CHAPTER III

METHODS

1. Participants and Equipments

Sixteen individuals with spastic diplegia (8 males and 8 females) were participated in the study. The participants were recruited from the Srisangwan Chiang Mai School.

Inclusion criteria: A participant was included in the study if;

- He/she had a diagnosis of cerebral palsy with spastic diplegia
- He/she aged between 8-21 years.
- He/she was received a conventional physical therapy
- He/she had a level II-III of gross motor function classification score (GMFCS)
- He/she was able to understand and follow simple verbal instructions
- He/she had a minimum of 6 months after botulinum toxin injection to the LE
- He/she had popliteal angle $\leq 30°$ (Appendix B)
- He/she had hamstrings muscle tone equal or less than ≤ 3 on a Modified Asworth Scale (Appendix C)

Exclusion criteria: A participant was excluded from the study if;

- He/she missed the follow-up appointment or 3 consecutive sessions of training or a total of greater than 4 sessions (20%) of the whole sessions

- He/she had an abnormality in the cardiovascular system or respiratory system (such as heart disease, asthma)
- He/she obtained orthopedic surgery in the previous six months.
- He/she had a problem of the musculoskeletal system (such as pain and inflammation of hip and knee)
- He/she had used of electrical stimulation in the previous six months
- He/she had unexpected medical change during the study period that affected the exercise or assessment
- He/she had contraindication of ES application (Appendix D)

Equipments

- A portable electrical stimulator (MH 8000 TENS and EMS Combo; Medihightec medical co., ltd)
- Self adhesive electrodes (50 mm, round and 50x90 mm, rectangular; En-Trode, Enraf-Nonius B.V.)
- Alcohol and cotton wool for skin cleaning
- A digital camera
- Tripods 1 unit for adjust level of camera.
- A standard goniometer (360 degrees)
- A timer (ALBA Citizen) 1 unit for reckon time 1 minute during assessment
- Sand bags or ankle weight (Size; 250, 500, and 1000 gram)
- A digital weight (Sony® Cyber-shot DSC-W70 7.20 Mpixel)
- A hand held dynamometer (MicroFET^3 Hoggan Health Industries, USA)
- A modified chairs (Appendix E)

2. Study design

A 2 x 3 mixed model with one repeated measures design (control group vs combined group x pre-test vs post-test vs follow up-test) was used in this study (Figure 5). All participants were measured all variables for 4 times at the pre- training 1, pre- training 2, the post-training, and follow up with a blinded investigator. An investigator and a trainer (researcher) were different persons. The results between the pre- training 1 and pre- training 2 were found no statistically significant differences. Therefore, all outcome measures only at pre- training 2 were used to compare in this study (Appendix I). All measurements were taken on both legs and single blind method was used in this study.

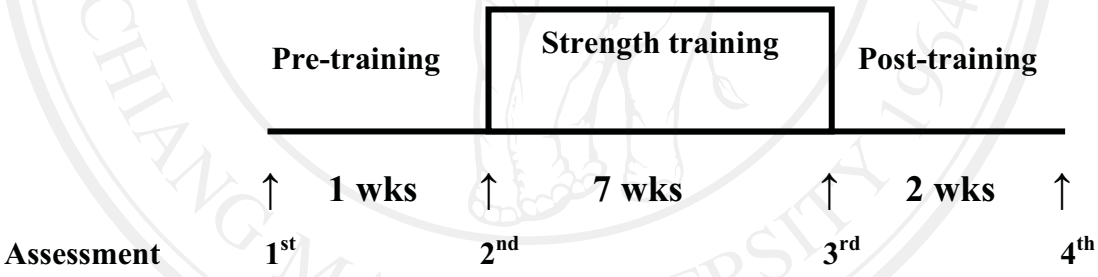

Figure 5 The assessment and the weeks of the strength training

3. Outcome measures

The participants were measured the quadriceps maximum voluntary isometric contraction (QMVIC), quadriceps lag, muscle tone of quadriceps and hamstrings, and angles of hip, knee and ankle joints during standing. The outcome measures were measured in the following order.

3.1 Muscle tone of Quadriceps and Hamstrings

To assess quadriceps and hamstrings muscle spasticity, the MAS (Appendix C) (37) was selected because this scale is easily and commonly used in clinical practice (37). 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 (Figure 6). 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 (Figure 6). Three trials were performed for each muscle and the one which same score two of three times was selected for statistical analysis.

