

CHAPTER III

METHODS

1. Participants

Twenty male and female outpatients with hemiplegia were recruited for the study. All patients were given an informed consent prior to entry into the study and the ethical clearance was obtained from the Research Ethics Committee, Faculty of Associated Medical Sciences, Chiang Mai University. Age, gender, lesion diagnosis and onset of hemiplegia were recorded for each subject. After being recruited, the participants were evaluated for baseline information. Patients were matched using sex, age, dominant hand, MAS, and then were randomly recorded the order of treatment conditions.

1.1 Inclusion criteria

1. First onset unilateral hemiplegia that occurred no less than 2 months prior to study commencement
2. Age 21 to 65 years
3. Had the hand movements of Motor Assessment Scale (MAS-H) less than or equal to score 5
4. Had biceps brachii and triceps brachii spasticity measured using modified Ashworth scale less than or equal to score 2
5. Had at least functional passive range of motion (ROM) of the elbow and shoulder joints of the goal task
6. At least 50% of passive ROM of finger flexion and extension
7. Able and willing to participate in a 8-week study

1.2 Exclusion criteria

1. Implanted electronic pacing or defibrillation device, unstable vital signs, or potentially fatal cardiac arrhythmia, because the safety of stimulation under these conditions is not known
2. Inability to sit at least 30 minutes
3. Had peripheral nerve or orthopedic conditions that involved arm movement.
4. Had any comorbid neurological diseases
5. Had global aphasia or had significant communication barrier to understand the experimental protocol
6. Had neglect or depression that could limit participation
7. Had skin rash, allergy or wounds at the locations where stimulating electrodes were placed
8. Had seizure episodes
9. Had Thai Mini Mental Status Examination (TMMSE) score lower than 24
10. Barthel Index (BI) more than 70 scores

2. Outcome parameters

1. Passive Range of Motion (shoulder flexion / extension, elbow flexion / extension, wrist flexion / extension)
2. Active Range of Motion (shoulder abduction, elbow flexion / extension, wrist flexion / extension)
3. Two items of upper extremity subscales of Motor Assessment Scale
 - 3.1 Upper arm function of Motor Assessment Scale (MAS-UA)
 - 3.2 Hand movements of Motor Assessment Scale (MAS-H)

4. Modified Wolf Motor Function Test (mWMFT)
 - 4.1 Time completed tasks of mWMFT (mWMFT-sec)
 - 4.2 Functional ability of mWMFT (mWMFT-FA)
5. Movement time of the goal functional task (MT)

2.1 Other collected parameters

1. Modified Ashworth scale (biceps brachii, triceps brachii, wrist flexors and extensors spasticity)
2. Sensory assessment (touch and pinprick)

3. Equipments

1. Electrical stimulators
2. A standard chair and table
3. An universal goniometer
4. A digital watch
5. A Flexible ruler

4. Experimental setup

4.1 Electrical stimulation

A local made two-channel electrical stimulator with the external foot-switch was used (Appendix I). The foot-switch could turn on or turn off the stimulator after pressing. Different modes of stimulations (synchronization vs. asynchronization of two channels) could be selected from the stimulator. Therefore, patients could be easily control the stimulation using the unaffected foot. This maneuver allows patients to have the unaffected hand to assist the task-specific exercise.

Burst-modulated, biphasic pulsed current was applied via self-adhesive electrodes. The current parameters were: biphasic pulsed current with frequency 62-65 Hz; pulse duration 0.1-1 msec. The stimulation and the relaxation time were adjusted by each patient based on the task and the ability of each participant using an external foot-switch. An intensity of contraction was determined by the therapist and patient during the initial visit to the laboratory room. The manual of an electrical stimulator and the stimulation method was prepared for all patients (Appendix I).

The self-adhesive electrodes (EN-trode®) were placed over muscles involved in the tasks (e.g. reaching (shoulder flexion and elbow extension; elbow and wrist extension), elbow flexion and extension, grasping, hand opening, or thumb opponen) such as the wrist and finger extensors, thenar muscles, deltoids, biceps brachii, triceps brachii, and serratus anterior etc. Detailed information of stimulated muscles presents in Appendix J.

4.2 Task-specific exercise

Patients were individually guided by the researcher on how to exercise the UE and promote motor retraining of the paralyzed muscles. The exercises were adjusted and varied in complexity from simple and predominantly passive, to active assistive, to active and task-specific (90).

Exercise program consisted of seven stretching exercises for the spastic affected shoulder, elbow, and wrist muscles until the available range of motion was reached (Appendix H).

1) Pectorals stretch; the action consisted of slowly raise both arms above the head and reaching as high as possible. This action stretched the pectoralis major.

