CHAPTER 3

Methods

3. Methods

3.1 Subjects

Patients who had been diagnosed with ESRD and received hemodialysis at the Chiang Mai Kidney Clinic voluntarily participated in this study. Patients were selected under close supervision of an expert physician who was one of the investigators. The sample size was calculated based on the results of Giannaki et al. (14) using G*Power 3.1 for an independent t-test, the estimated sample at a power of 0.8, a value of $\alpha = 0.05$ required the recruitment of 14 subjects (hemodialysis with RLS) for the study. Patients who met the inclusion and exclusion criteria were divided into two groups, which were the hemodialysis with RLS group (n = 14) and the hemodialysis without RLS group (n = 14). Patients in the RLS group were diagnosed as RLS by a nephrologist using the IRLSSG criteria. The study protocol was approved by the Ethics Committee of the Faculty of Associated Medical Sciences, Chiang Mai University.

The inclusion and exclusion criteria were as follows:

Inclusion criteria

1. Hemodialysis patient aged > 20 years old, both male and female.

2. Received hemodialysis treatment 3 times/week for at least 3 months.

3. Had stable medical condition, including hemoglobin ≥ 10 g/dl and Kt/Vurea ≥ 1.2

4. Patients in the RLS group were diagnosed as RLS by a nephrologist using the IRLSSG criteria (6, 14). All four essential criteria must be met for a positive diagnosis. The essential criteria for RLS were as follows:

4.1. An urge to move the legs, usually accompanied or caused by uncomfortable and unpleasant sensations in the legs.

4.2. The urge to move or unpleasant sensations begin or worsen during periods of rest or inactivity, such as lying or sitting.

4.3. The urge to move or unpleasant sensations are partially or totally relieved by movement, such as walking or stretching, at least as long as the activity continues.

4.4. The urge to move or unpleasant sensations are worse in the evening or night than during the day or only occur in the evening or night.

5. Abled to walk independently without assistive device.

6. Had Mini-Mental State Examination (MMSE-Thai 2002) score more than 24 (88)

Exclusion criteria

1. Had cardiopulmonary disorders that affect tests, such as coronary artery disease, unstable angina, arrhythmia, myocardial infections prior to or within 6 weeks, asthma, or uncontrolled hypertension.

2. Had musculoskeletal disorder or neurological conditions that affect tests, such as severely arthritic knee, Parkinson's disease, stroke, or multiple sclerosis.

3. Had diabetic mellitus.

4. Unable to understand verbal communication.

5. Uncorrected vision or hearing impairment.

6. Patients who took any medication that might affect testing e.g., muscle relaxant drug.

7. Had enrolled in other RLS studies.

3.2 Equipment

1. Personal data collection form

2. Stopwatch (CASIO STOPWATCH HS-3, CHINA)

3. Standard chair (height of 45 cm)

4. Traffic cone

5. Pulse oxymeter (MASIMOTM, CA, USA)

6. Sphygmomanometer (HM-1100, Japan)

7. Modified Borg score (scale 0-10)

8. Measurement tape (Stanley, power lock)

3.3 Procedures

The experimental procedure of this study is presented in figure 1. Patients who met the inclusion and exclusion criteria were received information about study. After patients understood and decided to participate in the study, they signed a consent form. Next, the patients were asked to enter their personal information. The vital signs included heart rate, blood pressure, and respiratory rate were measured. If the vital signs were not in the normal range, the test was postponed. Weight and height was measured and recorded. Physical performance test including the sit-to-stand-to-sit test (STS) and the 6- minute walk test (6MWT) were performed.

Physical performance test was started with the sit-to-stand-to-sit test for 10 repetitions (STS-10). Patients started by sitting in a chair. Patients were asked to transition from sitting to standing to sitting as fast as they could for 10 repetitions. Patients had to fully extend in the standing position with their arms folded across their chests with rest between tests of five minutes. Time was recorded in seconds. Next, the sit-to-stand-to-sit test for 60 seconds (STS-60) was carried out. Patients started by sitting in a chair. Patients were asked to transition from sitting to standing to sitting as fast as they could for 60 seconds. In this test, patients must fully extend in the standing position with their arms folded across their chests with rest between tests of five minutes. The number of repetitions achieved in 60 seconds was recorded. The 6MWT was carried out after that. Patients were asked to walk along a 20-meter walkway. The patients were instructed to walk from end to end, turned at the cone mark without stopping, covered as much distance as they could in 6 minutes without running or jogging, but they were allowed to slow down or stop as necessary. The patients were received instruction and encouragement according to the standard procedures of the American Thoracic Society for the measurement of the 6MWT (85). Parameters including heart rate, blood pressure, respiratory rate, oxygen saturation, and a rating of perceived exertion (Borg

score, scale 0-10) of the legs and whole body was recorded before and immediated after performed the walking test. Distance was measured after the patient walks at his/her own pace at the individual's fastest speed in the period of 6 minutes, and data was recorded.

