

CHAPTER III

RESEARCH METHODOLOGY

3.1. Research design

A cross-sectional study was conducted to determine the association between particular factors and the presence of foot pain during the past month in pre-retirement aged.

3.2. Study area

The study was conducted at Chulalongkorn University, Thailand.

3.3. Study population

The staff of Chulalongkorn University with pre-retirement aged between 50 and 60 years who still have been working were recruited into the study.

3.4. Sampling technique

Cluster sampling technique was used to select the organizations within Chulalongkorn University. Then, the staff within the selected organization who were willing to participate and had age between 50 and 60 years would be recruited for the study. The self-reported questionnaires and physical examination tests for foot region were used in the present study.

3.4.1 Inclusion criteria of the subjects are 1) pre-retirement aged between 50 and 60 years who still have been working 2) staff of Chulalongkorn University 3) working at Chulalongkorn University more than 1 year, and 4) willing to participate in the research.

3.4.2 Exclusion criteria of the subjects are the participants with these conditions at least one item: 1) injury from accident at foot region (i.e. ankle sprain, open wound at foot region) for the last 1 month 2) history of foot fracture 3) history

of operation at foot 4) foot osteoarthritis 5) congenital spine abnormality 6) congenital foot abnormality 7) rheumatoid arthritis 8) cancer 9) gout 10) diabetes mellitus 11) osteoporosis 12) systemic lupus erythematosus (SLE) 13) neurological diseases (i.e. Stroke, Parkinson's disease).

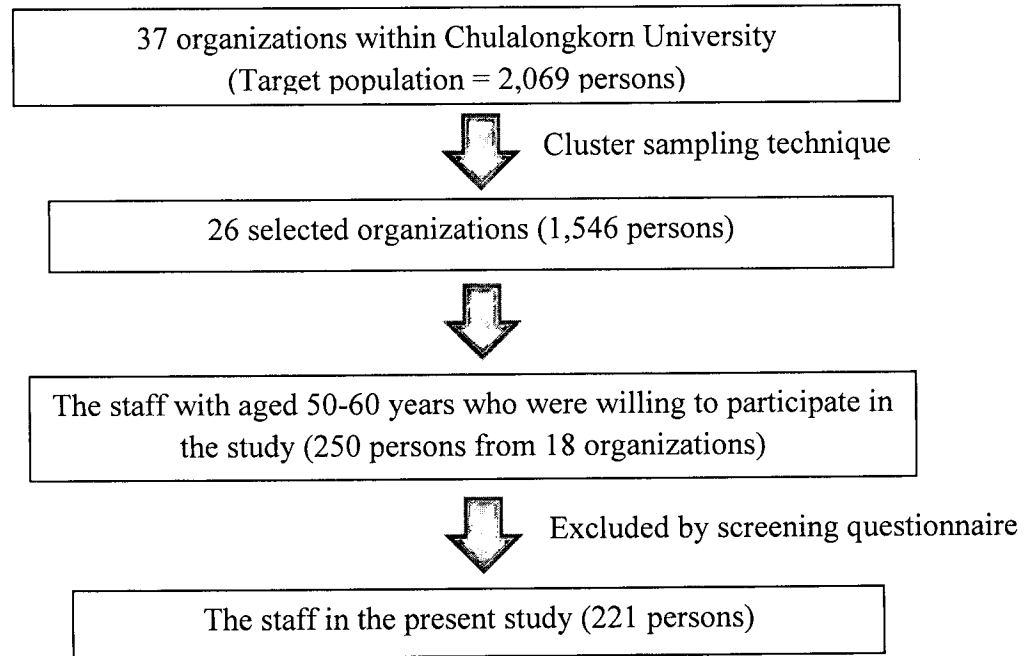


Figure 3: Sampling technique in the present study

3.5. Sample size

The sample sizes in the present study were calculated from the formula of Yamane (1967). When sample size for precision (e) = $\pm 5\%$, confidence level = 95%, $P = 0.5$, and the size of population (N) = 2,069, so the sample size (n) = 336.

$$n = \frac{N}{1 + N(e)^2}$$

After 10% add-up to cover the missing value, the sample size should be 370 participants.

