คุณภาพชีวิตในผู้หญิงวัยหมดประจำเดือนที่มีความเสี่ยงในการเป็นโรคกระดูกพรุน ในโรงพยาบาลตำรวจ

นางสาว อิสรีย์ จรรยาศักดิ์

วิทยานิพนธ์นี้เป็นส่วนหนึ่งของการศึกษาตามหลักสูตรปริญญาวิทยาศาสตรมหาบัณฑิต
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QUALITY OF LIFE IN POSTMENOPAUSAL WOMEN WITH RISK OF OSTEOPOROSIS IN THE POLICE GENERAL HOSPITAL

Miss Isaree Junyasak

A Thesis Submitted in Partial Fulfillment of the Requirements
for the Degree of Master of Science Program in Social and Administrative Pharmacy
Department of Social and Administrative Pharmacy
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อิสรีย์ จรรยาศักดิ์ : การศึกษาคุณภาพชีวิตของผู้หญิงวัยหมดประจำเดือนที่เป็นโรคกระดูกพรุนในโรงพยาบาลตำรวจ. (QUALITY OF LIFE IN POSTMENOPAUSAL WOMEN WITH RISK OF OSTEOPOROSIS IN THE POLICE GENERAL HOSPITAL). อ.ที่ปรึกษาวิทยานิพนธ์หลัก: ผู้ช่วยศาสตราจารย์ ดร. ฐณัฏฐา กิตติโสภี, 109 หน้า.

การศึกษานี้มีวัตถุประสงค์เพื่อศึกษาคุณภาพชีวิตในผู้หญิงวัยหมดประจำเดือนที่เป็นโรคกระดูกพรุน โดยใช้แบบสอบถาม Qualeffo 41 และเพื่อศึกษาหาปัจจัยที่ส่งผลต่อคุณภาพชีวิตในผู้หญิงวัยหมดประจำเดือนที่เป็นโรคกระดูกพรุน โดยการศึกษาเชิงพรรณนา ณ จุดเวลาใดเวลาหนึ่ง (cross-sectional descriptive study) เพื่อหาระดับคุณภาพชีวิตของผู้หญิงวัยหมดประจำเดือนที่มีอายุตั้งแต่ 45 ปีขึ้นไป ที่มีมวลกระดูก (BMD) น้อยกว่าหรือเท่ากับ - 2.5 หรือ ได้รับการวินิจฉัยว่าเป็นโรคกระดูกพรุนหรือได้รับยารักษาโรคกระดูกพรุน ทำการเก็บข้อมูลกลุ่มตัวอย่างจำนวน 134 คน ซึ่งเป็นผู้ป่วยโรงพยาบาลตำรวจ ระหว่างเดือนธันวาคม 2552 ถึง เดือนมีนาคม 2553 แบบสอบถามที่ใช้ในการศึกษานี้ประกอบด้วย 4 ส่วน ได้แก่ ข้อมูลทั่วไปของผู้ป่วย, แบบวัดคุณภาพชีวิต (Qualeffo 41) ปัจจัยเกี่ยวกับความสนใจในสุขภาพและปัจจัยเกี่ยวกับการรักษา สถิติที่ใช้ คือ ค่าเฉลี่ย ค่าเบี่ยงเบนมาตรฐาน ค่าสูงสุดและค่าต่ำสุด รวมทั้งใช้การวิเคราะห์ความถดถอยเชิงพหุ (multiple regression analysis) คุณภาพชีวิตมีค่าคะแนนตั้งแต่ 0 ถึง 100 โดยที่ค่าคะแนน 0 แสดงถึงคุณภาพชีวิตที่ดีที่สุด และค่าคะแนน 100 แสดงถึงคุณภาพชีวิตแย่ที่สุด ผลการศึกษาพบว่า ค่าเฉลี่ยคุณภาพชีวิตของผู้หญิง วัยหมดประจำเดือนที่เป็นโรคกระดูกพรุนเท่ากับ 34.86 (±15.67) โดยในแต่ละด้านมีค่าดังนี้ ด้านความเจ็บปวดมีค่าเฉลี่ยเท่ากับ 30.34 (±25.27), ด้านการทำงานของร่างกายมีค่าเฉลี่ยเท่ากับ 36.82 (±21.52), ด้านการใช้เวลาว่างและกิจกรรมทางสังคม มีค่าเฉลี่ยเท่ากับ 44.53 (±22.35), ด้านการรับรู้เกี่ยวกับสุขภาพโดยทั่วไปมีค่าเฉลี่ยเท่ากับ 44.47 (±18.53) และด้านจิตใจ มีค่าเฉลี่ยเท่ากับ 24.60 (±15.59) ปัจจัยที่ส่งผลต่อคุณภาพชีวิตของผู้ป่วย ได้แก่ 1) ลักษณะอาชีพ 2) ระยะเวลาหลังหมดประจำเดือน 3) การออกกำลังกายและ 4) การรับประทานอาหารที่มีแคลเซียมและโปรตีน โดยที่ระยะเวลาหลังหมดประจำเดือนมีความสัมพันธ์ส่งผลให้คุณภาพชีวิตของผู้ป่วยแย่ลง ในขณะที่การออกกำลังกายและการรับประทานอาหารที่มีแคลเซียมและโปรตีนที่ผู้ป่วยรับประทานมีส่งผลให้คุณภาพชีวิตของผู้ป่วยดีขึ้น ดังนั้นจึงควรสนับสนุนให้มีการออกกำลังกายและรับประทานอาหารที่มีแคลเซียมและโปรตีนมากขึ้นเพื่อให้มีคุณภาพชีวิตที่ดีขึ้น

ภาควิชา เภสัชศาสตร์สังคมและบริหาร ลายมือชื่อนิสิต อิสรีย์ จรรยาศักดิ์

สาขาวิชาเภสัชศาสตร์สังคมและบริหาร ลายมือชื่อ อ.ที่ปรึกษาวิทยานิพนธ์หลัก

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5176853033 : MAJOR SOCIAL AND ADMINISTRATIVE PHARMACY
KEYWORDS : QUALITY OF LIFE / OSTEOPOROSIS / POSTMENOPAUSAL WOMEN / QUALEFFO 41

ISAREE JUNYASAK : QUALITY OF LIFE IN POSTMENOPAUSAL WOMEN WITH RISK OF OSTEOPOROSIS IN THE POLICE GENERAL HOSPITAL. THESIS ADVISOR: ASSISTANT PROFESSOR TANATTHA KITTISOPEE, Ph.D., 109 pp.

The objectives of this study were to measure quality of life (QOL) in postmenopausal women with osteoporosis, using Qualeffo41 and to examine factors influencing quality of life in postmenopausal women with osteoporosis. A cross-sectional descriptive study investigated quality of life in 45-year-old and older postmenopausal women with low bone mineral density (BMD) ($\leq$ - 2.5 standard deviations (S.D.) below normal peak bone mass) or were diagnosed as an osteoporosis or taking osteoporosis drug. A total of 134 subjects were recruited from the Police General Hospital during December 2009 to March 2010. The interview-administered questionnaire consists of 4 parts which are demographic and clinical characteristics, quality of life, factors in health concerning and factors in treatment. The mean, standard deviation, range and multiple regression analysis were used for statistical analysis. Quality of life assessment was performed using the Qualeffo41 (Thai version) which express in values ranging from 0 to 100, where 0 represents the best and 100 represents the worst quality of life. Results showed that the mean ($\pm$S.D.) total QOL score of postmenopausal women with osteoporosis was 34.86 ($\pm$15.67). In each domain, the result showed that the score of pain domain was 30.34 ($\pm$ 25.27), physical function domain was 36.82 ($\pm$21.52), social activities domain 44.53 ($\pm$22.35), general health perception domain was 44.47 ($\pm$18.53) and mental domain scored was 24.60 ($\pm$15.59). The patient's QOL was affected by four predictor variables which are 1) occupation, 2) duration of menopause, 3) exercise, and 4) dietary calcium and protein intake. Duration of menopause related to worse QOL in the patients. While exercise and dietary calcium and protein intake related to better QOL in the patients. Thus, getting more exercise or consuming more calcium and protein diet is recommended in order to have better quality of life.

Department : Social and Administrative Pharmacy Student's Signature Isaree Junyasak

Field of Study: Social and Administrative Pharmacy Advisor's Signature Tanattha Kittisopee

Academic Year : 2009

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ADL	Activities of daily living
BMI	Body Mass Index
BMD	Bone mineral density
DXA	Dual energy X ray absorptiometry
HRQOL	Health-related quality of life
PTH	Parathyroid hormone
QOL	Quality of life
SERMs	Selective estrogen-receptor modulators
S.D.	Standard deviations
WHO	World Health Organization

CHAPTER I
INTRODUCTION

Rational and Background:

Osteoporosis is a common and serious disease associated with aging which affects an estimated 90 million people worldwide (1, 2). The prevalence of osteoporosis among Thai women rose progressively with increasing age to more than half of woman population after the age of 70. The age adjusted prevalence of osteoporosis was 19.8%, 13.6%, and 10% for lumbar spine, femoral neck, and intertrochanteric in age from 40-80 year (3, 4). Osteoporosis is a skeletal disease characterized by low bone mass and micro-architectural deterioration with a resulting decrease bone strength and increase risk of fracture. The World Health Organization's definition of osteoporosis is based on bone mineral density in the spine and proximal femur measured with dual energy X ray absorptiometry (DXA). Osteoporosis is classified as a bone mineral density 2.5 or more standard deviations below normal peak bone mass, which means T score $\leq$ -2.5 (5, 6). The disease is more commonly seen in women than in men especially in postmenopausal women. The studies show that factors causing osteoporosis are age, estrogen deficiency, oral glucocorticoids, vitamin D insufficiency, secondary hyperparathyroidism, decreased production of insulin-like growth and genetics. The role of estrogen deficiency in menopausal and age which related bone loss starts in the fourth or fifth decade of life are It is a result of increased bone breakdown by osteoclasts and decreased bone formation by osteoblasts. As well as oral glucocorticoids, which are taken by about 1% of the population and 2.5% of those aged over 75, vitamin D insufficiency and secondary hyperparathyroidism are also common in elderly people and may cause osteoporosis. Moreover, genetic factors have a strong influence on peak bone mass, which is attained during the third decade of life and is an important determinant of bone mass later in life (6).

Until recently, 20–50% of postmenopausal women were taking hormone replacement therapy, while the Women's Health Initiative recently documented

an efficacy of hormone replacement therapy against fractures; it also documented an unfavorable ratio beneficial and adverse effects. Thus, many women face the choice of continuing, stopping or changing therapy. Fortunately, several other options for pharmacological intervention have been demonstrated to decrease the risk of fractures in randomized studies. Anticatabolic drugs include calcium, vitamin D, estrogen, raloxifene and bisphosphonates such as, etidronate, alendronate, risedronate, ibandronate and pamidronate. Anabolic drugs include parathyroid hormone. Finally, strontium ranelate has both anticatabolic and anabolic effects (7).

Fracture is the important outcome of osteoporosis affecting mainly the hip, vertebrae, and wrist. The estimated number of hip fractures worldwide will rise from 1.7 million in 1990 to 6.3 million in 2050. In Thailand, almost 6.7 million Thai women more than 50 years being diagnosed of osteoporosis according to the WHO's criteria, around 42,000 hip fractures occurs annually. This can be estimated to the risk of an approximated 2 % of hip fracture taking place annually once osteoporosis being diagnosed (5). Hip fractures always lead to hospitalization and cause pain, serious disability and excess mortality. Most hip fractures take place after a fall about 80% occurs in women and 90% in people older than 50 years. In 2001 the Asian Osteoporosis Study (AOS), a multi-national research survey, found that the age-adjusted rates incidence of hip fractures (per 100,000) were 114 and 289, in men and women, respectively in Thailand. Hip fractures are associated with significant morbidity (4). One year after hip fracture, 40% of patients are still walk with help, 60% have difficulty with at least one activity of daily living, and 80% are limited in independent activities of daily living such as driving or grocery shopping and 27% enter a nursing home for the first time(2). The prevalence and incidence of vertebral fractures is likely more than hip fracture. The incidence of vertebral fracture increases with increasing age and the female to male ratio is approximately 2:1. Only about a quarter of vertebral fractures result from falls and most result from routine activities such as bending, lifting objects and climbing stairs. Vertebral fractures may cause pain and loss of function although no serious symptom revealed. Most wrist fractures happen in women, 50% of whom are older than 65 years. Wrist fractures also leads to acute pain and loss of function but functional recovery is good or excellent. In addition to pain and disturbance

of physical function the osteoporotic fracture may reduce mobility and social interaction and cause emotional problems effecting quality of life impairment (2, 8, 9).

In health services research and in clinical trials, quality of life is used increasingly as an outcome measure in order to evaluate to gain data on the burden of disease, morbidity and health care use, and often in comparison with other diseases (8). Utilities represent a person's or a group of people's preference for a health status. Utilities range from 0 to 1, where perfect health is assigned a value of 1 and death is assigned a value of 0. The mean quality of life weight for hip fracture patients, on average 5.3 years after the fracture, was 0.63, while the corresponding value for vertebral fracture patients, on average 2.3 years after the fracture, was 0.82. The mean quality of life value for women without a previous fracture was 0.91(10).

Health related quality of life can be assessed by two different type instruments which are generic and disease-specific instruments. The outcome of generic questionnaires can be compared with other diseases. However, these tools are not specific for any disease or age group. Examples of generic questionnaires are Nottingham Health Profile (NHP), the Short Form 36 of Medical Outcomes Study (SF-36), and the EuroQol (EQ-5D). Disease-specific questionnaires were designed for patients with specific disease such as depression, myocardial infarction, and osteoporosis. There are many instruments were being developed to measured the quality of life in osteoporosis patient, like osteoporosis quality of life questionnaire (OQLQ), osteoporosis assessment questionnaire (OPAQ), quality of life questionnaire of the European foundation for osteoporosis 41 (Qualeffo41) and quality of life questionnaire in osteoporosis(QUALIOST). In the sense that disease-specific instruments measure quality of life more accurately in that particular disease than generic instruments because of more relevant questions, shorter administered and being more valid (4, 8, 11, 12).

The Qualeffo41 accepted by the International Osteoporosis Foundation (IOF) is self-ministered and the most complete questionnaire. The English version Qualeffo41 has been translated into various languages and validated in 10 countries in Europe. It contains five domains which are pain, physical function, social function, general health perception and mental function. Thus, it is more suitable and useful to evaluate quality of life in osteoporosis patients by using Qualeffo41. One aim of this study, therefore,

is to measure quality of life in postmenopausal women with risk of osteoporosis patients in Thailand, using Qualeffo41.

Health related quality of life is one key indicator that can reflect the effectiveness of the treatment. In order to caring postmenopausal women with osteoporosis efficiency, it is critical to concern its influencing factors. There are many factors influenced quality of life in postmenopausal osteoporosis patients including socio-demographic characteristic, health concerning, and treatment. Socio-demographic is a general factor which may influence quality of life in patients such as, occupation, Body Mass Index (BMI) and duration of menopause. Although many studies have investigated this issue, they produced conflicting results few studies in Thailand has examined. The association between quality of life and health concerning for instance exercise, dietary calcium and protein taking and life style habits. Furthermore, few studies have examined effect of medications use: duration of osteoporosis drugs, side effect of osteoporosis drugs, duration of calcium and side effect of calcium on quality of life in patients. Consequently, the main purpose of this study explored the factors influenced quality of life in postmenopausal women with risk of osteoporosis in Thailand.

Objectives of the Study:

1. To measure quality of life in postmenopausal women with risk of osteoporosis, using Qualeffo41.
2. To examine factors influencing quality of life in postmenopausal women with risk of osteoporosis.

Expected Benefits:

1. The findings of this study would provide better understanding in the health status of postmenopausal women with risk of osteoporosis.
2. The obtained information can be a used as basis to develop holistic care plan better quality of life in postmenopausal women with risk of osteoporosis.
3. The result of this study can be used in economic evaluation to influence public policy decisions, including the development of strategic healthcare plans.
4. The knowledge obtained from this study can be applied as a guideline in the allocation of healthcare resources to improve quality of life in patients with risk of osteoporosis.

Definition used in this study:

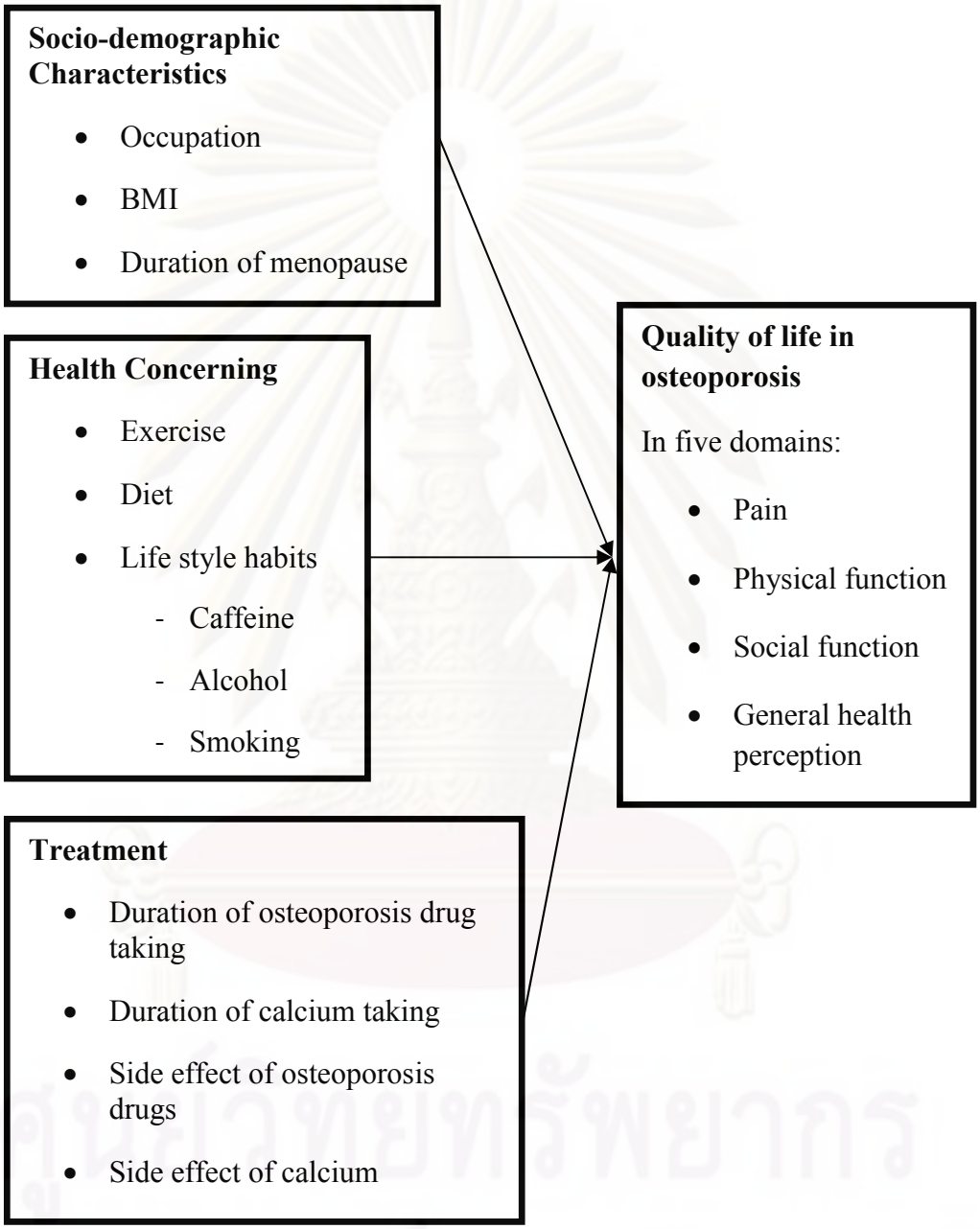
A. Postmenopausal woman with risk of osteoporosis is a woman aged 45 years and older with low bone mineral density (BMD) ($\leq$ - 2.5 standard deviations (S.D.) below normal peak bone mass) or were diagnosed as an osteoporosis or taking osteoporosis drugs.

