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Effects of a robot intervention on visuospatial hemineglect in postacute stroke patients: a randomized controlled trial

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Abstract

Objective: To evaluate the effects of an intervention using the robot device PARO on visuospatial hemineglect and activities of daily living, and its acceptance during stroke rehabilitation. PARO is an interactive robotic toy with the appearance of a baby seal, which can move, produce sounds, and react to speech and touch.

Design: A randomized controlled trial.

Setting: Hospital for neurorehabilitation.

Subjects: Patients above 60 years old who have suffered their first stroke within the previous three months with left hemineglect ($n = 39$).

Interventions: The PARO group ($n = 21$) was exposed to PARO over a period of two weeks, three times per week. The participants of the control group ($n = 18$) were read to aloud.

Outcome measure: Visuospatial hemineglect was measured by a cancellation test and a Line Bisection Test, and independence in the activities of daily living was assessed by Scores of Independence Index for Neurological and Geriatric Rehabilitation (SINGER) test. The acceptance of PARO was also evaluated. Data were collected blinded at three times: baseline (T0), after two weeks of interventions (T1), and after additional two weeks as follow-up (T2).

Results: Improvement of hemineglect at T1 and T2 was significantly higher in the PARO group (T1: mean (SD) = 6.23 (3.81); T2: mean (SD) = 7.85 (3.68)) compared to the control group (T1: mean (SD) = 2.66 (4.19); T2: mean (SD) = 3.33 (4.16)) (T1: $P < 0.05$; T2: $P < 0.05$).

Conclusion: The study showed that the use of the PARO is well accepted and can help to improve neglect symptoms in patients with subacute stroke.

Keywords

Hemineglect, activities of daily living, PARO, subacute stroke

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Introduction

Hemineglect is a cognitive impairment typically occurring after damage to the right hemisphere, in particular to the parietal cortex.[1] In stroke patients, it is associated with an unfavorable outcome.[2,3]

Current treatments have a limited effect, especially regarding the improvement of activities of daily living.[4] However, hemineglect can be improved by the presentation of stimuli and verbal instructions, as well as by visuospatial, vestibular, and proprioceptive stimulation of the affected side.[5] The aim of the activation of sensory channels is an expanding exploration of the neglected side.[6,7]

PARO is an interactive robot in the shape of a baby seal (Supplemental Figure S1).[8] The term PARO is composed of the Japanese term "*pa*sonaro *ro*botto," which means "personal robot."[9] The robot was developed by Takanori Shibata at the National Institute of Advanced Industrial Science and Technology (AIST) in Japan.[10,11] It is 57 cm long and weighs approximately 3 kg. The synthetic white coat is antibacterial and dirt-repellent, and is suitable for use in hospitals.[10] PARO belongs to the category of interactive stimulation robots designed specifically for therapeutic purposes.[9,12] It is an emotionally stimulative robot with artificial intelligence and variable behavior designed to appeal to the human mind.[9,12] It contains various sensors and responds to auditory and haptic stimuli with a 32-bit reduced instruction set computer (RISC) processor that allows for the movement of the fins and the eyes, with eyelids that open and close.[10,13]

Several studies indicate that the use of this robot could motivate verbal and behavioral interaction[11,14] and improve levels of activity, social interaction,[14–17] and general well-being.[15,16,18,19] However, these results mainly relate to the studies involving people with dementia in nursing homes.

The aim of this study was to investigate the effects of PARO on patients with postacute stroke regarding visuospatial hemineglect, and activities of daily living.

Methods

Inclusion criteria included a minimum age of 60 years and a diagnosis of first stroke of the right hemisphere occurring within the previous three months, with hemineglect of the left side. Excluded from participating were patients for whom an upright sitting position was impossible. Also not included were patients colonized with multiresistant bacteria, for example, methicillin-resistant *Staphylococcus aureus* (MRSA), and patients with major cognitive impairment.

Participants of the study gave their written informed consent before participating. The participants received written and verbal information on the purpose and course of the study.

After informed consent was given, the participants were randomly assigned to either the PARO or the control group. The group assignment followed a random computer-generated list composed by an individual not involved in the study. The recruitment of study participants and assignment to the study groups were carried out by the researcher.

