CHAPTER III
METHODOLOGY

3.1 Design and setting

A randomized controlled trial was conducted in the Department of Physical Therapy, Faculty of Associated Medical Sciences, Khon Kaen University, Thailand. The research protocol was approved by the ethical committee of Khon Kaen University on August 17, 2009.

3.2 Subjects

Thirty-three chronic mechanical neck pain subjects, aged between 18-60 years (Cleland et al., 2005, Cleland et al., 2007, Gonzalez-Iglesias et al., 2008) were recruited from Physical Therapy Unit, Srinakarin Hospital, Faculty of Medicine, Khon Kaen University, Thailand. All subjects were examined by a rehabilitation medicine physician and then were screened using a screening questionnaire. The subjects were required to sign the informed consent before participating in the current study.

3.2.1 Inclusion criteria (Gonzalez-Iglesias et al., 2008)

- Aged between 18-60 years.
- The subjects had experienced of unilateral or bilateral pain on posterior neck and/or shoulder that may be included cervical spondylosis with mechanical characteristics including symptoms provoked by neck postures, neck movement or palpation of the cervical musculature.
- The symptom more than three months in duration.

3.2.2 Exclusion criteria (Gonzalez-Iglesias et al., 2008)

The subjects were excluded in the current study if the subjects had following conditions or diseases.

- Cervical radiculopathy
- Cervical myelopathy

- History of the cervical and/or thoracic spine injuries including fractures, dislocation
- History of surgery of the cervical and/or thoracic spine
- Fibromyalgia syndrome
- Spinal osteoporosis
- Spinal infection
- Hypertension, heart disease or meningitis
- Female who is pregnancy

3.3 Sample size

The sample size was calculated using the pain level at rest in the study of Cleland et al., (2005). In their study, the averaged of the pain level at rest in the thoracic manipulation group was 15.5 ± 7.7 mm and the averaged of the pain level at rest in the control group was 4.2 ± 4.6 mm. Therefore, a pooled variance estimate ($\sigma^2 = (n_1-1)s_1^2+(n_2-1)s_2^2 / (n1+n2)-2$) of 41.35 had been used to calculate the sample size. The effect side (Δ) was 11.3 mm in their study. The significant level of lower than 0.05 ($Z_{\alpha(0.05)}$) and a power of test at 90 percent ($Z_{\beta(0.1)}=1.28$) had been used to calculate as follow:

$$\text{n/group} = \frac{2(Z_{\alpha/2c}+Z_{\beta})^2 \sigma^2}{\Delta^2}$$

$$\text{n/group} = \frac{2(Z_{0.05/2x3} + Z_{0.1})^2(41.35)}{11.3^2}$$

$$\text{n/group} = \frac{2(Z_{0.0084} + 1.28)^2(41.35)}{127.69}$$

$$\text{n/group} = \frac{2(2.39+ 1.28)^2(41.35)}{127.69}$$

$$\text{n/group} = \frac{1113.88}{127.69}$$

n/group = 9

n/group = 11 (20% drop out)

Thus, the appropriate number of subjects in the current study was 11 subjects in each group. The total number of subjects in the current study was 33 subjects.

3.4 Randomization

The subjects, who met the above inclusion criteria, were randomly assigned to receive the single thoracic manipulation, the single thoracic mobilization, or prone lying (control group) by using a block randomized allocation.

3.5 Instruments

3.5.1 A Cervical Range of Motion (CROM) device (Performance attainment Associates, USA) was used to measure the cervical range of motion (Figure 2). The CROM device consists of a CROM mainframe with rotation arm, which has three dial angle meters, was used to take the measurements. Firstly, a sagittal plane meter is a gravity meter which used to measure cervical flexion, extension movements. Secondly, a lateral plane meter is a gravity meter which used to measure cervical lateral flexion movements. Finally, a rotation meter is a magnetic meter which used to measure cervical rotation movements. The dial meter is marked in two degree increments. The CROM mainframe is aligned on nose bridge and ears. It is fastened to the head by a velcro strap. Additionally, it has a magnetic yoke, which is placed on the subject's shoulders with the arrow pointing north for controlled rotation meter. The reliability test had been shown that the CROM was a high reliable device with an intra-tester reliability. (ICC values ranged from 0.91 to 0.95).

