

## CHAPTER III

### METHODS

#### 1. Participants

Eighteen volunteers with CP (12 males and 6 females) were participated in this study. Participants were recruited from Srisangwan Chiang Mai School and nearby.

**Inclusion criteria:** participant was included in the study if she/he;

- Had a diagnosis of CP with spastic diplegia
- Had a characteristic of crouch posture/gait
- Aged between 6-20 years
- Had a level II-III of gross motor function classification system (GMFCS) (APPENDIX A)
- Had popliteal angle less than or equal to 30 degrees (APPENDIX B)
- Had spasticity of hamstrings less than 3 of Modified Ashworth Scale (MAS) (APPENDIX C)
- Had ability to understand and followed simple verbal instructions
- Had a seizure free or controlled

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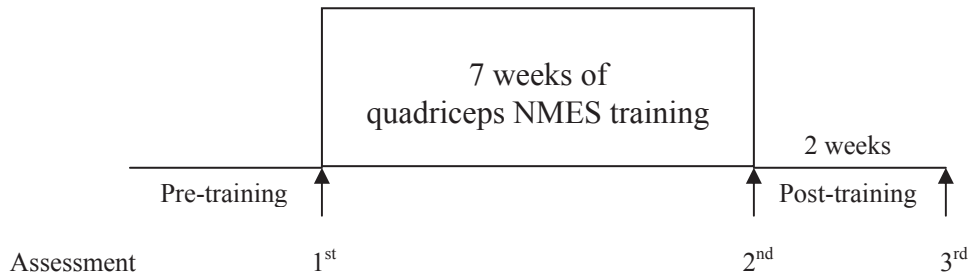
**Exclusion criteria:** participant was excluded from the study if she/he;

- Had been used of ES, or used in the previous 6 months
- Had contraindication for ES (such as an inflammation or skin diseases over lower-limb area, sensation absent over lower-limb area, demand cardiac pacemakers and unable to provide clear feedback)
- Had a minimum of 6 months after botulinum toxin type-A injection to the lower extremities
- Obtained orthopedic surgery to the lower extremities in the previous 6 months
- Had the musculoskeletal problems/deformities (such as pain or inflammation of hip and knee)
- Missed 3 consecutive sessions or missed greater than 4 non-consecutive sessions (20%) of the whole 21 sessions.

## **2. Study design**

A 2 x 3 mixed model with one repeated measures design (Control group vs NMES group and pre-test vs post-test vs follow up-test) was used in this study. All outcome measures were assessed before training (pre-test), at the end of training (post-test) and 2 weeks after training (follow up-test). All measurements were taken on both legs and single blind method was used in this study. An investigator and a trainer (researcher) were different persons. The investigator was blind from the participant which group was randomly assigned.

## Assessment



**Figure 8** The assessment and the weeks of the NMES training

### 3. Equipments

1. Portable electrical stimulator (MH 8000 TENS and EMS Combo; Medihightec medical co., ltd)
2. Adhesive electrodes (50 mm, round and 50x90 mm, rectangular; En-Trode, Enraf-Nonius B.V.)
3. Handheld dynamometer (MicroFET<sup>3</sup> Hoggan Health Industries, USA)
4. Motion Analysis Tools DX9 Shareware Version 2.7.3
5. Digital camera (Sony<sup>®</sup> Cyber-shot DSC-W70 7.20 Mpixel)
6. Modified chair (APPENDIX D)
7. Goniometer (360 degrees)
8. Velcro

#### **4. Outcome measures**

1. Quadriceps maximum voluntary isometric contraction (QMVIC)
2. Quadriceps lag
3. Angles of hip, knee and ankle joints during standing
4. Quadriceps and hamstrings modified Ashworth scale (QMAS and HMAS)

#### **5. Procedures (Figure 14)**

Before the formal data collection, a reliability study of all measurements was conducted. Ten volunteers with spastic diplegia were recruited to attend QMAS, HMAS, quadriceps lag, angles of hip, knee and ankle joints during standing and QMVIC measurements. Each test was composed of two trial sessions with 1 day apart to allow establishment of the test-retest reliability of the measurements. Intra-rater reliability of each measurements was determined using the intra-class correlation coefficients ( $ICC_{(3,k)}$ ) and the results found that the test intra-rater reliability for all measurements were relatively high (APPENDIX E).

After the reliability study, participants were recruited using the inclusion and exclusion criteria and then, filled in the patient information form (APPENDIX F). All participants and/or their parents signed an inform consent form for parents and children prior to data collection (APPENDIX G and H). This experimental protocol was approved by the ethical research committee of the Faculty of Associated Medical Sciences, Chiang Mai University (APPENDIX I).

