Chapter 3
Methodology

3.1 Location and study time

Research was conducted at Department of Physical Therapy, Faculty of Allied Health Sciences, Thammasat University (Rangsit Campus).

Study period was eighteen months which started from August 2008 to March 2010.

3.2 Ethical Approval

The study was approved by the University Human Research Ethics Committee of Thammasat University (MTU-P-1-38/51) on 23 September 2008.

3.3 Instrumentations

3.3.1 Questionnaire about personal information (Appendix D)

3.3.2 Questionnaire about work-related factors and habitual physical activity (Appendix D)

3.3.3 Questionnaire about LBP history (Appendix D)

3.3.4 Modified Oswestry LBP disability questionnaire (Thai) (Appendix D)

3.3.5 History and physical examination form (Appendix D)

3.3.6 Isokinetic Biodex™ System-3 (Biodex Corp Shirley, NY) as shown in figure 3.9

3.3.7 Stabilizer ™ pressure bio-feedback (CHATTANOOGA Group, INC) as shown in figure 3.8

3.3.8 Stopwatch

3.3.9 Table with belts

3.3.10 Tape measurement

3.3.11 Sit-and-reach box for measuring the flexibility of the legs

3.3.12 Blood pressure measuring machine

3.3.13 Computer

3.3.14 Computer program for statistical analysis

3.3 Population

3.3.1 Population and sample size calculations

Staff aged 18-45 years, worked only at Thammasat University Rangsit Campus, both male and female with experienced in current job at least 1 continuous year were recruited.

Research was a form of a prospective cohort study of proportion, so the sample size can be calculated by the following formula (Pathummanon, 1998) ;

$$N = \frac{Z_a{}^2 \, PQ}{d^2}$$

The assumptions were as follows

N = total population

Z_a = Z value from the standardize table of type I error at α

P = proportion of the incidence of LBP is expected to be found

Q = 1 - P

d = the width of the error acceptable (The unit of measurement compared with P)

In the study to determine incidence of LBP in staff at Thammasat University Rangsit Campus only, supposed that the incidence was estimated for 10% and the 95% confidence interval was needed, so the error would not exceed 2.5%. (allow incidence to differ materially from actual values not exceeding 2.5% or up from 7.5% to 12.5%, which is equal to the width of 5%).

$$N = \frac{1.96^2 \times (0.1) \times (0.9)}{(0.025)^2}$$

$$= 553.19 = 554 + \text{non-responder } 10\% = 610$$

That was the samples of 610 staff in this study.

Inclusion criteria, volunteer who had no history of LBP during the past 6 months distinguished by the questionnaire which volunteer answered "no" in the question number 1 and 2 about low back history and an examination.

3.3.2 Exclusion criteria;

3.3.2.1 could not communicate

3.3.2.2 could not read out

3.3.2.3 had serious chronic diseases including hypertension disease, diabetes and coronary heart disease, kidney disease and cancer

3.3.2.4 LBP with leg pain (radicular pain)

3.3.2.5 neurological disorders

3.3.2.6 pregnant

3.3.2.7 had history of abdominal surgery

3.3.2.8 structural scoliosis

3.3.2.9 hypolordorsis or hyperlordosis of lumbar spine

3.3.2.10 other musculoskeletal disorders may hinder the assessment of trunk muscle performance including leg length discrepency is longer than 1 cm., had different flexibility of trunk and leg muscle less than 3 cm in male and less than 5 cm in females.

Criteria to terminate the program; Volunteer conditions were complications that was attributable to receive medical cause. Volunteers left from current job or death or terminate participation in the project or end time in this study takes 6 months.

3.4 Research Procedures

3.4.1 Phase 1 cross-sectional study. The aim of this phase was to evaluate the 6-month prevalence and risk factors of LBP among Thammasat University staff.

Step 1

Review literature related to the questionnaire in order to bring content and language improvements. After the questionnaire was proved, the reliability and accuracy was conducted in a population of 30 Thammasat University staff to improve questionnaire.

