CHAPTER 3

METHOD

3.1 Study design

Randomized-controlled with single blind design.

3.2 Blinding procedure

This section deals with issues regarding facilitation of the blinding status of the investigator in this study. The investigator who evaluated outcomes was not known the condition of group randomization.

3.3 Randomized assignment

Controlled random allocation helped to reduce bias and any potential order effects between the experimental conditions (39-41). Participants were selected randomly using concealed envelop into two groups (e.g. Pilates-based conditioning group, control group).

3.4 Participants

Forty healthy male and female volunteers (age 20-45 years) were recruited into the study (9, 12, 15, 17-19). Participants were randomly divided into 2 groups: 20 subjects in Pilates-based training, and 20 subjects in control groups. The Pilates training group attend 45 minutes, 2 times per week for a period of 8 week-duration (42). In the control group, the participants were allowed to perform normal activities.

Control group was also permitted to perform normally exercise or sport activities less than 2 times per week and should not be greater than 30 minutes per session. Each subject gave informed consent prior to entry into the study and ethical clearance was obtained from the Research Ethics Committee of the Faculty of Associated Medical Sciences.

3.5 Inclusion / exclusion criteria

Subjects were eligible to participate if they (14):

1). are 20-45 years of age.

2). have no back pain at least 2 months before attending the study

3).indicate a willingness to participate in the daily exercise program during the training period and to participate in supervised exercise sessions, 2 times a week.

Subjects were excluded if they (43):

1). have participate in any kind of exercise and sport activities more than 30 minutes for 2 times or more per week

2). have a diagnosed psychological illness or taking anti-depressant drugs

3). have difficulty understanding written and spoken Thai (which preclude them from completing questionnaires)

4). have diagnosed inflammatory joint disease

5). have overt neurological signs (e.g., sensory deficits, motor paralysis)

6). have low back or abdominal surgery, diabetes, cardiovascular conditions, or current pregnancy

3.6 Outcome measures

3.6.1 The lumbo-pelvic stability test

A stabilizer pressure biofeedback unit or PBU (Chattanooga Group, Inc.) will be used to directly monitor lumbo-pelvic stability (Figure 1). It has been shown to be a reliable and valid equipment for evaluation of deep abdominal muscle function (44), lumbar stabilization (45) and rotational control (46).

The subjects were in supine crook position, with 70 degrees of hip flexion to place the lumbar spine in mid-position (45). A barrier was positioned to standardized and limit leg movement to 90 degree hip flexion (Figure 2). After randomly selecting the initial test leg, the PBU was placed beneath the lumbar spine from S1 to L1 and inflated to 40 mmHg. The resting leg was placed on weighting scales ensuring that the subject was not pushing through this leg for stability and counterbalance (47). Subjects were instructed to breath in and out, and then held the abdominal hollowing action throughout, beginning the test movement on the end of exhalation (48). A unilateral heel-lift in the sagittal plane was performed requiring flexion of the hip from the starting position (70 degrees), to the barrier (90 degrees) (Figure 3), then returning to 70 degrees with the knee flexed approximately 35-40 degrees (49). An ability to maintain the registered pressure at 40 mmHg (± 2 mmHg) during this maneuver indicates a successful performance. The investigator was blinded to the exercise grouping of the subjects, their intra-tested reliability was examined in pilot study prior to the study commencing.

Figure 1 Stabilizer pressure biofeedback unit or PBU (Chattanooga Group, Inc.).

