Study protocol

1.1 SUMMARY

Title:	Effect of Structured Progressive Task-Oriented Circuit Class Training With Motor Imagery on Gait in Stroke
Clinical registration no:	NCT03436810
Document Date:	January 18, 2017
Study Description:	Structured Progressive Circuit Class Training (SPCCT) has developed on the basis of task-oriented therapy, provides the enriched benefits on the patients' motivation and motor function. Training with the Motor Imagery (MI) alone can improve gait performance in patients with stroke, but the better effect may observe if combined with the SPCCT. Thus, the aim of this study was to investigate the effect of MI with SPCCT on gait in patients with stroke. The study involved forty patients with stroke from 3 hospitals in Yangon, Myanmar. All participants received the 90 min intervention in a session. The experimental group received MI with SPCCT and control group received HE with SPCCT intervention 3 times a week for 4 weeks. The assessments were taken at the baseline, 2 week and 4 weeks after intervention. The outcomes measures involved spatio-temporal variables, walking endurance, dynamic balance, mobility function and muscle strength.
Objectives:	General Objective: To investigate the effect of MI with SPCCT on gait performance in patients with stroke Specific Objectives: To investigate the spatio-temporal and functional gait variables in patients with stroke after receiving MI with SPCCT To investigate the spatio-temporal and functional gait variables in patients with stroke after receiving HE with SPCCT To compare the effect of MI with SPCCT and HE with SPCCT on the spatio-temporal and functional gait variables in patients with stroke.
Outcome measures:	Spatio–temporal variables, walking endurance, dynamic balance, mobility function, muscle strength
Study Population:	Forty patients with stroke, age for experimental group was 49.90 ± 11.59 years and control group was 55.55 ± 10.74 years, 15 males and 5 females for experimental group and 11 males and 9 females for control group, Mean height for experimental group was 163.89 ± 6.55 centimeters and control group was 162.03 ± 13.04 centimeters. Mean weight for experimental group was 63.65 ± 6.63 kilograms and control group was 63.35 ± 13.04 kilograms
Description of Sites/Facilities Enrolling Participants:	National Rehabilitation Hospital (NRH), the departments of the Physical Medicine and Rehabilitation in North Okkalapa General Hospital (NOGH) and East Yangon General Hospital (EYGH), Yangon, Myanmar
Description of Study Intervention:	The experimental group received MI with SPCCT and control group received HE with SPCCT intervention 3 times a week for 4 weeks.
Participant Duration:	4 weeks

1.2 METHODS

Participants

All participants will be diagnosed as a stroke and will be recruited from the departments of the Neuromedical and Physical Medicine and Rehabilitation, Yangon General Hospital (YGH) and the National Rehabilitation Hospital (NRH) in Yangon, Myanmar. Eligible participants will be randomly allocated into either the experimental or control groups. For allocation of the participants, a computer-generated list of random number will be used. In order to maintain recruitment balance between groups throughout the trial, a permuted block randomization process will be used within each strata using block sizes of at least 2 with all blocks divisible by 2. The sequence generation and allocation concealment will be managed by the researcher. To prevent inadequate concealment of allocation sequence, properly randomizing method using sequentially numbered, opaque sealed envelopes (SNOSE) will be used in this study. The allocation envelop will be prepared by using the aluminum foil and carbon paper. The aluminum foil will be used to ensure opaque and the allocation sheet inside cannot read against the light. The carbon paper will be used to prevent violations of allocation concealment. The treatment allocation sheet of standardized-size paper will be fold to fit with envelop. Place 1 sheet of carbon paper on top of the folded allocation sheet with the carbon side facing the paper so that writing on the front of the envelop is transferred to the treatment allocation paper inside. Then place this carbon paper and allocation sheet together inside aluminum foil wrapper. Finally, place complete insert into the envelope properly (290). Group assignment will be communicated directly to the therapist for the implementation on a single participant basis. In this study, the assessments will be done by the researcher. The assessor and the participants will be blinded from the study.

