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A study on additional early physiotherapy after stroke and factors affecting functional recovery

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Objective: To investigate whether additional early physiotherapy after stroke improved functional recovery in stroke patients.
Design: A prospective, randomized, controlled study.
Setting: One stroke ward and an acute stroke unit in a large teaching hospital, southern China.
Subjects: Patients with first-onset stroke consecutively admitted to the stroke centre.
Interventions: One group ($n = 78$) received additional early physiotherapy (AEP) for 45 minutes, five days a week for four weeks starting within the first week since stroke onset; the routine therapy (RT) group ($n = 78$) received no professional rehabilitation therapy.
Main outcome measures: Glasgow Coma Scale, Mini-Mental State Examination, Fugl-Meyer Assessment of Motor Recovery, Clinical Neurological Deficit Scale and Modified Barthel Index (MBI).
Results: Patients from the AEP group had a high drop-out rate ($n = 28$), but those remaining made relatively better functional recovery at 30 days than those from the RT group if measured by MBI. Multiple linear regression analysis revealed that cognitive disturbance, aphasia, double incontinence, site of lesion and sensory impairment might affect functional recovery after stroke.
Conclusions: Additional early physiotherapy might improve independence of patients after stroke but failed to show benefit in other aspects in our study. Cognitive disturbance, aphasia, double incontinence, site of lesion as well as sensory impairment might affect functional outcome after stroke.

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Introduction

Stroke is a common disease that leads to mental and physical disability.[1] In China, there are 1.5 million stroke patients newly diagnosed every year, and approximately 75% of those who survive the acute phase have disabilities. The mortality of stroke in Mainland China in 2001 is about 111.01/100 000, the second leading cause of death.[2] As a result of many factors including improved surveillance in acute stage and control of risk factors, stroke mortality has been declining in China,[3] leading to an increase in disabilities from stroke. It not only affects the daily life of survivors, but also creates a major economic and social burden.

There are theoretical grounds for believing that early rehabilitation intervention might be beneficial to functional outcome: starting treatment within the first 20 days may be associated with good functional outcome.[4] Theoretically, early rehabilitation could result in the avoidance of secondary acquired abnormal movements as well as nonuse of extremities due to musculoskeletal changes. Although several reports investigated the role of early rehabilitation in the functional recovery in stroke patients,[4,5] few have provided an accurate design, assessment and documentation of effectiveness of early physiotherapy. Furthermore, early rehabilitative therapy may not begin for a considerable time after stroke, either because stroke survivors need time to reach an appropriate level of consciousness to make response to demand or because usually inadequate professional physiotherapists are available for all the stroke patients in acute phase, especially for patients from rural areas in China.

Physiotherapy is commonly used to enhance the functional recovery of stroke patients in the acute phase, because of its convenience and practicability. Some people suggest that rehabilitation research should focus on specific components of therapy and then get an evidence base for the effective components.[6] Bobath techniques are some of the most commonly used methods in stroke physiotherapy in the UK.[7] They are also very popular in China. Bobath techniques aim to improve the coordination of patients by obtaining normal active reactions of the affected side in response to being moved and to inhibit abnormal patterns of movement. Passive movement training for the paralytic limb could prevent contraction and malformation of the affected joint.

There have been rare prospective, randomized, controlled studies in this area in Chinese populations. Thus, the aim of the current study was to investigate the effects of early physiotherapy, including Bobath techniques and passive movement training, evaluated by a series of outcome measures in stroke patients. Our study is a controlled prospective study investigating the effects of additional early physiotherapy (AEP) on functional outcome, performed within one week after stroke onset.

Early prediction of functional recovery is an important factor in planning and utilizing rehabilitation resources in clinical practice. Therefore, it is critical to evaluate the patients at stroke onset and to identify who will benefit from rehabilitation therapy. Many stroke concomitant factors have been found to correlate with post-stroke functional recovery.[8] Little is known about the factors influencing post-stroke functionaly recovery evaluated by different research measures. Thus, the second aim of the study was to determine the factors that might influence functional recovery of stroke through a series of different evaluation measures.