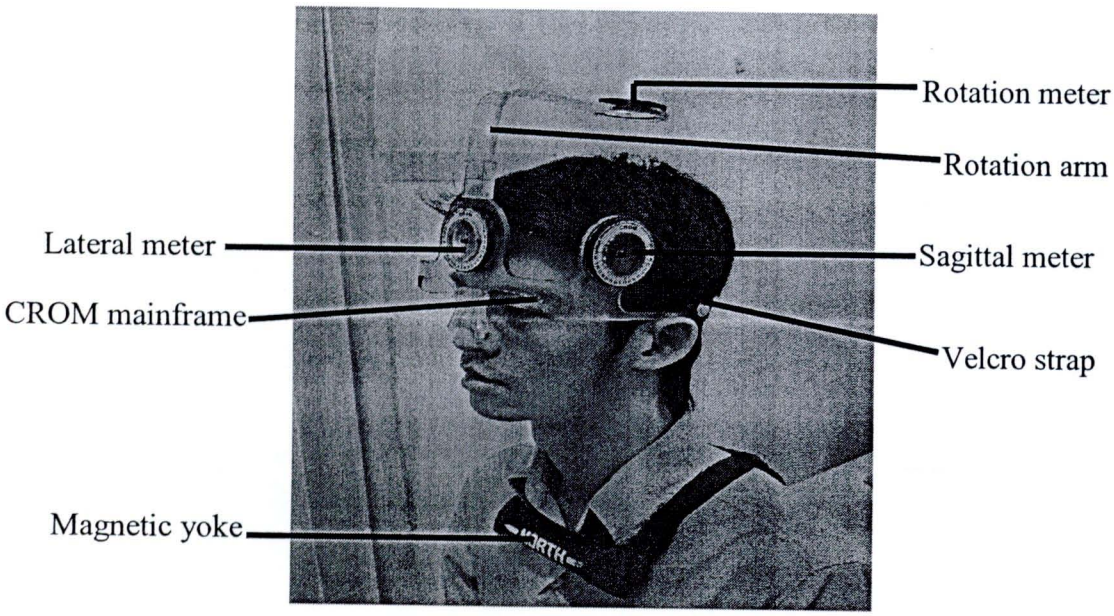

Figure 2 A Cervical Range of Motion (CROM) device

3.5.2 A visual analog scale (VAS) was used for measuring pain level at rest in the current study. The VAS is a 100 millimeters (mm) line anchored with a "0" which means no pain and "100" which means the worst pain. The subjects placed a mark along the line corresponding to the intensity of pain level. The VAS is a high reliability to detect immediate changes in pain level at rest (ICC = 0.97) (Bijur et al., 2001; Bird and Dickson, 2001; Gallagher et al., 2001).

3.5.3 A pressure algometer (Ufam Clinique Company Limited, Thailand) was used to measure the pressure pain threshold (PPT) on the cervical muscles in the current study (Figure 3). The pressure algometer has a surface area at the round tip of one cm^2. The compressive pressure is gradually increased at the rate of approximately one kg/second perpendicularly onto the muscle tissue. The subjects were told to state immediately when the sensation of pressure turned to a sensation of pain. When the subjects had pain sensation at a compressive point, the compressive pressure was stopped. After 30 seconds interval, the next measurement was taken. The PPT measurements were assessed; firstly, the PPT measurements were performed at sternum as the reference site, which were located two centimeters below the upper border of the sternum in the midline. After that, the subjects were asked to prone lying position. Next, the PPT measurements were performed on both splenius capitis

muscles which laterally located two centimeters to spinous process of the axis and then were performed on both levator scapulae muscles which were located two centimeters above the superior aspect of medial border of scapular. Finally, the PPT measurements were performed on both upper trapezius muscles which were located half-away between the midline and lateral border of the acromion process (Ylinen et al., 2007). The reliability test showed that the pressure algometer was a high reliable device (ICC = 0.95-0.98).