B. Quality of life is used in healthcare to refer to an individual's emotional, social and physical wellbeing, including their ability to function in the ordinary tasks of living.

C. Factors influenced quality of life included socio-demographic characteristic, health concerning, and treatment.

1. Socio-demographic characteristics that affect quality of life are occupation, BMI, and duration of menopause.
2. Health concerning related to quality of life in patients with risk of osteoporosis are exercise, dietary calcium and protein taking and life style habits including caffeine, alcohol drinking and smoking.
3. Treatment means osteoporosis drugs and calcium, its side effect and duration of taking.

Conceptual Framework



CHAPTER II
LITERATURE REVIEW

This cross-sectional descriptive study aimed to measure quality of life in postmenopausal women with risk of osteoporosis and examine factors influenced quality of life in postmenopausal women with risk of osteoporosis. This literature review was undertaken by reviewing the relevant literature on the following topics:

Part 1: Osteoporosis

Part 2: Quality of life

Part 3: Quality of life impact of osteoporosis

Part 4: Factors influencing quality of life in postmenopausal women with risk of osteoporosis

Part 5: Related studies

Part 1: Osteoporosis

Osteoporosis is a disease characterized by low bone mass and micro-architectural deterioration of the bone tissue, leading to bone fragility and increased risk of fracture, particularly of the spine, wrist, hip, pelvis and upper arm. Osteoporotic fractures are associated with significant reductions in quality of life due to disability, pain, and deformity; as well, they constitute an important cause of death among the elderly and impose a considerable economic burden on health services worldwide (13). In 2000, the United States National Institute of Health (14) has defined osteoporosis as follows:

"A skeletal disorder characterized by compromised bone strength predisposing a person to an increased risk of fracture. Bone strength reflects the integration of two main features: bone density and bone quality"

A. Operational definition

The definition recommended by The European Foundation for Osteoporosis and Bone Disease, The National Osteoporosis Foundation of the United States, and the World Health Organization 1994 was used to categorize bone mineral density (BMD)

into 4 levels which are: (15, 16) Normal: A value of BMD greater or less than one standard deviation below the peak bone mass of healthy adults.

Osteopenia: A value of BMD between -1.0 S.D. and -2.5 S.D. below the average value of the peak bone of healthy adults.

Osteoporosis: A value of BMD more than -2.5 S.D. below the average value of the peak bone mass of healthy adults.

Severe osteoporosis: A value of BMD more than -2.5 S.D. below the young adult mean in the presence of one or more fragility fractures.

B. Disease Prevalence

In the United States, the National Health and Nutrition Survey (NHANES III) estimated that 13% to 18% of women have osteoporosis and 27% to 50% have osteopenia. Osteoporosis risk rises with age evidenced by the finding that approximately 70% of women with age of 80 in the United States have postmenopausal osteoporosis (17). BMD measurements can be taken at a number of sites including the femoral neck, the lumbar spine, and distal forearm. It is estimated that 7.8 million women in the United States are currently affected from osteoporosis of the hip alone. This figure is expected to rise to 10.5 million by 2020, primarily due to the aging population (18). In the United States, the number of persons aged 65 years and over is expected to increase from 32 to 69 million between 1990 and 2050 (19). The number of persons aged 85 and older is expected to rise from 3 million in 1990 to 15 million in 2050 (18). The same demographic changes are also predicted globally with the number of persons aged 65 and older expected to rise from 323 million in 1990 to 1555 million by 2050 (19) which could cause increasing number of hip fractures globally from 1.7 million (1990) to an estimated 6.3 million in 2050 (20). If fracture incidence rates simultaneously increase worldwide by 1% annually, the projected number of hip fractures would be 8.2 million by 2050 (21). If rates were stable in North America and Europe, but increase in developing countries by 3% annually, the total number of hip fractures globally would surpass 21 million by 2050 (21).

C. Prevalence of osteoporosis in Thailand

It is significant to calculate the osteoporosis prevalence to address the overall magnitude of the problem in Thai population particularly women who are the risk group. In a nation-wide survey during 2000-2001, the age-adjusted prevalence of osteoporosis in Thai women ranging in age from 40-80 years was 13.6% and 19.8% for femoral neck and lumbar spine, respectively (3). The age-specific prevalence of osteoporosis among Thai women below 50 years of age was less than 5% and the prevalence increased with advancing age, i.e., more than 50% found after the age of 70. Comparatively, a study from Khon Kaen province in north-east Thailand reported the prevalence of osteoporosis showing a bit higher than the aforementioned studies which are 19.3 and 24.7% at the femoral neck and lumbar spine, respectively (22). Differences in the disease prevalence are probably due to the dissimilarity of the reference database of the mean peak bone mass used for the WHO measurable criteria. The study in Khon Kaen province used the mean peak bone mass developed from rural women that was higher than the one developed mainly from an urban area. For men, the age-adjusted prevalence of osteoporosis was 12.6, 4.6 and 3.9% at the femoral neck, lumbar spine and both sites, respectively (23). These figures of prevalence in both men and women are comparable with previous studies in Western countries and in some other Asian countries (19).

D. Disease Incidence

The main clinical manifestation of osteoporosis is represented fractures which commonly occurring fractures include vertebral fractures, fractures of the distal radius and hip fractures. For Caucasian women living in North America, the lifetime risk of fractures at age 50 is 17.5%, 15.6%, and16%, for the hip, spine and forearm respectively. This translates into a lifetime risk of 40% for any fragility fracture (24). Similar rates have been reported from parts of Europe; however there is a marked variation in fracture risk between countries, regions, and within countries (25).

E. Incidence of fractures in Thailand

The public health and clinical importance of osteoporosis lies in the fractures associated with the disease. According to conservative estimates, a 50 years old

Caucasian woman has a remaining lifetime risk of 40% for hip, vertebral, or wrist fracture (24). Although white women are primarily affected, African, Hispanic, and Asian women, as well as men, are also at significant risk. It is projected that by the end of this century, 50% of all hip fractures in the world will occur in Asia (20). Prevention of osteoporotic fractures in Asia is therefore of paramount importance. In 1994, a multicenter study on hip fractures in Thailand was reported that the age-adjusted incidence of hip fractures was 7.45 per 100,000 populations. The incidence was higher in women (14.93 per 100,000) than in men (6.68 per 100,000). In 2001, the Asian Osteoporosis Study (AOS), a multi-national research survey was documented the incidence of hip fracture in Thailand (26). The age-adjusted rates (per 100,000) were 114 and 289, in men and women, respectively. These were lower than the incidence for men and women of hip fracture in Hong Kong, (180 and 459), Singapore (164 and 442) and US White (187 and535) but comparable with Malaysia, (88 and 218). The higher rate of hip fracture was associated with urbanization (27-32). However, the incidence of hip fracture in both men and women was higher in a community based survey compared with hospital based survey (185.2 vs. 151.2 per 100,000) (33). While the incidence of hip fracture in Thai population has been well documented, there is a dearth data on morphometric, clinical vertebral fracture and non-vertebral fracture in Thai population that need more research to explore the occurrence.

F. Hip Fractures

Hip fractures that occur globally approximately 1.7 million each year are the result of a fall from the standing position and its incidence rates increase with age. Hip fracture rates are highest in Caucasian women living in temperate climates, lower in women from Mediterranean and Asian countries and are the lowest in women living in Africa (34, 35). Despite the fact that hip fracture incidence rates have been increasing with the urbanization of central parts of Africa. Other countries in economic transition, such as the Hong Kong Special Administration Region (SAR) of China, have also seen significant increases in age-adjusted fracture rates in recent decades (36, 37). Conversely, rates in industrialized countries appear to have plateau (1, 36, 37). Among Caucasians the ratio of hip fractures for females to males is approximately 2:1 which differ from Blacks or Asians where the ratio between males and females approaches unity (38).

Although hip fractures account for only 4.7% of all osteoporotic fractures among women aged 50-55 years and 33.3% of osteoporotic fracture for women aged 85-89 years, the event receives the most attention presumably because of their high cost to individuals and to healthcare payers (5). The average hospital admission for a hip fracture in Europe is 20-30 days (39). In addition, hip fractures are associated with significant mortality: about 15-30% of the patients will die within six months of experiencing a hip fracture (40, 41). Approximately 20% Patients who survive hip fracture experience significant disability, which results in the need for long-term care (42). The long term care in industrialized countries occurs at the institutional level, conversely, in developing countries the majority of patients return home to receive long-term care.

G. Vertebral Fractures

Less than 50% of all vertebral fractures come to clinical attention and only few clinically symptomatic fractures require hospitalization (43, 44). Thus, unlike hip fractures, which all come to clinical attention, the incidence of vertebral fractures is hard to estimate (43), although it is generally estimated that the rates are roughly twice that of hip fracture incidence rates. The incidence of vertebral fracture increases with increasing age and the female to male ratio is approximately 2:1. Vertebral fractures are most common among Caucasian and Japanese women and are less common among Black women (44). Vertebral fractures are believed to be important predictors for future osteoporotic fractures (45, 46). Estimate 20-26% of postmenopausal women will experience a new vertebral and/or non-vertebral fracture (i.e. hip, forearm/wrist, other) within 1 year of an incident vertebral fracture (45, 46). And this risk increases with the number of prevalent vertebral fractures (46). This “fracture cascade” results in pain, kyphosis, loss of height, disability, and increased mortality among osteoporotic (47-49). Patients hospitalized for a vertebral fracture spend approximately 6-30 days in hospital.

H. Available Drug Treatments

The purpose of drug therapy among osteoporotic patients is to reduce the risk of fracture, stabilize or achieve an increase in bone mass, relieve symptoms of fractures and skeletal deformity, and maximize physical function (50). Although there have been many agents have been used for treatment in postmenopausal women with the incidence

of vertebral and non-vertebral fractures as primary endpoints, several agents reduce the risk of fracture by as much as 30-50%.

1. Calcium and Vitamin D

Calcium is an important nutrient in the prevention and treatment of osteoporosis especially in elderly women and in those with a low calcium intake. As well as Vitamin D, obtained either from food or synthesis in the skin during sunlight exposure, is also given as a supplemental treatment for osteoporosis. Calcium and vitamin D are often taken as an adjunct to other therapies for osteoporosis due to their ability to reduce the risk of fracture by controlled clinical trials. In a French study showed that 3,270 elderly women who treated for 3 years with calcium (1,200 mg daily) and vitamin D (800 IU daily), the probability of hip and all non-vertebral fractures was significantly reduced by 29% and 24% respectively, compared to placebo (51, 52)

2. Bisphosphonates

Bisphosphonates are stable analogues of naturally occurring pyrophosphate (53). Clinical trials of bisphosphonates consistently provide solid evidence of efficacy in preventing both vertebral and nonvertebral fractures. The availability of the different bisphosphonates varies across countries; however etidronate, alendronate, and risedronate seem to be most commonly used. Etidronate was the first bisphosphonate developed. The agent is administered intermittently, typically at 400 mg per day for 2 weeks and then repeated every 3 months (54). Findings of a meta-analysis suggested relative risk reduction of 37% (95% CI 8% to 56%) for vertebral fractures, but no significant effect was noted for non-vertebral fractures (55).

Alendronate is given continuously at a daily dose of 5 mg for prevention of osteoporosis and 10 mg for treatment of established osteoporosis (50). Results from a study (56) of 2,027 osteoporotic women with at least one prevalent vertebral fracture who were treated with 5 mg alendronate for the first two years and 10 mg of alendronate during the subsequent years suggested a relative risk reduction of 47% (95% CI 32% to 0.59%) for radiographic vertebral fractures and 51% (95% CI 1% to 77%) for hip fractures.

Risedronate is given at a daily dose of 5 mg (50). Recently two large, 3-year multicenter RCTs have evaluated the efficacy of risedronate in the treatment of

postmenopausal osteoporosis (57, 58). In one study, 5 mg of risedronate resulted in a relative risk reduction of 49% (95% CI 27% to 64%) for vertebral fractures (58). The overall incidence of non-vertebral fractures was reduced by 33% however the results were not significant (58). In the Harris study, (57) treatment with risedronate resulted in a 41% (95% CI 18% to 57%) risk reduction of vertebral fractures and 40% (95% CI 6% to 61%) of non-vertebral fractures. Another study conducted by McClung MR, G. P., et al. (59) on women 70-79 years of age with osteoporosis with a previous vertebral fracture calculated a relative risk reduction for hip fractures of 60% (95% CI 23% to 77%) and for nonvertebral fractures of 30% (95% CI 10%-50%).

Ibandronate, a daily dose of 2.5 mg, has recently received an indication for the treatment and prevention of osteoporosis in postmenopausal women. In addition to the oral formulation, ibandronate can also be administered intravenously. The effect of ibandronate has been demonstrated in a three-year, randomized, double blind, placebo-controlled, multinational study of 2,946 postmenopausal women aged 55 to 80 years who have had one to four previous vertebral fractures. The incidence of new vertebral fractures was significantly reduced in the ibandronate arm compared to the placebo with a relative risk reduction of 52% (95% CI 29% to 68%), but no significant effect was noted for non-vertebral fractures (60). The Monthly Oral iBandronate In LadiEs (MOBILE) study conducted in 1,609 women demonstrated that the non-inferiority of once-monthly oral ibandronate to the daily oral regimen. Greater benefit was derived from the ibandronate 150 mg once-monthly tablet than from either the daily regimen or 100 mg once-monthly, without detriment to tolerability (61, 62).

3. Selective estrogen-receptor modulators (SERMs)

SERMs are non-hormonal agents that bind to estrogen receptors with an affinity equivalent to that of estradiol, but can act either as estrogen agonists or antagonists depending on issue (54). Raloxifene is the only SERM approved in some countries for the prevention and treatment of osteoporosis. In early postmenopausal women, raloxifene prevents postmenopausal bone loss at all skeletal sites. The MORE (Multiple Outcomes of Raloxifene Evaluation) study (53), which involved 7,705 women with osteoporosis, noted a 43% (95% CI 3% to 52%) reduction of incident vertebral

fractures in women with prevalent vertebral fractures when they were treated with raloxifene. No significant effects on non-vertebral fractures were observed.

4. Calcitonin

Calcitonin is a naturally occurring peptide hormone. The route of administration is via the nasal mucosa in the form of a spray. The exact mechanism of action is not well understood, however at pharmacological dose levels, calcitonin acts as an anti-resorptive agent. There is only one study (53) to date that has sufficient power and was designed to detect a change in fracture rates. In the PROOF (Prevent Recurrence of Osteoporotic Fractures) study, a daily dose of 200 IU of nasal salmon calcitonin significantly reduced vertebral fractures by 36% (95% CI 4% to 57%). However the study had a high dropout rate and there was no effect shown for doses of 100 and 400 IU of calcitonin. The study was not powered to detect a reduction in non-vertebral fractures (63).

5. Parathyroid hormone (PTH)

Clinical studies have been conducted to determine the benefits of parathyroid hormone (PTH) in the prevention and treatment of osteoporosis. A double blind placebo controlled prospective study (64) was conducted in 1,637 postmenopausal women with previous vertebral fractures. Women in the treatment arm received a daily subcutaneous injection of 20 or 40 g. 1-34 fragment recombinant human PTH, for a median of 19 months. The incidence of new vertebral fractures was reduced by 65% (95% CI 45% to 78%) among women treated with PTH.

6. Strontium ranelate

Strontium ranelate is composed of an organic moiety (ranelic acid) and of two atoms of stable nonradioactive strontium. In vitro, strontium ranelate has been suggested to have a dual effect on bone however, in vivo long term dosing of strontium ranelate in OVX rats and monkeys resulted in increased bone formation but trends of bone resorption is non-significant. In human studies (phase III trials), there is some evidence of increases in bone formation markers (serum bone-specific alkaline phosphatase and C-terminal propeptide of type I procollagen) and decreasing bone resorption (serum C-telopeptide and urinary N-telopeptide cross links) from the third month of treatment (2 g of strontium ranelate daily) up to three years (65). Strontium

ranelate has been investigated in a large phase III program, included two extensive clinical trials for the severe osteoporosis treatment. Spinal Osteoporosis Therapeutic Intervention (SOTI) is aimed assessing the effect on the risk of vertebral fractures (66). TReatment Of Peripheral OSteoporosis (TROPOS) is aimed at evaluation of the effect on peripheral (nonspinal) fractures (67) in 5 years, with the main statistical analysis planned after 3 years of follow-up. Of 1,649 patients with a mean age of 70 years were included in SOTI and 5,091 patients with a mean of 77 years were included in TROPOS. The primary analysis of the SOTI study, revealed a 41% risk reduction for first new vertebral fracture throughout the 3-year study. The PROTOS study, showed a significant reduction in the relative risk of a first nonvertebral fracture compared with placebo. A 41% reduction in the relative risk of experiencing a hip fracture was demonstrated in the per protocol population.