Methods

This was a prospective controlled study with random allocation to a treatment group and a control group. The ethics committee approved the trial and patients gave written informed consent. Subjects were free to withdraw from the trial at any stage if they, or their relatives, requested this.

Subjects used in this study were recruited from the stroke centre of the First Affiliated Hospital of Sun Yat-Sen University in southern China, a large teaching hospital with acute and rehabilitation facilities. Approximately 700 stroke patients are admitted to the hospital every year. Stroke patients were treated in a 45-bed stroke ward and a 12-bed stroke intensive care unit. All patients with stroke admitted from 1 August 1998 to 1 November 2001 were considered for inclusion in the study.

Stroke was defined as acute onset of neurological deficit lasting more than 24 hours or leading to death, with no apparent cause other than cerebrovascular disease. The diagnosis of stroke was based on history and clinical examination. All stroke patients had a CT scan or MRI scan within the first week of stroke onset to confirm the diagnosis.

We excluded patients who had signs and symptoms of subarachnoid haemorrhage, transient ischaemic attack, and those with severe cerebral oedema. Subjects with Glasgow Coma Scale score of 8 or less or with affected limb muscle power grading 3 or more were excluded. Patients with premorbid dementia or premorbid severe impairment of the limb were excluded. Those who reached the hospital more than one week after stroke onset were excluded. Patients with abnormal high fever, severe pneumonia and cardiac infarction were also excluded. Other exclusions included severe high blood pressure over 200/120 mmHg, not being able to tolerate a 45-minute physiotherapy session daily or those scheduled to be discharged from the hospital within the first week.

Randomization was achieved through computer-generated random numbers in sealed envelopes. Patients were assigned to either additional early physiotherapy intervention (AEP group) or routine therapy without early professional physiotherapy (RT group).

Early physiotherapy intervention procedures

Additional early physiotherapy was provided to subjects in the treatment group by two experienced rehabilitation therapists from the department of rehabilitation in the hospital. Therapists were blinded to patients' groupings. The early therapy included Bobath techniques and passive movements training of the affected limb, and was initiated within the first week after stroke onset. Passive movement training included a series movements of the joints of completely paralytic limbs to prevent contracture and malformation. Each subject received the therapy for 45 minutes a day, five days a week for four weeks. Subjects from the routine therapy group received no professional or regular physiotherapy during the whole hospitalization period. Stroke-related symptoms and complications in each group were treated with multidisciplinary approaches in the stroke centre by a special team. No specific cognitive or acupuncture therapy was administered.

Evaluation

Demographic properties of the patients such as age, sex and educational status were noted. Data on the date of stroke onset, type of stroke, lesion site, muscular tension change, somatic sensory impairment, ataxia or not, swallowing dysfunction, cognitive disturbances, initial post-stroke conscious state, incontinence or not, aphasia or not, psychiatric disturbance (depression, anxiety, etc.) were collected from medical records.

All patients were assessed at admission with respect to the following evaluations: Conscious level was evaluated by Glasgow Coma Scale (GCS)[9]; cognitive status was assessed by Mini-Mental State Examination (MMSE)[10] (serious cognitive function is defined as MMSE at admission lower than 17); motor function was assessed by Fugl-Meyer Assessment of Motor Recovery[11]; stroke severity was measured by Clinical Neurological Deficit Scale (CNDS),[12] which is recommended by the Chinese Medical Association (see Appendix 1; there are eight items in the chart); independence in activities of daily living were assessed by Modified Barthel Index (MBI).[13] Follow-up assessments of the above outcome measures were performed 30 days and six months respectively since stroke onset. All the above evaluations were performed in the rehabilitation clinic and general outpatients department by two trained neurologists who were blinded to the grouping of the subjects.