3.6. Measurement Tools

3.6.1 Subjective Examination

The content of the survey questionnaire in this study was developed based on literature review and a set of standardized questionnaires. A self-reported questionnaire was divided into 6 sections consisting of individuality, work-related physical factors, health behavior, quality of life, history of MSDs during the last 12 months, and foot pain assessment. The individuality, work-related physical factors, and health behavior sections were developed based on literature review. Health-related quality of life was adapted from a 12-item short-form health survey (SF-12) Thai version (Chariyalertsak et al., 2011). The prevalences of MSDs at lower back and lower extremities during the last 12 months were collected by Standardized Nordic questionnaires (Kuorinka, et al., 1987). Also, the prevalence of foot pain during the past month was assessed by the Manchester foot pain and disability index (MFPDI) Thai version (Yamsri and Pensri, 2011).

3.6.2 Physical Examination

The anthropometric variables in the present study were assessed by the physiotherapist including data on body mass index, waist hip ratio, foot problem, types of foot posture, types of foot arch, foot muscles strength, and leg length.

3.6.2.1 Foot problem assessment

Checklist questions (Menz et al., 2001) that were used to report foot problem consisted of the presence of callus formation (the area with hard skin from high pressure), lesser toe deformities (i.e. claw toes, hammer toe, mallet toe), and hallux valgus deformities/bunions (a bony prominence usually defined as lateral deviations of great toe at the metatarsophalangeal joint caused painful and inflammation). The checklist that was adapted from the Manchester scale categorized each deformity into three levels of the severity i.e. mild, moderate, and severe (Garrow et al., 2001).

3.6.2.2 Foot posture index (FPI)

The measurement of foot posture index was described by Redmond et al., (1998). The participants were instructed by the examiner to stand still about 2 minutes in relax position with arms by side and look straight ahead. Then, the examiner assessed the foot posture and reported the scores on left and right sides with six items of figure 3.

Rearfoot Score	-2	-1	0	1	2
Talar head palpation	Talar head palpable on lateral side/but not on medial side	Talar head palpable on lateral side/slightly palpable on medial side	Talar head equally palpable on lateral and medial side	Talar head slightly palpable on lateral side/ palpable on medial side	Talar head not palpable on lateral side/ but palpable on medial side
Curves above and below the malleoli	Curve below the malleolus either straight or convex	Curve below the malleolus concave, but flatter/ more shallow than the curve above the malleolus	Both infra and supra malleolar curves roughly equal	Curve below malleolus more concave than curve above malleolus	Curve below malleolus markedly more concave than curve above malleolus
Calcaneal inversion/eversion	More than an estimated 5° inverted (varus)	Between vertical and an estimated 5° inverted (varus)	Vertical	Between vertical and an estimated 5° everted (valgus)	More than an estimated 5° everted (valgus)
Forefoot Score	-2	-1	0	1	2
Talo-navicular congruence	Area of TNJ markedly concave	Area of TNJ slightly, but definitely concave	Area of TNJ flat	Area of TNJ bulging slightly	Area of TNJ bulging markedly
Medial arch height	Arch high and acutely angled towards the posterior end of the medial arch	Arch moderately high and slightly acute posteriorly	Arch height normal and concentrically curved	Arch lowered with some flattening in the central portion	Arch very low with severe flattening in the central portion – arch making ground contact
Forefoot abd/adduction	No lateral toes visible. Medial toes clearly visible	Medial toes clearly more visible than lateral	Medial and lateral toes equally visible	Lateral toes clearly more visible than medial	No medial toes visible. Lateral toes clearly visible

Figure 4: Scoring assessment in each item of Foot posture Index (FPI)
(Keenan et al., 2007)

The sum of scores from six items was used to predict the types of foot posture which consisted of normal foot (scores from 0 to +5), pronated foot (scores from +6 to +9), highly pronated foot (score from +10 to +12), supinated foot (score from -1 to -4), and highly supinated foot (score from -5 to -12) (Keenan et al., 2007).

3.6.2.3 Staheli's arch index (SAI)

Staheli's arch index (SAI) was used to describe the types of foot arch from footprint analysis (Staheli et al., 1987). The present study used podograph to perform the static footprint (Kanatli et al., 2001; Urry and Wearing, 2005). As seen in Figure 6, the participants were instructed by the examiner to take a step of non-tested foot on one side of podograph, followed by the placement of tested foot on the inked mat of podograph. Then, the examiner asked the participants to walk off the podograph by the tested foot first, followed by the non-tested foot. As shown in Figure 7, the footprint was used to calculate SAI. It was obtained by calculating the ratio of the width in mid-foot region (A) divided by the width in heel region (B). The value of SAI between 0.44 and 0.89 was defined as normal arch. Therefore, the value less than 0.44 and more than 0.89 were defined as high arch and flat arch, respectively (Onodera et al., 2008).