Patients were treated for two weeks on three days per week, resulting in six sessions per patient. The duration of the individual intervention, including data collection, was 30 minutes. In order to ensure that patients were able to focus on the therapy, the intervention was performed as a single session in a quiet environment.

As control intervention, patients were read aloud from a book for the same time as the PARO intervention. Both interventions were planned as supplement to the individual rehabilitation program. They were carried out by the researcher, a nurse scientist with experience in neurological care.

Preparation of each therapy session

Preparation of each therapy session included mobilization of the patient in a wheelchair or in a sitting position on the bed in cooperation with the therapists, providing necessary tools like glasses or hearing aids and implementation of hygienic measures.

Introduction (PARO and control group)

Each treatment began with providing information to the patient. This was done verbally as well as by

initial physical contact on the left upper arm: "I am now on the left side of your body, the side affected by your stroke."

Treatment of the PARO group

PARO was placed on the neglected side so that it was possible for the patient to see and grasp it. The task for the patient was focussing the attention on the robot. As soon as the patient had fixed his or her attention on PARO, it was successively moved further to the neglected side.

Treatment of the control group

A book was also given to the patient to see and grasp. The patient was then read aloud from the book.

Termination (PARO and control group)

At the end of the intervention, the patient was informed that the therapist was now switching from the left "neglected" side to the right side of his or her body. The change was signaled verbally and also by contact on the left upper arm.

The participants of the study were recruited between February 2014 and October 2015, at a hospital for neurological rehabilitation (Asklepios Neurologische Klinik Falkenstein, Königstein, Germany).

Outcome data were visuospatial hemineglect and activities of daily living. In addition, we examined the acceptance of the participants regarding the robot.

The cancellation tests, Cats Test[20] and Line Bisection Test[21] were carried out. Both tests are used to diagnose and monitor visuospatial hemineglect. The Cats Test contains 24 pictures of cats and requires the participant to cross out all 24 pictures. In the Line Bisection Test, participants have to cross the center of a horizontal line (27.4 cm in length and 0.5 cm in width).

Activities of daily living were assessed, based on observation using the Scores of Independence Index for Neurological and Geriatric Rehabilitation (SINGER).[22] This instrument is based on the theoretical foundation of the International Classification of Functioning, Disability and Health (ICF) and was developed specifically for neurological and geriatric rehabilitation. The SINGER contains a total of 20 items, grouped into four subcategories (self-care, mobility, communicative abilities, and cognitive abilities). Each of these subcategories consists of 4–7 items, each item being valued on a Likert scale between 0 and 5 points.

Finally, the degree of acceptance of PARO was investigated using two open questions: "What do you like about PARO?" and "What do you not like about PARO?"

At the start of the interventions, the following data were collected to describe the sample: age, gender, side of lesion, type of stroke, and cognitive and physical functions. Cognitive status was assessed using the Mini-Mental State Examination (MMSE) tool.[23] The National Institute of Health Stroke Scale (NIH-SS) was used to quantify the impairment caused by the stroke,[24] and Barthel Index (BI) for assessing the impairment in activities of daily living.[23]

The outcome data of visuospatial hemineglect were collected blinded by a neuropsychologist at three points in time: baseline (T0), after the two weeks of interventions (T1), and after an additional two weeks as a follow-up (T2).

The outcome data of the activities of daily living (SINGER) were collected blinded by neuropsychologists, or therapeutic and nursing staff at measurement times T0, T1, and T2. The questions pertaining to acceptance were asked by the researcher at the first and the final PARO sessions. All involved neuropsychologists, therapists, and nurses were trained on the use of the assessment tools before the start of the study.

Descriptive statistics were calculated for all variables: mean values, SDs, and frequencies for categorical variables and median difference (confidence interval (CI)). The *t*-test and Mann–Whitney *U*-test were used to test the significance of group variations. The significance level was set at two-tailed $P = 0.05$. Effect sizes were determined using Cohen's *d* and Cohen's *r*. Missing data were handled using a pairwise exclusion of cases (SPSS). For statistical analysis, SPSS version 22 software (IBM SPSS Statistics for Windows, New York, NY: IBM Corp., USA) was used.

