CHAPTER 3

Methods

3.1 Participants

Participants were recruited from communities in Chiang Mai province (Muang district and vicinity) through flyers and poster announcement.

A G*Power 3.1.7 program, a statistical power analysis program for the biomedical science, was used to determine the number of participants (sample size) required in the present study. The sample size was calculated based on a study by Kennedy et al (79) which indicated a minimal level of detectable change for the self-pact walking time test for calculation of the effect size. The calculated effect size is 0.6 (medium to large effect size). Therefore, to achieve 80% statistical power with an alpha level of 0.05 for a dependent mean study design, at least 24 participants were required.

Inclusion criteria

Individuals of both genders were eligible for the study if they are aged ≥ 50 years and diagnosed with unilateral knee OA by an orthopedic surgeon based on the clinical criteria of the American College of Rheumatology (17) with mild to moderate severity (86).

Exclusion criteria

Individuals were excluded from the study if:

- They were diagnosed with other knee conditions such as rheumatoid arthritis, gouty arthritis, or fractures of the lower extremity.

- They were diagnosed with neurological disorders, cardiovascular diseases or other medical conditions that compromise physical function such as stroke, brain injury, Parkinson's disease or uncontrolled hypertension.
- They had previous surgery in the knee or hip total or partial prosthesis of the knees or hips

3.2 Instrument

1. Knee Orthoses (knee sleeve and unloading knee braces)
2. Height-adjustable chair
3. Stopwatch (Casio® HS-3(V), Tokyo, Japan)
4. Tape measure
5. Bright-colored masking tape

Knee orthoses

Two types of off-the-shelf knee bracing for knee OA (knee sleeve and unloading knee brace) were used (Figure 2).

- Knee sleeve: FUTURO™ Comfort Lift Knee Support (3M, St. Paul, MN, USA) was selected based on information on monthly sales statistics at Out-patient Pharmacy Unit, Pharmacy Department, Maharaj Nakorn Chiang Mai Hospital.
- Unloading knee brace: FLA OA/Arthritis Knee Support Brace (BSN medical Inc., Charlotte, NC, USA.) met criteria of unloading knee brace as it provides the off-loading mechanism through hinge and strapping system to apply a corrective force to the knee joint.

The properties and characteristics of the two selected knee braces are comparable to those used in previous studies (11, 12, 87). According to the manufacturers, both types of knee braces are available in different sizes for individually fit. The size was chosen based on knee circumference (Appendix B). The knee orthoses were fit according to the manufacturer's instructions.

(A)  (B) 

Figure 2 (A) Knee sleeve (B) OA knee brace

3.3 Procedures

The thesis proposal was approved by the Research Ethics Committee of the Faculty of Associated Medical Science Chiang Mai University. Prior to data collection, participants were informed on the procedures to be performed, and provided written informed consent. Upon agreement to participate, participants' demographic data including age, body height, body mass, history about knee pain and a self-report questionnaire were obtained. The Thai version of the Knee injury and Osteoarthritis Outcome Score (KOOS) was used to assess self-reported knee disability. The Thai KOOS consists of 42 items in five separately scored subscales: KOOS Pain, KOOS Symptoms, Function in daily living (KOOS ADL), Function in Sport and Recreation (KOOS Sport/Rec), and knee-related Quality of Life (KOOS QOL). The participants were also asked to indicate on scale, the degree of pain and difficulty he/she experienced on their knee OA condition in the previous month. The response is in a form of 11-point Likert scale. Level of pain and difficulty was indicated as following: 0 = None, 5 = Moderate, 10 = Extremely (57). After completing all the tests, the participants indicated the knee orthosis that they felt most satisfied with.

Performance-based measures of function were performed during one testing session. There were three testing conditions for each participant; a condition without knee orthosis and two conditions with different knee orthoses in random order. An experienced physical therapist was responsible for preparing the test environment and timing or counting the test outcomes. A testing assistant was responsible for taking care of the participants and ensuring the participant safety during the administration of the test.

For all participants, the condition without knee orthosis was tested first to serve as baseline data. The two conditions with different knee orthoses were counter-balancing to eliminate testing order effect. Half of participants (n = 14) was assigned to perform the tests while wearing a simple knee sleeve first and the other half (n = 14) was tested while wearing an unloading knee brace first. Flowchart of data collection procedure is shown in Figure 3.

The sequence of the performance-based to be administered was from less to more vigorous intensity physical activity to eliminate fatigue effect. Therefore, participants performed the 30-second chair stand test first; followed by the 40-meter fast paced walk test and the stair climb test was performed last. At the end of each test, each participant was asked with pain rating by use of the Numerical Rating Scale (NRS) for pain. Participants were allowed to rest between tests as long as needed until pain and symptoms reduced, with are minimum of ten minutes between tests to avoid excessive fatigue (88).

