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A randomized controlled trial of Cognitive Sensory Motor Training Therapy on the recovery of arm function in acute stroke patients

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五、 請協助作者以英文寫出本篇論文的摘要，內容包含：(1)Aim, (2)Method, (3)Results, 與 (4)Conclusions 四部分，每部分以 1 至 4 句為原則。(30 分)

(背面仍有題目,請繼續作答)

Introduction

Large numbers of people who survive a stroke are left with permanent impairment of arm and hand function, even after completion of conventional rehabilitation programmes.[1] It has been reported that only 5–20% of patients regain full arm and hand function,[2] with a number of prospective cohort studies suggesting that 33–66% of stroke patients with a paretic arm do not show any recovery of upper limb function six months after stroke.[3,4] Recent review of the randomized clinical stroke rehabilitation trials on interventions for motor recovery after stroke showed that constraint-induced movement therapy, robotic arm treatment, therapist-provided exercise programmes (when self-administered by patients during their off-therapy time in a rehabilitation setting) and repetitive task training did not improve affected arm–hand function when used in acute stroke.[5,6] Cognitive Sensory Motor Training Therapy is a unique comprehensive rehabilitation programme incorporating systematic coaching and retraining of sensory guided motor control. First proposed by Professor Carlo Perfetti, this rehabilitation programme is now known as Perfetti's Method.[7,8] It is widely used in many European countries, including Italy, Germany and Austria.

The hallmark of Perfetti's Cognitive Sensory Motor Training Therapy is that it focuses on sensory retraining, with particular emphasis on joint position perception. For example, for patients who cannot give accurate feedback on joint position, the therapist passively moves the involved limb and then asks the blindfolded patient to sense and guess where the limb has been moved. Initially, only one joint is moved at a time. Later on, several joints are moved simultaneously to add complexity and difficulty as appropriate to the patient's improved perception. Only patients who can adequately sense limb positions may move on to the next stage of training. In this 'assisted explorative movement' stage, they are asked to exert force to actively move the training limb over a stationary object and to sense the length, height, hardness or shape of the object.

Very few studies on the efficacy of this type of therapy have been published in international medical journals. Wongphaet et al. reported on seven chronic stroke patients who underwent 2.5 months of outpatient-based training using the Perfetti Method.[9] Arm and hand functions were assessed by the Action Research Arm Test (ARAT),[10] which demonstrated improved function of the hemiparetic arm in every patient. The mean improvement in ARAT score for the whole group was 7.7 points. Since the maximum possible score is 57, this equates to 13.5% improvement. This high degree of improvement in chronic stroke patients, whose arm function recovery is generally expected to be poor,[11] suggests that the Perfetti Method might be more effective than conventional therapy for arm function rehabilitation. In a pilot functional magnetic resonance imaging (fMRI) study, a chronic stroke patient who underwent such training showed activation of the lesion-side of the primary sensory motor cortex over that seen prior to treatment.[12]

To date, there has been no prospective, randomized study to determine the effectiveness of the Perfetti Method in acute stroke patients. The purpose of this study is to evaluate the effectiveness of the method versus conventional occupational therapy on arm function recovery after acute stroke.

Methods

Records of acute stroke admissions at the Prasat Neurological Institute and Ramathibodi Hospital, Bangkok, Thailand were screened for the study. Participants who met the inclusion criteria were randomly assigned by means of block randomization to receive therapy using either Perfetti's technique training (group A) or conventional occupational therapy (group B). The inclusion criteria were as follows: age 18–79 years; stroke confirmed by MRI; no previous history of stroke; time from stroke onset until enrollment in research less than two weeks; absence of other neurological or orthopaedic diseases impairing arm function; observably impaired arm function as determined by the ARAT; ability to sit, with or without support, for at least one hour; ability to understand the meaning of the study and follow the instructions; underwent normal 12-lead electrocardiogram and general screening physical examination; provided written informed consent to participate. This study was approved by two

authorized institutional human research review boards which are the Committee on Human Rights Related to Researches involving Human Subjects, Ramathibodi Hospital, Mahidol University, and the ethical review board of Prasat Neurological Institute. The registration number is NCT01374152 under the 'clinicaltrial.gov' trial registry.