Part 2: Quality of life

A. Definition of quality of life

Quality of life is very significant for human life both in health and illness. The context of quality of life was found that it is difficult to constructs, define, and measure because cultural, ethical, religious and other personal value influence perceptions of the meaning and consequences of quality of life (68) cited by (69). Therefore, the concept of quality of life has been given different meanings, depending on the users. The term “quality of life” is defined differently by various experts as follows:

The World Health Organization (WHO) defines quality of life as individuals’ perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards, concerns. It involves aspects of physical health, psychological state, levels of independence, social relationships, environmental factors, and personal beliefs (70).

Consistent with McDaniel & Bach (71), quality of life is the congruence or lack of congruence between actual life conditions and one’s hopes and expectations.

Grant et al. (72) define quality of life as a personal statement of the positivity or negativity of attributes that characterize one’s life.

Zhan (68) defines quality of life as the degree to which a person’s life experiences are satisfactory.

Hinds (73) defines quality of life as children's and adolescents' subjective and changeable sense of well-being that reflects how closely their desires and hopes match what is actually happening and their orientation toward the future, both their own and that of others.

B. Definition of health-related quality of life

The World Health Organization (WHO) defines health as "a state of complete physical, mental and social well-being and not merely the absence of disease" (74). The last decade has evidence a dramatic increase in the development and utilization of health-related quality of life (HRQOL) measures in an effort to improve patient health and determine the value of healthcare services. Definitions of HRQOL vary widely, but there are two central aspect of this construct (75). First, HRQOL is subjective, and hence, it should be assessed from the patient's perspective whenever possible. Second, HRQOL is a multidimensional construct that integrates a broad range of outcomes. One definition that includes both of these components describes HRQOL as an individual's subjective perception of the impact of health status, including disease and treatment, on physical, psychological, and social function (76).

C. Component of quality of life

The overall concept of quality of life consists of a number of distinct domains. The four major domains of quality of life generally by most researchers include the following categories: 1) Physical status and functional abilities 2) Psychological status and well-being 3) Social interactions 4) Economic and/or vocational status and factor (74). According to Faulker (77), the three underlying dimensions of quality of life are physical, psychological, and social aspects of one's existence affecting life satisfaction and personal well-being. Physical well-being is associated with functional health status, perceived health, physical symptoms, and ability to meet basic needs. Psychological well-being reflects a degree of contentment, productivity, control, self-perception, and emotional adjustment appropriate to life span development. Social well-being is dependent upon attaining an acceptable level of interaction with friends, support from family members, and role fulfillment.

D. Measuring quality of life in osteoporosis

Quality-of-life questionnaires can be classified into generic, disease-specific, and study-specific questionnaires. Generic questionnaires pose general questions on health status, can be used in various diseases and are able to compare between different diseases. On the other hand, they may contain superfluous questions, as they are not specific for any disease or age group. Examples of generic questionnaires are the Nottingham Health Profile (NHP) (78), the Sickness Impact Profile (SIP) (79), the Short Form 36 of the Medical Outcomes Study (SF-36) (80), and the EuroQol (EQ-5D) (81). Disease-specific or disease-targeted questionnaires are designed for patients with a specific disease such as depression, myocardial infarction, or osteoporosis. They are meant for use in one disease or group of diseases. As these questionnaires contain more specific questions, they may be less of a burden for the patients, because they may recognize their individual problems (Table 1).

Table 1 Characteristics of generic and disease-specific questionnaires for evaluation of quality of life

Generic	Disease-specific
Suitable for many diseases	Suitable for one disease only
May contain superfluous questions	Less of a burden for the patient
Enables comparison between diseases	Comparison between diseases impossible
Examples: SF-36, Euroqol, NHP, SIP	Examples: Qualeffo-41, OPAQ, OQLQ

A disadvantage of disease-specific questionnaire is that different diseases cannot be compared (82, 83). Hence, many investigators recommend combinations of generic and specific questionnaires, and many clinical trials contain one of each type. Examples of disease-specific questionnaires are the Geriatric Depression Scale (84), the Inflammatory Bowel Disease Questionnaire, for patients with inflammatory bowel disease (85), and the Qualeffo41, for patients with osteoporosis (86). Both generic and disease-specific questionnaires usually consist of several domains such as pain, physical function, mobility, general health, emotions, and fears. Osteoporosis-specific

questionnaires six questionnaires have been developed for patients with osteoporosis, and other questionnaires have been derived from these. The characteristics of these questionnaires are summarized in Table 2. These questionnaires have been developed along different lines, and they exhibit different characteristics.

Table 2 Characteristics of quality-of-life questionnaires specific for osteoporosis

Name	Mode of administration	Number of questions	Domains
OQLQ	Interviewer	30	Physical function, ADL, emotional function
OFDQ	Interviewer	69	General health + back pain, ADL, socialization, depression (CES-D), confidence
OPTQOL	Interviewer	33	Physical activity, adaptations, fears
OPAQ	Self-administration	67	Physical function, emotional status, symptoms, social interaction
Qualeffo-41	Self-administration	41	Pain, physical function, social function, general health perception, mental function
QUALIOST	Self-administration	23	Physical function, emotional status

The Osteoporosis Quality of Life Questionnaire (OQLQ) was developed by identifying items in generic questionnaires, and asking patients, nurses, specialists, physiologists and rheumatologists about them. In this way, 168 items were identified, which were condensed into 30 questions in several steps following well-defined procedures (87). The OQLQ is interviewer based and also exists in a shortened version with 10 questions (88). The Osteoporosis Functional Disability Questionnaire (OFDQ) was developed to assess disability in patients with osteoporosis and back pain due to

vertebral fractures, including pain indices, a depression scale, and measurements of functional abilities, social activities, and confidence in treatment (89). The Osteoporosis-Targeted Quality of Life Questionnaire (OPTQOL) was developed as an instrument for community- or population-based studies to assess the burden of osteoporosis in women living in the community. The items in this questionnaire were identified in the literature and in focus groups. The 299 identified items were reduced to 37 items through ranking by a large group of women and after validation reduced to 33 questions (90, 91). The Osteoporosis Assessment Questionnaire (OPAQ) was developed from the Arthritis Impact Measurement Scales Health Status Questionnaire 2, for self-assessment of health-related quality of life in all types of osteoporotic patients (92). It contained 80 questions, later condensed to 59 questions in four domains: physical, psychological, symptoms, and social.

The Quality of Life Questionnaire of the International Osteoporosis Foundation (formerly the European Foundation for Osteoporosis) was developed for patients with vertebral deformities, by a working party of clinicians and quality-of-life specialists from eight countries (86, 93). A questionnaire of 54 questions (including 6 visual analogue scales) was constructed (Table 3). After validation it was condensed to 41 questions (Qualeffo-41). Subsequent testing showed that Qualeffo-41 also is suitable for postal administration (94). The Questionnaire Quality of Life in Osteoporosis (QUALIOST) has a different place, as it was developed as a disease-specific module, in addition to the generic SF-36 questionnaire (95). After discussion with patients it was developed and contains 23 questions after validation. The patients have to complete 59 questions, but this includes the generic questionnaire SF-36.

Table 3 Qualeffo41: contents of the quality-of-life questionnaire of the International Osteoporosis Foundation

Domain	Sub-domain	Number of questions
Pain	Back pain, sleep disturbance	5
Physical	ADL: dressing, bathing, toilet	4
	Jobs around the house: cleaning, cooking, washing dishes, shopping, lifting	5
	Mobility: standing up, bending, kneeling, stairs, walking	7
	Body image	1
Social	Sport, gardening, hobby, friends	7
General	(Change in) overall QOL	3
Mental	Fatigue, depression, loneliness, energy, cheerfulness, hope, fear	9

Part 3: Quality of life impact of osteoporosis

Central to the evaluation of quality life is the patient's ability to perform the tasks of daily life, engage in social activities, and function without pain. Osteoporotic fractures, particularly vertebral fractures, often cause disability, deformity and chronic pain. More than half of hip fracture patients over 60 years of age need more assistance with activities of daily living after fracture than before (96). A growing number of studies show that fractures have a considerable impact on health relating to quality of life. Previous studies have shown more or less severe impairment of quality of life after hip, vertebral, or forearm fractures (11, 97-106). Duration of quality of life impairment after fracture varies markedly between various studies and different fractures. Furthermore, osteoporosis related fractures will cause 6.7% of women to become dependent in basic activities of daily living during the remaining lifetime (42). A previous study in a Thai population demonstrated clearly the deterioration in quality of life after fracture. Hip fracture patients required more help with every task, socialize less, and walk more slowly with diminished balance and confidence (107). All patients suffered a certain

degree of deficits in health perception, mental health, emotional, physical, social function and experiencing bodily pain as measured by modified SF-12 health survey (108). The present report showed that one fifth of patients (22.1%) could not walk after hip fracture. Moreover, hip fracture patients needed a wheel chair (23.2%), transferring assistance (11.2%), bathing assistance (11.2%), tooth-brush assistance (4%), dressing assistance (10%), feeding assistance (4.8%), and toileting assistance (21.6%) (108).

Part 4: Factors influencing quality of life in postmenopausal women with osteoporosis

Based on literature reviews the factors related to quality of life in osteoporosis patient were divided into three groups as following;

A. Socio-demographic characteristics

First, socio-demographic characteristics are general factors that may be affected to patient's quality of life including occupation, BMI and duration of menopause. Kessenich, CR., et al found that several socio-demographic factors proved important for quality of life in osteoporosis elderly women (109).

1. Occupation

Most vertebral fractures resulted from general activities such as, bending, lifting objects and climbing stairs (2, 8, 9) which implies that different types of occupation may associate the risk of vertebral fracture

2. Body Mass Index

A low body mass index is an important risk factor for osteoporosis probably because of its effect on bone size (110, 111). A recent report found that women whose body mass index was < 22 – 24 kg/m^2 had increased risk for osteoporosis leading to lower quality of life than the women whose body mass index > 26 – 28 kg/m^2 (112). Cockerill, W., et al. (102) and de Oliveira Ferreira, N., et al. (11) pointed out, higher BMI influences quality of life while Badia, X., et al. (100) indicated that there were weak relations between BMI and the OQLQ usual activities domain.

3. Duration of menopause

During the menopause, there is an increase in bone turnover and decrease in bone formation within individual remodeling units, leading to rapid bone loss. In women, there is acceleration in the rate of bone loss around the time of

the menopause to about 2% per year (110). It should be noted that in the first 5 years of postmenopausal there is a rapid rate of bone loss, which shows after 6 years of postmenopausal (113). As a result duration of menopause affects osteoporosis associating with quality of life in postmenopausal osteoporosis women. On the other hand, Bianchi, M. L et al. (114) explored that quality of life in the control group and the two group of women (osteoporosis without fractures and osteoporosis with vertebral fractures) affected by osteoporosis were not significantly different in age at menopause.

In conclusion, although many studies have investigated whether socio-demographic characteristics influence the quality of life, they produced conflicting result and some aspects are still not well-documented or poor data.

B. Health concerning

Second, health concerning is a measurement of osteoporosis awareness by evaluating the three factors, exercise, diet and life style. Increased physical exercise, cessation smoking and reduced alcohol intake are considered as primary prevention of osteoporosis (7) including calcium nutritive dietary. If factors associate negatively with osteoporosis may causes quality of life impairment in patients.

1. Exercise

Inadequate exercise may contribute the cause of bone loss (115). From the several studies (116-119)healthy adults should engage in exercise three time per week lasting 20 to 30 minutes continuously (3 hr/wk) and suggest that weight-bearing exercise (walking, jogging and aerobics) may reduce bone loss by the increase in muscle strength and bone mass (120, 121). Thereby, exercise decreases the risk of suffering from osteoporosis which relates to the quality of life in postmenopausal women. Adachi, J., et al. and Moriyama, C.K., et al. investigated that exercise was also positively associated with quality of life influences quality of life (99, 122).

2. Diet

Dietary intake plays a significant role in prevention the skeleton from the impact of a fall. In this study we will focus on diet which contains calcium and protein as an essential nutrients involving in increasing bone mass, for example, milk-product, high-calcium bean curd, and leafy green vegetables including meats.

a) Calcium

Calcium is an essential nutrient that is involved in most metabolic processes and the phosphate salts of which provide mechanical rigidity to the bones and teeth, where 99% of the body's calcium resides (123, 124). If calcium intake is insufficient for other vital function, secretion of PTH, an increase, which draws calcium from the bone's reserves, leading to enhanced bone fragility and the increases in fracture risk of osteoporosis (125).

Postmenopausal osteoporosis is one of the most common diseases of older woman in the world and is responsible for considerable morbidity, mortality, and monetary cost. Inadequate dietary intake of calcium has been suggested to cause this disease, and many studies have suggested that a high dietary intake of calcium will prevent postmenopausal bone loss and hence the development of osteoporosis (126-128).

Dietary sources are the preferred means of obtaining adequate calcium intake because there are other essential nutrients found in high-calcium foods. Examples of food sources of calcium are, milk, yogurt, bean curd, small fish and leafy green vegetables (128).

b) Protein

Protein is an important structural component of bone and protein supplementation improves the medical outcome of hip fracture patients. Patients with hip fracture are commonly malnourished, enter the hospital with low serum albumin levels, and typically become more severely hypoproteinemic during hospitalization (129). Dietary protein intake was positively associated with bone mineral density of the femoral neck and lumbar spine in a study of elderly Swiss patients (130) and with bone mass of the distal radius and proximal femur in pre-menopausal women in America (131).

3. Life style habits

This study investigated the behavior of caffeine, alcohol taking and smoking which increase the risk for decreased bone mineral density (BMD) considerably.

a) Caffeine

Caffeine increases urinary calcium excretion and is therefore implicated as a risk factor of osteoporosis (132). A study by Rapuri, P.B., et al. (133) examined caffeine intake and the rate of bone loss. The result showed that subjects with an intake of

caffeine more than 300 mg/d had increased bone resorption at the lumbar spine higher than those who have an intake of caffeine less than 300 mg/d. And some recent studies suggest that subjects who have an intake of greater than 2 cups of coffee/d (caffeine ~ 176 mg) or 4 cups of tea/d (caffeine ~ 165.6 mg/d) have increase risk of fracture (134).

b) Alcohol

Alcohol is often associated with decreased calcium and vitamin D intakes and with excessive urinary loss of calcium (135). In severely affected alcoholics, the loss of protein intake contributes the specific toxics effects of ethanol which can depress osteoblast function and reduce bone formation (136). Hutchison, T.A., et al. (137) reported that alcoholism (undefined) was associated with an increased risk of fractures in postmenopausal women. The association between alcohol intake and fractures may be explained by a combination of acute and chronic effects of alcohol. The increased prevalence of fractures in alcoholics is due, in part, to intoxication, which is associated with an increased risk of trauma. A marked reduction in bone remodeling independent of hormonal factors suggests that the consumption of alcohol may also directly relate to development of osteoporosis (138).

c) Smoking

Cigarette use is a risk of increased bone mineral density (BMD) loss but the biological mechanisms by which smoking, or components of cigarette smoke, influence BMD and bone loss are not well understood. They may include local and systemic toxic effects on bone collagen synthesis, alterations in metabolism of adrenal cortical and gonadal hormones, and other undetermined mechanisms. An additional contributing factor may be decreased calcium absorption efficiency among smokers (139). Additionally, Krall, E.A. and Dawson-Hughes, B.(121) studied smoking and bone loss among postmenopausal women. These results demonstrated an increased rate of bone loss at the radius after menopause and suggested that smoking is associated with decreased calcium absorption (140).

C. Treatment

Last, treatment means osteoporosis drugs, its side effects and duration of osteoporosis treatment are factors influencing quality of life of postmenopausal women with osteoporosis.

The aim of any osteoporosis drugs is the decrease in the risk of fractures in patients who have not yet sustained an osteoporosis fracture or of the progression of the disease in patients with fragility fractures. Osteoporosis drugs in this study are bisphosphonate, calcitonin, raloxifene, strontium renelate and calcium supplement. According to a study by Badia, X., et al. (100), the correlation between the number of pharmacological treatments and all OQLQ domains was extremely high, especially; bisphosphonate use was also positively associated with HRQL (99).

1. Side effects of osteoporosis drugs and calcium

Bisphosphonate given orally can induce GI side effects such as heart burn, nausea, or vomiting. To reduce these side effects the proper instructions of taking the medication is taking with full glass of water and not lying down which is quite inconvenient and complicated (141). Other pharmacological intervention in osteoporosis may have side effects such as, side effects of raloxifene are hot flush, myalgia, leg cramp, calcitonin induces nausea, vomiting and vertigo, strontium renelate may causes nausea, diarrhea and headache, besides calcium supplement also induces constipation and abdominal pain. From these reasons side effects of osteoporosis drugs and calcium and inconvenient taking of bisphosphonate may have an effect on the quality of life in osteoporosis patients.

2. Duration of osteoporosis treatment

In this study osteoporosis treatment is divided into two groups: pharmacological intervention, bisphosphonate which should be given long-term for up to 7 years, calcitonin, raloxifene, strontium renelate, and prevention, calcium which are often taken as prevention and an adjunct to other therapies for osteoporosis. Low calcium intake is identified as risk factor for osteoporosis, so the long period of calcium supplement intake lowers the risk of osteoporosis. The different duration of osteoporosis treatment in each patient may associates osteoporosis and risk of fracture which affect different quality of life in patients.