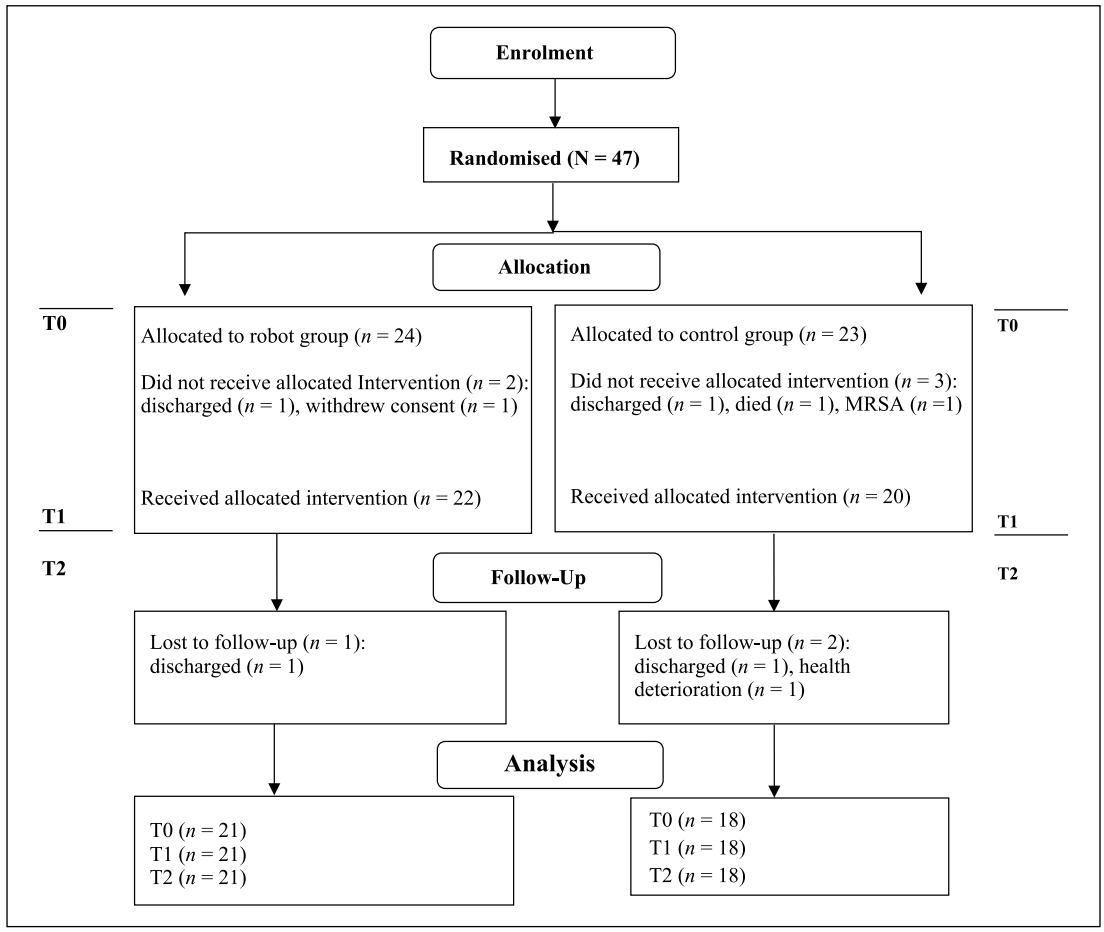

Figure 1. Flow diagram of enrolment, allocation, follow-up, and analysis.

The answers of the participants were recorded verbatim. The data were analyzed by content analysis and clustered thematically.[25]

The study was approved by the Ethics Committee of the Faculty of Medicine of the Martin-Luther-University Halle-Wittenberg (2013-90). The trial was registered by the German Registry of Clinical Studies (DRKS00005427) and from 2012 to 2014 funded by Hessisches Ministerium and Frankfurt University of Applied Sciences.

Results

During the study period, 47 stroke patients met the inclusion criteria and provided informed written consent for participation. These 47 participants were randomly assigned to one of the two study groups (Figure 1). During the study period, eight participants were lost to the study, three in the PARO group and five in the control group (Figure 1).

Two participants of the PARO group received only five instead of six therapy sessions. The reasons were refusal because of fatigue (n=1) and deterioration of health (n=1). In the control group, two participants also received only five therapies because of an external medical examination (n=1) and rejection due to acute pain (n=1). None of the reasons were study-related.