Blocks of four treatment allocations were randomly generated in an MS Excel spreadsheet program. They were printed out and separately sealed in opaque envelopes sequentially with no labelling outside. Only one person (neither assessor nor therapist) had access to these envelopes and concealed the sequence until arm interventions were assigned.

Each participant received their arm training therapy in a separate room, with only one participant per therapist, with or without caregiver observation. Patients received either conventional occupational therapy or Perfetti's Cognitive Sensory Motor Training Therapy for a 30-minute therapy session every working day (i.e. five times a week), conducted one-on-one by an occupational therapist for four consecutive weeks. Participants had the option of taking a break of no longer than 15 minutes during the training. Additional time of up to 15 minutes for preparation was allowed, limiting the total therapist contact time to 60 minutes daily. The total treatment time for both groups was 600 minutes per patient. Other services of the rehabilitation programme were similar for the two groups, including physiotherapy and swallowing therapy, and were provided according to individual patient needs.

Treatment protocols were developed for each group. The therapy in both groups concentrated exclusively on the restoration of upper limb function. In group A, the participants were blindfolded during the exercises and asked to concentrate on sensing the position of the limb. The therapist passively moved either the shoulder, elbow, wrist, or finger to different positions. In the beginning, only one joint was moved at a time. After the therapist had finished repositioning the joint, the participants reported their perception of the joint position. Initially, the participant had to discriminate between just two positions. If they could reliably answer correctly, they were then asked to differentiate between three, four or five points. During this stage of training, patients were instructed not to attempt any active movement but rather to relax and to feel the movement. For joints with many possible planes of movement, training was conducted separately for each plane. For example, forward flexion and backward extension of the shoulder were trained separately from abduction/adduction and internal/external rotation of the shoulder.

Patients who could correctly differentiate between positions in many joints were challenged with more complex, 'perceptive tasks'. For example, those who could sense both shoulder and elbow positions well were challenged to tell where their arms were positioned on the table in front of them. Another example of an exercise given at this stage is one in which the therapist passively moved the patient's arm up and down while it rested on a tabletop or other firm object which could be tilted to desired angles. The patient had to sense the tilt. Again, only two positions had to be distinguished in the beginning. Up to five different positions were typically offered to the more able patients. Similar training was applied to the wrist, fingers and forearms.

Those patients who could accurately distinguish these complex, multi-joint movements could move on to the next stage of training. At this stage, the therapist placed a part of the patient's limb, typically the fingertip, on one external object (e.g. a stick or a tabletop) and asked the patient to actively move his or her limb over the object and try to sense the shape, position or size of the object. The patients were instructed to exert limited force and to allow the therapist to support the movement enough that there was no observable muscular co-contraction according to the mass flexion or extension synergy pattern. The training object was repositioned, and another object of a different shape or size was offered. The patients had to differentiate between the two objects. Once they could do this, increasing numbers of objects (up to five) were offered. Manual support from the therapist was gradually reduced until the patient could complete the exploratory task with no support.

Group B participants received conventional occupational therapy, consisting of many purposeful

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kinetic activities such as skateboard-supported arm-sliding exercises on a tabletop, picking up a ball and putting it into a basket, bimanual placing cone, shoulder curved arch, double curved arch, arm bicycling, donut on base, putty kneading, block stacking, peg board exercise, graded pinch exercise and plastic cone stacking. Therapists could offer passive, active-assistive or active training, as deemed appropriate to the patient's ability.

The primary outcome variable was the score on the Action Research Arm test (ARAT). Secondary outcome variables were scores on the box and block test and Extended Barthel Index. All assessments were made for all participants before and after treatment.