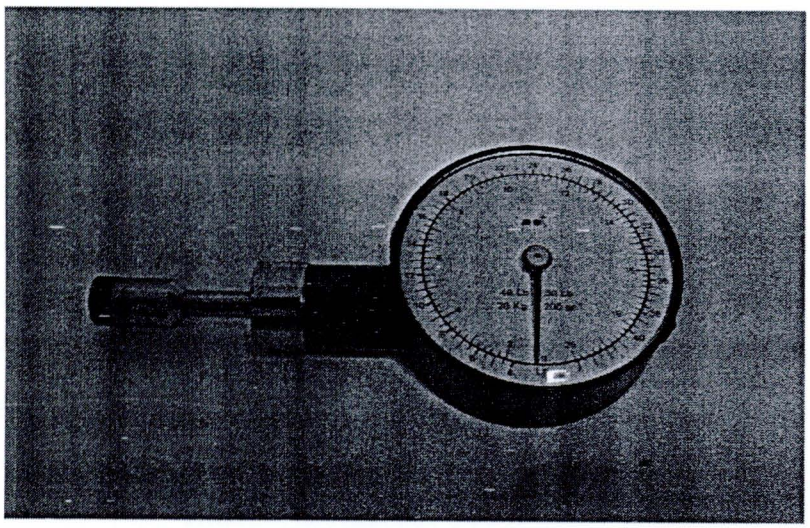

Figure 3 A pressure algometer

3.6 Procedures

Subjects were examined by a rehabilitation medicine physician. After that, a screening questionnaire was applied to ensure that they met the inclusion criteria. The principal investigator explained the objectives of the current study, experimental procedures, benefits of the thoracic manipulation and the thoracic mobilization, adverse effects of thoracic manipulation and thoracic mobilization including aggravation of symptoms, muscle spasm, neck stiffness, headache, and radiating symptoms. After that, the principal investigator asked the subjects if they had any questions regarding the current study and they were asked to sign an informed consent. Each subject was randomly assigned to receive the single thoracic manipulation, the single thoracic mobilization, or prone lying in control group. Then,

all subjects were asked to change their shirts or blouses and put on the sleeveless waistcoat, which revealed the visualization of the spine. After that, the subjects were measured their pain level at rest using the VAS, cervical range of motion using the CROM and pressure pain threshold (PPT) using the pressure algometer on baseline.

After finishing measured cervical range of motion, pain level at rest and pressure pain threshold, the sequences of the interventions were conducted as the following.

3.6.1 Single thoracic manipulation group

Each subject was asked to lie in a prone position on the experimental table and was marked on both sides of zygapophyseal joint of T6-T7. Each subject was instructed to take a deep inhalation and exhalation. At the end exhalation, the principal investigator performed thoracic manipulation (Screw thrust) to produce a high velocity, low amplitude thrust at both zygapophyseal joints of T6-T7 as described by Maitland et al., (2000) (Figure 4) and the principal investigator listened for a popping sound. If popping sound was not heard on the first attempt, the subjects were instructed to reposition and was performed the same technique again. This procedure was performed for two maximal attempts (Cleland et al., 2007, Gonzalez-Iglesias et al., 2008). This process was finished within two minutes. After that the subjects were measured cervical range of motion using the CROM, pain level using the VAS at resting period and pressure pain threshold using the pressure algometer in immediately after performing the thoracic manipulation.

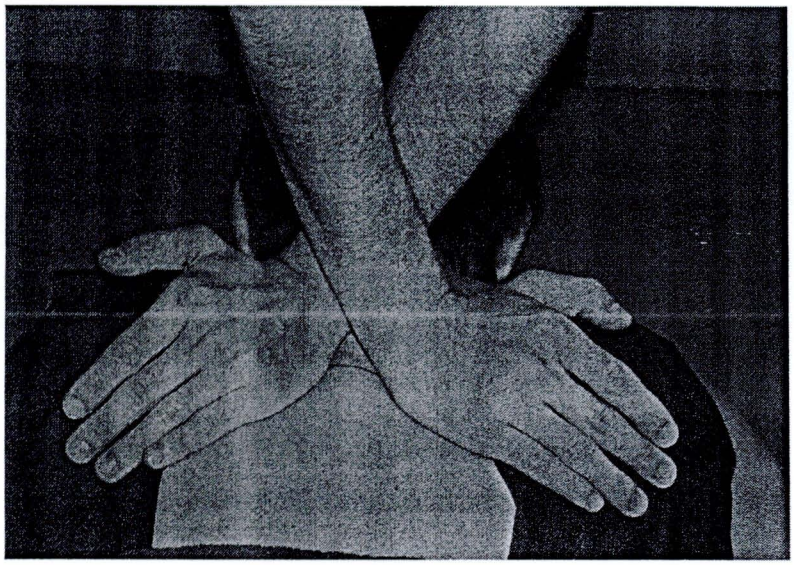

Figure 4 Single thoracic manipulation (screw thrust)