Data obtained from pre- and postrehabilitation evaluation were analysed by a nonparametric *t*-test. Correlation assessments were performed by Spearman correlation analysis. Stepwise linear regression analysis was used to indicate the factors that affected functional recovery. Analysis of variance (ANOVA) was used in the comparison of numerical variables. The Wilcoxon rank-sum test was used to evaluate the difference of functional assessments between pre- and postrehabilitation and between the AEP and RT group. Statistical Package for Social Sciences (SPSS) version 9.0 (Chicago, IL) for Windows was used for data analysis. All numeric data are showed as

the form of mean ± SD. A p-value of <0.05 was considered significant.

Results

We identified 2184 potential trial participants who had suffered from stroke between August 1998 and November 2001 (Figure 1). We excluded 1976 patients: 27 had symptoms from other causes, 208 had transient ischaemic attack, 56 had subarachnoid haemorrhage, 536 had muscle power grades more than three, 667 had been admitted more than one week after stroke onset, and 216 had severe cerebral oedema with GCS score 8 or less. Sixty-three were eligible but not recruited in error, 98 had premorbid dementia recorded in the medical notes and 87 had premorbid severe impairment of the limb. Another 18 were planned for discharge from the hospital

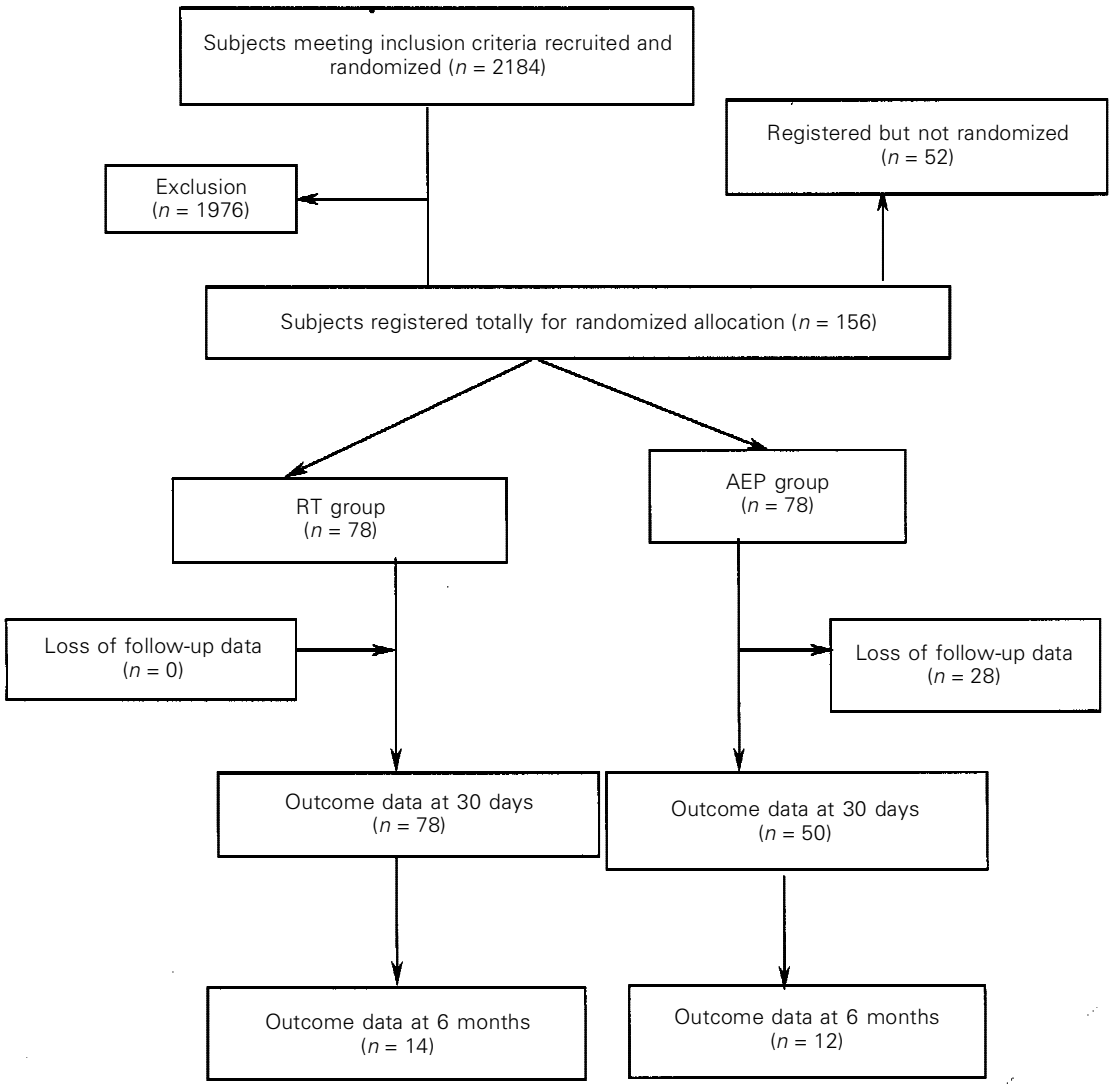

Figure 1 Flow diagram of randomization procedure.

within the first week. Of the remaining 208 patients, 52 refused consent. Thus, we recruited 156 patients, 78 of them were randomly assigned to additional early physiotherapy and other 78 patients were assigned to routine therapy.

Twenty-eight in the AEP group were not able to tolerate a 45-minute physiotherapy session daily with or without deteriorating illness and were lost to follow-up at six weeks, and a further 102 were lost at six months.