Study Design
The study design will be a randomized double blind balanced parallel-group (1:1).

1.3 SELECTION CRITERIA

Inclusion criteria
1. First stroke diagnosed by neurologists and has paresis on the unilateral side of the body
2. Age between 18 and 75 years
3. Poststroke duration between 3−12 months confirmed by CT report.
4. Patients with middle cerebral artery (MCA) involvement
5. Ability to walk at least 10 meters with or without using assistance (walking aid and/or orthosis).
6. Functional Ambulation Category (FAC) ≥ 3 from the total of 5 score
7. Good cognition assessing by the Mini Mental State Examination (MMSE) ≥ 24 from the total of 30 score
8. National Institutes of Health Stroke Scale (NIHSS) < 14 from the total of 42 score
9. Proper MI ability assessing by the Kinesthetic and Visual Imagery Questionnaire (KVIQ–10) ≥ 3 from the total of 5 score

Exclusion criteria
1. Unstable cardiopulmonary problems (resting heart rate > 120 bpm, resting systolic blood pressure > 180 mmHg and resting diastolic blood pressure > 100 mmHg)
2. Other neurological conditions such as Parkinson's disease, Alzheimer's disease, or epilepsy
3. Orthopedic and rheumatologic disorders with weight bearing pain
4. Unable to communicate or unable to follow commands
5. Serious cardiac conditions such as hospitalization for heart disease within 3 months, active angina, serious cardiac arrhythmias, hypertrophic cardiomyopathy, severe aortic stenosis
6. Patients with unilateral spatial neglect
7. Patients with ataxic movement
8. Patients under medications with muscle relaxing effect

Termination Criteria
1. Borg scale for Rating Perceived Exertion (RPE) > 13 from the total of 20 score
2. Drop in systolic blood pressure 10 mmHg (persistently below baseline), despite an increase in workload, when accompanied by any other evidence of ischemia
3. Central nervous system symptoms such as dizziness, or near syncope
4. Signs of poor perfusion such as cyanosis or pallor
5. Severe adverse event, this means falls or incidents leading to injury requiring hospital or general practitioner visit
6. Another episode of stroke

1.4 INSTRUMENTATION

Two dimensional gait measurement system compose of;

1. 8meter walkway
2. Video camera
3. Personal computer

Calibrated ruler
Stop watch
Measuring wheel
Standard armchair (approximately 46 cm in height)
A 7.5 cm height step
Sphygmomanometer and stethoscope
Tape measure
Hand-held dynamometer
Oximeter
Metronome

1.5 PROCEDURE

All participants will be explained about details of the study and the interventions. After that, they will be asked to sign on the written consent approving by the committee of the institution prior to participate in study. All participants will be randomly allocated the participants into the experimental (SPCCT with MI) or the control (SPCCT with health education) groups. All participants will be screened following the criteria and will be collected the demographic data.
Both groups will receive the same program of SPCCT by physiotherapist who have 5 years experienced in neurological condition. Prior to training, tasks will be demonstrated using clear instructions. Seven lower extremity mobility tasks will be used in the SPCCT program. The tasks were selected from the study of Dean et al and adapted to be appropriate for improving gait function in patients with stroke. The trained tasks for the MI will be similar to the tasks in SPCCT to getting the transfer effects of training. The experimental group will receive MI training, whereas, the control group will receive health education which both will be provided by the researcher. Both groups will be matched for duration and frequency of the therapy sessions.
All outcome measures will be assessed by the therapist who have been trained the outcome measures of the study. As the primary outcome measurements, spatio-temporal variables will be measured by using two dimensional motion analysis method. The protocol of this method was proved to be valid and reliability from previous pilot study. For functional gait variables, six-minute walk test will be assessed for determining walking endurance, step test will be assessed for dynamic balance, and Timed Up and Go (TUG) test will be assessed for mobility function.
As the secondary outcome measure, the strength of hip flexor, hip extensor, knee flexor, knee extensor, ankle dorsiflexor, and ankle plantarflexor muscles will be assessed by using hand-held dynamometer. Muscle spasticity will be assessed by using the Modified Ashworth Scale (MAS). The outcome measures will be assessed at the baseline, after 2 weeks and 4 weeks intervention. For the safety, the therapist will measure blood pressure, pulse rate and fatigue level in the assessments, just before the training, and rest period during the training program.