3.6.2 Single thoracic mobilization group

Each subject was asked to lie in a prone position on the experimental table and was marked on both sides of zygapophyseal joint of T6-T7. The principal investigator performed one minute of grade III unilaterally postero-anterior mobilization technique at the zygapophyseal joint of T6-T7 as described by Maitland et al., (2000) (Figure 5). This process was finished within two minutes. After that, the subjects were measured cervical range of motion using the CROM, pain level using the VAS at resting period and pressure pain threshold using the pressure algometer in immediately after performing the thoracic mobilization.

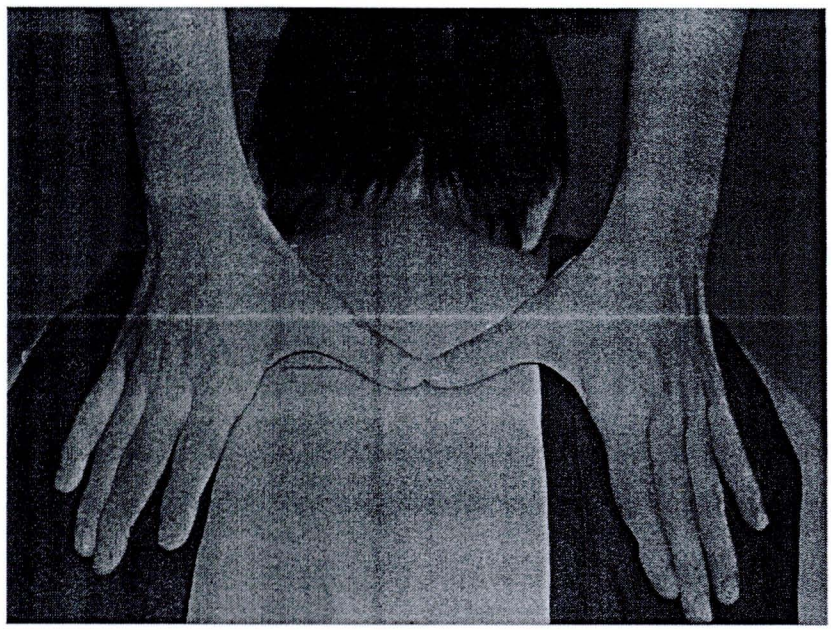

Figure 5 Single thoracic mobilization (grade III unilateral posterior-anterior)

3.6.3 Control group

Each subject was asked to lie in a prone position on the experimental table. The prone position was taken totally for two minutes. After that, the subjects were measured cervical range of motion using the CROM, pain level using the VAS at resting period and pressure pain threshold using the pressure algometer in immediately after lying in prone position.

A principal investigator in the current study finished a Professional Skill of Manipulative Therapy subject and had been working as a physical therapy for almost 10 years.

All subjects were instructed about neck education including sitting position (relaxation exercise) and postural exercises and were received conventional treatment for chronic mechanical neck pain in control group and intervention group with not change of pain.

3.7 Variables in this study

3.7.1 The cervical range of motion, the pain level at rest and the pressure pain threshold before and after each intervention were compared.

3.7.2 The differences of the cervical range of motion, the pain level at rest and the pressure pain threshold provided from each group were compared.

3.8 Data analysis

The cervical range of motion, pain level at rest, and pressure pain threshold (PPT) were examined within group. Additionally, the cervical range of motion, pain level at rest and PPT were examined to compare between the single thoracic manipulation, the single thoracic mobilization and control groups. The Kolmogorov-Smirnov Goodness of fit-test was used to test assumption of normal distribution of the data. The paired sample t-test was employed to calculate the cervical range of motion, pain level at rest and PPT within group. An analysis of covariance (ANCOVA) was employed to calculate the differences of the cervical range of motion, pain level at rest and PPT between each group after adjusting for differences in baseline values, for each outcome measure. The level of significance was set at $\alpha = 0.05$.

