOL

The results showed that a home-based DVD rehabilitation programmeis feasible and improves the QOL among patients who have had a stroke compared to usual care. Unfortunately, we could not find asimilar intervention study using the SS-QOL to measure the QOL for home rehabilitation interventions.

Evaluation of patient improvement is essential to monitor a patient's progress and to assess the effectiveness of the module. Zuraida et al. suggested pre-and post-intervention therapy assessments for patients' QOL measured by using the SS-QOL.[4] The minimum score is 49 points and the maximum is 245 points andthe higher the points obtained, the better the QOL. However, in this study, we used a cut-off point of 60% from 245 points (>147) as a good QOL, as suggested by Rangel et al.[6]

The BI, which has a ceiling effect and captures only physical domains of health status, is not adequate inassessing the full impact of stroke-related disability and is ineffective in detecting the psychosocial dimensions of impaired function.[16] Thus, other health status measures, such as the SS-QOL, wereused in addition to the BIwhen stroke outcomes are assessed. It is necessary to measure the QOL to provide a more accurate and complete picture of the post-stroke level of disability.[17] This is why this study assesses the QOL besides functional improvement in survivors of ischaemic stroke.

A similar finding was found in a study involving Brazilian patients with stroke who attended a rehabilitation programme for more than 3 months, in which their total SS-QOL mean (SD) score was 139.7(38.4).[9] This result shows that rehabilitation helps improve the QOL of survivors of stroke. However, that study differs from ours because it included all types and severity of stroke, including haemorrhagic and ischaemic stroke andpatients spentat least 3 months in the outpatient rehabilitation programme. No home intervention was conducted in thatstudy.

Limitations and recommendations

Our research had several limitations. Participants in this study did not represent the overall survivors of stroke in Kelantan or even in the HUSM, as the patients who willingly participated in this study are those who lived nearby, could afford the money and time to attend follow-ups, or had good social support. There was also no evaluation of patients' comorbidities, which may affect the rehabilitation and process of stroke recovery. This RCT studied only the early effectsof the intervention on stroke rehabilitation,which may be confused with the natural healing process of astroke. Most spontaneous stroke recovery occurs in the first 30 days and may continue up to 6 months after the stroke.[16] The long-term outcomes and lasting effectsof the intervention, which are the foremost important goals in managing stroke,cannot be evaluated.

There are a few recommendations to improve the stroke rehabilitation intervention studies in the future. More RCTs comparing rehabilitation approaches are required to investigate the effects of different combinations of physiotherapy approaches for patients who have had a stroke. Long-term studies are needed to measure the lasting effectsof the intervention for patients with stroke and which groups of patients benefit most from HBR programmes.

Conclusion

This study has provided additional data supporting the remarkable benefits of a HBR programme for stroke patients in Malaysia. After 4months of home rehabilitation, it was found that the intervention had produced greater gains and higher rates of functional independence and better QOL among these patients than among patients receiving usual care without such an intervention. Moreover, there were significant changes in ADL and QOL with the Bal-ex module among patients in the IG compared to thoseof patients in the CG. Although patients in the IG seemed to experience accelerated recovery within 4 months compared to patients in

the CG, the changes may not be associated solely with the Bal-ex module. The effect of baseline physiotherapy follow-up sessions, which were different between bothgroups,also plays some role. Thus, a Bal-ex module would provide a way to improve the patients and caregivers' skills and serve as a motivation as well as a reminder to perform therapy more often.

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Conflict Of Interest And Funding

All authors did not have any conflict of interest to declare.

Ethical Clearence:

This study was approved by the USM Human Research Ethics Committee in 2014 (USMKK/PPP/JEPeM [253.3.(5)].

Authors's Contribution:

Data gathering and idea owner of this study: R.M., and Z.Z.

Study design and supervision: R.M., J.S., Z.Z. N.M.Y., A.M.N., S.S.M.Y., N.D., and R.Z.

Data gathering and analysis: N.A.S., N.M.Y., and A.M.N.

Writing and submitting manuscript: N.A.S., and R.M.

Editing and approval of final draft: R.M., J.S., Z.Z., N.M.Y., A.M.N., S.S.M.Y., N.D., and R.Z.

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