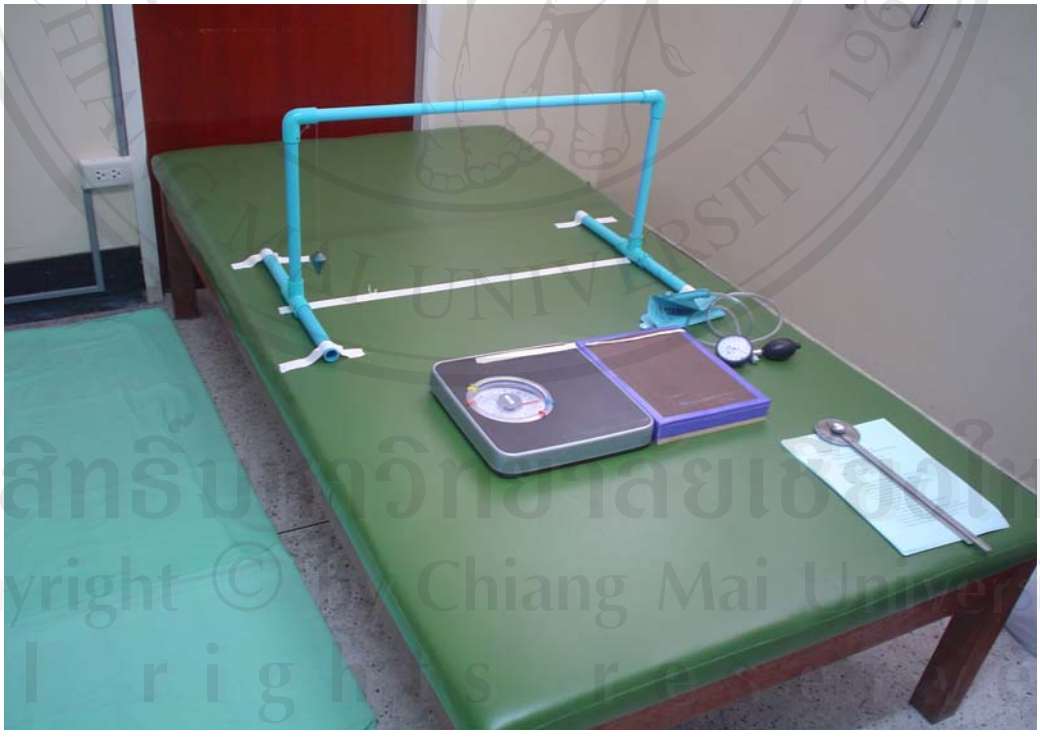

Figure 2 Lumbo-pelvic movement control testing equipment (i.e., Barrier, scale, monometer, and Pressure Biofeedback Units).

Figure 3 Lumbo-pelvic movement control test.

3.6.2 Sit-and-reach flexibility test

The sit-and-reach test has been commonly used to assess low back and hip joint flexibility (50). The test demonstrated a good intra-reliability (ICC 0.99)(51, 52). Methods for administering this test are recommended as following (53):

1. The participant's shoes should be removed.
2. The participant sits with legs extended which are held in the position of zero degree and heels are placed against the edge of the box.
3. The participant should slowly reach forward with both hands as far as possible, holding this position momentarily. It is also recommended that the participant refrain from test, jerky movements, which may increase the possibility of an injury. Be sure that participant keeps the hands parallel

and does not lead with one hand. Fingertips can be overlapped and should be in contact with measuring portion of the sit-and-reach box (Figure 4).

4. The score is the most distant point (centimeters) reached with the fingertips. The participant performs this for 2 times and the best score will be used for data analysis. To assist with the best attempt, the participant should exhale and drop the head between the arms when reaching. Testers should ensure that the knees should be pressed down. The participant should breathe normally during the test and should not hold his or her breathe at any time (54).

Figure 4 Sit-and-reach box test.

3.6.3 Psychological stress test

Stress was assessed using Stress Inventory (Sensitivity=70.4, specificity=64.6, and Cronbach's Alpha coefficient=0.86) (36). The Stress inventory test consists of 20 items (see appendix). Participants were asked to respond to each item on scale from 1 "not al all" to 4 "very much so", which it takes for 5-10 minutes to complete questionnaire. Therefore, the total scores ranges from 0-60 with higher scores indicating greater stress. On the stress scale, participants were asked to respond to each item based on how they "generally feel".

3.7 Pilates exercise program:

The instructor in this study was a certified physiotherapist. The Pilates class consists of 10 subjects for each group (2 groups in total). There was 45 minutes, 2 times per week for a period of 8 weeks duration in total. Modification of Pilates-based training program was consistent with those detailed in Comprehensive Mat Pilates-based concepts (55). The exercise program was progressed in difficulty during the second 2-month periods of training. During the initial period (0-1st month) and the second period (1st-2nd month) involved a standard Pilates-based mat exercises as following:

Week 1-4

Pilates program consisted of 10 minutes in warm-up, 25 minutes in exercise, and 10 minutes in cool down phases. Each position of Pilates exercise was performed for 3 repetitions with controlling breathing pattern (55).