The ARAT, developed by Lyle,[10] is a standardized measure of the upper extremity (arm and hand) function based on four movements: grasping, gripping, pinching and gross movements of shoulder, elbow and fingers. ARAT has an ordinal 4-point scale (0–3) for 19 items. Scoring is determined as follows: 0, patient cannot perform any part of task; 1, patient is able to lift the object completely from the platform; 2, function is performed fully but clumsily or with great difficulty; and 3, the movement is performed normally. The maximum score for each arm is 57 points. The test can be completed in an average of 10 minutes but requires specific materials.

The box and block test[13] was used to evaluate gross manual dexterity. The setup consists of two adjacent boxes of the same size (53.7 × 25.4 × 8.5 cm), one of them filled with 150 blocks (2.5 cm^3). Between the two boxes, there is a partition 15.2 cm in height. The patient must move blocks one by one from one box to the other, over the partition. The number moved in 60 seconds is the recorded score. This test is very easy to administer and takes a very short time to complete.

The ease of performing basic activities of daily living and the degree of independence from any form of help were evaluated by the Extended Barthel Index. The Extended Barthel Index[14] was developed to address shortcomings in the Functional Independence Measure (FIM) and the existing Barthel Index by adding items for comprehension, expression, social interaction, problem solving, memory/learning/orientation and vision/neglect. The Extended Barthel Index is more sensitive to changes over time than the Barthel Index, and the time required to administer the test has been described as significantly shorter than the time needed to administer the FIM. The score range is from 0 to 64 points.

All of these tests were previously proven as valid and reliable (both intra- and inter-rater reliability).[15–17]

The effects of the intervention were examined by a blinded assessor who was trained in test administration. The baseline tests were performed in the week prior to treatment. The follow-up tests were perform after treatment phase was terminated by one of the following reasons: (1) completion of four weeks of treatment, (2) complete recovery of upper limb function as evaluated by a perfect score on the ARAT, (3) request of the participant to terminate treatment, or (4) development of any serious medical condition.

The sample size required for detecting a meaningful difference of 10 points on the ARAT between two groups was determined by SISA sample size calculations. These calculations are based on a statistical power of 80% (preventing type II error) with an alpha of 5% (preventing type I error).The expected variance of samples on ARAT scores for each group is 10, assuming the mean difference in ARAT scores in the treatment group is 20. Assuming the mean difference in ARAT scores in the control group is 10, the expected allocation ratio between groups is 1; z for double-sided alpha is 1.96. The expected numbers needed per intervention group equals the expected numbers needed per control group, which is 16 (excluding an expected drop out of less than 25% = 4); total N per group = 16 + 4 = 20.

An intention-to-treat analysis was performed for primary and secondary outcome data. If a subject dropped out, assessment continued; if this was not possible, the last available score was used.

The homogeneity of the groups was tested before the study began using the Mann–Whitney U-test. All data were interpreted descriptively (median,

interquartile range (IQR), mean, standard deviation, range).

To determine the differences of ARAT, box and block test and Extended Barthel Index, we calculated intra-individual differences of the follow-up from the baseline. The differences were not normally distributed; accordingly, improvements over time were calculated by the non-parametric Wilcoxon test and differences between groups by the non-parametric Mann–Whitney test.

The chi-square test (Fisher's exact test) was used for subgroup analyses in cross-table data between the two groups. SPSS software program 19.0 was used (SPSS Inc., Chicago, IL, USA).

Results

Over a period of 31 months, 1542 potential participants were identified. A diagram of participation recruitment is shown in Figure 1. The groups of participants were not different in all demographic characteristic tests. The number of participants who dropped out did not differ between the two groups with respect to their demographic data, as shown in Table 1. Therapy-related side-effects did not occur in either group. All 40 participants had very good compliance and could follow every training section completely.