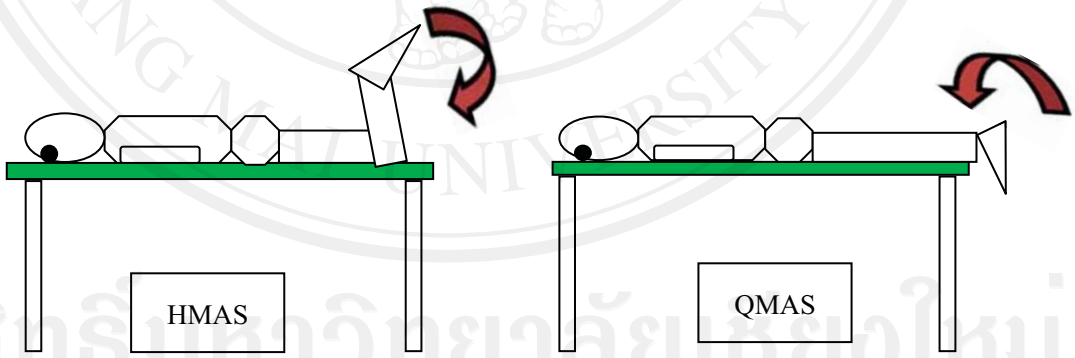

Figure 6 Position of subject for spasticity assessment

3.2 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, leteral 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.

3.3 Angles of hip, knee and ankle joints during standing

These angles were measured using the Motional Analysis Tools DX9 Shareware version 2.7.3. Reference markers were placed on the anatomical landmark of the lower limb (60) including the mid axillar, the greater trochanter, the lateral epicondyle of the femur, lateral malleolus, and the 5^{th} head of metatarsal (Figure 7). A digital camera was used to record the participants during standing position. The digital camera was placed perpendicular to the participant and at a distance of six meters away from him/her. After that, the Motion Analysis Tools was used for digitizing the markers, and then calculating for hip, knee and ankle angles during standing position.

3.4 Quadriceps Maximum Voluntary Isometric Contraction (QMVIC)

Muscle strength of knee extensors was measured using a hand held dynamometer (HHD). Each participant was asked to sit with hip flexion of 90° and knee flexion of 30° on a modified chair. The HHD was held in a stationary position at the anterior part of the shake with 2-inches proximal to lateral malleolus. The participant was instructed to gradually extent or pushing the leg as hard as possible against the HHD over a period of three seconds. Before testing, the participant performed 2 submaximal voluntary isometric exercises to familiar with the test. After that, they performed 3 maximal voluntary isometric contractions which each maximal effort was last for 3 seconds separated by a 3 minutes rest. The highest MVIC value (in ponds) was selected and was used to calculate 65% MVIC. The quadriceps femoris MVIC force was normalized to body weight for data analysis.

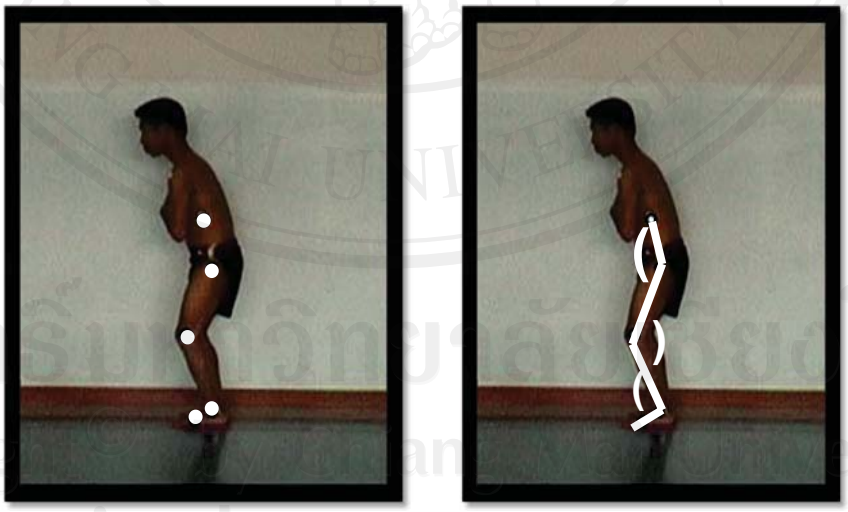

Figure 7 Angles of hip, knee and ankle joints during standing

4. Procedures

Before data collection, a pilot study was conducted to test intrarater reliability. Intra-rater reliability of each measurements was determined using the intra-class correlation coefficients ($ICC_{(3,k)}$). Ten participants were recruited from Srisangwan Chiang Mai School in Chiang Mai Province (5 boys and 5 girls). The averag age and weight of participants were 12.60 ± 3.10 year and 35.85 ± 10.03 kg, respectively. The results showed high intrarater reliability (Appendix F).