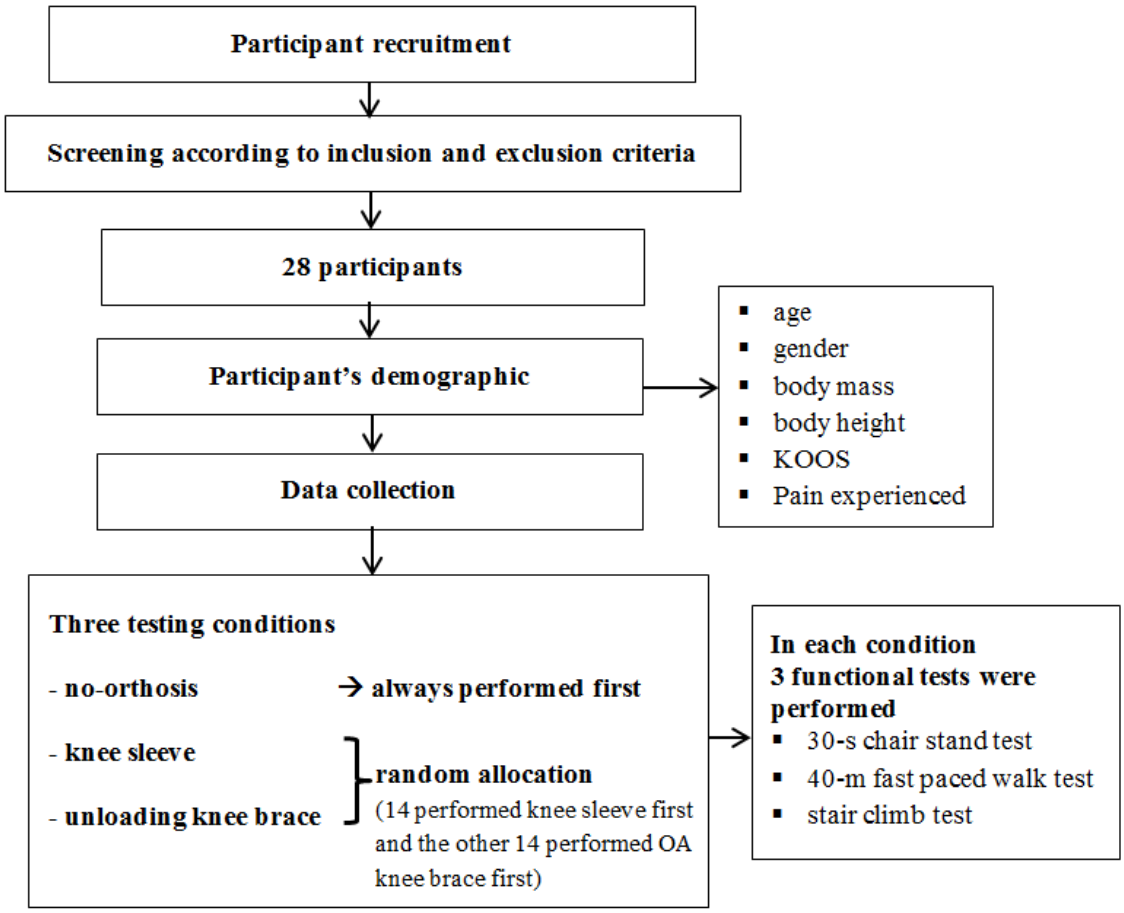

Figure 3 Flowchart of data collection procedure

3.4 Primary outcome measures

Three functional performance-based tests were obtained during a single testing session. The functional performance-based tests consisted of a 30-second chair stand test, a 40-meter fast paced walk test, a stair climb test. One trial was performed for each type of test. For all tests, the participants were informed to wear their habitual and comfortable footwear.

3.4.1 A 30-second chair stand test (14, 71)

A 30-s chair stand test was administered using a chair without an armrest, with adjustable seat height to eliminate the effect of participants' varying height. For each participant, seat height was adjusted to 110% lower leg length (89). The chair was placed against a wall to prevent it from moving during the test.

For the starting position, the participant was seated in the middle of the chair, back straight, feet approximately shoulder-width apart and placed firmly on the floor at an angle slightly back from the knees. The arms were crossed at the wrists and held against the chest.

Prior to the trial, a demonstration of a proper form of sit-to-stand movement was performed by the tester. A practice trial of one repetition was given to check proper form of movement. For the actual test, at the signal "go" the participant rose to a full stand (hips and knees fully extended) and then returned back to the initial seated position without touching the back of chair. The participants were encouraged to complete as many full stands as possible and within 30 seconds. The tester monitored the participant's performance to assure proper form while silently counted the completion of each correct stand.

The performance score was the total number of stands executed correctly within 30 seconds. Up and down movement equals one stand. A movement of more than halfway up at the end of 30 seconds was counted as a full stand. Incorrect stands were not be counted.