The average age was 73.8 years (SD = 7.22), 22 females and 17 males took part. Thirty-two of the participants had an ischemic stroke and seven a

Table 1. Characteristics of the participants.

	PARO group ($n=21$), mean (SD)	Control group ($n=18$), mean (SD)	*P*-value
Age (years)	74.21 (6.53)	73.34 (8.13)	0.922[a]
Gender (female/male)	10/11	12/6	0.334[b]
Diagnosis (ischemic/hemorrhagic)	18/3	14/4	0.682[b]
Side of lesion (right/left)	21/0	18/0	–
Time after stroke, mean (SD)	49.24 (29.12)	55.17 (22.75)	0.379[a]
MMSE, mean (SD)	22.10 (3.73)	21.33 (3.61)	0.512[a]
NIH-SS, mean (SD)	11.43 (2.69)	10.72 (3.10)	0.568[a]
Barthel Index, mean (SD)	23.75 (14.84)	20.28 (14.99)	0.460[a]

MMSE: Mini-Mental State Examination; NIH-SS: National Institutes of Health Stroke Scale.
[a]Mann–Whitney *U*-test.
[b]Fisher exact test.

Table 2. Cats Test and Line Bisection Test.

		PARO group ($n=21$)	Control group ($n=18$)		PARO group ($n=21$)		Control group ($n=18$)	
		Mean (SD)	Mean (SD)		Mean difference (SD)	Median difference (95% CI)	Mean difference (SD)	Median difference (95% CI)
Cats Test	T0	8.86 (4.44)	10.56 (5.81)	T1 − T0	6.23 (3.81)[*,a]	6 (4–8)	2.66 (4.19)	1.5 (0.6–3)
	T1	15.10 (5.98)	13.22 (7.76)	T2 − T1	1.61 (2.94)[**,b]	1 (0.3–3)	0.66 (2.30)	0.5 (–0.5 to 2)
	T2	16.71(5.95)	13.89 (7.44)	T2 − T0	7.85 (3.68)[*,a]	8 (6–10)	3.33 (4.16)	3 (1–5)
Line Bisection Test	T0	9.30 (4.15)	11.05 (3.05)	T1 − T0	1.82 (2.87)[**,c]	2 (0.5–3)	–0.016 (3.1)	0.5 (–1.5 to 2)
	T1	11.12 (2.52)	11.03 (3.35)	T2 − T1	0.10 (2.09)[**,c]	0.3 (–1 to 1)	–0.16 (2.95)	0.1 (–2 to 1)
	T2	11.22 (2.83)	10.87 (4.05)	T2 − T0	1.92 (2.79)[**,c]	1 (0.1–3)	–0.17 (3.10)	1 (–2 to 3)

Outcome measures at the baseline (T0), after the two-week period of robot and control interventions (T1), and after further two weeks as follow-up (T2).
[a]Large effect size Cohen's *d* (>0.8).
[b]Small effect size Cohen's *d* (<0.5).
[c]Small effect size Cohen's *r* (<0.3).
*Significant difference between improvements of the study groups ($P<0.01$).
**Significant difference between improvements of the study groups ($P>0.05$).

hemorrhagic stroke. All of them had a right-sided supratentorial lesion. The average time elapsed after the stroke was 51.9 days (SD = 26.21).

The mean score of the MMSE was 21.74 (SD = 3.65), the mean of NIH-SS was 11.10 (SD = 2.87), and the mean of the Barthel Index was 22.05 (SD = 14.81). Table 1 gives an overview of the group-specific characteristics. There were no significant differences between the groups.

Table 2 shows the group differences in the Cats Test and Line Bisection Test at baseline (T0), T1, and T2. In the Cats Test, the improvement between T0 and T1 was significantly greater in the PARO group compared to the control group with a large effect size. This improvement remained significant at the follow-up assessment T2. There was no significant group difference in the Line Bisection Test.

Table 3. SINGER assessment.