Patient demographics were essentially similar between the AEP and RT group (Table 1). There were no differences in age, sex and educational status. The groups were comparable regarding the frequency of previous stroke, type of stroke, incontinence or not, aphasia and psychiatric disturbances.

Table 2 shows that there were no differences between the AEP and RT groups in conscious level, cognitive state, motor function, stroke severity, independence of daily living at prerehabilitation. Also, Table 2 shows that all functional

Table 1 Basic characteristics of patients in intervention and control groups

	AEP (n = 50)	RT (n = 78)	p-value
Age	65.49 ± 10.94	61.8 ± 10.94	0.064
Sex			
Male	33	44	0.370
Female	17	34	
Education status			
No education	7	16	0.095
Primary education	21	42	
High school and university	22	20	
Frequency of having previous stroke	4	15	0.136
Type of stroke			
Cerebral infarction	37	67	0.146
Cerebral haemorrhage	13	11	
Incontinence	14	21	0.944
Aphasia	16	26	0.971
Mental disorder	20	18	0.064

AEP, additional early physiotherapy group; RT, routine therapy group.

Table 2 Admission and follow-up evaluation data of all the included patients

Scales	Admission		30 days after stroke		6 months after stroke	
	AEP	RT	AEP	RT	AEP	RT
GCS	14.04 ± 1.97	13.10 ± 2.67	14.43 ± 1.69[a]	13.89 ± 1.81[a]	15.00 ± 0.00[a]	14.33 ± 1.78
MMSE	19.37 ± 9.05	18.85 ± 10.68	23.41 ± 7.70[a]	21.87 ± 9.80[a]	28.21 ± 2.19[b]	24.82 ± 8.21
CNDS	22.90 ± 9.49	22.69 ± 11.96	17.04 ± 10.37[a]	17.65 ± 11.03[a]	9.14 ± 7.40[a]	8.92 ± 11.26[b]
Fugl-Meyer score (upper limb)	16.50 ± 16.34	22.99 ± 21.91	25.89 ± 20.83[a]	28.66 ± 21.40[a]	41.86 ± 23.82[a]	48.52 ± 25.65[a]
Fugl-Meyer score (lower limb)	13.58 ± 8.67	14.88 ± 10.24	19.73 ± 10.03[a]	18.05 ± 9.92[a]	26.86 ± 7.06[a]	26.00 ± 9.51[b]
MBI	25.70 ± 19.56	33.53 ± 31.04	47.67 ± 28.75[a,c]	47.16 ± 28.73[a,c]	83.93 ± 19.63[a]	80.00 ± 32.96[a]