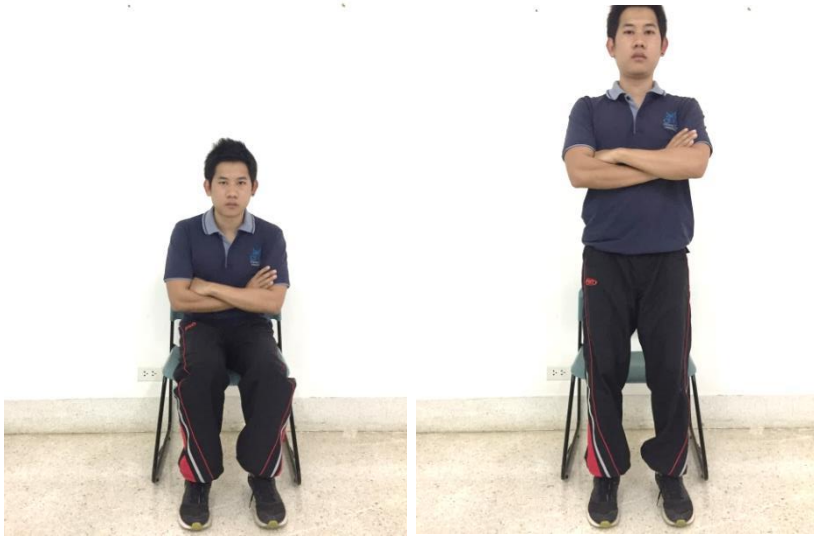

Figure 4 A 30-second chair stand test

3.4.2 A 40-meter fast paced walk test (14)

The participants completed the 40-meter walk test in a hallway (4 lengths of a 10-meter course). The 10-meter walkway was measured and marked with long strips of bright-colored masking tape at the beginning and end of the course. Cones were placed approximately 2 meter before the start mark and beyond the finish mark of the 10-m walkway to indicate turning.

Before the actual test, the tester demonstrated the proper manner of walking that is expected. The participants were asked to walk as quickly but as safely as possible without compromising safety, such as running, along a 10-m walkway and then turned around a cone, returned then repeated again for a total distance of 40 meters (3 turns). During the actual walking test, participants were given an instruction, "When I want you to start, I will say ready, begin." When the participants started walking, the stopwatch started, and the tester followed slightly behind and to the side of the participant. The tester stopped timing as soon as the participant's first heel completely crossed the strip of the finish mark tape.

The performance score was the time recorded starting on the signal to start at the start line and terminating once the participants crossed back over the start line after completing the 40 m (4x10 m). Timing was paused during the participant turns around the cone and resumed once they crossed the mark lines again. Time of one trial was recorded to the nearest 100th of a second and expressed as speed meter/second by dividing distance by time. Regular walking aid was allowed and was noted down.

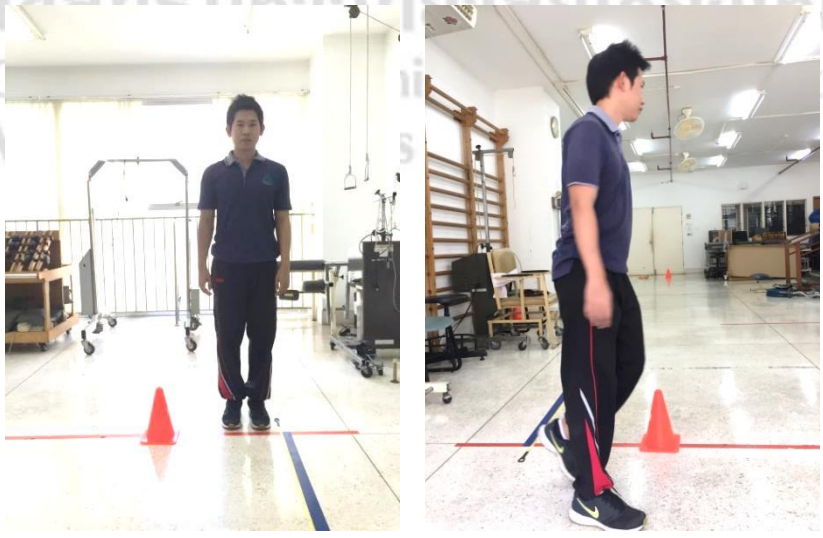

Figure 5 A 40-meter fast paced walk test

3.4.3 A stair climb test (14)

A stair climb test was administered using a flight of stairs, consisting of 10 steps with step rise of 16 cm, step tread of 30.5 cm, and step width of 185 cm.

Prior to the trial, demonstrations of the proper way of going up and down stairs were performed by the tester. Participants were instructed to ascend and descend the flight of stairs as quickly as possible while still ensuring safety. Participants were allowed to perform one practice trial for familiarization, and to verify their understanding of the test and instructions given.