Step 2

Researcher contacted the Division of Personnel, Thammasat University for information for staff database. Staff who regularly worked only at Rangsit Campus, aged between 18-45 years, both male and female and had experience as a continuous current of at least 1 year were recruited. Staff was surveyed by questionnaire set sent

to each agency personnel. This set contains the documents detailed the research projects, application consent form and questionnaire sets. A set of self-reported questionnaires including 3 questionnaires; first was about personal history, second was resume and habitual activity and the third questionnaire was about back pain history. Staff who answered "ever" in the question number 1 and "yes" in the question number 2 in the LBP history questionnaire that meant they had a history of LBP during the past 6 months would be excluded from the study. Moreover, staff with a underlying disease that impede muscle performance assessments, such as heart disease, high blood pressure, pregnant would be also excluded from participating in this study.

3.4.2 Phase 2 cohort study. The aim was to evaluate the 6-month incidence of LBP and the effect of trunk muscle performances among Thammasat University staff.

Step 1

Researcher made appointments with the volunteers through phone for physical examination and trunk muscle performance evaluation at The Department of Physical Therapy, Faculty of Allied Health Sciences, Thammasat University. Researcher took of medical history and clinical examination for screening lower back abnormalities that took approximately 30 minutes. If the examination was found the exclusion criteria, the volunteers would be excluded from the study. In addition, researcher would measure and record blood pressure at rest before and after the test. Once through the examination successfully, volunteer warmed up the body before the trunk muscle performance evaluations by stretching back and abdominal muscles. Then volunteer should practice actual movement with testing tools.

1. Evaluation of spinal stability. The starting position providing volunteers laid in the supine with knee bend about 90 degrees, arms placed aside the body, and placed feet flat on the floor. Researcher put a Stabilizer ™ pressure bio-feedback under the lower back of the volunteers as shown in Figure 3.1.

Figure 3.1 Stabilizer ™ pressure bio-feedback (CHATTANOOGA Group, INC).

The lower edge of the air bag match the sacral bone level 2 (S_2) and the upper edge on the lumbar vertebrae level 1 (L_1) (Thongjunjua, 2007 1505). All subject were received 10 minutes for training session before the pretest. Training exercise helped volunteer to learn how to use back muscle as well as abdominal muscle to stabilize the lumbar spine before the pretest. Moreover, this training helped volunteer to be accustomed to pressure transducer before the pretest. The training session before pretest consisted of abdominal breathing, volunteers were in supine lying with knee bent and feet flat on the floor. The researcher laid the weigh or book approximately 1 kg on the belly and below the navel. Volunteers took one hand on the chest and another hand on the abdomen. When subjects inhaled, they kept their chest stable while abdominal expands. When they exhaled, they let abdominal recoil toward the spine and continued this pattern for 5 minutes without rotation of pelvis, muscles around shoulder contraction, and muscles around hip contraction. Before actual test, the researcher pumped the air into the air bag for 40 mmHg and then closed the valve. Criteria for passing each level was pressure changes not over or less than $\pm$ 4 mmHg. The test composed of 6 levels that repeated 3 continuous rounds with normal breathing cylce in each level. Researcher recorded the highest level that volunteer could done as following;

Figure 3.2 The testing position of spinal stability with the Stabilizer ™ pressure bio-feedback

Figure 3.3 The testing position of spinal stability with the Stabilizer ™ pressure bio-feedback in level 1

Level 1: Volunteers placed hands on lower belly navel to realize a sense of contraction of the muscle belly. Researcher issueed to volunteer to relax trunk muscles that line the spine in neutral alignment. Volunteers started testing while breathing in and out around 3 consecutive times, then while exhaling while contracting the stomach muscles and pull up the top umbilicus (abdominal hollowing) do hold while breathing in and out normally, repeated 3 continuous rounds with normal breathing cylce. If pressure did not change more than ± 4 mmHg that meant the test level 1 completed.

Figure 3.4 The testing position of spinal stability with the Stabilizer ™ pressure bio-feedback in level 2

Level 2: Volunteer was set at the same position. Exhaled while contracting the abdominal muscles and pull up the top umbilicus (abdominal hollowing) do hold while inhaling to open with the right knee out 45 degrees and the left leg placed no movement. Exhaled with the right knee close to pull back from positions, repeated 3 continuous rounds with normal breathing cylce. If pressure did not change more than ± 4 mmHg that meant the test level 2 completed.