Warm-up phase

1. Powerhouse control (breathing control) in standing position
2. Powerhouse control with arm movement
3. Powerhouse control with shoulder flexion/extension
4. Spine stretch in squat position
5. Spine stretch in finger-to-floor position.

Exercise phase

1. Leg slides
2. Spine curls
3. Hip rolls
4. Single knee folds (Figure 5)
5. Abdominal curl-ups
6. Single leg circle with knee flexion
7. Single leg circle with knee extension
8. Basic one hundred
9. One hundred with single knee flexion raise
10. One hundred with double leg raise
11. Roll up in sitting position
12. Roll up in lying to sitting position with knee flexion
13. Roll up in lying to long sitting position
14. Spine stretch in sitting position
15. Spine stretch forward in long sitting position
16. The saw

Cool-down phase

1. Spine stretch in finger-to-floor position
2. Powerhouse control with both arms abduction in standing position
3. Powerhouse control with both arms flexion
4. Powerhouse control with relaxation

Figure 5 Pilates exercise initial period.

Week 4-8

Advanced Pilates program consisted of 10 minutes in warm-up, 25 minutes in exercise, and 10 minutes in cool down phases. Each position of Pilates exercise was performed for 3 repetitions with controlling breathing pattern (55).

Warm-up phase

1. Powerhouse control (breathing control) in standing position with both arms flexion
2. Spine stretch in squat position
3. Back stretch with push-up
4. Spine curls
6. Abdominal curls up.

Exercise phase

1. Double knee fold
2. Single leg circles with knee extension
3. One hundred with both knee flexion
4. One hundred with both knee extension and hip flexion 70 degrees
5. One hundred with knee extension and hip flexion 30 degrees (Figure 6)
6. Roll up in sitting position
7. Single leg stretch
8. Double leg stretch
9. Straight single leg raises
10. Criss-cross

11. Spine stretch forward
12. Neck pull
13. Spine twists
14. Side kicks (front and back)
15. Side kick lift
16. Push-up

Cool-down phase

1. Spinal stretching in finger-to-floor position
2. Powerhouse control with both arms abduction in standing position
3. Powerhouse control with both arms flexion
4. Powerhouse control in sitting position with relaxation

Figure 6 Pilates exercise advanced period.

3.8 The study procedures

1. The first step was to recruit the volunteers from public by a combination of media releases (e.g. advertising on notice boards, letter and university's web-board)
2. Volunteers were then screened for their suitability as mention in the inclusion/exclusion criteria.
3. Each subject gave informed consent prior to entry into the study, and ethical clearance was obtained from the Institutional Review Board.
4. Participants were selected randomly using concealed envelop into two groups (e.g. Pilates-based conditioning group, control group).
5. All outcomes measures (flexibility, lumbo-pelvic stability test, psychological test was evaluated at pre-test (0 week), 4 weeks, and 8 weeks of the studying program. The sequence of the outcome measures was measured randomly to reduce bias.
6. All participants were asked to record their exercise/sport activities and special performance in the daily logbook
7. The Pilates-based conditioning group commenced within a week after the base-line data was collected. The Pilates-based conditioning was designed into 4 weeks of basic training and 4 weeks of advanced training. The Pilates group was asked to participate in exercise 2 times per week, for approximately 45 minutes of each session and for a total of 8 weeks in duration. In total, the Pilates group participants would attend a minimum of 12 sessions.

3.9 Statistical Analysis

All statistical analysis will be undertaken using statistical software package.

3.9.1 Lumbo-pelvic movement control data

To determine whether a pass/fail in the lumbo-pelvic movement stability test, an extended X^2 test was performed using cross tabulation at 0, 4, and 8 weeks after training at significance level of 5%.

3.9.2 Flexibility data

The flexibility data was analyzed by using ANOVA to determine whether a better flexibility at 0, 4, and 8 weeks after training.

3.9.3 Psychological stress data

The statistical hypothesis was tested by using pre-test and post-test scores from the Stress Inventory questionnaire as dependent variables. The non-parametric statistical, Friedman's test was used to describe the pre-test and post-test scores at 0, 4 and 8 weeks after training. Mann-Whitney statistical test was analyzed the difference between control and Pilates groups.

3.10 Location

The study was conducted in the exercise room at the Department of Physical Therapy, Faculty of Associated Medical Sciences.

3.11 Duration

The data collection commenced in June and completed in December 2005. The overall study took approximately seven months to complete.