Part 5: Related studies

de Oliveira Ferreira, N., et al. (11) conducted a cross-sectional study in 220 postmenopausal women (ages ranging from 55 to 80 years). Of the total number, 110 women had osteoporosis and 110 women did not have osteoporosis and these women

were age-matched (±3 years). The purposed of this study was to evaluate quality of life (QOL) in women with postmenopausal osteoporosis, correlating the Qualeffo41 with the short-form health survey 36 (SF-36) and evaluated some factors that can influenced the QOL of women with osteoporosis. Two questionnaires were administered to all subjects for evaluation of QOL: the quality of life questionnaire of the European foundation for Osteoporosis 41 (Qualeffo41) and the short-form health survey 36 (SF-36). The findings indicated that women with osteoporosis had a worse QOL both in the Qualeffo41 and in the SF-36, in all domains studied. There was a significant correlation between all domains in the Qualeffo41 questionnaire and their corresponding domains in the SF-36 ($p < 0.001$). The only factors related to worse QOL were BMI > 25 and sedentary lifestyle. In contrast, paid work was associated with a better QOL(CI = 95%). In summary, these data suggest that women with osteoporosis have impaired QOL especially relating to the physical and psychosocial aspects. There is a good correlation between the Qualeffo41 and SF-36. The factors that led to impairment of QOL were BMI and sedentary lifestyle. The single factor that enhances QOL is the paid work. Actions such as investing in public education, early diagnosis and appropriate interventions should be prioritized to reduce the incidence of osteoporosis and minimize repercussions on QOL.

Bianchi, M. L., et al. (114) studied the impact of osteoporosis on the patients' quality of life of 100 post-menopausal women (age 50-85), 62 with uncomplicated primary osteoporosis and 38 with primary osteoporosis complicated by vertebral fractures; all already treated - were studied using two validated questionnaires: Qualeffo-41 for quality of life in osteoporosis, and Zung for depression. Data were compared to those of 35 controls of comparable age, affected by a different chronic disease (hypothyroidism). They found that the patients affected by osteoporosis perceived it as a disease affecting their personal life with undesirable consequences: chronic pain (66% of women with fractures and 40% of women without fractures), impaired physical ability, reduced social activity, poor well-being (21% of women without fractures) and depressed mood (42% of women irrespective of fractures). Overall, 41% of the women showed a reduced quality of life. On the contrary, in the control group only 11% reported a reduced quality of life. In summary, this study recommended that the quality of life in osteoporotic patients should be investigated even before fractures, in order to develop

appropriate counseling, support and care interventions to help patients develop efficient strategies for accepting the disease and coping with it.

Adachi, J., et al. (99) examined in relationship between health related quality of life (HRQOL) and incident fractures in 2009 postmenopausal women 50 years and older who were seen in consultation at their tertiary care, university teaching hospital-affiliated office and who were registered in the Canadian Database of Osteoporosis and Osteopenia (CANDOO) patients. Patients were divided into three study groups according to incident fracture status: vertebral fractures, non-vertebral fractures and no fractures. The disease-targeted mini-Osteoporosis Quality of Life Questionnaire (mini-OQLQ) was used to measure HRQOL. This study revealed that subjects who had experienced an incident vertebral fracture had lower HRQOL difference scores as compared with non-fractured participants in total score, functioning, emotional functioning, activities of daily living, and leisure domains of the mini-OQLQ. Patients who experienced an incident non-vertebral fracture had lower HRQOL difference scores as compared with non-fractured participants in total score, the symptoms, physical functioning, emotional functioning and the activities of daily living domains. A limitation of this study was not all spinal fractures were confirmed by x-ray. X-rays were performed only in patients with back pain. Therefore, subclinical vertebral fractures may have developed in all groups. The presence of subclinical vertebral fracture has been documented to be associated with decreased activity. As a consequence, the actual differences in HRQOL scores may have been underestimated for those with documented vertebral fractures versus those without. In addition, the presence of non-vertebral fractures were based on self-reports. This method of ascertainment may lead to fracture misclassification. In conclusion, this study demonstrates the detrimental impact of clinically recognized incident vertebral and non-vertebral fractures on quality of life in post-menopausal women. Despite improvements in the medical management of osteoporotic fractures, it is clear that fractured patients continue to experience decreased quality of life and that these deficits may often go unnoticed by clinicians. Thus, the challenge for the future is to develop treatment strategies to prevent and also reduce the pain associated with the fractures and to determine how patient satisfaction is impacted when quality of life issues are considered during care.

A study by Cvijetić, S., et al. (103) aimed to analyze the quality of life in osteoporotic patients with hip fracture and those without fractures. The study included postmenopausal women, 35 with hip fracture and 33 without fractures. The control group included 44 age–matched healthy women. Osteoporosis Quality of Life Questionnaire was used to assess the health–related quality of life (HRQOL). They found that patients with hip fracture had significantly lower scores in symptoms, physical function and leisure ($P<0.05$), than patients without fractures. Both groups of patients had significantly lower scores than controls in all domains except Leisure. Analyzing several health and social factors that could influence HRQOL, we found that bone mass in spine and femoral neck significantly correlated with HRQOL. In summary, this study also recommended that early diagnosis and the treatment of the disease are of key importance to the quality of life in these patients, since patients with osteoporosis usually have no symptoms before fracture.

In Thailand, Jongjit, J., et al. (107) conducted a population-based case-control study six months after hip fracture. The purpose of their study was to investigate the association between functionality and quality of life. The Functional Independence Measure (FIM), the Frenchay Activities of Daily Living Index (FAI), and the Berg Balance Scale (BBS) were used to measure physical function, and quality of life was measured by completing a Short Form-36 (SF-36). This study found that the hip fracture group scores were significantly lower ($P<0.05$) than the control group in all measurements of physical function. The quality of life was assessed by SF-36, which has eight domains: physical function, physical role, bodily pain, mental health, emotional role, social function, general health and vitality. All eight domains were significantly lower in the hip fracture group compared with the controls ($p<0.05$). The present study has two limitations that could limit the conclusion of the results, such as selection bias and study design. There were two potential sources of selection bias: overly-healthy controls and a poor recruitment rate. As the controls were recruited through the media and various community groups, there was a chance of overly-healthy controls. While a prospective cohort study could evaluate this aspect, it was not feasible with this study, as any attempt to estimate pre-fracture functional status retrospectively, with an elderly population, would be open to bias due to memory deterioration. In summary,

this study provides some evidence that the reduction in function was reflected in a reduction in the quality of life. Thus, clinically reported hip fracture impairs both the functionality and quality of life of these subjects. The adverse impact of hip fracture on quality of life and functionality needs to be recognized by health personnel in the community, so that adequate health resources can be devoted to preventing and treating this debilitating condition.

Suriyawongpaisal, P., et al (108) evaluated health-related quality of life (HRQOL) before and after hip fractures in 250 Thai patients, using a longitudinal follow-up approach in a Thai setting. Measurement of HRQOL was based on a modified SF-12 questionnaire, which was developed with a realization of the following demands: 1) cultural sensitivity of measurement tools; 2) disease-specific HRQOL measurement and 3) feasibility of conducting field work. Functional status was measured using an adapted version of the Index of Activity of Daily Living (ADL), which was previously developed in another setting in Thailand. The result of this study was mild, moderate and severe deficits in quality of life were found in 36%, 60%, and 4% respectively, of surviving patients. The number of patients with physical functioning dependency, as measured by the ADL, also increased significantly in all 10 activities assessed. Co-morbidities were associated with deficits in health-related quality of life but age, sex, income, education level, and surgery were not. A limitation of this study was the lack of control group casts doubt on the relationship between hip fracture and the adverse outcomes and some error was inevitable in this retrospective study due to recall bias present in such elderly patients. The findings indicate that hip fracture could lead to crippling consequences, with a pronounced effect on the quality of life of Thai patients.

CHAPTER III
METHODOLOGY

There are several strategies for determining health state utility values: (1) to use expert opinion; (2) to use indices obtained from the literature and (3) to directly measure the preferences of an appropriate population. The first two approaches have been widely used in the field of osteoporosis where economic evaluations have used judgments either by the authors or by expert panels, or have extracted values from previous studies using these methods. There is evidence that experts may focus on different aspects of health to patients. Moreover, valuations obtained from the literature, such as those found by this review, may be inappropriate. The preferred approach is to collect stated preference data for a set of health states using quality of life questionnaire in an appropriate population (142). Despite, there have been increased studies that document the impact of fractures on general health status, as evidenced by development of osteoporosis-specific health status instruments however, mostly from developed countries. Few studies in a Thai population have examined in osteoporotic fracture quality of life. In addition, there are no data available regarding using disease-target questionnaires to assess quality of life in Thai osteoporotic patients. The objectives of the current study were to measure quality of life of postmenopausal women with risk of osteoporosis in Thailand, using Qualeffo41, and to examine factors influenced quality of life of postmenopausal women with risk of osteoporosis.

Study design

A cross-sectional descriptive study investigated quality of life in postmenopausal osteoporotic patients. Quality of life assessment was performed using the Qualeffo41. Written informed consent was obtained from all participants. This study was approved by the Research Ethics Committee of the Police General Hospital.

Study population

The subjects of this study were 45-year-old and older postmenopausal women with low bone mineral density (BMD) ($\leq$ - 2.5 standard deviations (S.D.) below normal

peak bone mass) or were identified as osteoporosis by the specialists or by mean of osteoporosis drug taking. All patients were recruited from the Police General Hospital.

Sample size

Sample size required in this study was calculated using the formula by Polit, D.F. and Beck, T.C. (143) which was the most widely used method for multiple regression analysis. To calculate multiple regression, the estimated population effect size was as follow:

$$\gamma = \frac{R^2}{1 - R^2}$$

Researcher must either predict the value of R^2on the basis of earlier research, or use this convention that the effect size will be small (R^2 =0 .02), moderate (R^2 = 0.13), or large (R^2 = 0.30). Next, the following formula is applied:

$$N = \frac{L}{\gamma} + k + 1$$

Where, N = estimated number of subjects needed

L = table value for the desired alpha and power

k = number of predictors

γ = estimated effect size

This study was planned to examine twelve factors influencing quality of life in postmenopausal women with risk of osteoporosis, with a moderate effect size (R^2 = 0.13), a power of 0.80 and an alpha of 0.05. With R^2 = .13, the estimated population effect size (γ) was 0.149(0.13÷0.87). According to the Power Analysis Table for Multiple Regression, the value of L was equal to 17.268. Therefore,

$$N = \frac{17.268}{0.149} + 12 + 1 = 128.89$$

Finally, a sample of this study was 129 postmenopausal women was needed to detect a population R^2 of 0.13, with twelve predictors, and with a 5% chance of a Type I error and a 20% chance of a Type II error.

Measurement

There were four parts of the questionnaire.

Part 1: Demographic and clinical characteristics questionnaire included occupation, Body Mass Index (BMI) and duration of menopause.

Part 2: Quality of life was evaluated by a specific instrument for osteoporosis, named the quality of life questionnaire of the European foundation for osteoporosis 41 (Qualeffo41) which presents five domains: pain, physical function (divided in three sub-domains: activities of daily living, jobs around the house and mobility), social function, general health perception and mental function. All scores are expressed in values ranging from 0 to 100, where 0 represents the best and 100 represents the worst quality of life. Translation was done by the researcher and sent it back to the International Osteoporosis Foundation to back translation. The back translation was conducted by two Thai orthopedic physicians, Associate Professor Thawee Songpatanasilp, M.D., and Dr.Suthorn Bavonratanavech, M.D., independently.

Part 3: The question about factors in health concerning included exercise, dietary calcium and protein intake and life style habits (caffeine, alcohol taking and smoking).

Exercise was designed to obtain type and frequency data of physical activity to derive information about the usual exercise behavior pattern during the past 6 months for each subjects. The investigator developed this part considering study objectives and modified from previous study of "Bouchard Three-Day Physical Activity Record" for assessment of energy expenditure in adult in Canada (144) which physical activities were separated in to 14 categories. Then for proper apply for Thai postmenopausal women it was modified into 4 categories as follow:

1. Light manual work e.g. quick walking, sweeping, stair climbing.
2. Moderate manual work e.g. plantation work
3. Light sport or leisure activities e.g. cycling, yoga, thaichi chuan, Chinese dancing, golf
4. Moderate sport or leisure activities e.g. jogging, aerobics, swimming, tennis, badminton

Diet questionnaire was designed by the researcher in order to ask patient about their frequency of dietary calcium and protein intake. There were 5 items in this part which

asked about milk product, dried prawn or fish product, vegetable, bean product and meat or egg consuming with 5 choices range in everyday, 4-6 days/wk, 2-3 days/wk, 1 day, and not take in value ranging from 5 to 1, respectively.

The questionnaire about life style habits included 3 yes-no question about caffeine, alcohol drinking and smoking.

Part 4: The questions about factors in treatment including duration of osteoporosis drugs, side effect of osteoporosis drugs, duration of calcium and side effect of calcium.

Data Collection Methods

All eligible patients were approached as they come in routine follow-up at postmenopausal clinic and orthopedic clinic in the Police General Hospital during the study period, which is from December 2009 to March 2010. All respondents were informed the purpose of the study. Written informed consent was obtained from all participants prior to participate in the study. Data from all parts were collected using interview-administered questionnaires by the researcher.

Scoring algorithm

QUALEFFO41

The Qualeffo41 questionnaire consisted of 41 questions and presented five domains as follwing:

Pain domain: question 1-5

Physical function domain: question 6-22

Social function domain: question 23-29

General health perception domain: question 30-33

Mental function domain: question 34-41

All scores are expressed in values ranging from 0 to 100

1. All answers were standardized so that 1 represented the best and 5 (or 3, or 4) represented the worst quality of life (reverse scores on questions 33, 34, 35, 37, 39, 40).

2. Answers of questions with 3 answer options (question 23-26):

- disregard "not applicable" (question 24) and "no cinema ….." (question 26)
- score 1 → 1, 2 → 3, 3 → 5.

3. Answers of questions with 4 answer options (question 27-28-29):

- disregard “not applicable” (question 29)
- score 1 → 1, 2 → 2.3, 3 → 3.6, 4 → 5.

4. Domain scores were calculated by averaging the answers of one domain and transforming the scores to a score from 0 to 100, e.g. pain questions 1-5; the average score ranges from 1 to 5 and this is transformed to scores from 0 to 100. Missing values should be disregarded.

Examples: Pain

Q1: 3, Q2: 3, Q3: 4, Q4: 1, Q5: 3. Average score 14/5 = 2.8.

Transformation to domain score

$$\frac{\text{(average score – lowest possible score) x 100}}{\text{score range}} = \frac{(2.8 - 1) \times 100}{5\text{-}1} = 45$$

Q1: 3, Q2: 3, Q3: 4, Q4: 1, Q5: missing. Domain score 11/4 = 2.75.

$$\frac{(2.75 - 1) \times 100}{5\text{-}1} = 43.75 \ (\rightarrow 44)$$

5. The total score was calculated by summing all answers of questions 1-41. The raw total score ranges from 41 to 205 (or less when some answers are missing) and this was transformed to scores from 0 to 100.

$$\frac{\text{(actual score - lowest possible score) x 100}}{\text{score range}} = \text{total QUALEFFO score}$$

Examples:

In case of no missing answers: $\frac{\text{(actual score - 41) x 100}}{164}$

In case of 5 missing answers: $\frac{\text{(actual score - 36) x 100}}{144}$

Exercise assessment

The exercise assessment instrument was developed by considering study objectives and modified from previous study of “Bouchard Three-Day Physical Activity Record” for assessment of energy expenditure in adult in Canada (150). Categories of activity for Bouchard Three-Day Physical Activity Record were group into 4 category groups. Each activity was calculated for energy expenditure using the approximate energy expenditure as shown in the table 4.

Table 4 Category of activity and approximate energy expenditure

Category of activity	Example of activity for each category	Approximate energy expenditure (Kcal/kg/15 min)
1. Light manual work	quick walking, sweeping, stair climbing	0.83
2. Moderate manual work	plantation work	1.40
3. Light sport or leisure activities	cycling, yoga, thaichi chuan, Chinese dancing, golf	1.20
4. Moderate sport or leisure activities	jogging, aerobics, swimming, tennis, badminton	1.50

The physical activities were computed as follows.

a) Frequency of each activity per week computed from

$$Frequency = \frac{F_L + F_H}{2 \times 7}$$

When F_L = low frequency of activity in 1 week

F_H = high frequency of activity in 1 week

2 = number of low and high frequency

7 = number of days in week

For example 1-2 times/wk, were computed as follows

$$Frequency = \frac{1+2}{2 \times 7} = 0.21 = 0.2$$

Then assigned scores of frequency/wk were follows

5-7 times/wk 0.8 point

3-4 times/wk 0.5 point

1-2 times/wk 0.2 point

b) Time for physical activity.

Duration of time of physical activity has 5 stages/ wk as follows.

< 15 min equal 1 point

15-30 min equal 2 points

31-45 min equal 3 points

46-60 min equal 4 points

> 60 min equal 5 points

c) Energy expenditure of physical activity computed from the following formular

Energy expenditure = Energy × Weight × Frequency × Times

Energy = energy expenditure of activity (Table 4)

Weight = body weight of individual subject

Frequency = Frequency of activity/wk

Times = duration of time of each activity/wk

Example 50kg postmenopausal woman had type and frequency of physical/wk activity as follows:

Type of activities	**1-2 time/wk (min.)**					**3-4 time/wk (min.)**					**5-6 time/wk (min.)**				
	< 15	**15-30**	**31-45**	**46-60**	**> 60**	**< 15**	**15-30**	**31-45**	**46-60**	**> 60**	**< 15**	**15-30**	**31-45**	**46-60**	**> 60**
Physical activity Quick walking	✓														
Yoga							✓								
Plantation work	✓														
Stairs climbing											✓				

Physical activity consisting of quick walking, yoga, plantation work, and stair climbing

Energy expenditure = Energy × Weight × Frequency × Times

Energy was used in quick walking = 0.83 × 50 × 0.2 × 1

Energy was used in yoga = 1.20 × 50 × 0.5 × 2

Energy was used in planting work = 1.40 × 50 × 0.2 × 1

Energy was used in stair climbing = 0.83 × 50 × 0.8 × 1

Therefore, energy expenditure of physical activity = 8.3+60+14+33.2 = 115.5 Kcal/d

Data Analysis

Collected data from questionnaires and medical record were analyzed by using SPSS statistical package 17.0 for windows

Descriptive statistics

In this part, general characteristics of the patients included socio-demographic characteristics, health concerning and treatment data were described. The results were presented by mean, standard deviation, range for continuous data, and frequency and percentage for category data.

Inferential statistics

1. The mean and standard deviation of the Qualeffo41 score were presented.

2. Factors associated with quality of life in postmenopausal women with risk of osteoporosis were identified by a multiple regression analysis.