Figure 3.5 The testing position of spinal stability with the Stabilizer ™ pressure bio-feedback in level 3

Level 3: Volunteer was set at the same position. Exhaled while contracting the abdominal muscles and pull up the top umbilicus (abdominal hollowing) do hold while inhaling stretches with the right knee by the thigh at the same level with the left leg. Then exhale while pulling the right leg back to starting position, repeated 3 continuous rounds with normal breathing cylce. If pressure did not change more than ±4 mmHg that meant the test level 3 completed.

Figure 3.6 The testing position of spinal stability with the Stabilizer ™ pressure bio-feedback in level 4

Level 4: Volunteer was set at the same position. Exhaled while contracting the abdominal muscles and pull up the top umbilicus (abdominal hollowing) a hold time of inhalation with the right knee toward chest. Until the hip flex about 90 degrees while the knees bend comfortably. Then exhaled with the right leg pulled back from positions, repeated 3 continuous rounds with normal breathing cylce. If pressure did not change more than ± 4 mmHg that meant the test level 4 completed.
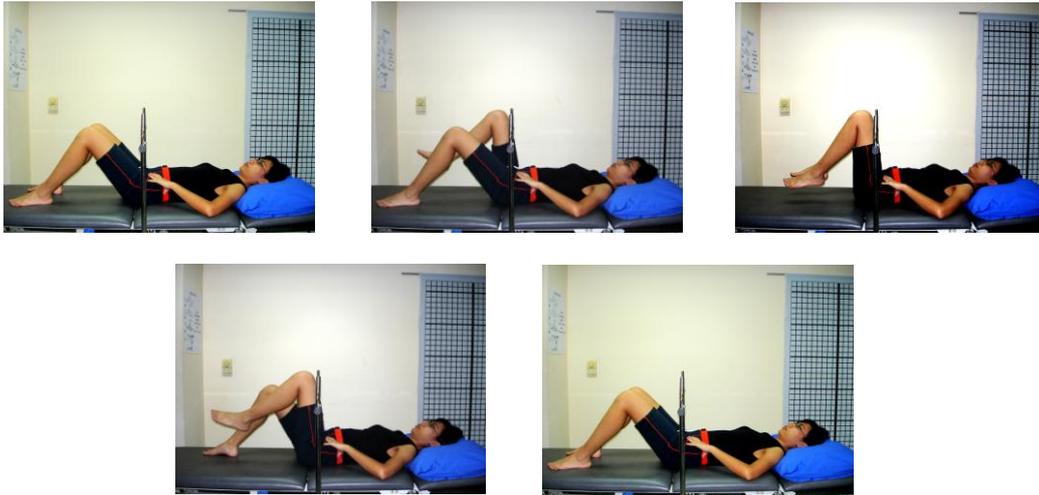
Figure 3.7 The testing position of spinal stability with the Stabilizer ™ pressure bio-feedback in level 5

Level 5 : Volunteer was set at the same position. Exhaled while contracting the abdominal muscles and pull up the top umbilicus (abdominal hollowing). While inhalation pulled the right knee toward chest until an estimated 90 degrees hip bend and held the right knee in the position. Then exhaled while the left leg raised with the same right leg. Then inhaled with right leg to pull back to starting position. Then exhaled while pulling the left leg back to starting position. Repeated 3 continuous rounds with normal breathing cylce. If pressure did not change more than ± 4 mmHg that meant the test level 5 completed.

Figure 3.8 The testing position of spinal stability with the Stabilizer ™ pressure bio-feedback in level 6

Level 6: Volunteer was set at the same position. Exhaled while contracting the abdominal muscles and pull up the top umbilicus (abdominal hollowing) do hold. While the inhalation pulled both knees toward chest until an estimated 90 degrees hip

bend with both knees in the bending position. Then exhaled with put both leg back to the starting position. Repeated 3 continuous rounds with normal breathing cylce. If pressure did not change more than ± 4 mmHg that meant the test level 6 completed.