1.6 INTERVENTION PROGRAM

Training schedule for the experimental and control groups

Experimental group	Duration (min)	Control group	Duration (min)
MI:			
- Relaxation	3		
- MI practice (Visual) 4 tasks	8.5	***Health education***	25
- Rest	2		
- MI practice (Kinesthetic) 4 tasks	8.5		

Experimental group	Duration (min)	Control group	Duration (min)
- Refocusing	3		
	25		25
TOCCT: - Warm up - TOCCT practice 7 tasks (4 min practice, 4 mins rest, 1 min transfer in a task)	3 62	***TOCCT:*** -Warm up -TOCCT practice 7 tasks (4 min practice, 4 mins rest, 1 min transfer in a task)	3 62
	65		65
Total	90	**Total**	90

MI Training

The MI practice will be carried out in a quiet room of Physical Medicine and Rehabilitation, NRH clinic. In the MI training, there will be familiarization of the MI technique for 2 days in the 1st week and from other days of the 1st week up to 4th week, it will be the MI gait training. In MI gait training program, there will be 4 phases; 1) the body relaxation and awareness for 3 minutes, 2) visual imagery for 8.5 minutes, 3) kinesthetic imagery for 8.5 minutes, and 4) refocusing of body and environment for 3 minute. There will be 2 minutes rest period between the visual imagery and kinesthetic imagery. MI training during 4 weeks are described below;

1st week: Familiarization

The participants will be trained to familiarize with the MI tasks. The participants will be explained about the procedures. During the training, they are not supposed to perform the activity but only imagine about the tasks. Video will be used together with the explanation to perform and demonstrate about the tasks performing. After this session, the participants will perform the tasks physically. Then, the participants will be trained with both visual and kinesthetic MI tasks. Imagine the movement using the first person perspective both for visual imagery and the kinesthetic imagery. For the visual imagery, the participants will be requested to visualize their performing movements from inside of their body, as if they are looking through their own eyes while performing the movements. For the kinesthetic imagery, the participants will be requested to perceive their body sensations of the movements without any movement. During the MI practice, the participants will be asked to (a) avoid moving or contracting muscle from their leg, and keep a relaxed position (b) keep their eyes close throughout the practice (c) keep track of the number of sequences imagined with their fingers if necessary (d) if they lose their concentration during the practice, open their eyes, relax for a few moments and then continue the practice of the task. In the tasks of forward and then backward stepping tasks, the rhythm will be trained with metronome. In the walking tasks, the participants will be asked to walk along the 8 meters walkway and back towards the starting point and repeat the walking during the prescribed duration. The participants will be trained until they are able to reproduce the tasks correctly demonstrating declarative knowledge of the sequence.

2nd to 4th week Training

Stage 1: Body Relaxation and Awareness Stage

The participants will be asked to sit on the chair and the instructions will be given. They may open or close their eyes depend on preferring. Therapist will explain about two steps of the exercise. First, contraction of particular muscle group in the body. Next, releasing the tension and notice how the muscles feel in relaxation. The participants will be asked to contract their muscles when therapist say tense your muscle or move your body part, maintain this tension when therapist say hold, release this contraction when therapist say relax. Participants will be asked to maintain this relaxation up to the end of training.