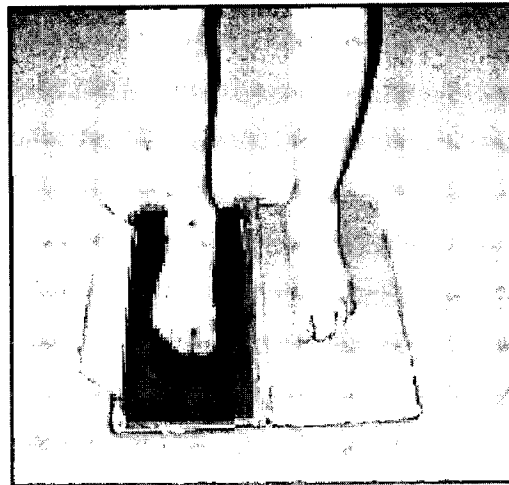


Figure 5: Static footprint on Podograph

(Kanatli et al., 2001; Urry and Wearing, 2005)

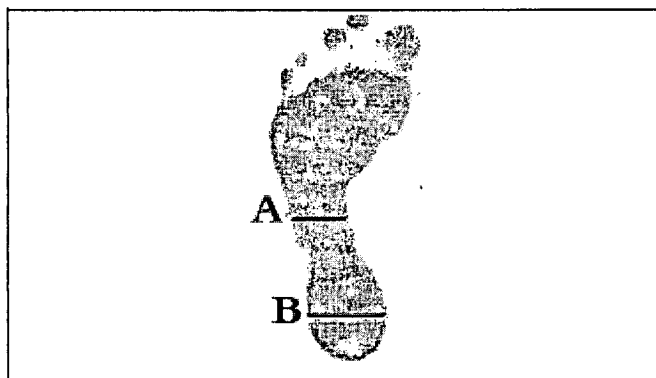


Figure 6: The Satheli's arch index measurement
(Staheli et al., 1987)

3.6.2.5 Foot muscles strength testing

The foot muscle strength was measured by paper grip test (PGT1, PGT2) for foot intrinsic muscles and manual muscle testing of ankle dorsiflexors and plantarflexors for foot extrinsic muscles followed by the study of Keysor et al., (2005) and Menz et al., (2006). Considering paper grip test, the participants were instructed by the examiner in sitting position to hold the piece of solid rough paper (2X10 cm, 100 g/m² type) against the force of physical therapist under the phalange of great toe (for PGT1) and under the lesser toes (for PGT2) as shown in Figure 7 (de Win et al., 2002). The examiner reported “Pass” level for the normal and “Fail” level for the weakness of foot intrinsic muscles.

Regarding ankle dorsiflexor strength testing, the examiner asked the participants to perform ankle dorsiflexion and hold against the force of examiner at dorsal foot surface in sitting position (Daniels and Worthingham, 2002). There were three levels of foot extrinsic muscle testing i.e. normal, good, and fair levels. The normal level was reported if the participants could hold ankle dorsiflexion through full range of movement; the good level was reported in case of inability to hold through full range

of movement; and the fair level was reported in case of inability to hold ankle dorsiflexion against the force of examiner. The strength of ankle plantarflexor was then measured in standing position. The examiner asked the participants to raise heel on tip toes through full range of flexion with knee straight and then go down to complete one time. The examiner reported fair level for repeating 1-9 times; good level for repeating 10-19 times; and normal level for repeating more than 19 times.



Figure 7: Paper grip test (de Win et al., 2002)

3.6.2.6 Leg length measurement

Leg length was measured in upright standing position with the distance from the tip of the greater trochanter to the floor through the lateral malleolus (Elbaz et al., 2009). The examiner reported “Equal” for the same distance of both sides and “Unequal” for a different distance of both sides. The intrarater reliability were assessed in the pilot study and shown very good agreement of kappa level with the kappa coefficient of 1.000 (APPENDIX H).

