

CHAPTER III

METHODOLOGY

3.1 Design and setting

This study is a randomized control trial which conducted in scleroderma patients of rheumatology department at Srinagarind hospital, Khon Kaen University and carried out at the Faculty of Associated Medical Sciences, Khon Kaen University, Thailand.

3.2 Participants

3.2.1 Inclusion criteria

- 3.2.1.1 Patients with SSc: male and female
- 3.2.1.2 Diagnosis: Systemic sclerosis, subtype: diffuse cutaneous Systemic Sclerosis (dcSSc) in indurative phase
- 3.2.1.3 The modified Rodnan skin thickness score (MRSS): 0-2 at dorsum of forearm, hand & proximal phalange of 3rd finger: scale 0 = normal skin thickness, 1 = mild skin thickness, 2 = moderate skin thickness, and 3 = severe skin thickness
- 3.2.1.4 Good consciousness and Co-operation
- 3.2.1.5 Interested in this study and sign consent form
- 3.2.1.6 Experimental groups and the control groups are received routine medication, routine range of motion exercise and heat.
- 3.2.1.7 Patient's relative will be trained Traditional Thai Massage home program by physiotherapist and will massage patient's upper limb at home everyday for 2-week duration.

3.2.2 Exclusion criteria

- 3.2.2.1 Past history: hand surgery within 6 months
- 3.2.2.2 Open wound or ulceration in hand
- 3.2.2.3 Loss of tactile and proprioceptive sensation of hand

- 3.2.3.4 Diabetes mellitus
- 3.2.3.5 Smoking
- 3.2.3.6 Psychiatric conditions



3.3 Sample size

Sample size calculation for mean comparison of two independent groups

Right hand calculation (Dominant hand)

$$n/\text{group} = \frac{2\sigma^2 (Z_\alpha + Z_\beta)^2}{(\mu_1 - \mu_2)^2}$$

- n = Sample size
- σ^2 = Variance of different
- Z_α = $\alpha/2 = Z_{0.025} = 1.96$ (two tailed test)
- Z_β = Power 90%, $Z_{\beta(0.1)} = 1.28$
- $(\mu_1 - \mu_2)^2$ = Different of Mean