Stage 2 and 3: **Visual and Kinesthetic Imagery**

There will be 4 specific gait MI tasks (Table 3.2). For the stepping task, progression will be provided by number of repetitions provided by the rhythm of the metronome. For the walking tasks, progression will be increased by the number of walking repetition in the walkway. The practice of the tasks will be assigned serially. Each task will be taken for 2 minutes. During the training, number of repetitions will be noted after finish the tasks and will be entered into the log-book using as a feedback for the next

practice session. The engagements of the MI practice will be checked by the pulse rate using the oximeter attached to the fingers of the affected hand. The fingers movements of the unaffected hand will be recorded for numbers of repetitions of the task completion during imagine. Moreover, during the imagery practice, therapist will ask participants to stop imagine unexpectedly and check position in the practice.

Training schedule for MI

MI tasks	Duration (min)
1. Stepping forward and backward onto block	2
2. Standing up from a chair, walking a short distance (3 m), and returning to the chair	2
3. Symmetrical walking (8 m)	2
4. Walking at fast speed (8 m)	2

Stage 4: Refocusing of Body and Environment

The instructions of the MI training according to the stages are described in the following;

Stages	Tasks
Stage 1	**Body relaxation and awareness**.
Stage 2	**Visual imagery**
	Task 1. Stepping forward and backward onto blocks; 1.a Stepping forward and backward onto the block with the unaffected leg 1.b Stepping forward and backward onto the block with the affected leg
	Task 2. Standing up from a chair, walking a short distance, and returning to the chair
	Task 3. Symmetrical walking
	Task 4. Walking at fast speed
Stage 3	**Kinesthetic imagery**
	Task 1. Stepping forward and backward onto blocks 1.a Stepping forward and backward onto the block with the affected leg 1.b Stepping forward and backward onto the block with the affected leg
	Task 2. Standing up from a chair, walking a short distance, and returning to the chair
	Task 3. Symmetrical walking
	Task 4. Walking at fast speed
Stage 4	**Refocusing of body and environment**.

Health Education (HE)

For the control group, they will receive25 minutes of health education. The education will be provided by the researcher using the documents. One HE topic will take 2 treatment sessions and there will be 6 topics for the whole intervention period, 4 weeks. The training schedule for health education is described.

Topic	Duration (min)	Treatment session	Content
1. Changes caused by stroke	25	1st and 2nd	The most common general effects of stroke Common changes with a left-brain injury Common changes with a right-brain injury Common emotional effects of stroke Factors on which improvement depends
2. Complications after stroke	25	3rd & 4th	Common complications of stroke Treatments for complications after stroke
3. Emotional changes after stroke	25	5th & 6th	The way stroke cause emotional changes Some common emotional changes after stroke The way to cope changing emotion
4. Living at home after stroke	25	7th & 8th	Factors to going home Changes to do at home
5. High blood pressure (HBP) and stroke	25	9th & 10th	What is HBP? HBP and stroke risk Persons at higher risk for HBP.

Topic	Duration (min)	Treatment session	Content
6. Preventing recurrent stroke	25	11th & 12th	Controllable risk factors Uncontrollable risk factors Stroke warning signs

SPCCT

SPCCT program will include 7 different workstations intended to meaningful tasks related to gait performance. To get the effect of increasing therapy, it will involve the practice of higher levels of functional activities such as standing and walking. The training package will be provided according to participant's condition in terms of muscle strength and mobility status. The practice of the tasks will be serial in order. In the training the participants will be in the pairs. The practice will be as the distributed pattern. During the rest period of one participants who will observe the performance of partner and give encouragement to do the best. Each participant will receive activity log book in which the number of repetitions of performance will be entered and it will be used as the feedback in next station. Training schedule of SPCCT is described in the following.

SPCCT details	Duration (min)
Warm up	3
1. Stepping forward-backward onto block	4 min practice, 4 min rest, 1 min transfer (9 min)
2. Stepping sideway onto block	9
3. Heel lifts in standing to strengthen affected planter-flexor muscles	9
4. Standing with a decreased base and reach for object	9
5. Standing up from a chair, walking a short distance, and returning to the chair	9
6. Symmetrical walking	9
7. Walking at fast speed	8
Total	65