[a,b]Refers to the difference in the corresponding functional assessments between admission and follow-up evaluation, [a]$p < 0.01$, [b]$p < 0.05$. [c]Refers to the difference of the AEP and the RT group considering change scores of functional assessments between 30 days after rehabilitation and that at admission, $p < 0.05$.
AEP, additional early physiotherapy group; RT, routine therapy group; GCS, Glasgow Coma Scale; MMSE, Mini-Mental State Examination; MBI, Modified Barthel Index.

Table 3 Related factors affecting the changes of scale values before treatment and 30 days after treatment

Independent variables	Dependent variables					
	Change of CNDs	Descending rate of CNDS	Change of Fugl-Meyer score for upper extremities	Change of Fugl-Meyer score for lower extremities	Ascending rate of Fugl-Meyer score for lower extremities	Change of MBI
Aphasia	–0.329			–0.467		–0.482
Serious cognitive function		0.318	–0.355			
Incontinence					–0.515	
MMSE at admission						0.399
Site of lesion						–0.435
Sensory impairment					–0.252	
F	5.710	5.272	6.926	11.343	10.499	16.748
p	<0.05	<0.05	<0.05	<0.01	<0.01	<0.01

The data in this table refer to the factors entering to the linear regression equation.
CNDS, Chinese Neurological Deficit Scale; MMSE, Mini-Mental State Examination; MBI, Modified Barthel Index.

and cognitive parameters improved significantly after the 30-day treatment period. MBI was improved significantly more in the AEP group than in the RT group (but the 28 patients missing were probably more severely affected). However, there were no statistically significant differences between the two groups concerning other parameters.

Table 3 shows the factors influencing cognitive and functional improvement 30 days after stroke onset using stepwise multiple regression analysis. The independent variables selected were age, educational status, frequency of previous stroke, type of stroke, site of lesion, muscular tension change, somatic sensory impairment, ataxia or not, incontinence or not, aphasia or not, existence of swallowing dysfunction, cognitive disturbances, psychiatric disturbances, and initial conscious state. And the dependent variables selected were the changes and descending/ascending rate of CNDS, Fugl-Meyer score of upper and lower extremities and MBI. Table 3 demonstrates that aphasia is associated negatively with CNDS changes ($r = –0.329$). Serious cognitive function is associated positively with descending rate of CNDS ($r = 0.318$). Serious cognitive function is negatively associated with changes of Fugl-Meyer score for upper extremities ($r = –0.355$). Aphasia is negatively associated with changes of Fugl-Meyer score for lower extremities ($r = –0.467$). Ascending rate of Fugl-Meyer score for lower extremities is associated negatively with double incontinence ($r = –0.515$) and sensory impairment ($r = –0.252$). Change of MBI is negatively associated with aphasia ($r = –0.482$) and site of lesion ($r = –0.435$), while positively associated with MMSE at admission ($r = 0.399$).

Discussion

An important aim of rehabilitation is to enable patients to perform the activities of daily living independently and achieve functional recovery, and this study suggests that early therapy may help.

Previous study on animal model showed that physical activity did improve post-stroke recovery.[14] A series of studies have reported that phys-

Clinical messages

- Early rehabilitation after stroke may be difficult to give due to patient choice or stroke severity.
- Additional early physiotherapy did not show major benefits except in independence in activities of daily living.

iotherapy improves functional recovery of stroke patients.[15] Also, there is evidence of association between early initiation of rehabilitation and better functional outcome.[4] However, some studies had small samples, without blind methods or only retrospective design.[16–19] So a prospective double-blinded randomized control design study to investigate the influence of early additional physiotherapy on functional recovery was needed.