CHAPTER IV

RESULTS

The results of this study were divided into six parts as follow;

Part 1: Demographic and clinical characteristics of patients with risk of osteoporosis

Part 2: Descriptive data of quality of life

Part 3: Reliabilities of Qualeffo41

Part 4: Descriptive data of health concerning

Part 5: Descriptive data of treatment

Part 6: The factors affecting quality of life in patients with risk of osteoporosis: a multiple regression analysis

Part 1: Demographic and clinical characteristics of patients with risk of osteoporosis

A total of 134 subjects were recruited based on criteria during the period of data collection from December 2009 to March 2010. They were enrolled at postmenopausal clinic and orthopedic clinic in the Police General Hospital. Demographic and clinical characteristics of all patients were summarized in range, mean, standard deviation (S.D.), as shown in Table 5.

Table 5 Range, mean, standard deviation of demographic and clinical characteristics of patients with risk of osteoporosis

Patient characteristics	N	Mean	S.D.
Age	133	70.23	8.96
Weight(Kg)	134	58.06	10.45
Height(cm.)	133	154.22	5.59
Body mass index (BMI)	133	24.35	3.96
BMD (T-score)	70	-2.68	0.63
Duration of menopause (year)	131	22.23	10.23

According to the Table 5, the subjects ranged between 49 and 95 years old, with the mean age of 70.23 years (S.D. = 8.96.) from 133 subjects, one data were missing from OPD card. Besides, to indicate if they are overweight, obese, underweight or normal can be calculated by BMI. A healthy BMI score is between 20 and 25. A score below 20 indicates that they may be underweight; a value above 25 indicates that they may be overweight. As the result shown, the mean BMI of the 133 subjects (one data were missing because the patient could not remember her height) was 24.35 (S.D. = 3.96) which means the average BMI of the subjects was at healthy level. There were only 70 subjects (52.24%) confirmed as osteoporosis by measuring with dual energy X-ray absorptiometry (DXA). The remaining 64 patients (47.76%) were identified as osteoporosis by the specialists or by mean of osteoporosis medication taking. In addition, age at menopause of the subjects ranged between 45-50 years old. Our data showed a wide range of menopausal duration because of the wide distribution of the subjects which ranged from 49 to 95 years old. The missing data occurred because three patients could not remember their age at menopause.

Table 6 Frequency, percentage of occupation of patients

Occupation	Frequency	Percentage
Labor	47	35.07
Sedentary job	56	41.79
Housework	31	23.13

Occupation of patients was summarized in term of frequency and percentage as shown in Table 6. Most of the subjects are employed sedentary job (41.79%) during working age (20 – 60 years old) followed by labor (35.07%) and housework (23.13%), respectively. The additional data about job after retirement or 60 years old and older presented that they are mostly unemployed and the other patients do the housework.

Part 2: Descriptive data of quality of life

Quality of life of 134 postmenopausal women with risk of osteoporosis was assessed using Qualeffo41. The 41-item Qualeffo41 encompassed the following 5 domains, pain (5 items), physical function (17 items), social function (7 items), general health perception (3 items) and mental function (9items). All answer were standardized so that 1 represented the best and 5 (or 3, or 4) represented the worst quality of life (reverse scores on questions 33, 34, 35, 37, 39, 40), so that lower scores indicate better quality of life. The results which were range, mean and standard deviation of descriptive data of each Qualeffo41 item is presented in following Table 7.

Table 7 Range, mean, standard deviation of descriptive data of each Qualeffo41 item

Items	N	Range	Mean	S.D.
Pain				
1. How often have you had back pain in the last week?	134	1-5	2.87	1.51
2. How long did you have back pain in daytime?	134	1-5	2.07	1.03
3. How severe is your back pain at its worst?	134	1-5	2.87	1.61
4. How is your back pain at other times?	134	1-5	1.81	1.10
5. Has the back pain disturbed your sleep in the last week?	134	1-5	1.44	1.14
Physical function				
6. Do you have problems with dressing?	134	1-5	1.45	0.94
7. Do you have problems with taking a bath or shower?	134	1-5	1.35	0.87
8. Do you have problems with getting to or operating a toilet?	134	1-5	1.46	0.93
9. How well do you sleep?	134	1-5	2.91	1.20
10. Can you do the cleaning?	134	1-5	2.51	1.42
11. Can you prepare meals?	134	1-5	1.92	1.30
12. Can you wash the dishes?	134	1-5	1.78	1.32
13. Can you do your day to day shopping?	134	1-5	2.25	1.42
14. Can you lift a heavy object of 20 lbs (e.g. a crate of 12 bottles of milk, or a one year old child) and carry it for at least 10 yards?	134	1-5	4.49	1.02
15. Can you get up from a chair?	134	1-5	1.90	1.19
16. Can you bend down?	134	1-5	2.31	1.30
17. Can you kneel down?	134	1-5	3.99	1.43
18. Can you climb stairs to the next floor of a house?	134	1-5	2.36	1.23
19. Can you walk 100 yards?	134	1-5	2.22	1.16
20. How often have you been outside in the last week?	134	1-5	3.15	1.61
21. Can you use public transport (bus) ?	134	1-5	3.22	1.68
22. Have you been affected by the changes of your figure due to osteoporosis (for example loss of height, increase of waist measurement, shape of your back) ?	133	1-5	2.77	1.32

Items	N	Range	Mean	S.D.
Leisure, social activities				
23. Do you play any sport now?	134	1-5	4.57	0.62
24. Can you do your gardening?	134	1-5	2.82	1.22
25. Do you perform any hobby now?	134	1-5	1.19	0.42
26. Can you visit a cinema, theatre?	134	1-5	2.27	0.92
27. How often did you visit friends or relatives during the last 3 months?	134	1-5	3.02	1.15
28. How often did you participate in social activities (clubs, social gatherings, church activities, charity etc.) during the last 3 months?	134	1-5	2.93	1.12
29. Does your back pain or disability interfere with intimacy (including sexual activity) ?	134	1-2	1.23	1.46
General health perception				
30. For your age, in general, would you say your health is?	134	1-5	2.83	0.98
31. How would you rate your overall quality of life during the last week?	134	1-5	2.35	1.03
32. How would you rate your overall quality of life compared with 10 years ago?	134	1-5	3.16	1.00
Mental function				
33. Do you tend to feel tired?	134	1-5	2.37	1.46
34. Do you feel downhearted?	134	1-5	1.70	0.90
35. Do you feel lonely?	134	1-5	1.51	0.88
36. Do you feel full of energy?	134	1-5	1.61	0.96
37. Are you hopeful about your future?	133	1-5	2.25	1.12
38. Do you get upset over little things?	134	1-5	2.51	0.96
39. Do you find it easy to make contact with people?	134	1-5	1.87	1.11
40. Are you in good spirits most of the day?	134	1-4	1.98	0.78
41. Are you afraid of becoming totally dependent?	134	1-5	2.04	1.27

As shown in Table 7, the maximum and minimum score in each domain was revealed as follow: the highest mean score in the pain domain were as follows: item 1: How often have you had back pain in the last week? (Mean= 2.87, S.D. = 1.51)

and item 3: How severe is your back pain at its worst? (Mean = 2.87, S.D. = 1.61). On the contrary, the lowest mean score in this domain was item 5: Has the back pain disturbed your sleep in the last week? (Mean = 1.44, S.D. = 1.14). In aspect of physical function, the highest mean score was item 14: Can you lift a heavy object of 20 lbs (e.g. a crate of 12 bottles of milk, or a one year old child) and carry it for at least 10 yards? (Mean = 4.49, S.D. = 1.02). On the other hand, the lowest mean score was item 7: Do you have problems with taking a bath or shower? (Mean = 1.35,S.D. = 0.87). As regards leisure or social activities, item 23: Do you play any sport now? (Mean = 4.57, S.D. = 0.62) has the highest mean score while item 25: Do you perform any hobby now? (Mean = 1.19, S.D. = 0.42) has the lowest mean score. The highest mean score in the general health perception domain was item 32. How would you rate your overall quality of life compared with 10 years ago? (Mean = 3.16, S.D. = 1.00). On the contrary, the lowest mean score in this domain was item 31: How would you rate your overall quality of life during the last week? (Mean = 2.35, S.D. = 1.03). As regards mental function, the highest mean score was item 38: Do you get upset over little things? (Mean = 2.51, S.D. = 0.96) while the lowest mean score is item 35: Do you feel lonely? (Mean = 1.51, S.D. = 0.88).

Table 7 showed that the three items with highest mean score of all 41 questions were as follows: item 23: Do you play any sport now? (Mean = 4.57, S.D. = 0.62), item 14: Can you lift a heavy object of 20 lbs (e.g. a crate of 12 bottles of milk, or a one year old child) and carry it for at least 10 yards? (Mean = 4.49, S.D. = 1.02), item 17: Can you kneel down? (Mean = 3.99, S.D. = 1.43). In contrast, the three items with lowest mean scores of all 41 questions were as follows: item: 25: Do you perform any hobby now? (Mean = 1.19, S.D. = 0.42), item 29: Does your back pain or disability interfere with intimacy (including sexual activity)? (Mean=1.23, S.D.=1.46) and item 35:Do you feel lonely? (Mean = 1.51, S.D. = 0.88).

See Appendix D for the frequency and percentage of each choice of Qualeffo41 items

Pain score, physical function score (divided in three sub-domains: activities of daily living, jobs around the house and mobility), leisure or social activities score, general health perception score, and mental function score were calculated to provide a quality of

life summary of the postmenopausal women with risk of osteoporosis in each domain. Table 8 show range, mean, standard deviation, Cronbach's alpha of total score of each domain and total quality of life score.

Table 8 Range, mean, standard deviation of total score of each domain and total quality of life score

Total score	N	Range	Mean	S.D.
Pain	134	0.00-100.00	30.34	25.27
Physical function	134	1.47-98.53	36.82	21.52
Social activities	134	0.00-100.00	44.53	22.35
General health perception	134	0.00-100.00	44.47	18.53
Mental	134	0.00-83.33	24.60	15.59
Quality of life	134	6.25-80.63	34.86	15.67

The total score of Qualeffo was calculated by summing all answers of questions 1-41. The raw total score ranged from 41 to 205. The mean score of actual quality of life score was 94.69$\pm$24.76 which were transformed into standardized quality score (0 to 100) was 34.86$\pm$15.67. As mentioned above 0 represented the best and 100 represented the worst quality of life.

Qualeffo41 presented five domains which were pain, physical function, social activities, general health perception and mental function. As shown in Table 8, mental domain revealed the lowest quality of life score which represented highest quality of life level.

Mental domain captured both positive and negative feeling and emotion such as fulfill of energy, hopeful, friendly, tired, downhearted, lonely, upset and scared. The second high quality of life level was pain domain. This domain was measured by asking about frequency of pain, duration of pain, severity of pain at worst and other time. The third rank was physical function domain which consisted of activities of daily living, jobs around the house and mobility. The forth rank was general health perception domain, in which subjects evaluated their health comparing to others with the same age at the present and in the past. The last was social activities domain such as doing hobby, playing sport, gardening, going to cinema, visiting friend or relative and having problems in sexual activity.

Part 3 Reliabilities of Qualeffo41

Table 9 Cronbach's alpha of total score of each domain and total quality of life score

Domains	Number of items	Cronbach's Alpha
Pain	5	0.837
Physical function	17	0.926
Activities of daily living (ADL)	4	0.690
Jobs around the house	5	0.885
Mobility	8	0.856
Social activities	7	0.675
General health perception	3	0.590
Mental	9	0.760
Quality of life	41	0.841

The internal consistency reliabilities of the whole instrument were good with Cronbach's alphas of 0.841 (Total score of Qualeffo-41; N=134). However, Cronbach's alpha correlation coefficient was lower than 0.7 in two items which are leisure or social activities and general health perception domain, namely Cronbach's alpha correlation coefficient of social activities domain was 0.675 and 0.590 for general health perception. Cronbach's alpha correlation of three sub-domains of activities of daily living (ADL), jobs around the house, and mobility of physical function were .690, .885 and .856, respectively.

Table 10 Correlation between BMD T-score and domains of Qualeffo-41 in 70 subjects

		QOL	Qualeffo domain				
		score	Pain	Physical function	Social activities	General health perception	Mental
T-score	Pearson Correlation	-.221	-.157	-.234	-.246*	.017	-.052
	Sig. (2-tailed)	.065	.193	.051	.040	.889	.670

* p-value < 0.05

Table 10 showed the correlation between the BMD T-score value and domains of Qualeffo-41 which are pain, physical function, social activities, general health perception, mental and total Qualeffo41 score. Only one domain particularly was significant, namely social activities ($p < 0.05$). Although the correlation between BMD T-score and total Qualeffo41 score was non-significant, the correlation was in the correct direction. From the correlation BMD T-score had a negative relationship to total Qualeffo41 score, in the other word: if the T-score was lower, the quality of life score would increase which implies the worse quality of life in patients.

Part 4: Descriptive data of health concerning

Health concerning consisted of five parts which were exercising, dietary calcium and protein consuming, caffeine taking, alcohol drinking and smoking. The range, mean, standard deviation of exercising, dietary calcium and protein consuming presented as energy expenditure and dietary calcium and protein consuming as dietary score which value 5-25 (the higher the score indicated the more patients take calcium and protein food) in the following Table 11.

Table 11 Range, mean, standard deviation of energy expenditure and dietary score

Health concerning	N	Range	Mean	S.D.
Energy expenditure (Kcal/d)	134	0.00 - 611.33	156.52	132.63
Dietary score	134	5.00 - 25.00	17.72	3.70

As in Table 11 showed, the mean($\pm$S.D.)of energy expenditure was 156.52 Kcal/d ($\pm$132.63) and most prevalence exercise of the subjects was quick walking, sweeping and stairs climbing which are considered as light manual work. Moreover, the mean ($\pm$S.D.) of dietary score was 17.72 ($\pm$3.70).

Table 12 Range, mean, standard deviation of dietary score

Calcium or protein diet	N	Range	Mean	S.D.
milk product	134	1-5	3.32	1.73
dried prawn or fish product	134	1-5	2.69	1.21
vegetable	134	1-5	4.28	1.09
bean product	134	1-5	3.28	1.31
meat and egg	134	1-5	4.41	.90

Table 12 showed range, mean and standard deviation of dietary score in each kind. It revealed that the mean (±S.D.) of meat and egg consuming is the highest mean score 4.41 (±.90) and followed by vegetable 4.28 (±1.09), milk product 3.32 (±1.73), bean product 3.28(±1.31) and dried prawn or fish product 2.69(±1.21), respectively. In addition, most of the subjects did not consume milk product. Only 30.6% (N= 41) consumed milk product. The frequency of dried prawn or fish product, bean product, vegetable and meat and egg consumption were 20.15%, 13.43%, 3.73%, and 0.75% respectively.

See Appendix E for the frequency and percentage of each dietary calcium and protein intake item.

Table 13 Frequency, percentage of caffeine taking, alcohol drinking and smoking

Life style	Frequency			Percentage	
	Yes	No	Total	Yes	No
Alcohol drinking	6	128	134	4.48	95.52
Caffeine taking	94	40	134	70.15	29.85
Smoking	0	134	134	0.00	100.00

The frequency, percentage of caffeine taking, alcohol drinking and smoking were shown in the following Table 13. It indicated that 1/20 or around 5% of subjects drink alcohol. The majority of subjects or 94% drink caffeine beverage such as coffee, tea and cocoa, while none of the subjects smoke.

Part 5: Descriptive data of treatment

The fourth part: Descriptive data of treatment was composed of two parts which were duration of medication taking and having side effect of medication. The study examined 6 osteoporosis drugs which were Alendronate (Fosamax®), Risedronate (Actonel®), Ibandronate (Bonviva®), Raloxifene (Celvista®), Calcitonin nasal spray, Strontium renelate (Protaxos®) and calcium.

Table 14 Range, mean, standard deviation of duration of medication taking

Duration of medication taking (month)	N	Range	Mean	S.D.
Osteoporosis drug				
Alendronate (Fosamax®)	58	2.00 - 89.00	26.04	24.17
Risedronate (Actonel®)	69	1.00 - 120.00	31.25	27.88
Ibandronate (Bonviva®)	33	1.00 - 54.00	19.73	12.88
Raloxifene (Celvista®)	23	4.00 - 126.00	50.83	31.57
Calcitonin nasal spray	17	1.00 - 78.00	22.12	22.01
Strontium renelate (Protaxos®)	12	1.00 – 15.00	5.08	3.92
Total	134	0.00 - 126.00	38.43	31.45
Calcium	134	0.00 - 252.00	61.35	46.07

Table 14 showed range, mean, standard deviation of duration of medication taking including 6 osteoporosis drugs and calcium. The subjects in this study consisted of patients who did not receive any drugs and patients who received only one drug or two or more. In case, patient received two or more than two drugs, Raloxifene (Celvista®) was always dispensed with other osteoporosis drugs. Compare to the other drugs the duration of Raloxifene (Celvista®) taking was also the longest or around 4 years and 3 months. In aspect of frequency of osteoporosis drug taking, the drug taken by most patients was Risedronate (Actonel®) (N = 69), in contrast, Strontium renelate (Protaxos®) was taken by few patients (N = 12) as it has been recently launched to market and patients has difficulty with drug administration which is sachet, that is, patients have to dissolve the drug in a glass of water and drink. Furthermore, as regards calcium, duration of calcium taking ranged between 0 to 21 years with mean score approximately 5 years and 2 months.

Table 15 Frequency, percentage of having side effect from medication

Having side effect from medication	Frequency			Percentage		
	Yes	No	Total	Yes	No	Total
Osteoporosis drug	17	109	126	13.49	86.51	100.00
Calcium	13	117	130	10	90	100.00

Side effects from medication were abdominal pain, dyspepsia, constipation, diarrhea, flatulence, esophageal ulcer, headache, nausea and vomiting for bisphosphonate, leg cramps, hot flushes, myalgia for Raloxifene (Celvista®), nausea, vomiting, dizziness for Calcitonin nasal spray and nausea, vomiting, headache for Strontium renelate (Protaxos®). Table 14 showed that most patients did not have side effects of medication but only 14% had side effects, as well as, side effects of calcium which did not occur in 90% of patients but the rest or 13 patients had side effects which was abdominal pain and constipation.