2) Scapular stretch; the action consisted of cross both arms in front of chest and placed each hand around the opposite shoulder and slowly stretch hand towards middle of the back as far as possible. The scapular stretch worked on the rhomboid muscles.

3) Posterior deltoid stretch: the action consisted of grasping an affected arm behind the elbow joint with the opposite hand. Slowly pull the arm in front of the body. This action stretched supraspinatus and posterior deltoid muscles

4). Weight bearing; the participant seated in an upright position and shifted the body weight through the affected arm in a position contrary to the typical pattern of spasticity. The action stretched the pectoralis, biceps brachii and wrist flexors.

5) Forearm stretch; the participant seated with an affected arm straight with elbow supported in front of the body, and the palm facing up. The unaffected hand grasped the fingers and slowly pull them down (extend wrist and fingers) toward the floor. The forearm stretch worked on the wrist flexors.

6) Anterior deltoid stretch; the action consisted of grasping hands together behind the back. Then, slowly raise both hands and arms up. This action stretched the anterior deltoid muscle.

7) Triceps stretch; the triceps stretch worked on the triceps brachii muscle. It was completed in a few simple motions. Patients were seated in an upright position with the affected hand resting on the shoulder of the same side and slowly raise the elbow up until it was positioned beside the ear. The less affected hand held the elbow for support.

Active or active assisted exercise consisted of 8 exercises which were following:

1) elevation of the scapula; 2) retraction and protraction of the scapula; 3) arm

exercise consisted of stretching arms in front of a body at the shoulder level after that raising hands over the head with keeping elbows straight; 4) rotating arms to the pronation then to the supination with elbow flex and shoulder contact to the body; 5) patients bent the wrist to the flexion then to the extension with elbows bent and hands clasped at chest; 6) both hand holding, flexion of the elbow to the right and to the left side of the shoulder; 7) radial deviation was supported by an unaffected side and twisting hand to the direction of thumb; 8) wrist extension via weight bearing and compress on a cushion in sitting position. Each action performed 10 repetitions per 1 set. A number of repetitions were depended on the patient's strength and edurance capacity. Both of stretching and active or active assisted exercise programs required about 1 hour to perform.

4.3 Electrical stimulation combined with task-specific exercise

This treatment consisted of a set of exercises aimed at restored hand opening, grasping, releasing, or reaching an object on desk using an affected side which was the most difficult to train in stroke patient. Some patients might receive the wrist splint to control the wrist position during electrical stimulation. During this treatment, patients were instructed to practice the reaching phase or other functional movements depended on their functional ability. Components of each task that the participant was unable to performing voluntarily were assisted using FES. The purposes of these interventions were to expose the range of motion during reaching, to increase strength of voluntary muscles such as the shoulder and the elbow muscles, in addition, to break the pattern of pathologic synergies commonly observed in individuals after brain lesion.

Functional movements were performed against gravity and sometimes against light manual resistance. A number of repetitions depended on the patient's endurance and strength capacity. Before self treatment at home, the patient was instructed to ensure the practice task. The therapist was manually guided of all movements in close approximation to normal movement, that is, FES-assisted movements must not oppose natural joint movements. Patients and family members or care takers learn how to operate the FES device and positioning electrodes. They were able to use the electrical stimulator by themselves after therapist instruction. During follow-up visits, therapist checked the settings device and modified parameter settings for each patient as needs.

4.4 Procedures and rehabilitation treatment

The protocol was approved by the Research Ethics Committee of the Faculty of Associated Medical Sciences, Chiang Mai University. A single-blinded, within subject cross over design was used in the study. Participants were screened based on the inclusion and exclusion criteria. Information regarding the purposes and procedures of the study were informed to the participants. Participants were stratified and then randomized into the treatment condition before initial assessments.

Twenty patients were randomly assigned to the two groups with different sequences of intervention, that is, group A: TSE followed by ES+TSE (TSE/ES+TSE) and group B: ES+TSE follow by TSE (ES+TSE/ TSE). The order of treatment conditions was randomized so that half of patients were started with ES+TSE and the other were started with TSE condition. Each treatment condition was 4 weeks. Participants were measured the baseline ability twice with one week interval before starting the intervention. They were repeated measures at the end of

the 5th and 9th week. In conclusion, four assessments were made during 9-week period (Figure 1). The tester who measured the outcome parameters was blinded to the protocol. Participants were perform home-based intervention using an electrical stimulator and/or task-specific exercise for at least 30 minutes, twice a day, and 5 days a week for 4 weeks. After the first 4-week treatment, participants then started another program for 4 weeks (Figure 2). The stimulation method and the electrodes placement were demonstrated to patients with a few trials of practicing. The number and complexity of the exercises were adjusted by the research therapist every 1-2 weeks for each patient so that he or she was able to practice independently or with assistance from a family member. Each patient followed an assigned schedule and recorded their home-based treatments in a provided log book. At least 3 hours out of the whole 5 hours a week and total 28 hours (70% of the whole 40-hour practice) was ultimately required. The patient being unable to meet the criteria was excluded from the study.