After that, all outcome measures including QMAS, HMAS, quadriceps lag, angles of hip, knee and ankle joints during standing and QMVIC were assessed respectively, in order to prevent order effects. Both legs were measured for all

outcome measures. Then, all participants were divided into two groups based on age, GMFCS level and all outcome measures as closely as possible. Next, the two groups were assigned conditions by drawing to either control or NMES group. For the control group, the participants only received the stretching program including stretching of hamstrings, hip adductors and hip flexors muscle for 10 times per each muscle, once a day, and 3 days per week. For the NMES group, the participants received the above stretching program and performed quadriceps strength training using the NMES for 7 weeks. After 7 weeks, all outcome measures were reassessed next day after training (post-test) and next 2-week after training (follow up-test) respectively for both groups. The procedures for all outcome measurements were shown as following:

### **Measurement of QMAS and HMAS**

To assess quadriceps and hamstrings muscle spasticity, the MAS (APPENDIX C) was selected because this scale is easily and commonly used in clinical practice (39). The MAS of quadriceps and hamstrings muscles were determined in prone lying position. The investigator flexed the participant's knee from maximum possible extension to maximum possible flexion and the score for QMAS was determined according to the level of resistance during passive movements of the antagonist (hamstrings) muscle. After that, the investigator extended the participant's knee from maximum possible flexion to maximum possible extension and the score for HMAS was determined according to the level of resistance during passive movements of the antagonist (quadriceps) muscle. Three trials were performed for each muscle and the one which same score two of three times was selected for statistical analysis.

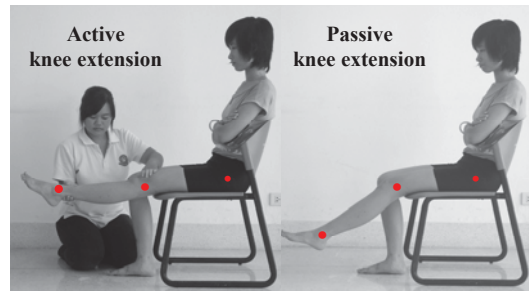


**Figure 9** Position of participant for assessment of quadriceps and hamstrings muscle spasticity

#### **Measurement of quadriceps lag**

To assess quadriceps lag, a 360 degrees goniometer was used to quantify the lag angle in a sitting position with hip and knee flexion approximately 90 degrees. Reference makers were placed on the participants' limb both sides at greater trochanter, lateral femoral epicondyle and lateral malleolus. The assistant investigator straightened the relaxed knee as much as possible with a hand under the participants' heel until full range of motion of knee extension occurred, then, the investigator placed goniometer over the knee joint of the participant. The axis hinge of the goniometer was placed on the marker on the lateral femoral epicondyle. The stationary arm of a goniometer was pointed to the marker on the greater trochanter and the moving arm of a goniometer was pointed to the marker on the lateral malleolus, then, the goniometric value or passive knee extension angle was recorded. Next, the investigator asked the participant to straighten his/her knee as straight as possible and to hold the fully extended position approximately 5 seconds, then, the

goniometer was placed as mentioned above. After that, the lag angle was calculated from the angular of passive knee extension minus the angular of active knee extension (42). The mean value of three trials was used for statistical analysis.



**Figure 10** Position of participant for assessment of quadriceps lag

#### **Measurement of the angles of hip, knee and ankle joints during standing**

To quantify the angles of hip, knee and ankle joints during standing, reference makers were placed on the participants' limb both sides at mid axillar, greater trochanter, lateral epicondyle of the femur, lateral malleolus and the head of fifth metatarsal (54). Next, the digital camera was used to record the picture of the participants during standing position. After that, picture from digital camera was conducted in Motional Analysis Tools DX9 Shareware version 2.7.3 program for measure the angles of hip, knee ankle joints in the sagittal plane as shown in Figure 11 (55).