Part 6: The factors affecting quality of life in patients with risk of osteoporosis: a multiple regression analysis

Table 16 Coefficients of predictor variables in multiple regression for quality of life in patients with risk of osteoporosis

Variables	Unstandardized Coefficients		Standardized Coefficients	t	Sig.
	B	Std. Error	Beta		
(Constant)	51.912	9.603		5.406	.000
BMI	.190	.282	.047	.676	.500
Occupation (Z1)	-5.157	2.944	-.139	-1.752	.082
Occupation (Z2)	-11.113	2.616	-.357	-4.248	.000
Duration of menopause	.248	.108	.164	2.290	.024
Energy expenditure (Kcal/d)	-.056	.008	-.473	-6.616	.000
Dietary score	-.656	.297	-.153	-2.206	.029
Alcohol drinking	-4.449	5.126	-.060	-.868	.387
Caffeine taking	-3.053	2.319	-.091	-1.316	.191
Duration of osteoporosis drugs taking	.086	.044	.174	1.937	.055
Duration of calcium taking	-.034	.030	-.100	-1.135	.259
Side effect of osteoporosis drugs	-2.756	3.259	-.060	-.846	.400
Side effect of calcium	3.323	3.575	.065	.930	.355

a. Dependent Variable: total mean QOL score
b. $R = 0.698$, $R^2 = 0.487$, $F = 9.254$

From the assumption of multiple regression analysis, the dependent variables must be normally distributed and independent variables included in the model should not be related to one another. In addition, when linear regression was being used, the relationship of independent variables and dependent variable assumed to be linear.

In this study, total mean QOL score for postmenopausal women with risk of osteoporosis was the dependent variable. All variables that were expected to relate to the total mean QOL score of postmenopausal women with risk of osteoporosis were screened to be included in the model. These factors were BMI, occupation, duration of menopause,

energy expenditure (Kcal/d), dietary score, caffeine taking, alcohol drinking, smoking, duration of osteoporosis drugs taking, duration of calcium taking, side effect of osteoporosis drugs, and side effect of calcium. From the assumption of multiple regression, the independent variables must not correlate with each other. Since none of the subjects smoke then smoking was not included in the model. Finally, the eleven selected variables (from 12 variables) were analyzed using multiple regression analysis.

It was found that BMI, alcohol drinking, caffeine taking, duration of osteoporosis drug taking, duration of calcium taking, side effect of osteoporosis drugs, and side effect of calcium were not related to QOL of postmenopausal women with osteoporosis. On the other hand, patient's QOL was affected by four predictor variables (occupation, duration of menopause, energy expenditure (Kcal/d), and dietary score). Occupation influenced on quality of life in postmenopausal women with risk of osteoporosis. Duration of menopause was positively related to total score of the QOL. It could be explained that if the duration of menopause of postmenopausal women with risk of osteoporosis increased 1 year, their QOL scores would increase .248 point (P= .024), while holding other variables constant. Energy expenditure (Kcal/d) and dietary score were negatively related to total score of the QOL. It could be explained that if energy expenditure increase 1 Kcal/d, their QOL scores would decrease .056 point (P< .000). Furthermore, while holding other variables constant, if dietary score increase 1 point, their QOL scores would decrease .656 point (P = .029), as shown in Table 16.

As the result shown in Table 16, the standardized regression coefficient value was considered and it indicated that energy expenditure (Kcal/d) had the highest beta coefficient which is -.473, followed by occupation (β = -.357), duration of menopause (β =.164), and dietary score (β = -.153), respectively. In the other word, energy expenditure (Kcal/d) had the most influence on quality of life of postmenopausal women with risk of osteoporosis, followed by occupation, duration of menopause, and dietary score, respectively. The influence on quality of life in postmenopausal women with risk of osteoporosis could be predicted by the following multiple regression equation:

Multiple regression equation

Y_{QOL} = 51.912-11.113 Occupation (Z2) + .248 Duration of menopause
- .056 Energy expenditure - .656 Dietary score

Z_{QOL} = -.357 Occupation (Z2) + .164 Duration of menopause
- .473 Energy expenditure - .153 Dietary score

Furthermore, in this study examined factors influencing quality of life in each domain of Qualeffo41. It found that occupation affected quality of life in pain and social activities domain with beta coefficient which are -.342 and -.323, respectively. Duration of menopause affected worse quality of life in physical function and social activities domain (β = .432, .275). Additionally, it also found that duration of osteoporosis drugs taking caused worse quality of life in mental domain with beta coefficient which is .295.

See appendix G for coefficients of predictor variables in multiple regression for each domain in Qualeffo41.

CHAPTER V
DISCUSSION AND CONCLUSIONS

This study focused on the quality of life in postmenopausal women with risk of osteoporosis or patients who had low bone mass and their risk of fractures were considered increasing. This chapter presented the discussion and conclusion of the findings of the study.

Discussion

A. Demographic and clinical characteristics of the subject

In this study, a total of 134 postmenopausal women with risk of osteoporosis were recruited as the study sample. They ranged in age from 49 – 95 years old, a mean age of 70.23 years (S.D. = 8.96). The age of subjects was higher than the age of those another studies conducted with osteoporosis patients (11, 99, 100, 114).

The mean BMI of the subject was healthy which differ from the studies of Bianchi, M. L., et al. (114), de Oliveira Ferreira, N., et al. (11), Badia, X. et al (100), and Jahelka, B. et al (145), in which the mean BMI of the subject are over 25 Kg/m^2 or overweight.

The dual energy X ray absorptiometry (DXA) measures T-score at lumbar spine, proximal hip, and forearm. The T-score showed in this study was the minimum T-score in each patient. The bone mineral density of 70 patients was measured by dual energy X ray absorptiometry (DXA) while the other 64 patients did not but they were examined by the experts according to their age, genetic, prolonged glucocorticiod use and/or having previous fractures and considered to receive osteoporosis treatment. In 70 patients whose bone mineral density was measured the T-score of 26 patients were during -1 to -2.5 which could be categorized into osteopenia but they received osteoporosis treatment, so they were recruited in this study as well on the ground of their high turnover rate bone mineral density and/or prolonged glucocorticiod taking, previous fractures. The mean of the bone mass in this study was a little bit higher than the other studies (11, 100, 114). The duration of menopause in this study was longer than other studies of Bianchi, M. L., et al. (114) and de Oliveira Ferreira, N., et al. (11) in which the duration of menopause were approximately 15 and 18 years.

Most of the studies did not examine the occupation in aspect of type of occupation but they studied which occupation correlate to quality of life and whether the subjects do paid work (11).

B. Qualeffo41

According to the study findings, the mean score of Qualeffo41 was 34.86 (S.D. = 15.67) similarly to the study of de Oliveira Ferreira, N., et al. (11) but lower than the study of Jahelka, B. et al. (145) in which the Qualeffo41 means score was 58.6 (S.D. = 15.70), in other word, the quality of life of the subjects was worse than this study. The domain which has the lowest mean score from five domains of Qualeffo41 was mental domain (Mean = 24.60. S.D. = 15.59). On the ground of the Thai cultural background that is extended family that compounds of the older adults and/or their husband/wife, their children's family, and relative lives together thus the quality of life of mental dimension in this study was better than the foreign study of de Oliveira Ferreira, N., et al. (11) (Mean = 36.9, S.D. = 16.2). In contrast, the score of social activities domain (mean = 44.53, S.D. = 22.35) was the highest score of five domains in Qualeffo41 or the worst part of quality of life was the social activities. It could imply that Thais did not often visit a cinema, friends or relatives (their friends and relatives visit them at home instead), and participate in social activities. This caused the high score in social activities in the subject or the quality of life of the subject in this part is not good comparing to the study in Italy of Bianchi, M. L., et al. (114).

C. Reliabilities of Qualeffo41

For reliability test, the Cronbach's alpha internal consistency reliabilities generally exceeded the recommended minimum alpha coefficient standard of 0.70. In this study the Cronbach's alpha value was 0.841 which is a bit lower than other studies (11, 100). Social activities domain produced a lower Cronbach's alpha value of 0.675 in this study, which was similar to study in Malaysia (146) ($\alpha = 0.67$) and in Mexico (147) ($\alpha = 0.463$). The cause of low Cronbach's alpha value would be in Qualeffo41 the social activities domain consisted of questions that represented a broad range of activities divided in three components. The first components consisted of the question as follow: Do you play any sport now? Can you do your gardening? Do you perform any hobby now? The second component: Can you visit a cinema, theatre? How often did you

visit friends or relatives during the last 3 months? How often did you participate in social activities (clubs, social gatherings, church activities, charity etc.) during the last 3 months? And the third component: Does your back pain or disability interfere with intimacy (including sexual activity)? (146) Another rationale could be that the social activities of elderly Asian was different from those of elderly European. For example, many older Asian do not visit cinema, do not often visit friend or relatives, do not often participate in social activities such as club or religious activities, and don't have any sexual intimacy. Compared to study in Malaysia (146) and in Mexico (147) the most not-applicable question is that the question about a sexual activity: Does your back pain or disability interfere with intimacy (including sexual activity)? because of age of subjects and culture of Asian as mentioned earlier. One hundred and eleven patients (82.8 %) of the subjects in this study answer 'not applicable' in this question and hence, if this question was eliminated, the Cronbach's alpha value would be 0.713 or more consistency. In addition, Cronbach's alpha correlation coefficient of general health perception domain and sub-domain, activities of daily living (ADL), in physical function which lower than 0.7 certainly was caused by small amount of the item in the domain.

D. Factor affecting the quality of life in postmenopausal women with risk of osteoporosis

According to the result of this study, quality of life of postmenopausal women with risk of osteoporosis was significantly associated with various factors.

This study examined correlation between quality of life in patients and type of occupation divided in three types which are labor, housework and sedentary job. In this study occupation influenced quality of life in patients with risk of osteoporosis.

Exercising and dietary calcium and protein intake positively associated with quality of life in patients. Physical activities influenced quality of life in the subjects positively which was similar to the study of Bennell, K.L., et al. in which they found that exercising had an positive effect on physical domain of Qualeffo in patients in intervention group (148), Moriyama, C.K., et al. (122) reported that physical exercise was associated with a better quality of life, and, in the same way of study in Canada (99) which found that HRQOL was positively associated with the amount of time spent exercising. Moreover, de Oliveira Ferreira, N., et al. (11) observed that sedentary lifestyle

effect worse quality of life in patients; therefore, patients should be advised to change their lifestyles and get exercising. Dietary calcium and protein intake also affected quality of life in the positive way or caused lower quality of life score which similar to de Oliveira Ferreira, N., et al. study (11) which showed that poor intake of calcium was associated with the risk of osteoporosis and may impaired quality of life as well.

On the other hand, duration of menopause negatively influence the quality of life in patients. It meant that the longer the time since menopausal was, the worse quality of life could be. This showed a parallel to study of Kobjit (113) that menopause resulted in increasing rate of bone loss which leads to having risk of fracture and impairing quality of life, but disagree with study of Bianchi, M. L., et al. (114).

In addition, the study showed that BMI, life style habits: caffeine intake, alcohol drinking, and smoking, duration of osteoporosis drug taking, duration of calcium taking, side effect of osteoporosis drugs and side effect of calcium did not have an effect on quality of life in postmenopausal women with risk of osteoporosis.

The study represented that BMI was not related to quality of life which similar to study of Badia, X. et al. (100), in which BMI had weak correlation to quality of life, but differ from the study of de Oliveira Ferreira, N., et al. (11), in which the higher BMI led to impairment in pain, physical, mental function. In term of life style habits, in this study caffeine and alcohol intake were not relevant to de Olivia's study, in which alcohol consuming related to the impairment quality of life of patients. Besides, the quantity of caffeine taking and alcohol drinking were not measured but the question only asked whether the patients consume caffeine and alcohol. None of subjects in this study smoked, thereby, an effect of smoking on quality of life could not be concluded. Besides, in this study the duration of osteoporosis drug taking did not make an impact on quality of life in patients which was different from the findings of Adachi, J., et al. (99), in which bisphosphonate using had a positive effect on quality of life, for the possible reason that the duration of osteoporosis drug taking in this study was derived from the sum total of duration of every osteoporotic medications. For example, a patient took raloxifene for 3 years and after 2 years of discontinuing the patient took alendronate for 2 years, so the duration of osteoporosis drug taking of the patient would be 5 years. The another reason was that the duration of osteoporosis drug taking data was from

reviewing the patients' profile which may cause several problems such as, unclear handwriting of specialists, uncertain the discontinuing of osteoporosis drug taking. Regards the duration of calcium taking, the problems were if patients have ever bought and took calcium by themselves before the specialists' prescription or not and patients could not remember the duration of calcium taking which results in the recall bias.

The study examined the side effect of osteoporosis drugs and side effect of calcium by asking if the osteoporosis drugs have ever had the side effects on patients or not. The result showed that most of the patients did not suffer from the side effects of the osteoporosis drugs. Moreover, this study found that the side effect of osteoporosis drugs and side effect of calcium did not influence quality of life in patients because if any side effects were found, the specialists would change the medication which leads patients not to have the side effects or discontinue drug taking. After examining correlation between factors influencing each domain of Qualeffo41, it found that the additional factor, duration of osteoporosis drugs taking, affected quality of life only in mental domain. Even though taking osteoporosis drugs heals osteoporosis, it may cause worse quality of life in aspect of mentality. The longer the duration of osteoporosis drugs taking is, the worse quality of life in aspect of mentality could be.

Conclusions

The objectives of this study were to measure quality of life in postmenopausal women with risk of osteoporosis, using Qualeffo41 and to examine factors influencing quality of life in postmenopausal women with risk of osteoporosis. The cross-sectional descriptive study investigated quality of life in 45-year-old and older postmenopausal women with low bone mineral density (BMD) ($\leq$ - 2.5 standard deviations (S.D.) below normal peak bone mass) or were diagnosed as an osteoporosis or taking osteoporosis drug. One hundred and thirty four (134) women were recruited at postmenopausal clinic and orthopedic clinic in the Police General Hospital from December 2009 to March 2010. The interview-administered questionnaire consists of 4 parts which are demographic and clinical characteristics, quality of life, factors in health concerning and factors in treatment. To analyze the data SPSS statistical package 17.0 for windows was used in this study in order to present mean, standard deviation,

minimum, and maximum and examine the correlation by using a multiple regression analysis.

Quality of life

Quality of life assessment was performed using the Qualeffo41 (Thai version) which presents five domains: pain, physical function (divided in three sub-domains: activities of daily living, jobs around the house and mobility), social function, general health perception and mental function. All scores are expressed in values ranging from 0 to 100, where 0 represents the best and 100 represents the worst quality of life. The mean (±S.D.) total QOL score of postmenopausal women with risk of osteoporosis was 34.86 (±15.67). In each domain, the result showed that the score of pain domain was 30.34 (± 25.27), physical function domain was 36.82 (±21.52), general health perception domain was 44.47 (±18.53) and mental domain scored was 24.60 (±15.59). Mental health quality of life is the best among all five dimensions.

Multiple regression was conducted to determine factors affecting the health-related quality of life of postmenopausal women with risk of osteoporosis. With this analysis the dependent variable was the total mean QOL score. The patient's QOL was affected by four predictor variables which are occupation, duration of menopause, energy expenditure (Kcal/d), and dietary calcium and protein intake. Occupation influenced quality of life. Duration of menopause were positively related to total score of the QOL, while energy expenditure (Kcal/d) and dietary calcium and protein intake were negatively related to total score of the QOL. It could be explained that if the subjects have long duration of menopause they might have worse quality of life, in contrast, if the subjects get more exercising and consume more calcium and protein diet they might have better quality of life. Furthermore, the standardized regression coefficient value was considered and it indicated that energy expenditure (Kcal/d) had the most influence on quality of life of postmenopausal women with risk of osteoporosis, followed by occupation, duration of menopause, and dietary score, respectively.

Limitation

1. The limitation of this study was the accuracy of classifying osteoporosis due to the limitation of DXA in the Police General Hospital. The subjects of this study were postmenopausal women with risk of osteoporosis. Bone mineral density (BMD) of

some of them were measured with dual energy X ray absorptiometry (DXA) according to the criteria of WHO, while the rest of the patients were identified by specialists or medication taking history in consequence of limit amount of dual energy X ray absorptiometry (DXA) in the Police General Hospital. For the reason mentioned, the study population in this study consisted of two groups: the patients whose bone mineral density was measured with dual energy X-ray absorptiometry (DXA) and the patients who identified as osteoporosis by specialists or medication taking history. Further study will need to recruit the same characteristic of patients.

2. Qualeffo41 is the specific questionnaire in order to evaluate quality of life in patients with osteoporosis. It was designed to be a self-administered questionnaire, but in this study the mode of administering was changed to interview-administered questionnaire for the reason that most of the patients were elderly women who had difficulty in reading and were unable to use the self-administration modality (impaired visual ability or low level of education). With the purpose of decreasing the error in this study, the researcher read the questions for every patient instead of self-administered questionnaire. In addition, Badia, X. et al revealed that the interview-administered questionnaire provided higher quality data (100) and Pérez E. R., et al. found that the result of interview-administered of Qualeffo41 was not different from the result of self-administered (147).

3. Some questions in Qualeffo41 were not fit with Thai lifestyle and culture of the participants. In physical function domain the limitation of the content was found in item 21: Can you use public transport (bus)? According to the fact that public mass transportation system (bus) in Thailand does not provide convenience to the passengers like in developed countries, especially the country where the questionnaire was developed, which bring about the invalid measurement, that is the patients could possibly use another transportations apart from bus such as, taxi or sky train, without difficulty or with little or moderate difficulty. The mode of transportation “taxi” would be a good proxy for “bus” in Thai version questionnaire. Another limitation of the content is item 26: Can you visit a cinema, theatre? Due to the Thai culture, most of the patients answered ‘not at all’ in this item but if they are asked about other activities such as eating

out, they can do these activities. Hence, the activity “eating out” would be a good proxy for “visiting a cinema” in Thai version questionnaire as well.

4. In term of diet, the overall frequency of calcium and protein diet in a week was asked, not the quantity. This could affect the data collection and lead to a rough data or not include all details in measuring dietary calcium and protein intake.