The participants were screened using the participant's information form based the inclusion and exclusion criteria as shown in Appendix G and filled in the patient information form. All participants signed an informed consent form which was approved by the ethical research committee of the Faculty of Associated Medical Sciences, Chiang Mai University prior to data collection (Appendix H).

After that, all outcome measures including QMAS, HMAS, quadriceps lag, angels 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, and all outcome measures as closely as possible. Next, the two groups were assigned conditions by drawing to either the control or combined group. For the control group, the participants only performed voluntary isometric knee extension alone. For the combined group, the participants performed isometric knee extension with NMES.

Training session

Voluntary isometric exercise:

Before performing the voluntary isometric exercise, each participant was asked to walk around the room for 10 minutes and stretch of hamstrings, hip adductors and hip flexors muscles for 10 times per each muscle before and after the voluntary isometric exercise training.

For the training, each participant was asked to extend each knee with a starting ankle weight of 65% of the MVIC and a starting position of the knee flexion approximately 30° in the modified chair (as same as position in the MVIC measurement) (Figure 8). The order of the training leg was random. The training was 10 repetitions and 3 sets with 2 minutes rest. For each repetition, the participant needed to hold for 10 seconds, however, all participants in this group were not able to hold at least 65% of their MVIC for 10 seconds. Thus, the ankle weight was decreased by 250 grams until he/she was able to hold for 10 seconds. Then, the ankle weight was recorded (Appendix J). The weight training was adjusted every week in order to reach the load principle for strengthening exercise. During the training program, manual guidance (the alignment of the knee flexion by marker level) was given verbal cueing (such as hold the sandbag, do not fall etc). The program took time approximately 70 minutes in both legs (35 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.

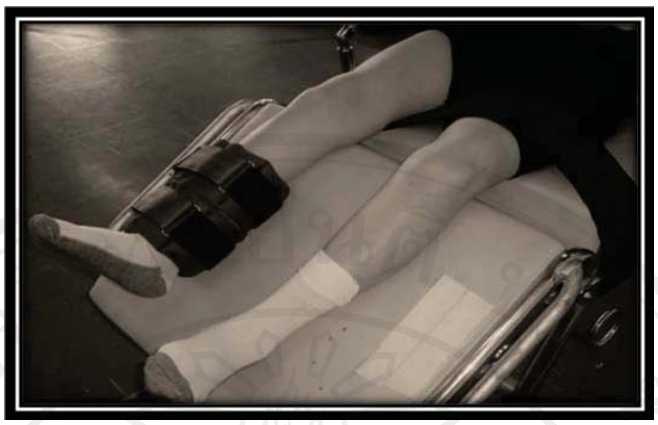

Figure 8 Voluntary isometric knee extension (Control group)

The NMES training:

The NMES was applied superimposed the voluntary isometric exercise only in the combined group (Figure 9). The protocol was identical to the voluntary isometric exercise. 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 (55). 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) (55). 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. The stimulation parameters for the NMES were chosen

based on the previous study (55) (Table 2). 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 (55). The current amplitude was recorded for all sessions (Appendix J)

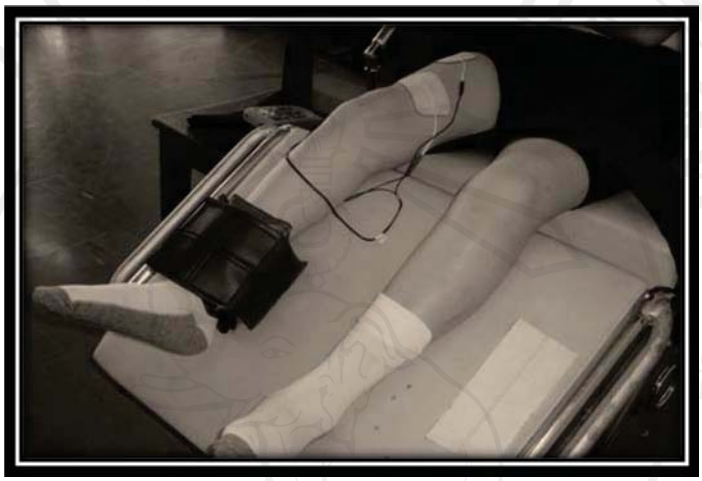

Figure 9 Voluntary isometric knee extension with NMES (Combined group)

Table 2 Parameters for neuromuscular electrical stimulation

Parameters	Value
Current type waveform	Asymmetrical biphasic
Ramp up/down	3/0
Pulse duration	350 μs
On/off time	10/50 seconds (10 contractions/set)
Current amplitude	20.8-40.0 mA
Frequency	35 H_z