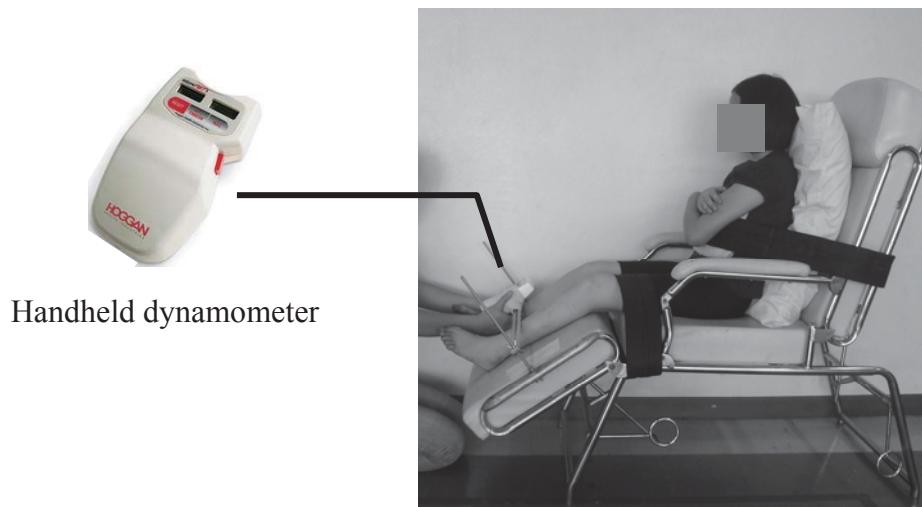


**Figure 11** Position of participant for assessment of hip, knee and ankle joints angle during standing

### **Measurement of the QMVIC**

To assess quadriceps strength, a HHD was used to determine the QMVIC in sitting position with hip flexion 90 degrees and knee flexion 30 degrees on a modified chair (Figure 12). Two crossover straps were used to stabilize participants' body. The HHD was fixed on a modified stationary bar of a modified chair anteriorly 2-inches proximal to the lateral malleoli (10). Each participant was given an instruction to gradually extend their leg as hard as possible against the HHD over a period of approximately three seconds to allow the participant to adjust and recruit the maximum number of muscle fibers. Three trials were performed for each leg and two minutes were allowed to rest between trials. The peak force value from three trials was normalized by dividing by body weight of each participant and then used for statistical analysis.





**Figure 12** Position of participant for assessment of QMVIC

### The NMES program

Only the participants in the NMES group performed bilateral knee extensors electrical stimulation via a portable battery powered electrical stimulator. The stimulation was completed with the participant in sitting position with knee flexion approximately 30 degrees on a modified chair (Figure 13). Two sizes of hypoallergenic self-adhesive electrodes were used (5 cm diameter round shape or 5x9 cm rectangular shape) depending on the sized of the participants' thigh. Electrodes were placed over the quadriceps muscle group (10). The proximal electrode was placed on the anterolateral aspect of the thigh, one-third of the distance between the anterior superior iliac spine and the mid-point of the superior border of the patella (proximal electrode was placed obliquely over the belly of the proximal rectus femoris and vatus lateralis muscles). The distal electrode was placed 1 to 3 cm proximal and medial from the mid-point of the superior border of the patella

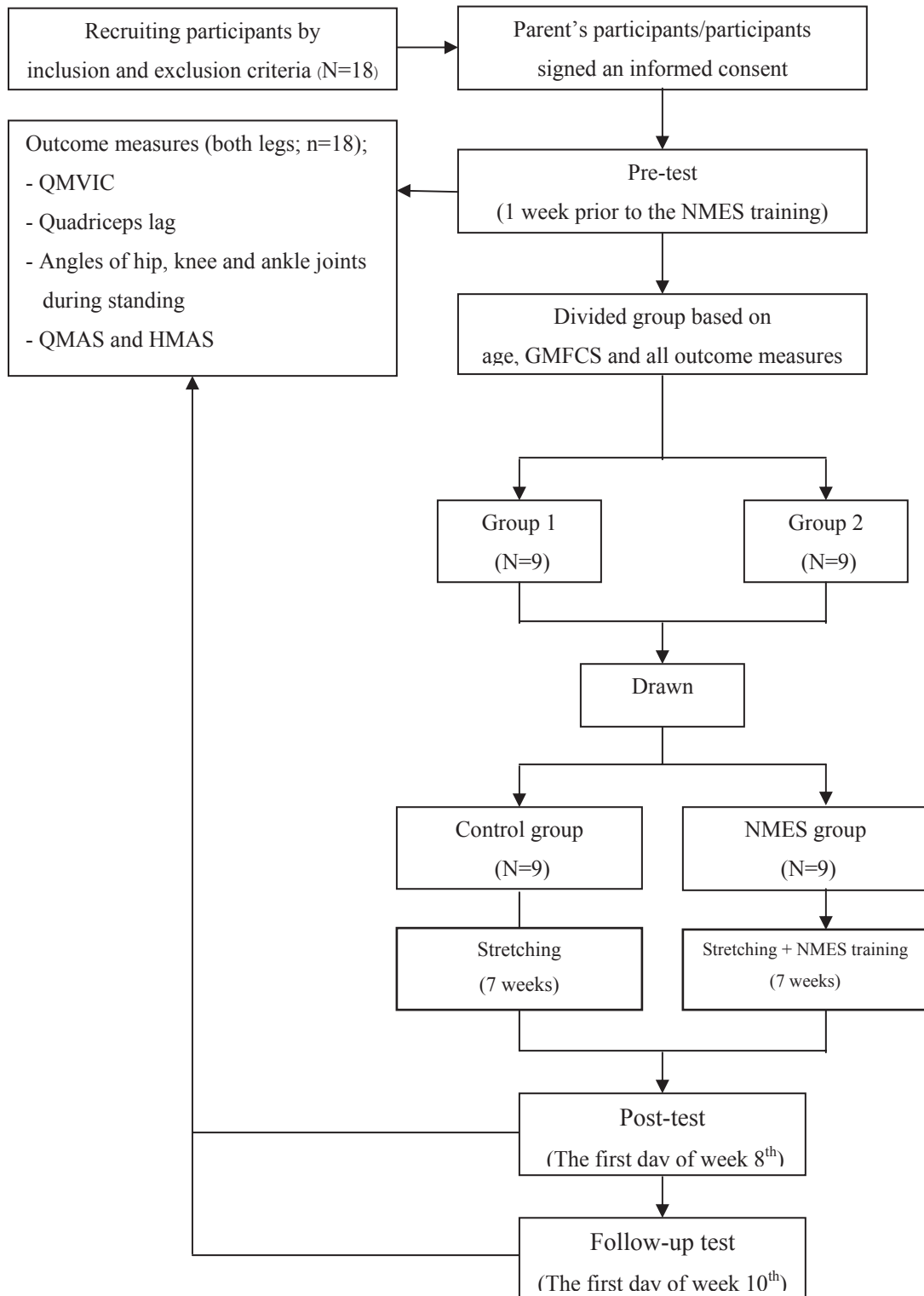
(depending on the length of the participants' limb) (10-11). Electrode position was altered slightly between participants to ensure that they spanned the muscle belly of vatus medialis. This was confirmed by palpation of the muscle while it was contracting. The researcher marked the location of the electrodes on the participants' legs with permanent marker. Before the NMES stimulation, the characteristic of muscle contraction was also observed. The stimulation parameters for the NMES were chosen based on the previous study (10) (Table 4). The current amplitude was set to produce full knee extension as much as possible, which was stronger than the participant could produce voluntarily, and the participant was asked to relax during stimulation. The maximum tolerable amplitude was determined prior to each session and the amplitude was adjusted to achieve the maximally contraction for each participant tolerance during stimulation (10, 13). The current amplitude was recorded for all sessions. The participants were stimulated 10 repetitions and 3 sets with 2 minutes rest. The program took time approximately 40 minutes in both legs (20 minutes per leg). The quadriceps strength training program was to be administered once a day, 3 days a week on every other day, for 7 weeks.