Recommendation

1. The questionnaire evaluating quality of life in this study was Thai version Qualeffo41 validated by using clinical data, which is bone mineral density or BMD. This study examined the correlation between BMD and quality of life and found that they were not significantly related in the accurate direction, therefore, to validate Thai version Qualeffo41 with other gold standard questionnaire such as, SF 36 etc. should be studied.

2. The further study should collect the data about concomitance diseases in patients because it may influence the answer in item 17: Can you kneel down? For example, if the patients were suffering from osteoarthritis or rheumatoid together with osteoporosis, they would answer ‘impossible’ in this item which could caused by rheumatoid or osteoporosis like the study of Canada, in which showed that the concomitance diseases such as, arthritis and rheumatoid which negatively associated with HRQOL (99).

3. Exercise assessment instrument was very complicated to be self-administered for patients. In further study the researcher should interview patients or improve the instrument to be easier to be self-administered for patients. Besides, the activities in the instrument should be adapted to be more relevant to lifestyle and culture of particular country.

4. According to the result of the study which found that health concerning related to exercising and dietary calcium and protein intake and then caused higher quality of life. Hence, postmenopausal women should be informed about the advantages of exercising and dietary calcium and protein intake in positively affecting quality of life in order to induce the women to pay more attention on their health. Moreover, women should be advised before they suffer from the osteoporosis.

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APPENDICES

Appendix A

องค์กรแพทย์ โรงพยาบาลตำรวจ
สำนักงานแพทย์ใหญ่
492/1 ถนนพระราม 1 แขวงวังใหม่
เขตปทุมวัน กรุงเทพฯ 10330

เอกสารรับรองโครงการวิจัย

โดย

คณะอนุกรรมการจริยธรรมการวิจัยในมนุษย์ องค์กรแพทย์ โรงพยาบาลตำรวจ

เลขที่หนังสือรับรอง...121.....

ชื่อโครงการ/ ภาษาไทย	การศึกษาคุณภาพชีวิตของผู้หญิงวัยหมดประจำเดือนที่เป็นโรคกระดูกพรุน ในแผนกอภิสาสตร์-นรีเวชวิทยาและแผนกออร์โธปิดิกส์ โรงพยาบาลตำรวจ
ชื่อหัวหน้าโครงการ / หน่วยงานที่สังกัด	นางสาวอิสรีย์ ธรรยาศักดิ์ คณะเภสัชศาสตร์จุฬาลงกรณ์มหาวิทยาลัย
รหัสโครงการ	-
สถานที่ทำการวิจัย	โรงพยาบาลตำรวจ
เอกสารรับรอง	- แบบเสนอโครงการวิจัยเพื่อขอรับการพิจารณา - หนังสือให้ความยินยอมเข้าร่วมโครงการ - แบบบันทึกข้อมูล
รับรองโดย	คณะอนุกรรมการจริยธรรมการวิจัยในมนุษย์ องค์กรแพทย์ โรงพยาบาลตำรวจ
วันที่รับรอง	14 ตุลาคม 2552
วันหมดอายุ	13 ตุลาคม 2553

หนังสือรับรองฉบับนี้ออกโดยความเห็นชอบในการพิจารณาของคณะอนุกรรมการจริยธรรมการวิจัยในมนุษย์ องค์กรแพทย์ โรงพยาบาลตำรวจ ตามกฎเกณฑ์สากล (ICH-GCP)

พันตำรวจเอก
(สุพัฒน์ เอาะวัฒนะ)
ประธานอนุกรรมการจริยธรรมการวิจัยในมนุษย์
โรงพยาบาลตำรวจ

Appendix B

เอกสารคำแนะนำเพื่อขอความยินยอมเข้าร่วมโครงการ

เหตุผลและความจำเป็นที่ต้องทำการศึกษาวิจัย

ภาวะกระดูกพรุนเป็นโรคที่พบมากและมีความเกี่ยวข้องกับอายุ โดยเฉพาะอย่างยิ่งกับผู้หญิงวัยหมดประจำเดือน ผลของการมีภาวะกระดูกพรุนอาจส่งผลต่อการแตกหักของกระดูกสะโพก สันหลัง และข้อมือ ในประเทศไทย หญิงไทยอายุกว่า 50 ปี เกือบ 6.7 ล้านคนถูกวินิจฉัยว่ามีภาวะกระดูกพรุนและมีอุบัติการณ์ของกระดูกสะโพกแตกร้าวหรือหักปีละ 42,000 คน กระดูกสะโพกแตกร้าวทำให้เกิดความเจ็บปวด ถึงแม้จะไม่ใช่อาการรุนแรงแต่ก็กระทบต่อการดำรงชีพมีผลต่อคุณภาพชีวิต คุณภาพชีวิตของผู้ป่วยจะเป็นตัวชี้วัดประสิทธิภาพตัวหนึ่งของการรักษา และการรู้ถึงปัจจัยที่มีผลต่อคุณภาพชีวิตจะทำให้ในการดูแลผู้หญิงวัยหมดประจำเดือนที่มีภาวะกระดูกพรุนให้มีประสิทธิภาพยิ่งขึ้น

คณะเภสัชศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย เล็งเห็นความสำคัญของการศึกษาปัจจัยที่มีผลต่อคุณภาพชีวิตจึงได้ทำการวิจัยเรื่อง “คุณภาพชีวิตในผู้หญิงวัยหมดประจำเดือนที่เป็นโรคกระดูกพรุนในโรงพยาบาลตำรวจ” เพื่อทำความเข้าใจเกี่ยวกับระดับคุณภาพชีวิตและปัจจัยที่มีอิทธิพลต่อคุณภาพชีวิต การวิจัยนี้มีวัตถุประสงค์เพื่อหาคุณภาพชีวิตของผู้หญิงวัยหมดประจำเดือนที่เป็นโรคกระดูกพรุนและปัจจัยที่ส่งผลต่อคุณภาพชีวิตของผู้หญิงวัยหมดประจำเดือนที่เป็นโรคกระดูกพรุน

ผู้วิจัยจึงมีความประสงค์จะขอความช่วยเหลือจากท่านในเรื่อง ข้อมูลเกี่ยวกับคุณภาพชีวิต และปัจจัยต่างๆ ที่เกี่ยวข้อง โดยผู้วิจัยจะทำการเก็บข้อมูลโดยใช้แบบสอบถามจำนวน 125 ชุด ผู้วิจัยจึงอยากเชิญท่านเข้าร่วมเป็นผู้ให้ข้อมูลในการวิจัย

วิธีการศึกษาวิจัย

การวิจัยครั้งนี้จะทำการเก็บข้อมูลโดยใช้แบบสอบถามจากผู้เข้าร่วมการศึกษาประมาณ 125 คน หากท่านตกลงที่จะเข้าร่วมการวิจัยจะมีขั้นตอนดังต่อไปนี้

ผู้วิจัยขอความร่วมมือจากท่านในการตอบแบบสอบถามเกี่ยวกับผู้ป่วยโรคกระดูกพรุน ซึ่งประกอบด้วยข้อมูลทั้งหมด 4 ส่วน <u>ส่วนที่ 1</u> เป็นแบบสอบถามเกี่ยวกับ ข้อมูลทั่วไปส่วนบุคคลด้านประชากรและสังคมศาสตร์ <u>ส่วนที่ 2</u> เป็นแบบสอบถามเกี่ยวกับคุณภาพชีวิต <u>ส่วนที่ 3</u> เป็นแบบสอบถามเกี่ยวกับ ความสนใจสุขภาพ ได้แก่ การออกกำลังกาย, อาหารที่ได้รับในแต่ละวัน, ลักษณะการใช้ชีวิต (Life style) โดยพิจารณา จากการได้รับคาเฟอีน, การดื่มแอลกอฮอลล์ และการสูบบุหรี่ <u>ส่วนที่ 4</u> เป็นแบบสอบถามเกี่ยวกับการรักษา โดยพิจารณาจากยาโรคกระดูกพรุนที่ผู้ป่วยได้รับในปัจจุบัน รวมถึงอาการข้างเคียงที่เกิดจากยาดังกล่าว ซึ่งผู้วิจัยคาดว่าจะใช้เวลาในการตอบประมาณ 25 นาที

ประโยชน์ที่จะได้รับ

ถึงแม้ว่าการเข้าร่วมการวิจัยในครั้งนี้จะไม่มีประโยชน์โดยตรงกับท่าน แต่ท่านสามารถที่จะช่วยให้นักวิจัยเข้าใจได้ดีขึ้นเกี่ยวกับคุณภาพชีวิตและปัจจัยต่างๆ ที่มีอิทธิพลต่อคุณภาพชีวิตของผู้ป่วยโรคกระดูกพรุน อันจะนำไปสู่การกำหนดแนวทางเพื่อป้องกันอันตรายต่อคุณภาพชีวิตต่อไป ผลการศึกษาที่ได้จะช่วยในการวางแผนดูแลผู้ป่วยโรคกระดูกพรุนแบบองค์รวมเพื่อให้ผู้ป่วยมีคุณภาพชีวิตที่ดีขึ้นและสามารถใช้เป็นแนวทางในการวางแผนการจัดสรรงบประมาณเพื่อพัฒนาคุณภาพชีวิตของผู้ป่วยที่มีภาวะโรคกระดูกพรุน

ความเสี่ยงในการเข้าร่วมการศึกษา

แบบสอบถามนี้ส่วนใหญ่จะไม่มีคำถามที่กระทบกระเทือนต่อจิตใจ อย่างไรก็ตามหากท่านรู้สึกอึดอัด ไม่สบายใจ หรือรู้สึกอับอาย ท่านไม่จำเป็นต้องตอบคำถามใดๆ หรือไม่ร่วมแสดงความคิดเห็นก็ได้ และสามารถยกเลิกการตอบแบบสอบถามได้ตลอดเวลา การเข้าร่วมการศึกษาครั้งนี้

การรักษาความลับ

ในการให้ข้อมูลครั้งนี้จะไม่มีการบันทึกชื่อผู้เข้าร่วมตอบแบบสอบถามและข้อมูลที่ท่านให้จะไม่สามารถเชื่อมโยงกลับไปหาท่านได้ ข้อมูลทุกอย่างจะเป็นความลับ โดยจะนำไปใช้เพื่อวัตถุประสงค์ ในการวิจัยเฉพาะในทีมงานผู้วิจัยเท่านั้น จะไม่นำไปเผยแพร่กับคนอื่นโดยเด็ดขาด ผู้วิจัยจะเก็บข้อมูล ทุกอย่างเป็นความลับ รวมทั้งไม่ให้เปิดเผยตัวบุคคลที่เข้าร่วมการตอบแบบสอบถามกับผู้อื่นด้วย

การถอนตัวออกจากการวิจัย

ท่านจะไม่ได้รับสิทธิประโยชน์ใดๆ โดยตรง และการเข้าร่วมการศึกษานี้เป็นไปโดยสมัครใจ ท่านมีสิทธิ์ที่จะปฏิเสธในการเข้าร่วมการศึกษาครั้งนี้ การตัดสินใจของท่านจะไม่มีผลกระทบใดๆต่อความสัมพันธ์ของท่านต่อโรงพยาบาลและคณะเภสัชศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย ผู้วิจัยจะเก็บข้อมูลของท่านเป็นความลับและจะเปิดเผยได้เฉพาะในรูปที่เป็นส่วนการสรุปผลงานวิจัยเท่านั้น การตัดสินใจเข้าร่วมให้ข้อมูลขึ้นอยู่กับตัวท่าน ท่านสามารถปฏิเสธการเข้าร่วมให้ข้อมูล หรือถอนตัวออกการวิจัยนี้เมื่อใดก็ได้ และหากท่านสมัครใจที่จะเข้าร่วมให้ข้อมูลแล้ว ท่านมีสิทธิที่จะไม่ตอบคำถามข้อใดหรือไม่ร่วมแสดงความคิดเห็นใดๆ ก็ได้ ซึ่งการปฏิเสธ หรือถอนตัวของท่านนั้นจะไม่มีผลใดๆ กับตัวท่านเลย

รายชื่อบุคคลที่สามารถติดต่อ

ถ้าท่านมีข้อคำถามหรือข้อสงสัยใดๆ ในการตอบแบบสอบถาม หรือภายหลังท่านยังมีคำถามเกี่ยวกับขั้นตอนของการวิจัยหรือในเรื่องอื่นที่เกี่ยวข้องกับการวิจัย ท่านสามารถติดต่อกับคุณอิสรีย์ จรรยาศักดิ์ คณะเภสัชศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย โทร 086-620-3069 ซึ่งยินดีให้คำชี้แจงแก่ท่านทุกประการ

ใบยินยอมเข้าร่วมการศึกษา

ถ้อยแถลงของผู้เข้าร่วมการศึกษา

การวิจัยเรื่อง ***คุณภาพชีวิตในผู้หญิงวัยหมดประจำเดือนที่เป็นโรคกระดูกพรุนในโรงพยาบาลตำรวจ***

ก่อนที่จะลงนามในใบยินยอมให้ทำการวิจัยนี้ ผู้วิจัยได้อธิบายถึงวัตถุประสงค์ของการวิจัย วิธีการ วิจัย อันตรายที่อาจเกิดขึ้นจากการวิจัย รวมทั้งประโยชน์ที่จะเกิดขึ้นจากการวิจัยอย่างละเอียด โดยข้าพเจ้า ได้รับทราบและมีความเข้าใจดีแล้ว

ผู้วิจัยรับรองว่าจะตอบคำถามต่างๆ ที่ข้าพเจ้าสงสัยด้วยความเต็มใจ ไม่ปิดบัง ซ่อนเร้น จนข้าพเจ้าพอใจ

ข้าพเจ้ามีสิทธิที่จะบอกเลิกการเข้าร่วมในโครงการวิจัยนี้เมื่อใดก็ได้ และเข้าร่วมโครงการวิจัยนี้โดยสมัครใจ และการบอกเลิกการเข้าร่วมการวิจัยนี้ จะไม่มีผลใดๆ ต่อตัวข้าพเจ้า

ผู้วิจัยรับรองว่าจะเก็บข้อมูลเฉพาะเกี่ยวกับตัวข้าพเจ้าเป็นความลับและจะเปิดเผยได้เฉพาะในรูปที่เป็นสรุปผลการวิจัย หรือการเปิดเผยข้อมูลต่อผู้มีหน้าที่เกี่ยวข้องกับการสนับสนุนและกำกับดูแลการวิจัย

☐ ข้าพเจ้าได้อ่านข้อความข้างต้นแล้ว และมีความเข้าใจทุกประการ และได้ลงนามในใบยินยอมนี้ด้วยความเต็มใจ

☐ ข้าพเจ้าไม่สามารถอ่านหนังสือได้ แต่ผู้วิจัยได้อ่านข้อความในใบยินยอมนี้ให้แก่ข้าพเจ้าฟังจนเข้าใจดีแล้ว และข้าพเจ้าจึงได้ลงนามในใบยินยอมนี้ด้วยความเต็มใจ

ลงนาม.....ผู้ยินยอม วันที่.....

Appendix C

แบบสอบถามคุณภาพชีวิตและปัจจัยที่ส่งผลต่อคุณภาพชีวิต ในผู้หญิงวัยหมดประจำเดือนที่เป็นโรคกระดูกพรุน

ส่วนที่ 1 ข้อมูลด้านประชากรศาสตร์

1. น้ำหนักตัว .....กก. ส่วนสูง .....ซ.ม.
2. ในช่วงอายุ 20-60 ปี ท่านประกอบอาชีพในลักษณะใด
   - O ใช้แรงงาน
   - O งานนั่งโต๊ะ
   - O งานบ้าน
3. ปัจจุบันท่านยังมีประจำเดือนหรือไม่
   - O ไม่มี หมดมาแล้ว.....ปี
   - O มี

ส่วนที่ 2 แบบสอบถามเรื่อง คุณภาพชีวิต ฉบับ Qualeffo-41

ด้านที่ 1 ความเจ็บปวด

คำถามทั้ง 5 ข้อในด้านนี้เกี่ยวข้องกับสถานการณ์ในสัปดาห์ที่ผ่านมา

1) ในสัปดาห์ที่ผ่านมาคุณมีอาการปวดหลังบ่อยเพียงใด
- O ไม่เคย
- O 1 วันต่อสัปดาห์หรือน้อยกว่า
- O 2-3 วันต่อสัปดาห์
- O 4-6 วันต่อสัปดาห์
- O ทุกวันในสัปดาห์

2) ในระหว่างวันหากคุณมีอาการปวดหลัง คุณจะมีอาการปวดนานเพียงใด
- O ไม่เคย
- O 1-2 ชั่วโมง
- O 3-5 ชั่วโมง
- O 6-10 ชั่วโมง
- O ตลอดทั้งวัน

3) อาการปวดหลังที่แย่ที่สุดของคุณมีอาการรุนแรงเพียงใด
- O ไม่มีอาการปวดหลัง
- O เล็กน้อย
- O ปานกลาง
- O รุนแรง
- O ปวดจนไม่สามารถทนได้

4) ช่วงเวลาอื่นๆคุณมีอาการปวดหลังมากน้อยเพียงใด
- O ไม่มีอาการปวดหลังเลย
- O เล็กน้อย
- O ปานกลาง
- O รุนแรง
- O ปวดจนไม่สามารถทนได้

5) ในสัปดาห์ที่ผ่านมาอาการปวดหลังรบกวนการนอนหลับของคุณมากน้อยเพียงใด
- O น้อยกว่าหนึ่งครั้งในสัปดาห์
- O หนึ่งครั้งต่อสัปดาห์
- O สองครั้งต่อสัปดาห์
- O คืนเว้นคืน
- O ทุกคืน

ด้านการทำงานของร่างกาย:

ด้านที่ 2 กิจกรรมในชีวิตประจำวัน

คำถาม 4 ข้อต่อไปนี้เกี่ยวข้องกับเหตุการณ์ในปัจจุบัน

6) คุณมีปัญหาในการแต่งตัวหรือไม่
- O ไม่มีความยากลำบากแต่อย่างไร
- O มีความยากลำบากเล็กน้อย
- O มีความยากลำบากปานกลาง
- O ต้องการความช่วยเหลือบ้าง
- O ทำไม่ได้เลยโดยไม่มีผู้อื่นช่วย