The intention-to-treat analysis of all functional outcome variables (ARAT and box and block test for arm function; Extended Barthel Index for self-care) is shown in Table 2. All tested outcome variables showed significant improvement from baseline to follow-up ($P < 0.001$) for both treatment groups. The improvements in ARAT and box and block test scores were higher for Perfetti's method, with the median ARAT score increasing by 17 points and the median box and block test score increasing by 13 points. This level of improvement approximates the minimum clinically important difference in ARAT values, which were 12 and 17 points for the dominant and non-dominant hand, respectively.[18] Median improvements in scores for conventional occupational therapy were lower, with 6.5 points for ARAT and 2.5 points for box and block test, but there was no significant statistical difference between the two groups ($P = 0.26$ (ARAT); 0.17 (box and block test)). Both groups had the same Extended Barthel Index, with P-value = 0.96. The complete case analyses had also given the same results.

For further analysis, participants were divided into subgroups based on the severity of arm function impairment. The authors define the ARAT score less than 10 as severe impairment because the ARAT score equal or more than 10 represents the opportunity to use hand and fingers in the tasks.[19] Of the 40 participants, 22 had severe impairment, defined by an initial ARAT score of <10; group compositions were 12 severely impaired out of 22 in group A and 10 severely impaired out of 22 in group B. Another noteworthy difference in the functional outcome between severely affected patients in the two groups is that while 0% of group B patients had good recovery (defined as ARAT score change greater than 15 points), 42% of group A patients had good recovery (Table 3). Analysis of subgroups showed significant difference ($P = 0.02$).

Discussion

The current research, which is the first randomized controlled study comparing Perfetti's method with convention occupational therapy, showed no evidence of a difference with respect to the restoration of hand and arm function after a stroke. Perfetti's method is more time-consuming for the therapist, requiring one-on-one training. For conventional occupational therapy, the therapist can train many patients at the same time.

Normally, from the evidence of other studies, the voluntary motor behaviour at initial phase predicts outcome of recovery after stroke.[20] However, for patients with severe paretic arm, the extra time required for Cognitive Sensory Motor Training Therapy may be worthwhile. Our data reveal that in these patients, Perfetti's method resulted in statistically significant improvements in recovery over that of conventional therapy ($P = 0.02$) (Table 3).

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Table 1. Demographic data

Characteristic	Group A (Perfetti's method)	Group B (conventional OT)	*P*-value
N	20	20	
Age (years)			
Mean (SD)	63.2 (10.1)	60 (10.8)	0.29
Median (IQR)	63 (59.25–70.75)	60.5 (50–69.25)	
Range	31–78	42–77	
Sex (male/female) (*n*)	9/11	11/9	1.00
Education			
<12 years, formal (*n*)	14	14	1.00
College or higher (*n*)	6	6	1.00
Hemiparesis (right/left) (*n*)	19/1	19/1	1.00
Bamford type[a]			
LACI/PACI/TACI (*n*)	14/4/1	12/0/4	0.82
LACH/TACH (*n*)	0/1	2/2	
Anxiety/depression[b] (*n*)	1/2	1/2	1.00
NIHSS[c]			
Mean (SD)	9.6 (4.0)	9.3 (4.2)	0.72
Median (IQR)	9.5 (6.25–13)	9.5 (6–12)	
Range	3–15	1–18	
Baseline ARAT score			
Median (IQR)	7 (0.25–19.75)	7 (0–34.75)	0.73
Baseline BBT score			
Median (IQR)	0 (0–13.5)	0 (0–16)	0.76
Baseline EBI score			
Median (IQR)	41 (34.5–48)	42 (37.5–53.5)	0.69
Baseline FAC score			
Median (IQR)	1 (0–2)	1 (0–2)	0.78

IQR, interquartile range; ARAT, Action Research Arm Test; BBT, box and block test; EBI, Extended Barthel Index; FAC, Functional Ambulation Classification; LACI, lacunar anterior circulation infarction; PACI, posterior anterior circulation infarction; TACI, total anterior circulation infarction; LACH, lacunar anterior circulation haemorrhage; TACH, total anterior circulation haemorrhage.
[a]Oxfordshire Community Stroke Project classification.[21]
[b]Hospital Anxiety and Depression Scale.[22]
[c]National Institutes of Health Stroke Scale.[23]

Therefore, Perfetti's method might be more valuable for treating patients with severe paresis and may have a major role in rehabilitation of severely impaired stroke patients. Further research combining conventional occupational therapy with Perfetti's method might have been more valuable for some patients' recovery.