3.7. Validity and Reliability test

3.7.1 Validity test

The screening and self-reported questionnaires were reviewed by 3 experts to score each item (+1, 0, -1) in aspect of content validity. The summation of all the scores was then calculated by the formula to assess Index of item-Objective Congruence (IOC) (Rovinelli and Hambleton, 1977). The results from calculation of IOC are 1.00 for the screening questionnaire and 0.79 for the self-reported questionnaire which are higher than 0.5 and reach the acceptable level (APPENDIX H).

3.7.2 Reliability test

To determine the test-retest reliability of the screening and self-reported questionnaire, the questionnaires were pre-tested in 30 subjects between 50 and 60 years of age. All subjects performed the questionnaire for two times, 1-week apart. The reliability of the questionnaires was determined by Kappa coefficient for categorical data and Intraclass correlation coefficient for continuous data (Landis and Koch, 1977; Bowling, 2002). The present study has the coefficients ranged from 0.713 to 1.000 for the screening questionnaire and ranged from 0.611 to 1.000 for the self-reported questionnaire (APPENDIX H).

To determine the intrarater reliability of the physical examination tests which were performed by the physiotherapist on 30 subjects for two times within time-length interval at least 45 minutes. The reliability of each test was determined by Kappa coefficient and Intraclass correlation coefficient. The present study has the coefficient of the physical examination tests ranged from 0.651 to 1.000 (APPENDIX H).

3.8. Research Procedure

The researcher developed self-reported questionnaire and selected appropriate physical examination tests based on literature review. Then, reliability test was performed both of the survey questionnaires and the physical examination tests before data collection.

The cluster sampling technique was firstly used to select 26 organizations within Chulalongkorn University. Then, the covering letters to publicize the research were sent to the selected organizations. A total of 250 participants from 18 organizations agreed to attend the study. The self-report questionnaire and physical examination tests were used to collect data of all 250 participants. Before data analysis process, the screening questionnaire was used to exclude the data of participants. After the screening stage, the remaining subjects were 221 participants in total. The research procedure was shown in Figure 8.