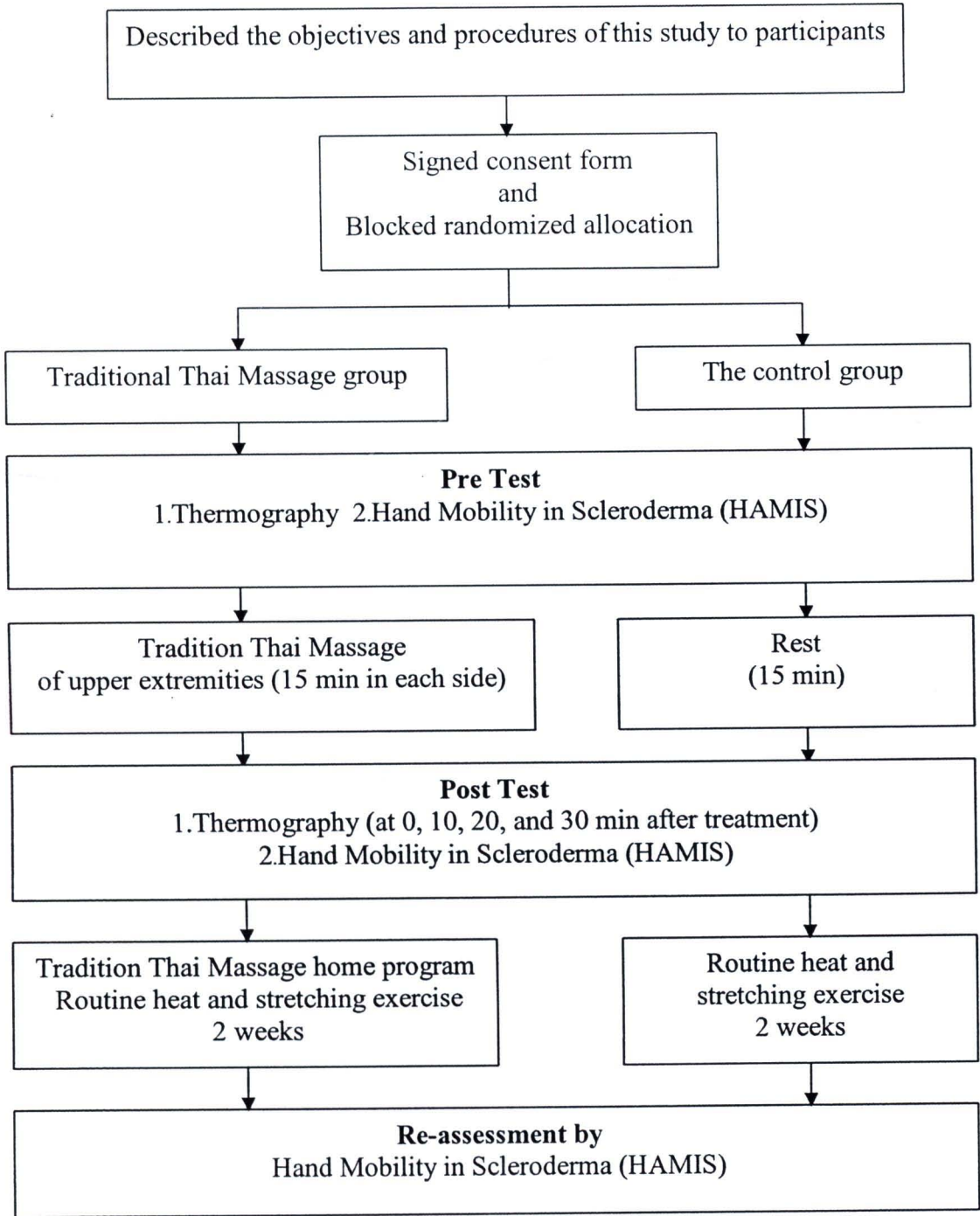
Include 20 percent drop out

$$\begin{aligned} n/\text{group} &= \frac{2(0.59)^2 (1.96 + 1.28)^2}{(1.5 - 20.5)^2} \\ &= 7.927 = 8 \text{ persons (include 20 percent drop out)} \\ &= 10 \text{ persons / group} \end{aligned}$$

All 2 groups = 20 persons

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3.4 Scope of study design



3.5 Method

Scleroderma patients (Diffuse subtype) were recruited in the study. They were asked to sign a consent form and were randomized into Traditional Thai Massage group or the control group by blocked randomized allocation.

3.5.1 Traditional Thai Massage group

Each participant in this group was treated by Traditional Thai Massage at the upper extremities for 30 min (15 min in each side). Hand temperature was investigated by Thermography at pre-treated time and post-treated times (0, 10, 20 and 30 min, respectively). Room temperature was adjusted at 27 Celsius degrees for preventing Raynaud's phenomenon. Hand mobility was investigated by HAMIS at pre and post-treated times (after treatment and 2 weeks later). In this study, patient's relative observed the practice of TTM and they were trained TTM method for caring the patient at home by physical therapist. Therefore, the patient was treated TTM by patient's relative everyday for 2 weeks. At the end of home program session, hand mobility was investigated with HAMIS by physical therapist.

3.5.2 The control group

Each participant in the control group was asked to rest in supine position for 15 min in each side. The environment was controlled as same as the experimental groups. Thermography was used at pre-treated time and post-treated times (0, 10, 20 and 30 min, respectively). Hand mobility was investigated by HAMIS at pre and post-treated times (after treatment and 2 weeks later). After the first investigation, patient was received routine treatment (heat, ROM exercise and medication) during 2 weeks. However, participant was treated by TTM as same as the experimental group at the end of this study.

3.6 Outcome measures

3.6.1 Thermography

Starting position for evaluation of hand temperature was sitting position. Participant placed the hand in mid position into the insulation box. Thermography was applied to the dorsum of the hand. Hand temperature was recorded in Celsius degree. Data were collected in Thermography software. The detail

of thermography was shown in Appendix A. Certification of Thermography (FlukeTi1) was showed in Appendix B.

3.6.2 Hand Mobility in Scleroderma (HAMIS)

HAMIS is a performance index that consists of 9 items (Appendix C). (Sandqvist, Eklund, 2000b). Assessing the hand movements included in an ordinary ROM test such as pronation and supination of the forearm, volar flexion and dorsal extension of the wrist, finger flexion and extension and thumb abduction.

It also evaluates the ability to make a thumb pincer grip and to make finger abduction. Each exercise is graded on a 0-3 scales, where 0 corresponds to normal function and 3 determines that the patient is unable to perform the task.

In this study, each participant was sit in starting position and performed the test following by 9 items in HAMIS under the instruction of physical therapist.

3.7 Instruments

3.7.1 Thermography (Fluke model Ti1 thermal imagers)

3.7.2 Hand Mobility in Scleroderma (HAMIS)

3.7.3 Cylinder objects, diameter 5, 15, 30, 60, 70 and 90 millimeter respectively and spool of thread

3.7.4 Coconut oil for lubrication

3.7.5 Stopwatch

3.7.6 Massage bed

3.8 Statistical analysis

Data of hand temperature were expressed as mean \pm SD and HAMIS in median:(Q1-Q3). Significance difference between Traditional Thai Massage and the control group of hand temperature was determined by using Independent sample t test and HAMIS by using Mann Whitney U test. Significance difference internal group of time periods in Traditional Thai Massage and the control group of hand temperature and HAMIS was determined by using one way repeated measure ANNOVA and Friedman test. The differences between groups are significant difference at p-value<0.05.