3.4 Independent and dependent variables

7.4.1 Independent variable

Subject group (hemodialysis patients with and without RLS)

7.4.2 Dependent variables

STS test was used to evaluate the lower extremity muscle strength and muscle endurance

6MWT was used to evaluate cardiopulmonary fitness.

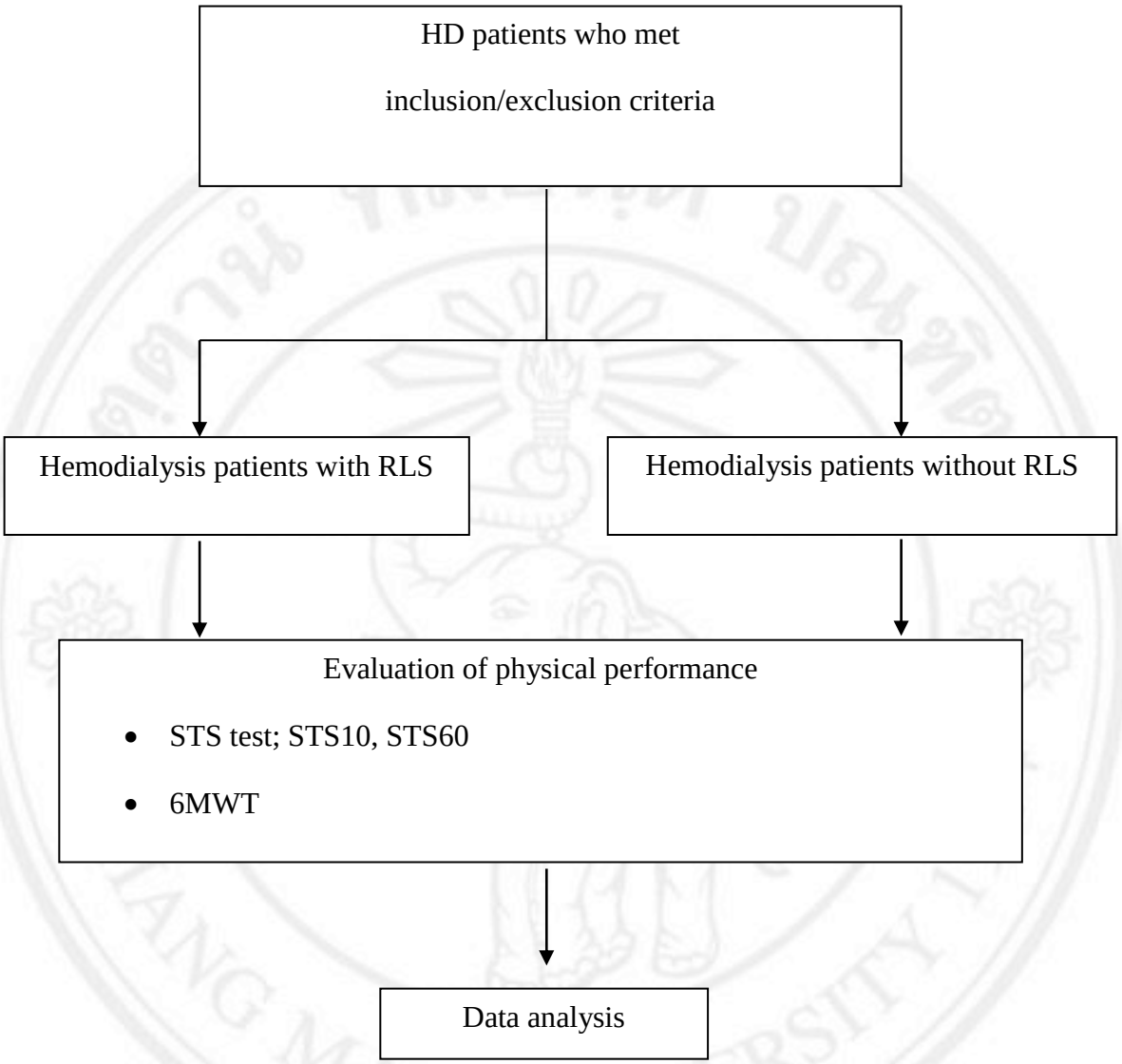

Figure 1 Experimental procedure

3.5 Location

3.5.1 The data collection was performed at Chiang Mai Kidney Clinic, Chiang Mai.

3.5.2 The data analysis was performed at the Department of Physical Therapy, Faculty of Associated Medical Sciences, Chiang Mai University.

3.6 Statistical analysis

Descriptive statistics were used to report demographic data. A measure independent t-test for parametric distribution was used to compare the differences between hemodialysis patients with and without RLS. All statistical analyses were used SPSS for data analysis. A probability level of 0.05 was set to denote significance.