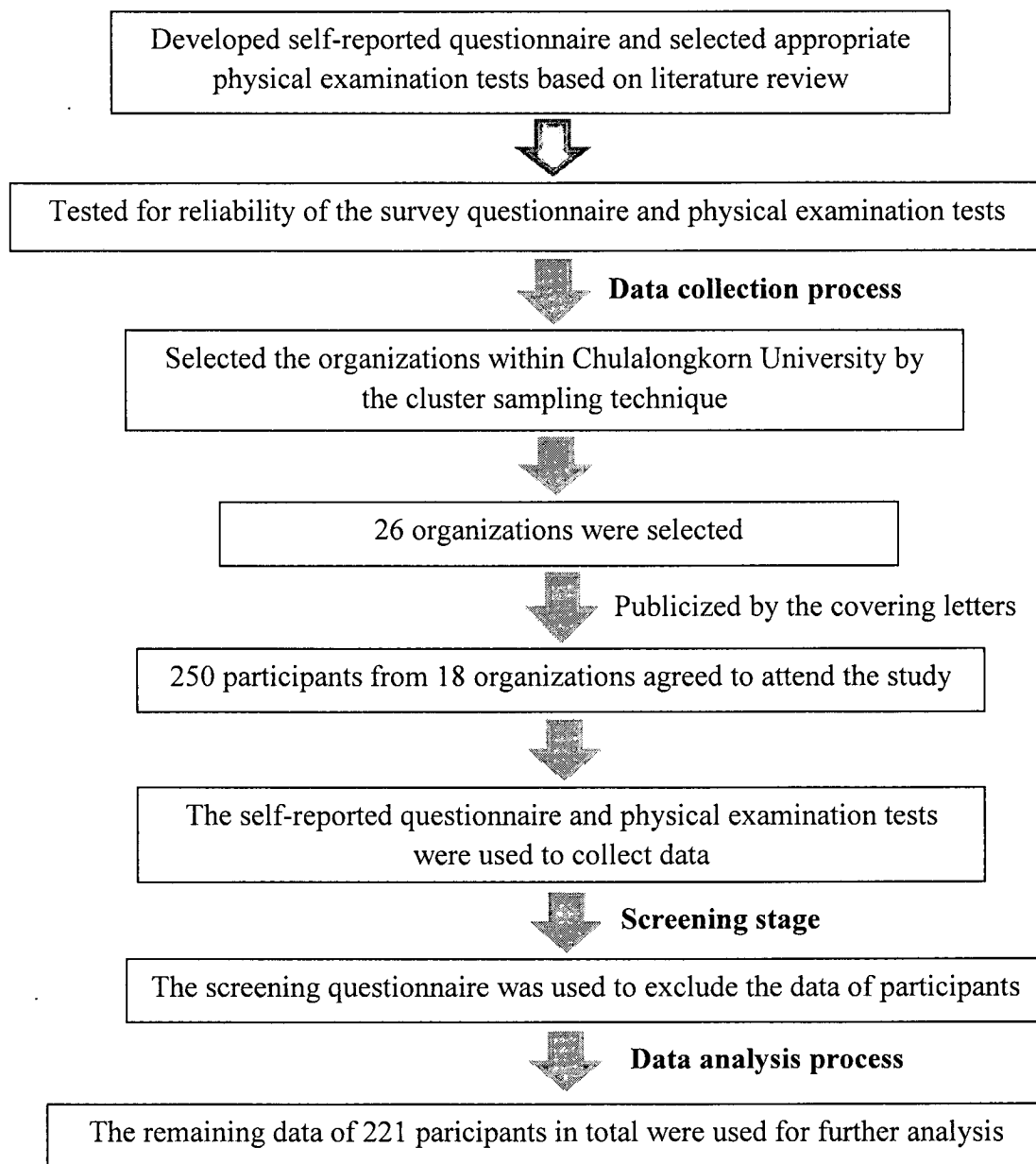


Figure 8: Research Procedure in the present study

3.9. Outcome measurement

3.9.1 Dependent variable

- **The prevalence of foot pain during the past month** was measured using the Manchester foot pain and disability index (MFPDI) Thai version. The participants with foot pain were identified by the persons with current foot pain and pain during the last month for at least 1 score of MFPDI (Garrow et al., 2000).

- **Health-related Quality of life** was measured using the 12-item short-form health survey (SF-12) Thai version. The scores from the SF-12 were calculated into the physical component summary (SF-12 PCS) and the mental component summary (SF-12 MCS). Each component had the scores ranged from 0 to 100; the higher scores indicated better physical and mental functioning (Hoffman and Dukes, 2008).

3.9.2 Independent variable

Independent variables in the study were composed of individual, work-related physical, health behavioral, and anthropometric variables.

- **Individual factors** included age, gender, marital status, education level, low back pain, hip/thigh and knee pain history during the last 12 months, sleeping duration, and falling history during the last 12 months.

- **Work-related physical factors** included job categories, working experience, working duration (hours per week), general working posture, time spent in each working posture per day (i.e. walking, standing, sitting), environmental factors, and rest break after every 2 hours.

- **Health behavioral factors** included leisure physical activity, types of exercise, smoking history, general foot wear, and general foot wear.

- **Anthropometric variables** were assessed by the physiotherapist including data on body mass index, waist hip ratio, foot problem, types of foot posture, types of foot arch, foot muscle strength, and leg length.

3.10. Data Analysis

SPSS software version 17.0 was used for quantitative data analysis.

3.10.1 Descriptive Statistics were used to present each independent variable, prevalence of foot pain, and health-related quality of life in pre-retirement aged. The frequency was shown for the categorical data and mean with standard deviation was shown for the continuous data.

3.10.2 Inferential Statistics were used to explore the associations between the related factors, quality of life and foot pain.

- **Independent t-test** was used to measure the significant differences of SF-12 PCS and SF-12 MCS between the participants with foot pain and without foot pain at significant level $p \leq 0.05$; and also used to compare the related factors (continuous data) between the participants with foot pain and without foot pain.

- **Chi-square analysis** was used to compare the related factors (categorical data) between the participants with foot pain and without foot pain.

- **Multiple logistic regression** was used to measure the significant association between particular factors and the prevalence of foot pain during the past month in pre-retirement aged at significant level $p \leq 0.05$. The factors with p-value less than 0.100 from Independent t-test and Chi-square analysis were used for the multiple logistics regression with backward stepwise method to finalize the adjusted odds ratio (adj. OR) and 95% confidence interval (95% CI). The factors associated with foot pain were reported by adj. OR and 95% CI.

3.11. Ethical Consideration

The study protocol was approved by the Ethical Committee of Chulalongkorn University (through the College of Public Health Sciences) No. 053/2556 on February 26, 2013 (APPENDIX F). The participants gave their permission by completing a consent form prior to the study (APPENDIX G).