2. Assessment of trunk muscle performance by using the Isokinetic Biodex [TM] System-3. Arranged the volunteer in the semi-standing position that placed the anterior superior iliac spine on match point of the center of dynamometer. Knees position were extended for 15 degrees and feet placed on the foot-pedal with belts. Chose the type of test con/con at the test speed of 60, 90, 120 degrees per second (Piriyaprasarth, 1999 1564). Overall 100 degrees of movement (Iwai, et al., 2004 1336) was set in each speed test. Volunteers had to practice the movement by 2 repetitions of submaximal contractions in the direction the extension and flexion, and followed by 2 repetitions of maximal muscle contraction. After that followed by the actual test 1 set provide maximal contraction 3 repetitions in each test speed with 180 seconds rest period between each repetition.
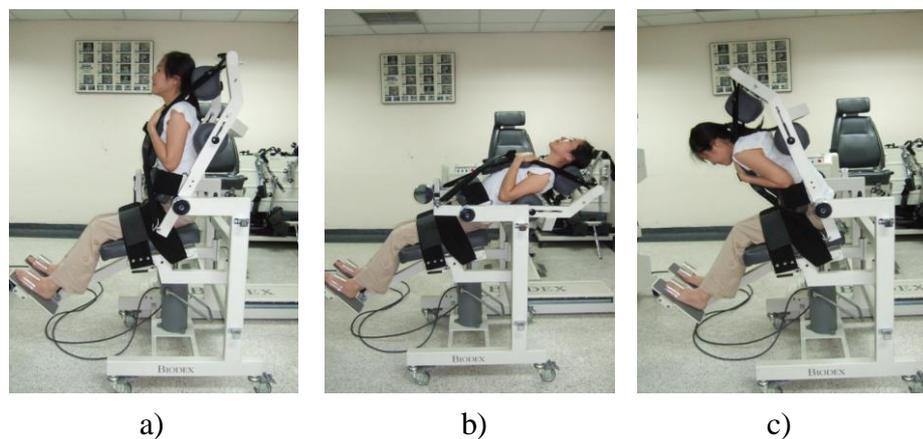

| a) | b) | c) |

Figure 3.9 The position semi-standing on the Isokinetic Biodex [TM] System-3;
a) starting position, b) trunk extension, c) trunk flexion

3. Test the endurance of the back muscles (Sorensen Test). Arranged the volunteer in prone lying position set the line between both the anterior superior iliac spine on the edge of bed while supprted the upper part of body by a chair. Fasten 3

straps to held both legs. Command volunteer to held back muscle contraction until the upper part of body is still floating on the floor (0 degree). Researcher recorded time that volunteer can held the trunk parallel to the floor as long as possible. Stopped timer when the upper part of body tilt into a corner over 10 degrees from the edge of bed. Measured a degree change by gravitational goniometer which attached on thoracic spine level $_1$ (T 1) (Moreau, et al., 2001).

Figure 3.10 The position for endurance test of back muscle (Sorensen Test)

Step 2 The 6-month follow-up period after the first trunk muscle performance evaluation.

After 6 months of first evaluation, researcher followed up by sending questionnaires about back pain history and Modified Oswestry LBP Disability questionnaire (Thai version) direct to volunteers. The questionnaires were sending back by mail or official messenger within 2 weeks. If volunteers did not respond, the researcher would re-send the quesionnaires to volunteers again. If they still did not respond, the researcher would follow by telephone interview.

3.5 Statistical data analysis

All data were coded and entered into Epidata software. Statistical analyses were conducted using STATA (Version 9.0). Frequency and percentage was used to describe qualitative data. Mean and standard deviation was used to describe quantitative data. The 6-month prevalence of LBP stratified by demographic characteristics, work-related characteristics and Habitual Physical Activity levels were calculated including their 95% confidence interval (95%CI). Chi-square and

Fischer' exact test were used to compare the characteristics between the LBP and non-LBP group. For quantitative data that is normally distributed statistics Unpaired t-test tested differences between groups. If not normally distributed, the Mann-Whitney test statistic testing differences between groups. Multiple logistic regression was used to explore risk factors on the 6-month prevalence of LBP. Variables that were associated with the LBP at the level of 0.20 from univariate analysis were selected into the multiple logistic model. The final model included gender, nutritional level, education, marital status, work-activity in a day, and habitual physical activity level. The Likelihood Ratio test (LRT) was used to test the parameter associated with the LBP by comparing the models with and without the referring parameter. All variable levels were coded so that the reference level (OR = 1) represented the hypothetical advantageous level concerning increased LBP. The Wald test was performed to test the significance of each level compared with the reference level on particular parameter. All tests were set the significance level at 0.05.