Our study is weakened by the large loss of patients in the group receiving additional therapy. The loss may be attributed to the intolerance of the patients because of deterioration of the illness and not believing in early physiotherapy of patients or their family. Other studies have found that early intervention was associated with a five times greater risk of drop-out than that of patients with delayed start of rehabilitation therapy.[4] This may also result in our failure to demonstrate the significant effect of additional physiotherapy. It seems that the benefit of additional early physiotherapy revealed in animal models may not be significant in stroke patients.

Table 2 showed that there were significant improvements of functional recovery with regard to MBI after 30 days and six months post stroke in both groups. It suggests that stroke patients would recover gradually and improve independence in daily living whether receiving rehabilitation therapy or not. This is in accordance with a previous study.[20] However, there were no significant difference in improvement of conscious level assessed by GCS, psychiatric status evaluated by MMSE, neurological deficit severity with regard to CNDS, or motor function according to Fugl-Meyer scores of upper and lower extremities in both groups at 30 days and six months post stroke. The main reason is that patients could achieve daily life dependence through compensation by nonparalytic extremities. And early additional physiotherapy may improve this process of compensation, while not showing benefit in neurological or functional recovery of the paralytic extremities. However, considering the relatively low number of subjects in the AEP group in our study, the results might be not very definite. According to our reports, a series of factors should be taken into account when evaluating the benefit of early rehabilitation. These include age and race of the inclusion subjects, stroke type and severity of the subjects studied, the extent and type of early rehabilitation therapy and, furthermore, the tolerance of patients and their attitude to the therapy.

The Bobath method plus passive movement training are commonly used in rehabilitation practice in China. In our study, these showed benefit in dependence of daily life, but not other perspectives in stroke rehabilitation. This suggests that although these method may improve the functional recovery of daily life to some extent and prevent the joint from contraction, they have some limitations in other aspects. Physiotherapy is just a part of all kinds of rehabilitation approaches. Further development of new innovative therapy and combined therapy strategies are needed.

Jones[21] proved that when rats with occluded middle cerebral artery (MCAO) exercised paralytic limbs spontaneously, dendrite branches of pyramidal neurons in cerebral cortex would increase significantly. On the other hand, MCAO rats without spontaneous exercise of paralytic limbs would have a reduction on the number of dendrite branches. It can be derived that spontaneous physical movements of paralytic limbs may be helpful for neural recovery after stroke.

Our study shows that aphasia as well as serious cognitive function affects functional recovery after stroke. The reason might be that stroke patients with aphasia or cognitive disturbance could not follow the guidance of rehabilitation therapists and exercise paralytic limbs spontaneously. Although provided with additional physiotherapy, these patients could not achieve the expected results because they lacked spontaneous physical movements. It is noted that passive exercise is not enough for stroke patients to achieve recovery. Thus it is necessary for them to accept cognitive therapy and language training simultaneously to improve the effect of physiotherapy. Our study also shows that double incontinence would affect the rehabilitation of lower limbs. This could be attributed to two facts. First, double incontinence makes it inconvenient for stroke patients to move, thus influencing recovery. Secondly, according to cerebral anatomy, the dominating region that controls the sphincter is very close to the region controlling the lower limbs. The stroke lesion probably involves these

two cerebral functional parts simultaneously. Therefore, double incontinence may be associated with severe paralysis of the lower limbs and predicts difficulty in functional recovery of the lower limbs.