3.9 Scope of this study

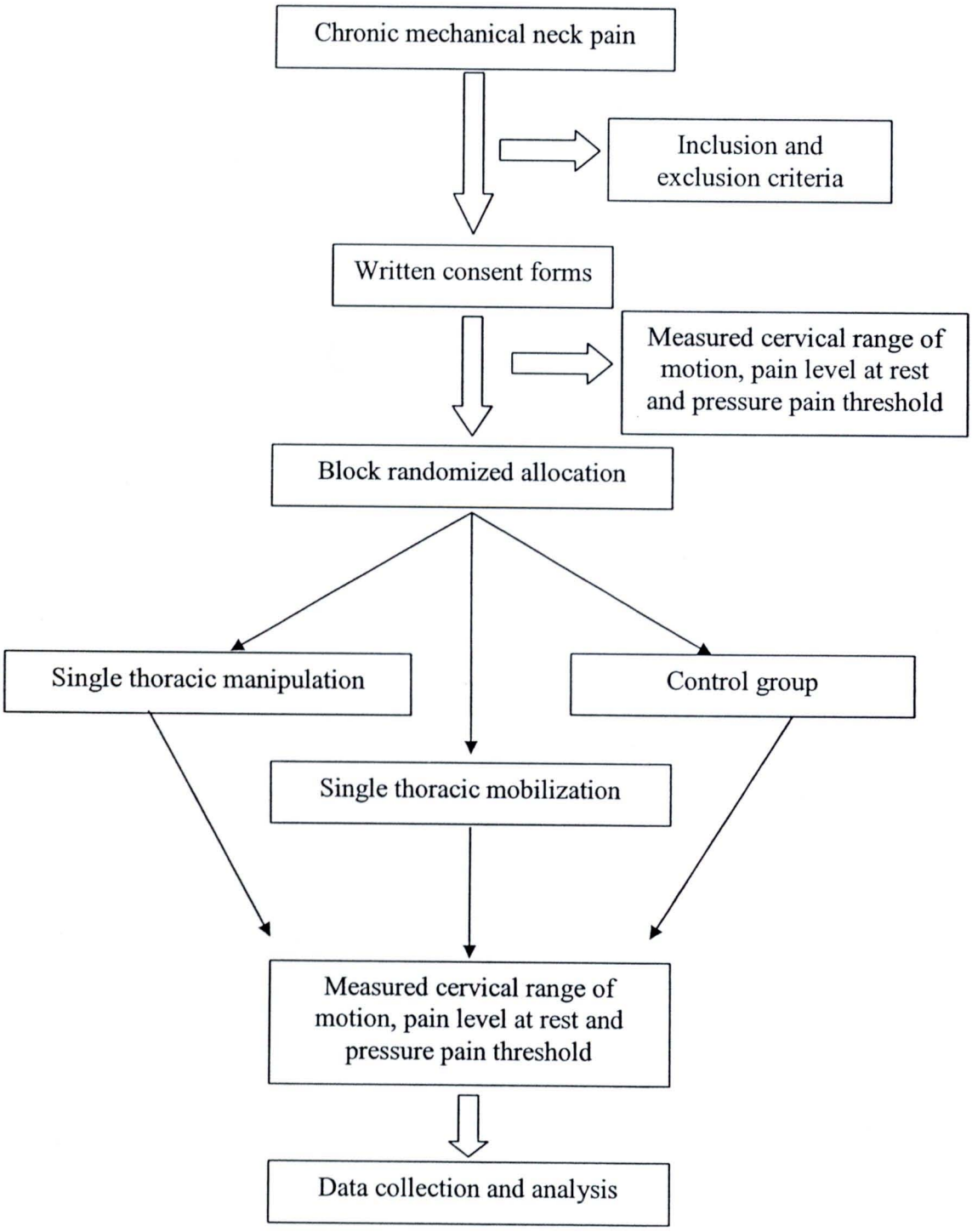

Figure 6 Scope of this study