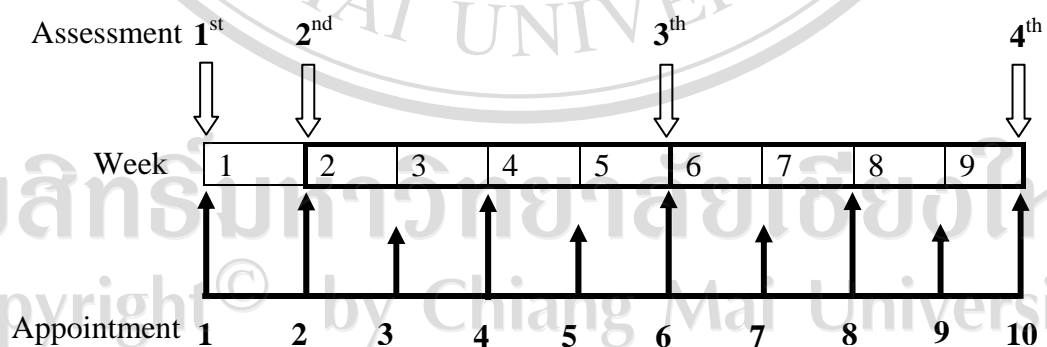


Figure 1 The assessment and the appointment schedule during the study

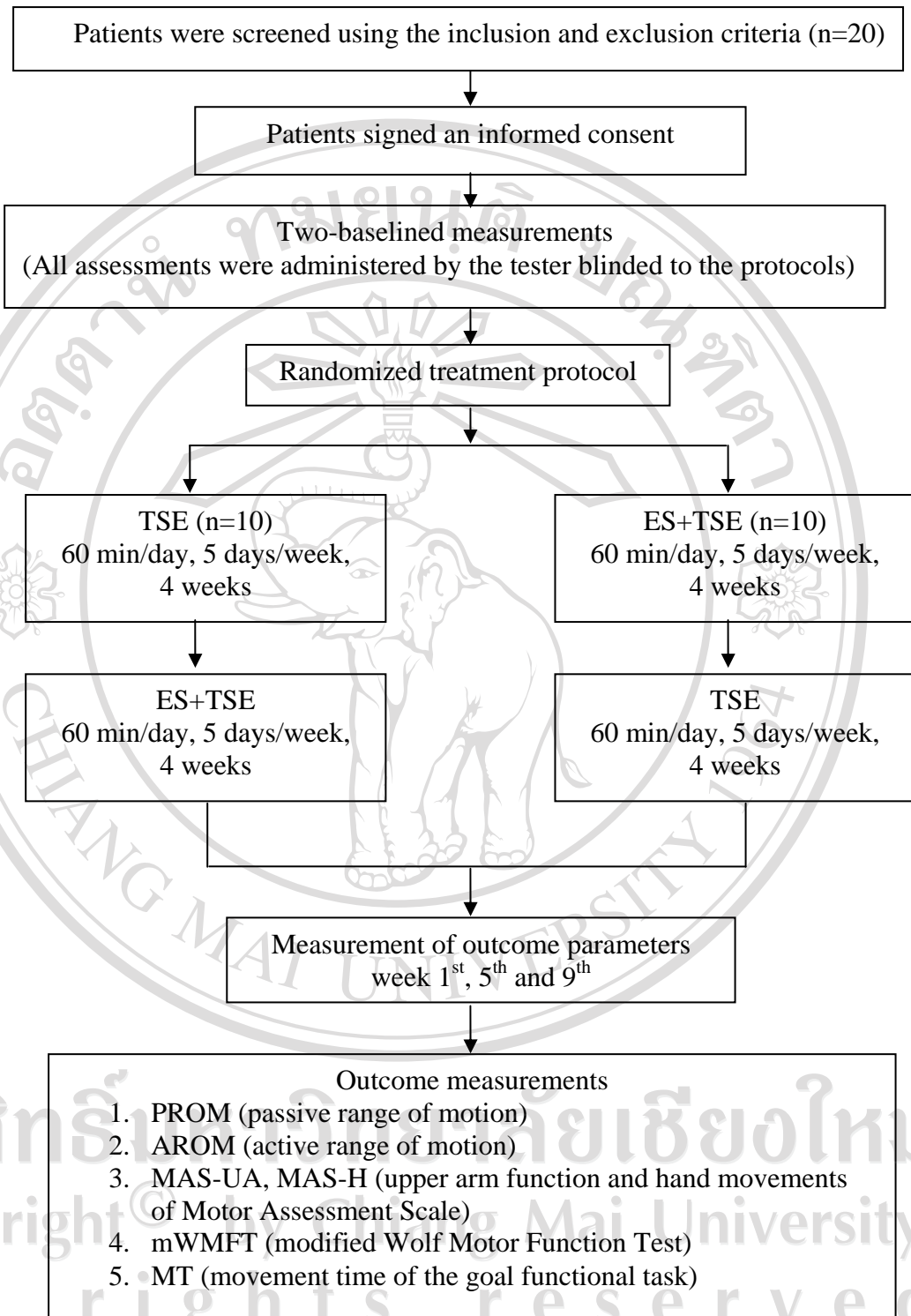


Figure 2 Procedural diagram

ES+TSE = electrical stimulation combined with task-specific exercise

TSE = task-specific exercise alone

5. Assessments

The same tester who was blinded to the subjects' treatment evaluated all measurements and used the same procedure and standardized test. The tester had experiences of using all outcome parameters in previous research (90). The sequence of assessment was set in the following order.

5.1 Sensation

Sensory examination was administered with the patient's eyes closed. The tester provided cotton tactile and pinprick stimuli to various UE sites, both proximal and distal, in a random pattern. The patient was asked to identify and localize the stimuli on the affected side using one finger of the unaffected side pointing to the position where the stimulation was delivered (25).

5.2 Spasticity

Spasticity assessment of the elbow and wrist flexor and extensor muscles was measured using modified Ashworth scale in a seated position.

5.3 Passive range of motion; the researcher performed passive movements and the tester measured ROM using a standard goniometer in a seated position.

5.4 Active range of motion was recorded by asking the patient to maximally moves the shoulder, the elbow, and the wrist joints. Each direction was measured twice using a standard goniometer in a seated position.

5.5 Motor assessment scale

MAS provided objective measures of patient's progress over time in motor ability. It is designed to measure the ability to perform functional tasks. An assessment was progressed using the standard items of MAS-UA and MAS-H, respectively.

5.6 Modified Wolf Motor Function Test

The patient was seated in a chair and with backrest (trunk unrestrained) but no armrests. Sitting position was standardized: ankles, knee, and hip at 90°. Hip against back of chair, hand in lap, both feet on floor (78). Target distance was 35 cm from the hand's resting position. At each target, there were 3 practice and 3 testing trials, with a 3-second rest between trials (91). A template indicating the position of each test object was marked to the test table in a standard position to enable