In Perfetti's method the therapy focuses on sensory retraining at the body functions and structure level according to the International Classification of Functioning (ICF). This function has not been measured since all variables of this study evaluate activity level. It would be interested to assess the association between sensory function and activity level in a future study.

While the improvement in ARAT and box and block test scores was greater in patients who were treated using Perfetti's method, the data were not statistically significant (Table 2). This may be because of a high degree of heterogeneity of stroke

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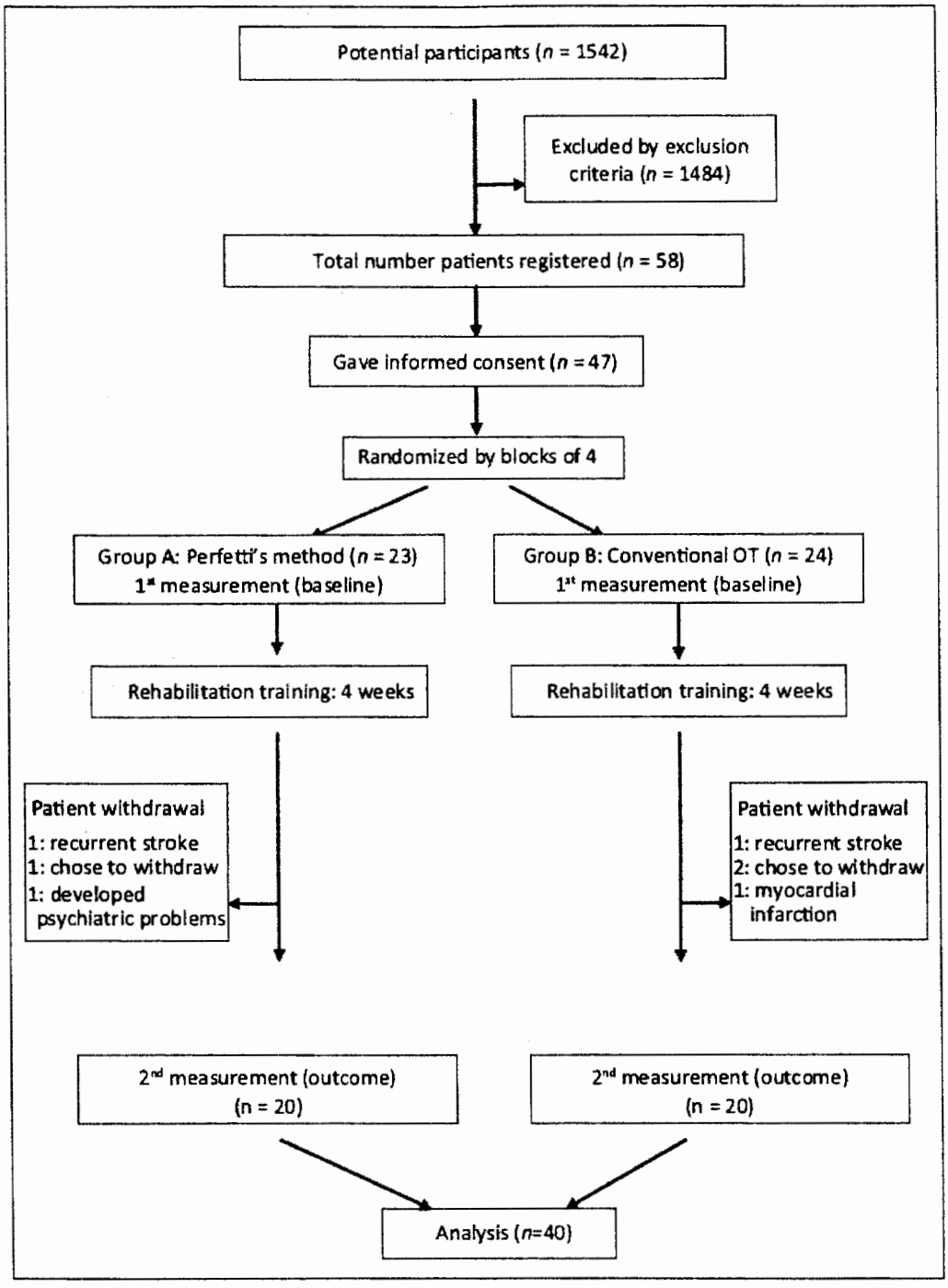