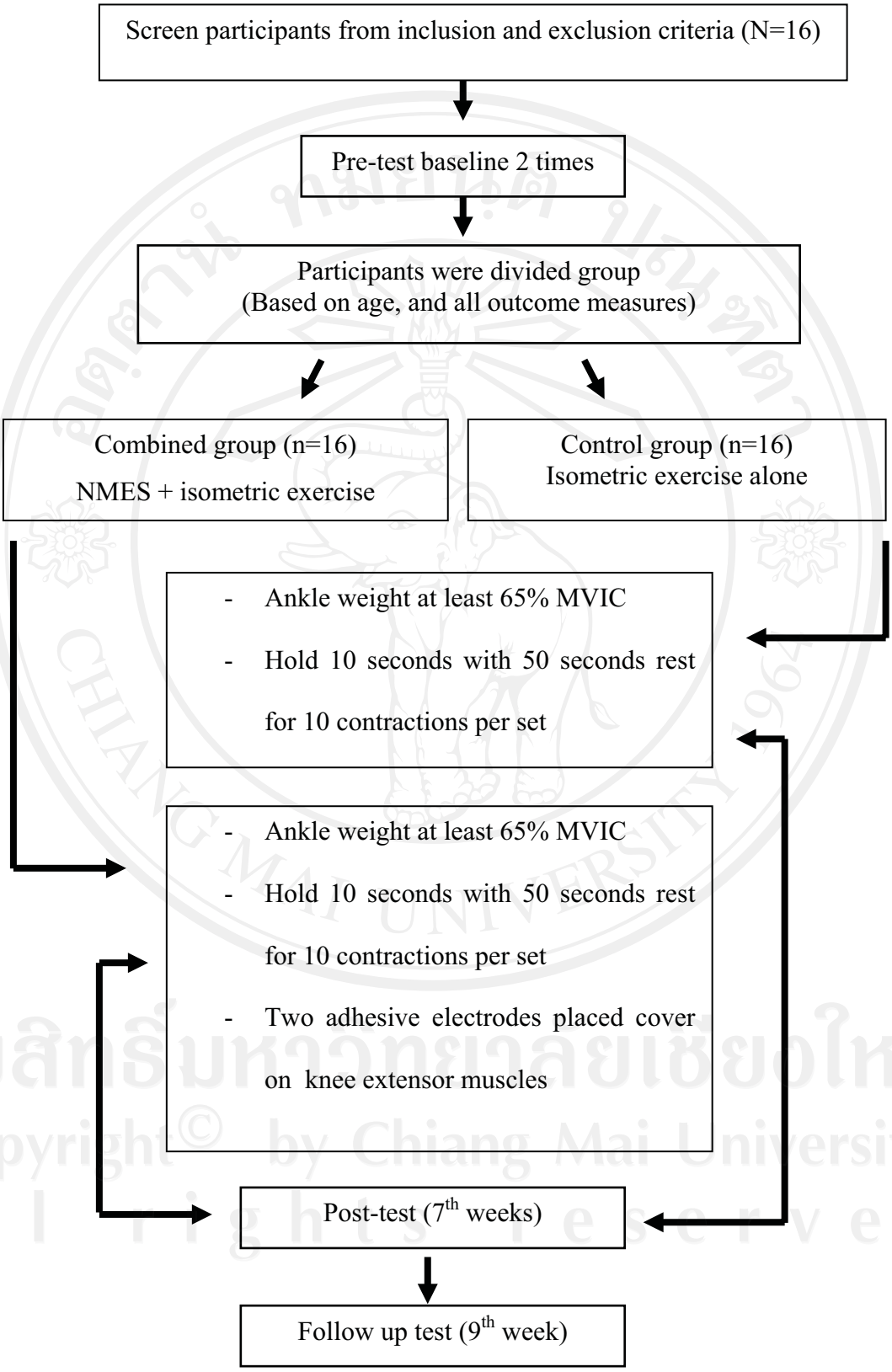

Figure 10 Procedure of the study

5. Data 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. The normalized QMVIC and quadriceps lag were found normality and compound symmetry using the one sample Kolmogorov-Smirnov test and the Mauchly's test of sphericity. Then, repeated measures analysis of variance (group [2] x time [3]) were used to test for the group-time interaction and main effects including the group effect and the time effect at $\alpha = 0.05$. The dependent t-test was also used as a post hoc analysis to test the differences 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.

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.

6. Location

The study was conducted at the Srisangwan Chiang Mai School, Chiang Mai Province and Department of Physical Therapy, Faculty of Associated Medial Sciences, Chiangmai University, Thailand