CHAPTER 3

Methods

3.1 Sample size calculation

There is no study investigating the size (thickness) of the lower trapezius muscle in patients with chronic unilateral neck pain. With respect to the study design and statistical analysis used, a total number of 40 subjects (20 with neck pain and 20 without neck pain) were required for the study (96).

3.2 Participants

Twenty female participants with chronic neck pain aged between 18-59 years were recruited into the study from general community. Twenty healthy controls of similar age, arm dominance, body mass index (BMI) and physical activity level were also recruited. Participants were eligible for the study if they met the following criteria.

3.2.1 Inclusion criteria

Participants with neck pain:

1) Having unilateral idiopathic neck pain (grade I-II)
2) Neck pain that has persisted for greater than 3 months
3) Neck pain caused by neck postures, neck movement, or muscle palpation
4) Neck Disability Index-Thai version (NDI-TH) $\geq$ 10 (0-100)

Participants without neck pain:

1) No previous history of neck pain for at least 12 months
2) No previous history of any headache for at least 12 months (< 5 times/year)

3.2.2 Exclusion criteria

Participants with and without neck pain:

1) Having back and shoulder pain
2) Having previous history of head and neck injury
3) Having musculoskeletal signs and symptoms/disorders that may affect outcome measures (e.g. myofascial pain, inflammation, severe scoliosis, rheumatoid arthritis)
4) Having neurological symptoms/disorders (e.g. numbness, tingling, stroke)
5) Having specific training program of the scapular muscles

The study was approved by Human Experimental Committee of Faculty of Associated Medical Sciences, Chiang Mai University and the informed consent was obtained from each participant prior to commencement of the study.

3.3 Measurements

3.3.1 Questionnaires

3.3.1.1 A screening questionnaire

A screening questionnaire was used to determine if participants met the inclusion and exclusion criteria. Details of the questionnaire were provided in Appendix A1.

3.3.1.2 A general questionnaire

A general questionnaire was used to collect demographic data and characteristics of neck pain. Details of the questionnaire were provided in Appendix A2.

3.3.1.3 Visual Analog Scale (VAS) questionnaire

The VAS was used to assess the intensity of neck pain. It consists of a 10 cm line with 0 on one end, representing no pain and 10 on the other end, representing the worst pain imaginable. The VAS has been shown to be valid and reliable (97). Details of this questionnaire were provided in Appendix A3.

3.3.1.4 Neck Disability Index-Thai Version (NDI-TH) questionnaire

The NDI-TH is a self-rated questionnaire assessing disability due to neck pain. The NDI-TH consists of 10 items including pain intensity, personal care, lifting, reading, headaches, concentration, work, driving, sleeping and recreation. Each item is scored on a 6 point scale (0-5). The total possible score ranges from 0 (the highest level of function) to 50 (the lowest level of function). The total score can be expressed as a percentage (score out of 100). The score of ≤ 8/100 is regarded as no disability, 9-29/100 mild disability, ≥ 30-48/100 moderate disability, 50-69/100 severe disability and > 70/100 complete (98). The NDI-TH has been shown to have a good validity and reliability (99). Details of this questionnaire were provided in Appendix A4.

3.3.2 Ultrasound imaging

USI of the lower trapezius muscle were measured using a real time B-mode ultrasound scanner (Toshiba, Famio 8, SSA-530A, Japan) (Figure 3). A 12 MHz linear array transducer (40-mm footprint) was used to image and measure the lower trapezius muscle at the T8 level (Figure 4). It was placed transversely in the midline over the inferior edge of T8 spinous process and move laterally and horizontally to image the lower trapezius muscle. The echogenic bone of the lamina and spinous process were identified and maintained as a consistent landmark. To obtain the sharpest image of the bone and fascia, the transducer was adjusted and angled slightly in cranial or caudate direction. The images were measured on bilateral sides of neck and recorded in freeze frame mode on the screen monitor of the ultrasound unit. Each image was performed twice on each side. Time interval between images was 30 seconds. The thickness measurements were measured using Image J software program (http://rsb.info.nih.gov/ij/docs/index.html). The thickness of the lower trapezius was taken with a caliper aligned 3 cm lateral to the lateral edge of the spinous process and perpendicular to the inside edge of the fascia borders of the muscle (100) (Figure 5). The average for each side was used for further analysis.