**Table 4** Stimulation parameters used in the present study (10)

Waveform	Asymmetrical rectangular biphasic pulsed current
Pulse duration	300 $\mu$ s.
Frequency	35 pps.
On : Off time	10 s: 50 s.
Ramp up : down	2 s: 0 s.
Current amplitude	
▪ Mean $\pm$ SD	33.03 $\pm$ 3.38 mA
▪ Range (min-max)	15-53 mA



**Figure 13** Position of participant for quadriceps strength training



**Figure 14** Diagram of experimental procedure

## 6. Data analysis

Before data analysis, the normalized QMVIC of all participants were transformed to percent changes of QMVIC and then also used for statistical analysis.

All data were analyzed using the Statistical Package for the Social Sciences (SPSS) for windows, version 11.5. Descriptive statistics were performed for all outcome measures. Data of all outcome measures in each condition were tested for normality, using one sample Kolmogorov-Smirnov test. In addition, the normalized QMVIC, percent changes of QMVIC and quadriceps lag were also tested for compound symmetry, using Mauchly's test of sphericity. Statistically significant level was set at  $p < 0.05$ .

For the normalized QMVIC, percent changes of QMVIC and quadriceps lag, data were found normality and compound symmetry. Then, repeated measures analysis of variance (group [2] x time [3]) was used to test for the group-time interaction and main effects including the group effect and the time effect at  $\alpha = 0.05$ . If interaction effect found significant differences, post hoc analysis would be used by independent t-tests to test the difference between groups among times of assessment at  $\alpha = 0.016$  (Bonferroni adjustment for three comparisons) whereas the dependent t-test was also used as a post hoc analysis to test the difference between times within group at  $\alpha = 0.008$  (Bonferroni adjustment for six comparisons). Bonferroni correction method was used for adjustment of familywise error rate or used to protect against inflating Type I error (56).

The non-parametric test was used for the QMAS and HMAS since the data were established as ordinal scale and for the angles of hip, knee and ankle joints during standing, since the data were not found normality. The Mann-Whitney U-test was

used to test the difference between groups among times of assessment whereas the Friedman test was used to test the difference between times within group at  $\alpha = 0.05$ . Then, the Wilcoxon Signed-Ranks test was also used as post hoc analysis to test the difference between times for the NMES group for only QMAS.

## **7. Location**

The study was conducted in the physical therapy room at the Srisangwan Chiang Mai School, Chiang Mai Province, Thailand.