		PARO group ($n=21$)	Control group ($n=18$)		PARO group ($n=21$)		Control group ($n=18$)	
		Mean (SD)	Mean (SD)		Mean difference (SD)	Median difference (95% CI)	Mean difference (SD)	Median difference (95% CI)
SINGER (subcategory: self-care)	T0	7.95 (4.63)	8.22 (4.49)	T1 − T0	4.52 (3.71)*,a	5 (3–6)	2.88 (2.16)	3.5 (2–4)
	T1	12.48 (5.84)	11.11 (5.41)	T2 − T1	1.00 (1.73)*,a	1 (0.5–2)	2.22 (2.18)	2 (1–3)
	T2	13.48 (5.89)	13.33 (5.83)	T2 − T0	5.52 (3.94)*,a	5 (4–7)	5.11 (2.72)	6 (4–7)
SINGER (subcategory: mobility)	T0	2.57 (3.07)	2.78 (3.49)	T1 − T0	2.04 (1.80)*,a	2 (1–3)	1.44 (1.54)	1 (0.7–2)
	T1	4.62 (4.20)	4.22 (4.41)	T2 − T1	0.71 (1.19)*,a	0 (0.2–1)	1.50 (1.19)	1 (0.7–2)
	T2	5.33 (4.95)	5.72 (5.06)	T2 − T0	2.76 (2.51)*,a	2 (2–4)	2.94 (2.12)	3 (2–4)
SINGER (subcategory: communication)	T0	10.90 (1.64)	10.17 (1.76)	T1 − T0	1.66 (1.28)*,a	1 (1–2)	2.33 (1.91)	3.5 (1–4)
	T1	12.57 (1.72)	12.50 (2.94)	T2 − T1	0.52 (1.21)*,a	0 (0.03–1)	0.44 (1.04)	0 (–0.1 to 1)
	T2	13.10 (2.23)	12.94 (3.40)	T2 − T0	2.19 (1.36)*,a	2 (1–3)	2.77 (2.32)	3.5 (2–4)
SINGER (subcategory: cognitive abilities)	T0	6.71 (2.43)	8.33 (3.25)	T1 − T0	1.90 (1.89)**,b	2 (1–3)	0.77 (1.48)	0 (0.5–2)
	T1	8.62 (3.25)	9.11 (3.77)	T2 − T1	0.95 (1.72)*,a	0 (0.9–2)	0.44 (0.92)	0 (–0.2 to 1)
	T2	9.57 (3.47)	9.56 (3.74)	T2 − T0	2.85 (2.33)**,b	3 (2–3)	1.22 (1.69)	1 (0.5–2)

SINGER: Scores of Independence Index for Neurological and Geriatric Rehabilitation.
Outcome measures at the baseline (T0), after the two-week period of robot and control interventions (T1), and after further two weeks as follow-up (T2).
[a]Small effect size Cohen's r (<0.3).
[b]Middle effect size Cohen's r (0.3–0.5).
*Significant difference between improvements of the study groups ($P<0.01$).
**Significant difference between improvements of the study groups ($P>0.05$).

Table 3 shows the results of SINGER at baseline (T0), T1, and T2. Both groups showed an improvement in the subcategories of self-care, mobility, and communication and cognitive ability over the study period. The differences between the groups in the subcategories of self-care, mobility, and communication were not significant. In the subcategory of cognitive abilities, we found a significant improvement in the PARO group compared to the control group at T1 and T2.

Supplemental Figure S2 presents the acceptance of PARO. Thirty-five positive and two negative aspects of PARO were expressed by the participants. Most frequently mentioned was that PARO responded to voice and touch ($n=11$) and that the eyes opened and closed ($n=10$). Another positive feature was the soft and cuddly fur ($n=5$). Five participants mentioned that PARO was patient. Two participants found value in the robot as they had something to tell their relatives. For two participants, PARO was a diversion of the routine in the hospital and a distraction from chronic pain. For two participants, the voice of PARO was unpleasant. One of them said it reminded him of a cat.

Discussion

The study examined the effects of the PARO in individuals with right hemisphere postacute stroke and left-sided hemineglect. The results of this study support the assumption that an interactive stimulating robot may have a positive effect on visuospatial hemineglect in subacute stroke patients. Compared to the control group, patients exposed to the PARO showed a significant improvement of visuospatial hemineglect symptoms. This improvement was present after a two-week intervention and persistent in a follow-up assessment after another two weeks.