Considering the results of our study, a number of limitations need to be taken into account. First of all, there is an obvious imbalance between the AEP group and the RT group. This could be attributed partly to the patient's decision when faced with AEP; patients with severe status are likely to drop out from the study due to the deteriorating process of disease. Secondly, the baseline MBI of patients in the AEP group seems lower than that in the RT group. The AEP group also showed significantly greater functional improvement compared with the RT group. The reason might be that stroke patients in a severe state may be more likely to reach hospital in time and get the chance of early physiotherapy. The two groups are comparable in time since stroke onset. Therefore, there may be a potential effect of AEP intervention on acute stroke, and the former subjects with lower MBI would get more opportunity to benefit from AEP than the latter.

In short, further clinical observation is needed to clarify the effect of early additional rehabilitation therapy on functional recovery of stroke patients. This study suggests that many factors might influence the rehabilitation course after stroke. It is important to consider these factors when applying physiotherapy and evaluating relevant clinical research results in clinical practice.

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Appendix – Clinical Neurological Deficit Scale; Chinese Medical Association

Items	Contents	Standard	Score
Level of consciousness	Ask the month and the patient's age	Answers both correctly	0
		Answers one correctly	1
		If answers neither correctly, then turn to next	
	Ask patient to close and open eyes and to grip and release nonparetic hand	Perform both tasks correctly	3
		Perform 1 task correctly	4
		If perform neither task correctly, then turn to next item	
	Intensive localized stimulation to nonparetic limb	Withdraw with orientation	6
		Flex with orientation	7
		Extension to stimulation	8
		No response	9
Best gaze	Test of horizontal movement	Normal	0
		Partial gaze paralysis	2
		Forced deviation or total gaze paralysis	4
Facial palsy	Encourage patient to smile and close eyes, or grimace symmetrically	Normal symmetrical movement	0
		Partial paralysis	1
		Complete paralysis	2
Language		Normal	0
		Some loss of fluency or comprehension, rely on facial expressions, gestures and motions, or fluency with incorrect words	2
		Severe aphasia, with difficulty in repeating and naming the object	5
		Aphasia, no useful speech or auditory comprehension	6

Shoulder/arm motor	Normal	0
	Not ataxia but slower than nonparetic side on finger/nose movement	1
	Performs movements independent of cooperation: 1) To stretch elbow and shoulder abduct at 90 degrees 2) Medial rotation and lateral rotation of forearm, anterior flexion of shoulder with extended elbow at 30–90 degrees 3) Anterior flexion of shoulder at 90–180 degrees with extended elbow and median forearm	2
	Performs movement independent of cooperation: 1) Medial rotation and lateral rotation with shoulder at 0 degrees and flexion of elbow at 90 degrees 2) Anterior flexion of shoulder at 90 degrees with extended elbow 3) Dorsal face of hand reaches lumbar and sacrum part	3
	Performs spontaneous random movements	4
	Only performs cooperative movements	5
	No movement	6
Hand motor	Normal	0
	Performs all the movement of grasping and pinching with decrease in velocity and accuracy	1
	Can grasp and seize with all the fingers, cannot extend and bend with single finger	2
	Can seize and relax thumb, extend other fingers in limited range	3
	Can seize or grasp in hook shape, but cannot relax or extend fingers	4
	Only bend fingers gently	5
	No movement	6
Lower extremities motor	Normal	0
	When standing, abduction of hip joint beyond the range that affected pelvis could reach; when sitting, medial and lateral rotation of lower limb and adduction and abduction of ankle joint with extended knee	1
	When standing, flexion of knee joint and extension of hip joint, dorsiflexion of ankle joint with extended knee	2
	When sitting, bend knee beyond 90 degrees, dorsiflexion of ankle with heel on the floor	3
	Concurrent flexion of hip joint, knee joint and ankle joint when standing or sitting	4
	Subtle random movements	5
	No movement	6
Walking	Normal	0
	Walking more than 5 m independently with lame steps	1
	Walking dependent on a cane	2
	Walking dependent on others or help from others	3
	Only standing, not walking	4
	Sitting without help, not standing	5
	Bedridden	6