placement of test objects in the same both of location and patients at each test administration. Tester was described and demonstrated each task 2 times. The patient did not practice the task while tester was describing and demonstrating it because of the possibility of practicing transfer of motor learning effects (78). Tester said "Ready, set, go" while a watch was starting. Patient attempted to complete an item within 2 minutes and carried out as rapidly as possible. At each target task, there were 3 testing trials.

5.7 Movement time of the goal functional task

Movement time of the selected goal functional task was measured individually to assess functional ability of each patient. The functional task of each patient was selected by the researcher. Patient attempted to complete of goal functional task 3 times as rapidly as possible.

6. Statistical analysis

Data analysis was determined using SPSS version 17.0 software package. Descriptive statistics were determined for all outcome parameters measured. Average and standard error (mean±SE) were determined for mWMFT, and active and passive ROM. Percent change was determined for movement time, median (min-max) was

calculated for MAS and muscle tone.

To compare the effects of ES+TSE and TSE alone, carrying over effects were reduced by using the change score for analysis. Differences in scores of all outcome parameters, obtained by subtracting pretreatment scores from the 4th-week scores, and 4th-week scores from the 8th-week scores were also analyzed. Data of the same treatment were grouped (TSE and ES+TSE) and compared using the Wilcoxon Signed Ranks test. A significance level was set at 5%.

The within-group factor was the four assessments and the between-group factor was the two orders of treatment protocols. Repeated measures analysis of within-group factor was evaluated using the Friedman test and the Wilcoxon Signed Ranks test was applied as the post hoc test. Between-group factor of all outcome parameters were compared using the Mann-Whitney U test. A significance level was set at 5%.

7. Location

The study was conducted at the laboratory room, the 3rd floor, the Department of Physical Therapy, Faculty of Associated Medical Sciences, Chiang Mai University and at the Huai-Kiang temple, Chaing Mai province.