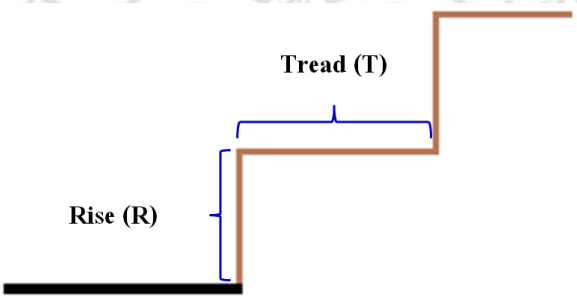

Figure 6 Rise and tread of regular stairs

For the starting position, the participants were positioned in front of a flight of stairs. They were then asked to ascend the stairs, turn around, and go down, as fast as possible, but safely to prevent them from falling. The tester guarded behind/below the participants while going up the stairs and ahead/to the side while coming down the stairs.

During the actual walking test, the participants were given the verbal command, “When I want you to start, I will say ready, begin.” “For this test, do the best you can by going as fast as you can but don’t push yourself to a point of overexertion or beyond what you think is safe for you”. When the participant started walking up the stairs, the stopwatch started. Once the participants came back down to the starting point and completely stopped moving (the participant's feet were no longer on the steps), the stopwatch stopped. During the test, the participants may stop and rest if needed but the timer kept going.

The performance score was the time recorded, starting from the signal to start and terminates when the participants returned with both feet to the ground level. Total time to ascend and descend steps for 1 test trial was recorded to nearest 100th of a second. The use of any walking aid or handrail was allowed and recorded.

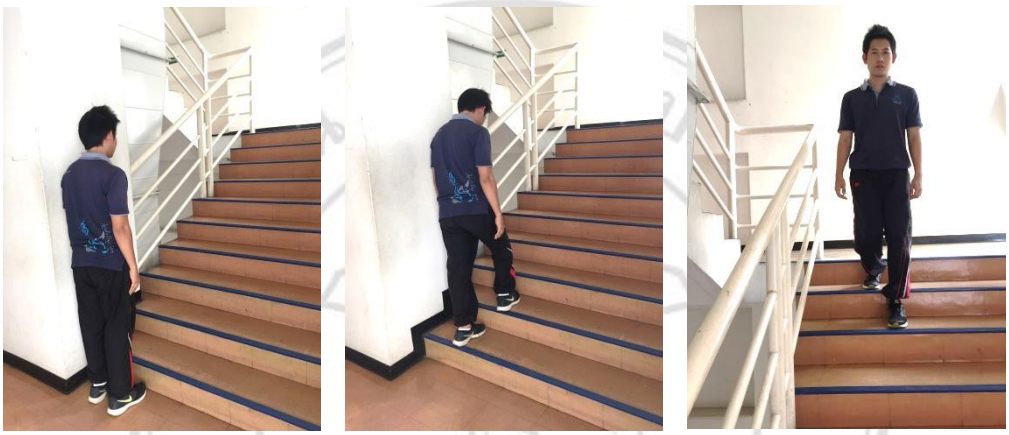

Figure 7 A stair climb test

3.5 Secondary outcome measure

Pain scale

The Numerical Rating Scale (NRS) for pain was used to quantify the pain of the participants after each performance-based test (90, 91). The scale consisted of an 11-point numeric scale (NRS 11) with 0 representing “no pain” and 10 representing “pain as bad as you can imagine” or “worst pain imaginable”. Participants were asked to indicate the numeric value on the scale that best describes their pain intensity.

3.6 Statistical Analysis

Descriptive statistics was used to describe the demographic characteristics of the participants. A one-way repeated measure analysis of variance was used to determine the effect of different knee brace conditions on the primary outcomes of the study (the performance score of the 30-second chair stand test, the 40-meter fast paced walk test, and the stair climb test. The Friedman test was used to compare the secondary outcomes of the study (the Numerical Rating Scale (NRS) for pain). A chi-square test was used to determine whether the pain experienced in the previous month was related to patient’s preference of the orthosis. The statistical packages for social sciences (SPSS) version 17.0 was used for all statistical analysis. The level of significance was set at $p < 0.05$.

3.7 Reliability of the scores of the functional performance-based tests

Test-retest reliability of the scores of the functional performance-based tests without wearing orthosis was determined prior to the main study. Five participants were randomly chosen from list of potential participants to determine test-retest statistics. Participants were retested within the same day after at least 1-hour rest from the first test session. Intraclass correlation coefficient was used to determine the test-retest reliability.

3.8 Location

Exercise room, 3rd floor, 12-story Building, Department of Physical Therapy, Faculty of Associated Medical Sciences, Chiang Mai University.