Figure 1. Flowchart of the study.

severity combined with a small sample size. The sample size determines the amount of sampling error inherent in a test result. Other things being equal, effects are harder to detect in smaller samples. Increasing sample size is a way to boost the statistical power of a test. In future studies, larger numbers of participants with severe arm paresis should be enrolled. Because of a limited budget and time constraints, this study does not have the follow-up data for 3 or 6 months after training.

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Table 2. Improvement in arm function in relation to treatment method

Outcome variable		Median score (IQR) Mean (SD)		*P*-value
		Perfetti's method (*n* = 20)	Conventional method (*n* = 20)	
Action Research Arm Test	Baseline	7 (0.25–19.75)	7 (0–34.75)	0.73
		12.45 (15.06)	16.4 (17.96)	0.46
	Follow-up	27 (7.5–42.75)	26 (3.5–49.75)	0.82
		27.85 (19.65)	27.40 (22.94)	0.95
	Difference	17 (3.75–26.25)[a]	6.5 (3–20.25)[a]	0.26
		15.4 (11.38)[a]	11 (10.39)[a]	0.21
Box and block test	Baseline	0 (0–13.5)	0 (0–16)	0.76
		7.53 (11.8)	7.44 (12.17)	0.98
	Follow-up	14 (0–37)	2.5 (0–40.75)	0.37
		21.35 (20.53)	15.69 (20.17)	0.43
	Difference	13 (0–25)[a]	2.5 (0–20)[a]	0.17
		13.82 (12.02)[a]	8.25 (10.42)[a]	0.16
Extended Barthel Index	Baseline	41 (34.5–48)	42 (37.5–53.5)	0.69
		41.90 (8.48)	43.65 (9.98)	0.55
	Follow-up	58.5 (48.75–64)	60 (55–64)	0.57
		57.05 (9.70)	58.6 (6.47)	0.56
	Difference	13 (10.25–21.75)[a]	14.5 (7.5–22)[a]	0.96
		15.15 (8.17)[a]	14.95 (8.26)[a]	0.94

[a]Within each group, the difference in scores between before and after intervention was statistically significant for all outcome variables tested; $P < 0.001$.

Table 3. Number of severely impaired participants showing improvement in arm function in relation to treatment method

	Number of participants (*n* = 22)	
Treatment method	Change in ARAT score ≤15 points: poor (*n* = 17)	Change in ARAT score >15 points: good (*n* = 5)
Perfetti's method (*n* = 12)	7 (58%)	5 (42%)
Conventional occupational therapy (*n* = 10)	10 (100%)	0 (0%)

P-value = 0.02 by the chi-square test (Fisher's exact test).

Clinical messages

- There was no evidence of a difference between Cognitive Sensory Motor Training Therapy of Perfetti's method and conventional occupational therapy with respect to the restoration of hand and arm function after a stroke.
- Severely affected subacute stroke patients with Action Research Arm Test scores less than 10 may possibly achieve better hand and arm functional recovery if they are trained with Perfetti's method.

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