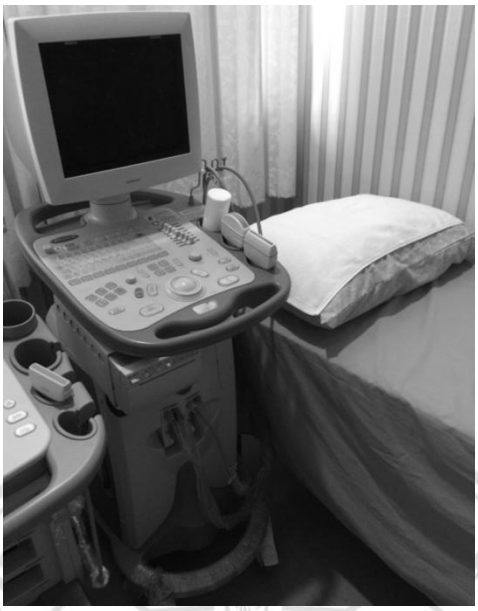

Figure 3 Ultrasound imaging unit

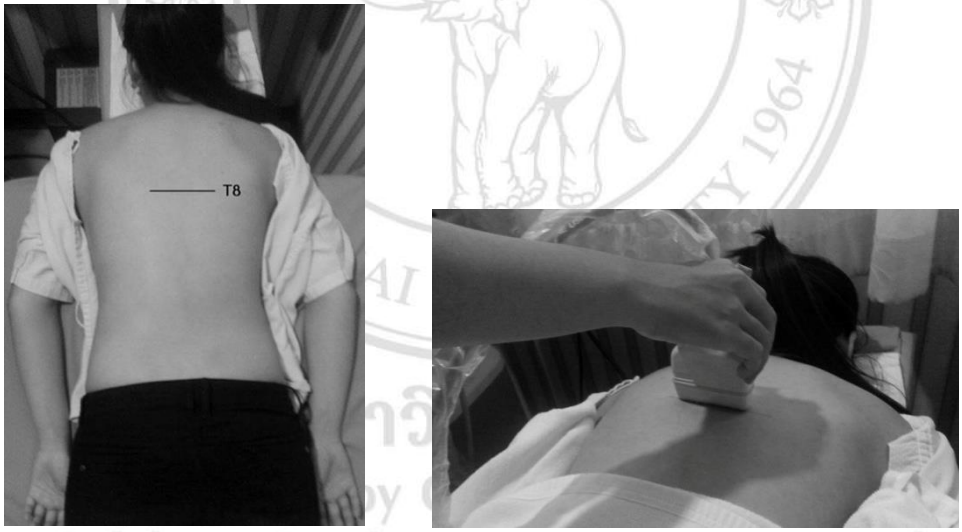

Figure 4 Ultrasound imaging of the lower trapezius muscle thickness at T8

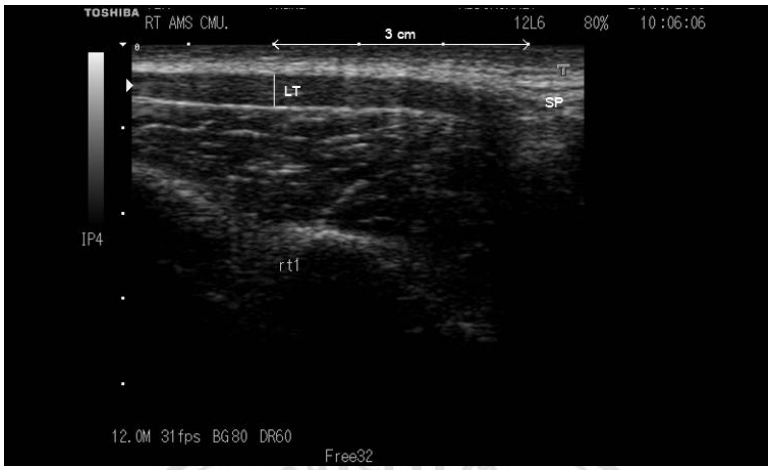

Figure 5 Measurement of the lower trapezius muscle thickness using Image J program

3.4 Procedures

Participants were initially screened for inclusion/exclusion criteria and appointed to attend the study. All eligible participants were asked to refrain from doing moderate to heavy activity of upper limbs and scapular region and taking muscle relaxant medications at least 24 hours before the testing day. On the testing day, all eligible participants were asked to sign the consent form and complete the questionnaires (the general questionnaire, VAS, NDI-TH). The participants were positioned in prone on an examination table with both arms by their sides, the palms facing the ceiling, and ankle supported with a pillow. The participants were rest their face in the hole of the head section of the plinth, which maintains the head and neck position in a neutral position without rotation and side bending. The examiner was palpated the participants' superficial neck and back muscles to ensure that they were relaxed. The spinous process of T8 was identified and marked horizontally with a marker pen as a reference line for placement of the ultrasound probe. The images of the lower trapezius muscles were measured bilateral sides (ipsilateral and contralateral sides of pain) at the resting position. To image the muscle at resting position, the participants were instructed to relax as much as possible. The images were measured twice on each side and the sides tested were measured randomly. The examiner was blinded to the participants' conditions (with or without neck pain). The flowchart for the study procedure was presented in Figure 6.

