CHAPTER 3

METHODS

3.1 Sample size calculation

To estimate the number of subjects to be recruited for the study, the sample size was initially calculated based on the results of Javanshir et al's study (12). Using G*Power 3.0.10. for independent t-test, the estimated sample at a power of 0.8, α = 0.05 required recruitment of 16 subjects (as regards the pressure pain threshold results) and 28 subjects (as regards the cold pain threshold results) for the study. However, the results of the previous study were conducted in a general population. There was no result of similar studies available in elders with neck pain. Therefore, the sample size was then determined based on Roscoe's rule of thumb (77). A minimal sample size of 60 subjects (30 per each group) was recruited for this study.

3.2 Participants

Sixty female elderly participants (30 elders with neck pain and 30 otherwise healthy controls), aged between 65-75 years (78) were recruited into the study from the general community. The age range of 65-75 years is widely considered as young-old (78, 79). Participants were eligible for the study if they met all of the inclusion and none of exclusion criteria. All eligible participants were asked to refrain from taking analgesic/muscle relaxant medications and doing heavy exercise at least 24 hours before the testing day as well as drinking caffeine on the day of testing (12, 80).

3.2.1 Inclusion criteria

Elders with chronic idiopathic neck pain:

1. Having a history of idiopathic neck pain for greater than 3 months
2. Neck pain provoked by neck postures, neck movement, or muscle palpation
3. Neck pain presenting as a predominant symptom
4. NDI-TH score $\geq$ 10 (0-100)
5. Independence in functional abilities

Elders without chronic idiopathic neck pain:

1. No previous history of neck pain for at least 12 months
2. Independence in functional abilities

3.2.2 Exclusion criteria

Elders with and without chronic idiopathic neck pain:

1. Previous history of head, neck and leg injury
2. Previous history of head, neck and leg surgery
3. Any musculoskeletal problems/disorders that would have an effect on measures and for which they have sought for medical treatment (e.g. rheumatoid arthritis, advanced osteoporosis)
4. Neurological abnormalities (e.g. numbness, tingling, pin and needles) or diseases (e.g. stroke, Parkinson's disease, Alzheimer's disease)
5. Psychiatric problems

The study was approved by the Faculty of Associated Medical Sciences research ethic committee and written informed consent was obtained from each participant prior to enrollment into the study.

3.3 Equipments

1. Questionnaires (a screening questionnaire, a general questionnaire, VAS, NDI-TH, TGDS, STAI)
2. Electronic digital algometer (Somedic AB, Sollentuna, Sweden)
3. TSA-II Neurosensory Analyzer (Medoc Ltd., Ramat Yishai, Israel)

3.4 Measurements

3.4.1 Questionnaires

3.4.1.1 A screening questionnaire

A screening questionnaire was used to determine whether participants met the inclusion and exclusion criteria for the study. Details of the questionnaire were provided in Appendix B1.

3.4.1.2 A general questionnaire

A general questionnaire was administered to collect demographic data, comorbid musculoskeletal pain and neck pain characteristics. Details of the questionnaire were provided in Appendix B2.

3.4.1.3 Visual Analogue Scale (VAS)

The VAS was used to assess the intensity of neck pain; pain at its worst, on average and on the testing day (Appendix B3).

3.4.1.4 Neck Disability Index-Thai version (NDI-TH)

The NDI-TH was used to measure self-reported levels of neck pain and disability. The NDI-TH consists of 10 items designed to assess pain intensity, personal care, lifting, reading, headache, concentration, work, driving, sleeping and recreation. The score for each item ranges from 0 to 5, with 5 denoting the lowest level of function. The total score was calculated as the sum of the scores obtained from each item. The NDI-TH score of $\leq$ 8/100 is considered as no disability; 9-29/100 as mild pain and disability; and $\geq$ 30/100 as moderate/severe pain and disability. The NDI-TH has been shown to be a valid and reliable tool for use in Thai populations with neck pain (81). Further details of this questionnaire were provided in Appendix B4.

3.4.1.5 Thai Geriatric Depression Scale (TGDS)

Psychological factors can influence the measure of pain (21, 76). Thus the TGDS was used to measure self-rated depressive symptoms. The TGDS consists of 30 items of the original scale. A total score $\geq$ 13 indicates depressive symptoms (82). The validity of TGDS was shown to be excellent (0.94 for female, 0.91 for male and 0.93 for both) (82). Details of this questionnaire were provided in Appendix B5.

3.4.1.6 Thai version of State Trait Anxiety Inventory (STAI) (83)

The STAI was used to measure the severity of the overall anxiety level (84). The STAI is divided into two sections: the state and trait anxiety. Each section consists of 20 questions. Participants rated their anxiety on a 4-point Likert scale, where 1 = not at all and 4 = mostly. The range of total scores for each section is 20–80, with higher scores indicating a greater level of anxiety. The reliability of STAI-Thai version was shown to be good (0.89) (83). Further details of this questionnaire were provided in Appendix B6.