Significant improvements of neglect symptoms were seen only in the Cats Test, but not in the Line Bisection Test. We assume that the Line Bisection Test does not have sufficient sensitivity to detect changes on visuospatial hemineglect in patients in the subacute phase. This assumption is supported by a study by Ferber and Karnath,[26] which compared the Line Bisection Test and a cancellation test in patients with hemineglect.

We used the SINGER instrument to measure independent mobility, self-care, communication, and cognitive abilities. As expected in patients in the subacute phase after stroke, both groups improved in all four areas over the study period. While mobility, self-care, and communication abilities showed non-significant group differences, only patients treated with PARO showed significant improvement in cognitive abilities (including memory, concentration, ability to plan, and social behavior).

However, these results should be interpreted carefully. SINGER is not a validated assessment of cognition, but an observation-based clinical assessment of activities of daily living. The higher scores in the cognitive abilities could be at least partly explained by the larger improvement of neglect symptoms in the PARO group.

To our knowledge, this is the first study using a robotic device as a therapeutic tool for treating visuospatial hemineglect in patients during neurorehabilitation. PARO was positioned on the neglected side of the patient with the aim of sensing and exploring the neglected side. Our assumption was that PARO could stimulate the senses on a multimodal level and motivate interaction that involves the neglected side. The theoretical model of human-robot interaction by Libin and Libin[12] assumes that the interaction with a stimulation robot furthers the training of sensory motor and cognitive skills, emotional well-being, individual quality of life, and improvement of autonomy in personal competency through a sense of control and self-confidence.

Study findings from the literature have shown the effects of PARO as a therapeutic agent for sensory stimulation in people with dementia.[14,27,28] According to these studies, PARO contributes to enhanced human-robot interaction and social interaction. Furthermore, sensorimotor skills (e.g. stroking and touching) and emotional expression can be promoted. The developers of PARO assume that the robot has comparable psychological, physiological, and social effects as animal-assisted therapy or animal-assisted activity[13] and thus can be used instead of an actual animal. Compared to a real animal, PARO is more easily available and has preferable hygienic and allergic properties.[13]

Regarding the acceptance of the PARO, 34 positive and only 2 negative responses were collected. Although the use of such robotic devices is still uncommon in hospitals and for all patients is was the first experience of this kind, there seem to be no general reservations against robotic devices in the population of patients with an average age of above 70 years. In contrast, PARO arouse predominantly positive emotions. Its behavior was mostly experienced as authentic and its external appearance as appealing and pleasant. This emotional impact of PARO, in addition to the multisensory stimulation, might be considered as a reason for its therapeutic effect of neglect symptoms.

The study has some methodological limitations, which should be considered in the interpretation of the results. Because the participants themselves decide whether to participate in the study, we cannot exclude self-selection bias. These results are limited to patients over 60 years of age, after their first stroke within the previous three months with a diagnosis of left hemineglect, so it remains unclear whether these effects are also valid regarding patients with a more extended period of hemineglect or a right hemineglect.

With 39 participants, the sample size might be too small to identify more significant group differences. In addition, the treatment phase of two weeks and a follow up after two weeks may be too short to see any further effects. Another limitation is the two-group design. We did not have a study group without an intervention.

Another limitation is the lack of blinding. We observed that patients were talking about PARO to hospital staff and other patients. Therefore, we cannot be sure that the staff was completely blinded during the data collection.

Based on the experience from the study, we recommend the following suggestions for the application of PARO in a hospital for neurorehabilitation: (1) the stimulus presentation should be structured, well-targeted, and controlled in a single session; (2) patient preferences should be considered; (3) the use of robotics should be undertaken only by healthcare professionals and guided by ethical considerations; and (4) local conditions should be considered and hygienic guidelines followed.

In summary, the study indicates that the therapy with an interactive, stimulating robot is safe, well accepted and easily incorporated into the routine practice of a hospital for neurorehabilitation. The intervention with PARO suggests effectiveness in terms of improvement of visuospatial hemineglect in patients with postacute stroke.

We recommend further studies in neurological patients with larger sample sizes to investigate the potential of the PARO for improving neglect symptoms, well-being, and quality of life.

Clinical messages

- PARO therapy sessions were easily incorporated into early neurological rehabilitation and well accepted by patients.
- Interactive stimulating robotic intervention seems to have the potential to improve neglect symptoms in subacute stroke patients.

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Supplemental material

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