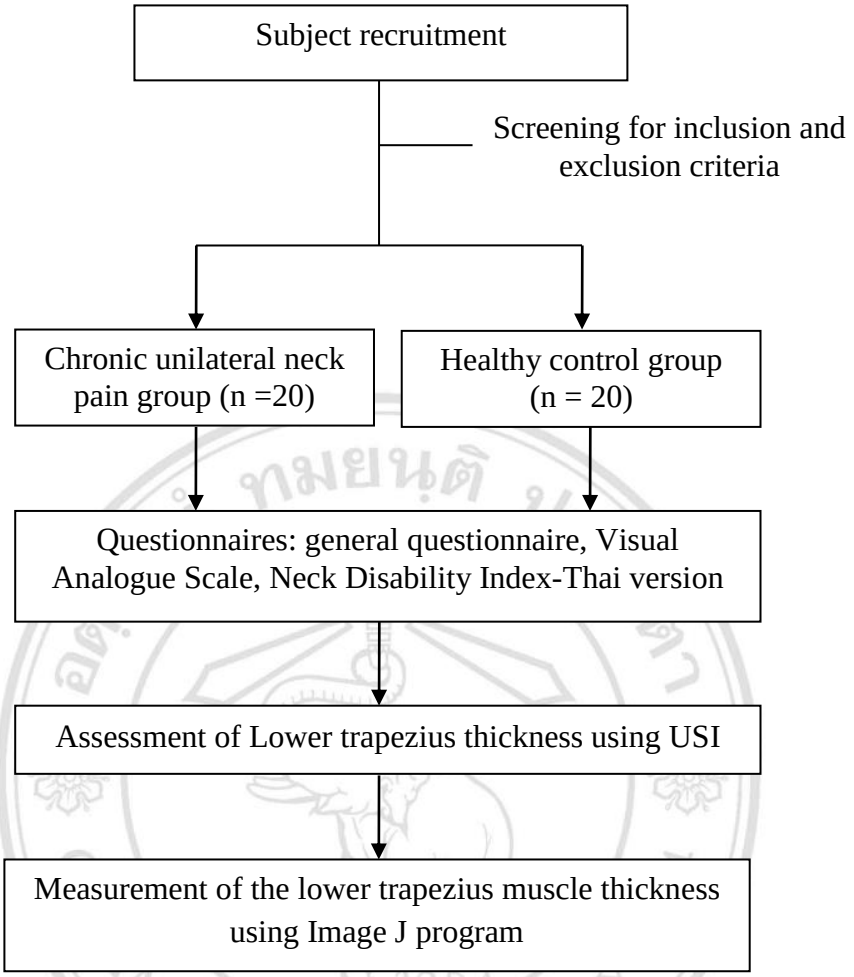

Figure 6 Flowchart of procedure in the study

3.5 Reliability of ultrasound imaging

Inter and intra rater reliability was conducted to ensure that measurements of thickness of the lower trapezius muscle could be used with a confidence to investigate dysfunction of the lower trapezius muscle in the main study. Fifteen healthy participants aged between 18-59 years were recruited into the study. Participants were had no history of neck pain, spine deformity and surgery, and any neuromuscular or neurological conditions.

To assess inter-rater reliability, participants were performed by two investigators (the principal investigator and a physiotherapy research assistant) within the same day. The participants were repositioned between the two measurement occasions. The marking was also wiped using alcohol. The orders of the investigators were determined randomly. The images of the lower trapezius muscle were measured two times on the

right side. The procedure and measurements were the same as those of the main study. The investigators were not presented in the testing room during each other's examination. They also were blinded to the results obtained from the other investigator until the completion of the study (Details of inter-rater reliability were provided in Appendix C1).

For intra-rater reliability, the measurements were measured by the principal investigator on day one and 24 hours later to minimize any memory of the measurements. The images were scanned at the similar time between each day to reduce changes in the muscle activities. The images of the lower trapezius muscle were measured two times on the right side at resting position. The procedure and measurements were the same as those of the main study. The measurement obtained from the first day was concealed until completion of the second measurements (Details of intra-rater reliability were provided in Appendix C2).

3.6 Independent and dependent variables

Independent variables

- Pain side (ipsilateral and contralateral sides) (objective I)
- Subject group (neck pain and control) (objective II)
- Lower trapezius muscle thickness (objective III)

Dependent variables

- The average thickness of the lower trapezius muscle (objective I and II)
- Neck disability Index and visual analogue scores (objective III)

3.7 Statistical analysis

Demographic and characteristic data of all participants were analyzed by using descriptive statistics. All dependent data were tested for normality by using Kolmogorov-Smirnov test. Independent *t*-test was tested for differences in the lower trapezius muscle thickness between groups and dependent *t*-test was tested for differences between sides. Pearson correlation analysis was used to analyze relationships between the VAS and NDI scores and the lower trapezius muscle

thickness. All statistical analyses were undertaken using the Statistics Package of Social Sciences. A level of significance was set at $p < 0.05$ for all analyses.

Inter-and intra-rater reliability was analyzed using intraclass correlation coefficient. ($ICC_{2,1}$ for inter-rater reliability and $ICC_{3,1}$ for intra-rater reliability). The interpretation of ICCs was interpreted below (101).

ICC > 0.90 = High or excellent

ICC 0.75-0.90 = Moderate or acceptable

ICC < 0.75 = Low or inadequate

3.8. Location

The study was conducted at the Radiological Clinic, AMS clinical service center, Faculty of Associated Medical Sciences, Chiang Mai University, Thailand.