3.4.2 Quantitative sensory testing (QST)

3.4.2.1 Pressure pain thresholds (PPTs)

Pressure pain thresholds was measured with an electronic digital algometer (Somedic AB, Sollentuna, Sweden), according to the method described by Scott et al (11). The algometer consists of a 1 cm diameter round rubber tip connected to a pressure transducer within the handle of the unit. Pressure was applied at a constant rate of 40 kPa/s (10, 11). Participants were instructed to press a button when the pressure sensation under the probe was perceived as pain. The PPTs were tested over the articular pillars of C5-C6 and the tibialis anterior muscle (upper one-third of the muscle belly) bilaterally three times and the mean values were used for further analysis. A 30-second interval was allowed between measures. An inter-and intra-reliability of PPT measurements was performed prior to data collection and has been shown to be good to excellent. Details of the reliability results were provided in Appendix C.

3.4.2.2 Thermal pain thresholds (TPTs)

Heat and cold pain thresholds were tested with TSA-II Neurosensory Analyzer (Medoc Ltd., Ramat Yishai, Israel), according to the method described by Scott et al (11). A Peltier thermode (30 x 30 mm) was applied directly over the skin. The baseline thermode temperature was set at 30°C with the rate of temperature change being 1°C/s. The maximum cut-out temperature of 50°C was set for heat pain threshold and of 0°C for cold pain threshold. Participants were instructed to press a patient-controlled switch when the heat or cold sensation under the probe first becomes painful. If the warm or cold pain threshold was not reached before the cut-out temperature of 50°C or 0°C, the cut-out temperature of 50°C or 0°C were recorded for that trial. The heat and cold pain thresholds were measured over the mid-cervical region and the tibialis anterior muscle (upper one-third of the muscle belly) bilaterally three times and the mean values were used for further analysis. A 10-second interval was allowed between measures.

3.4.2.3 Supra-threshold heat pain ratings

The supra-threshold is ratings of painful stimulation above threshold (42). The supra-threshold was tested with TSA-II Neurosensory Analyzer (Medoc Ltd., Ramat Yishai, Israel) and a Peltier thermode (30 x 30 mm) was applied directly to the skin. The test was consist of three heat pulses (45°C, 47°C and 49°C) (41). Baseline temperature for each pulse was set at 35°C and increase at a rate of 4°C/s. Each pulse was tested randomly and kept constant for five seconds before returning back to baseline. A 10-second pause was allowed between each pulse. Participants were instructed to rate each pulse using a numerical rate scale (NRS) ranging from 0 (no

pain) to 100 (worst pain imaginable). The supra-threshold heat pain ratings were measured over the mid-cervical region and the tibialis anterior muscle (upper one-third of the muscle belly) bilaterally two times and the mean values were used for further analysis.

3.5 Procedures

Participants were screened for inclusion and exclusion criteria, using a screening questionnaire. On the testing day, all eligible participants received an explanation about the QST measurements and were asked to sign an informed consent form. Each participant completed the general, TGDS and STAI questionnaires. Participants with neck pain also completed the VAS and NDI-TH questionnaires. Practice for familiarization was first given over the medial side of the forearm and the QST then was performed. The QST was tested in a quiet and temperature-controlled laboratory (24°C ± 1°C) (12) and in a standard order: PPTs, HPTs, CPTs and supra-threshold heat pain ratings (11, 12). The QST at the cervical region was measured when the participants were positioned in prone position and over the tibialis anterior muscle (upper one-third of the muscle belly) when the participants were positioned in supine position (11). The QST was tested bilaterally three times at each site, except for supra-thresholds that was tested bilaterally two times. The order of sites (cervical spine and tibialis anterior muscle) and sides (left and right) tested for each QST between each subject was randomized by picking up a number. An assessor was blinded to the subjects' condition for all tests.

3.6 Independent and dependent variables

3.6.1 Independent variables

Subject group (with and without neck pain)

3.6.2 Dependent variables

1. Pressure pain thresholds
2. Heat pain thresholds
3. Cold pain thresholds
4. Supra-threshold heat pain ratings
5. Thai Geriatric Depression Scale score
6. Thai version of State Trait Anxiety inventory score

3.7 Statistical analysis

Participants' demographic and characteristic data were analyzed using descriptive statistics and tested for differences between groups using Independent *t*-test or chi-square test. All dependent data were tested for normality. Parametric statistics were used if the data were normally distributed but if not, nonparametric statistics were used. Paired *t*-test was used to determine differences between sides for PPTs and Wilcoxon Signed Ranks Test for HPTs, CPTs and supra-threshold heat pain ratings. Univariate analysis of co-variance was preliminarily used to investigate influences of co-morbid musculoskeletal pain, TGDS and STAI scores on QST outcomes. No influences of these variables on QST outcomes were found. Therefore, Independent *t*-test was used to determine differences between groups for PPTs, TGDS and STAI scores and Mann-Whitney U test for CPTs, HPTs, and supra-threshold heat

pain ratings. The significant level was set at $p < 0.05$. All statistical analyzes were conducted using SPSS statistical package (version 17.0).

3.8 Data collection location

The study was conducted in the laboratory room at the Department of Physical Therapy, Faculty of Associated Medical Sciences, Chiang Mai University.