7) คุณมีปัญหาในการอาบน้ำหรือไม่
- O ไม่มีความยากลำบากแต่อย่างไร
- O มีความยากลำบากเล็กน้อย
- O มีความยากลำบากปานกลาง
- O ต้องการความช่วยเหลือบ้าง
- O ทำไม่ได้เลยโดยไม่มีผู้อื่นช่วย

8) คุณมีปัญหาในการใช้ห้องสุขาหรือไม่
- O ไม่มีความยากลำบากแต่อย่างไร
- O มีความยากลำบากเล็กน้อย
- O มีความยากลำบากปานกลาง
- O ต้องการความช่วยเหลือบ้าง
- O ทำไม่ได้เลยโดยไม่มีผู้อื่นช่วย

9) คุณหลับสนิทเพียงใด
- O หลับสนิท
- O มีตื่นบ้างบางครั้ง
- O ตื่นบ่อยๆ
- O บางครั้งข้าพเจ้านอนไม่หลับหลายชั่วโมง
- O บางครั้งนอนไม่หลับตลอดทั้งคืน

ด้านการทำงานของร่างกาย:

ด้านที่ 3 งานบ้าน

คำถามทั้ง 5 ข้อต่อไปนี้เกี่ยวข้องกับสถานการณ์ในปัจจุบัน หากในบ้านท่านมีผู้อื่นเป็นผู้ทำงานบ้าน ให้ตอบคำถามเสมือนคุณเป็นผู้ทำกิจกรรมเหล่านี้เอง

10)	คุณทำความสะอาดบ้านได้หรือไม่	O ทำได้โดยไม่มีความยากลำบาก O มีความยากลำบากเล็กน้อย O มีความยากลำบากปานกลาง O มีความยากลำบากมาก O ไม่สามารถทำได้
11)	คุณจัดเตรียมอาหารได้หรือไม่	O ทำได้โดยไม่มีความยากลำบาก O มีความยากลำบากเล็กน้อย O มีความยากลำบากปานกลาง O มีความยากลำบากมาก O ไม่สามารถทำได้
12)	คุณล้างจานได้หรือไม่	O ทำได้โดยไม่มีความยากลำบาก O มีความยากลำบากเล็กน้อย O มีความยากลำบากปานกลาง O มีความยากลำบากมาก O ไม่สามารถทำได้
13)	คุณเดินจับจ่ายซื้อของได้ตามปกติหรือไม่	O ทำได้โดยไม่มีความยากลำบาก O มีความยากลำบากเล็กน้อย O มีความยากลำบากปานกลาง O มีความยากลำบากมาก O ไม่สามารถทำได้
14)	คุณยกของหนักประมาณ 9 กิโลกรัม (เช่น ลังนม ขนาด 750 ซีซี 12 ขวดหรือเด็กอายุ 1 ขวบ) และ เดินถือไปอย่างน้อย 10 เมตรได้หรือไม่	O ทำได้โดยไม่มีความยากลำบาก O มีความยากลำบากเล็กน้อย O มีความยากลำบากปานกลาง O มีความยากลำบากมาก O ไม่สามารถทำได้

ด้านการทำงานของร่างกาย :

ด้านที่ 4 ความสามารถในการเคลื่อนไหว

คำถามทั้ง 8 ข้อเกี่ยวกับสถานการณ์ในปัจจุบัน

15) คุณลุกขึ้นจากเก้าอี้ได้หรือไม่
- O ทำได้โดยไม่มีความยากลำบาก
- O มีความยากลำบากเล็กน้อย
- O มีความยากลำบากปานกลาง
- O มีความยากลำบากมาก
- O ต้องมีผู้ช่วยเหลือเท่านั้น

16) คุณโค้งคำนับได้หรือไม่
- O ทำได้สบาย
- O ทำได้ค่อนข้างง่าย
- O พอทำได้
- O ทำได้เล็กน้อย
- O ไม่สามารถทำได้เลย

17) คุณคุกเข่าได้หรือไม่
- O ทำได้สบาย
- O ทำได้ค่อนข้างง่าย
- O พอทำได้
- O ทำได้เล็กน้อย
- O ไม่สามารถทำได้เลย

18) คุณขึ้นบันไดไปยังชั้นบนของบ้านได้หรือไม่
- O ทำได้โดยไม่มีความยากลำบาก
- O มีความยากลำบากเล็กน้อย
- O ต้องมีการพัก 1 ครั้ง
- O ต้องมีผู้ช่วยเหลือเท่านั้น
- O ไม่สามารถทำได้เลย

19) คุณเดิน 100 เมตรได้หรือไม่
- O เดินได้เร็วโดยไม่ต้องหยุดพัก
- O เดินได้ช้าโดยไม่ต้องหยุดพัก
- O เดินได้ช้าแต่ต้องหยุดพัก อย่างน้อย 1 ครั้ง
- O ต้องมีคนช่วยจึงจะเดินได้
- O เป็นไปไม่ได้

20) ในสัปดาห์ที่แล้ว คุณออกไปข้างนอกบ่อยเพียงใด
- O ทุกวัน
- O 5-6 วันต่อสัปดาห์
- O 3-4 วันต่อสัปดาห์
- O 1-2 วันต่อสัปดาห์
- O น้อยกว่า 1 วันในสัปดาห์

21) คุณสามารถเดินทางโดยรถประจำทางได้หรือไม่
- O ทำได้โดยไม่มีความยากลำบาก
- O มีความยากลำบากเล็กน้อย
- O มีความยากลำบากปานกลาง
- O มีความยากลำบากมาก
- O ทำได้เมื่อมีผู้อื่นช่วยเท่านั้น

22) คุณได้รับผลกระทบต่อการเปลี่ยนแปลงของรูปร่างอันเนื่องมาจากโรคกระดูกพรุนหรือไม่ (เช่น ส่วนสูงลดลง, ขนาดรอบเอวเพิ่มขึ้น, รูปร่างของหลัง)
- O ไม่มีผลกระทบเลย
- O มีผลกระทบเล็กน้อย
- O มีผลกระทบพอสมควร
- O มีผลกระทบค่อนข้างมาก
- O มีผลกระทบมาก

ด้านที่ 5 การใช้เวลาว่าง, กิจกรรมทางสังคม

23) ปัจจุบันคุณเล่นกีฬาได้บ้างหรือไม่
- O เล่นได้สบาย
- O เล่นได้โดยมีข้อจำกัด
- O เล่นไม่ได้

24) คุณสามารถทำสวนที่บ้านคุณได้หรือไม่
- O ทำได้
- O ทำได้โดยมีข้อจำกัด
- O ไม่สามารถทำได้
- O ไม่สามารถตอบได้

25) ปัจจุบันคุณทำงานอดิเรกบ้างหรือไม่
- O ทำ
- O ทำได้โดยมีข้อจำกัด
- O ไม่ได้ทำ

26) คุณสามารถไปชมภาพยนตร์ ดูละครได้หรือไม่
- O ไปได้
- O ไปได้แต่มีข้อจำกัด
- O ไปไม่ได้
- O ไม่มีโรงภาพยนตร์ โรงละครที่สามารถไปได้

27) คุณไปพบเพื่อนหรือเยี่ยมญาติบ่อยแค่ไหน ในช่วง 3 เดือนที่ผ่านมา
O สัปดาห์ละ 1ครั้งหรือมากกว่า
O 1-2 ครั้ง ต่อเดือน
O น้อยกว่า 1 ครั้ง ต่อเดือน
O ไปไม่ได้เลย

28) คุณไปร่วมกิจกรรมทางสังคมบ่อยแค่ไหน (ไปสโมสร,สังสรรค์, ไปทำบุญ เป็นต้น) ในช่วง 3 เดือนที่ผ่านมา
O สัปดาห์ละ 1ครั้งหรือมากกว่า
O 1-2 ครั้ง ต่อเดือน
O น้อยกว่า 1 ครั้ง ต่อเดือน
O ไปไม่ได้เลย

29) อาการปวดหลังหรือความพิการของท่านรบกวนความสัมพันธ์ทางเพศของคุณหรือไม่ (รวมทั้งกิจกรรมทางเพศ)
O ไม่รบกวน
O รบกวนเล็กน้อย
O รบกวนปานกลาง
O รบกวนมาก
O ไม่สามารถตอบได้

ด้านที่ 6 การรับรู้เกี่ยวกับสุขภาพโดยทั่วไป

30) สุขภาพของคุณโดยทั่วไปเป็นอย่างไร เมื่อเทียบกับคนอายุรุ่นเดียวกัน
O ดีมาก
O ดี
O เป็นที่น่าพอใจ
O พอใช้
O แย่

31) คุณจะให้คะแนนคุณภาพชีวิตโดยรวมของคุณในช่วงสัปดาห์ที่ผ่านมาอย่างไร
O ดีมาก
O ดี
O เป็นที่น่าพอใจ
O พอใช้
O แย่

32) คุณภาพชีวิตโดยรวมของคุณเมื่อเทียบกับ 10 ปีที่แล้วเป็นอย่างไร
O ปัจจุบันดีขึ้นมาก
O ปัจจุบันค่อนข้างดีขึ้น
O ปัจจุบันไม่เปลี่ยนแปลง
O ปัจจุบันค่อนข้างแย่ลง
O ปัจจุบันแย่ลงมาก

ด้านที่ 7 ด้านจิตใจ

คำถาม 9 ข้อต่อไปนี้เกี่ยวกับสถานการณ์เมื่อสัปดาห์ที่ผ่านมา

33) คุณมีแนวโน้มที่รู้สึกเหนื่อยหรือไม่
- O มีในตอนเช้า
- O มีในตอนบ่าย
- O มีในตอนเย็นเท่านั้น
- O มีหลังจากทำกิจกรรมที่ต้องออกแรงมาก
- O แทบจะไม่มี

34) คุณรู้สึกท้อแท้บ้างหรือไม่
- O เกือบทุกวัน
- O 3-5 วันต่อสัปดาห์
- O 1-2 วันต่อสัปดาห์
- O นานๆ ครั้ง
- O แทบจะไม่มี

35) คุณรู้สึกโดดเดี่ยวบ้างหรือไม่
- O เกือบทุกวัน
- O 3-5 วันต่อสัปดาห์
- O 1-2 วันต่อสัปดาห์
- O นานๆ ครั้ง
- O แทบจะไม่มี

36) คุณรู้สึกเต็มเปี่ยมไปด้วยพลังหรือไม่
- O เกือบทุกวัน
- O 3-5 วันต่อสัปดาห์
- O 1-2 วันต่อสัปดาห์
- O นานๆ ครั้ง
- O แทบจะไม่มี

37) คุณรู้สึกเต็มเปี่ยมไปด้วยความหวังเกี่ยวกับอนาคตของคุณหรือไม่
- O ไม่เคย
- O แทบจะไม่
- O บางครั้ง
- O ค่อนข้างบ่อย
- O ตลอดเวลา

38) คุณรู้สึกหงุดหงิดกับเรื่องเล็กๆ น้อยๆ หรือไม่
O ไม่เคย
O แทบจะไม่
O บางครั้ง
O ค่อนข้างบ่อย
O ตลอดเวลา

39) คุณพบว่าเป็นการง่ายในการติดต่อกับผู้คน
O ไม่เคย
O แทบจะไม่
O บางครั้ง
O ค่อนข้างบ่อย
O ตลอดเวลา

40) คุณอารมณ์ดีทั้งวันหรือไม่
O ไม่เคย
O แทบจะไม่
O บางครั้ง
O ค่อนข้างบ่อย
O ตลอดเวลา

41) คุณรู้สึกกลัวที่จะต้องพึ่งพาผู้อื่นตลอดเวลาหรือไม่
O ไม่เคย
O แทบจะไม่
O บางครั้ง
O ค่อนข้างบ่อย
O ตลอดเวลา

ส่วนที่ 3 ข้อมูลด้านความสนใจสุขภาพ

3.1 ข้อมูลความถี่ของการออกกำลังกายและการทำกิจกรรมโดยเฉลี่ยในปัจจุบัน

<u>คำชี้แจง</u> ในปัจจุบัน ท่านออกกำลังกายและทำกิจกรรมต่อไปนี้โดยเฉลี่ยประมาณกี่ครั้งและใช้ระยะเวลานานเท่าใดใน 1 สัปดาห์ โปรดกาเครื่องหมาย ✓ ตรงช่องจำนวนครั้งและจำนวนนาทีที่ท่านปฏิบัติโดยเฉลี่ย

ชนิดของกิจกรรม	**สัปดาห์ละ 1-2 ครั้ง ๆ ละ(นาที)**					**สัปดาห์ละ 3-4 ครั้งๆ ละ (นาที)**					**สัปดาห์ละ 5-7 ครั้งๆ ละ (นาที)**				
	< 15	15-30	31-45	46-60	> 60	< 15	15-30	31-45	46-60	> 60	< 15	15-30	31-45	46-60	> 60
<u>การออกกำลังกาย</u>															
เดินเร็ว															
วิ่งเหยาะ															
เต้นแอโรบิก															
ถีบจักรยาน															
ว่ายน้ำ															
แบดมินตัน															
ฝึกโยคะ															
รำมวยจีน															
ไทเก็ก															
กอล์ฟ															
เทนนิส															
อื่น ๆ โปรดระบุ															
<u>การปฏิบัติตัวในชีวิตประจำวัน</u>															
ทำสวน/ขุดดิน															
กวาดบ้าน/ถูบ้าน															
ขึ้นบันได (>5 ขั้น)															
อื่น ๆ โปรดระบุ															

3.2 ข้อมูลอาหารที่รับประทานและความถี่ในการรับประทานโดยเฉลี่ยในปัจจุบัน

คำชี้แจง ในปัจจุบัน ท่านรับประทานอาหารต่อไปนี้โดยเฉลี่ยประมาณกี่ครั้งต่อสัปดาห์ โปรดกาเครื่องหมาย ✓ ตรงช่องจำนวนครั้งต่อสัปดาห์ที่ท่านรับประทาน

ชนิดอาหาร	ความถี่ในการรับประทาน (วันต่อสัปดาห์)				
	ทุกวัน	4-6 วัน	2-3 วัน	1 วัน	ไม่เคยบริโภค
1. ท่านรับประทานนมและผลิตภัณฑ์ของนม เช่น นมรสจืด นมพร่องมันเนย นมเปรี้ยว ยาคูลท์ โยเกิร์ต					
2. ท่านรับประทานกุ้ง ปลาเล็กปลาน้อยที่รับประทานได้ทั้งกระดูก เช่น กุ้งแห้ง ปลาเล็กปลาน้อย ปลาไส้ตัน ปลากระป๋อง					
3. ท่านรับประทาน ผักใบเขียวต่าง ๆ (ผักสุก) เช่น ผักตำลึง ผักคะน้า ผักกาดขาว กะหล่ำปลี คะน้า					
4. ท่านรับประทานถั่วต่าง ๆ และผลิตภัณฑ์จากถั่ว เช่น เต้าหู้ ถั่วดำ ถั่วแดง ถั่วเขียว ถั่วลิสง นมถั่วเหลือง น้ำเต้าหู้					
5. ท่านรับประทานเนื้อสัตว์ ไข่ไก่ ไข่เป็ด เครื่องในสัตว์					

3.3 ข้อมูลด้านการดำเนินชีวิต

คำชี้แจง ในปัจจุบัน ท่านกิจกรรมต่อไปนี้หรือไม่ โปรดกาเครื่องหมาย ✓ ตรงช่องคำตอบ

1. ท่านดื่มเครื่องดื่มที่มีแอลกอฮอล์ เช่น เหล้า เบียร์ ไวน์ ค็อกเทล วิสกี้ เป็นประจำหรือไม่ O ใช่ O ไม่ใช่
2. ท่านดื่มเครื่องดื่มที่มีกาเฟอีน เช่น ชา กาแฟ โกโก้ ช็อกโกแลต โคล่าเป็นประจำหรือไม่ O ใช่ O ไม่ใช่
3. ท่านสูบบุหรี่หรือไม่ O ใช่ O ไม่ใช่

ส่วนที่ 4 ข้อมูลด้านการรักษา

กรุณาระบุชื่อยาและระยะเวลาใช้ยาที่ท่านได้รับในปัจจุบัน รวมทั้งอาการข้างเคียงที่เกิดขึ้นจากการใช้ยาดังกล่าว

O Fosamax® 10,70 mg (Alendronate) 	ท่านพบอาการข้างเคียงจากการใช้ยานี้หรือไม่ O พบอาการข้างเคียง เช่น แสบยอดอก, คลื่นไส้อาเจียน, แสบท้องหรือปวดท้อง, ท้องอืด แน่นท้อง, ท้องผูก, ท้องเสีย O ไม่พบอาการข้างเคียง ระยะเวลาที่ใช้ยานี้(โปรดระบุ).....ปี
O Actonel® 5,35 mg (Risedronate) 	ท่านพบอาการข้างเคียงจากการใช้ยานี้หรือไม่ O พบอาการข้างเคียง เช่น แสบยอดอก, คลื่นไส้อาเจียน, แสบท้องหรือปวดท้อง, ท้องอืด แน่นท้อง, ท้องผูก, ท้องเสีย O ไม่พบอาการข้างเคียง ระยะเวลาที่ใช้ยานี้(โปรดระบุ).....ปี
O Bonviva® 150 mg (Ibandronate) 	ท่านพบอาการข้างเคียงจากการใช้ยานี้หรือไม่ O พบอาการข้างเคียง เช่น แสบยอดอก, คลื่นไส้อาเจียน, แสบท้องหรือปวดท้อง, ท้องอืด แน่นท้อง, ท้องผูก, ท้องเสีย O ไม่พบอาการข้างเคียง ระยะเวลาที่ใช้ยานี้(โปรดระบุ).....ปี

O Celvista® 60 mg (Raloxifene)  	ท่านพบอาการข้างเคียงจากการใช้ยานี้หรือไม่ O พบอาการข้างเคียง เช่น ร้อนวูบวาบ หน้าแดง, ปวดกล้ามเนื้อ, ตะคริวที่ขา O ไม่พบ ระยะเวลาที่ใช้ยานี้(โปรดระบุ).....ปี
O Miacalcic® หรือ Tonocalcin® (Calcitonin naslal spray)  	ท่านพบอาการข้างเคียงจากการใช้ยานี้หรือไม่ O พบอาการข้างเคียง เช่น คลื่นไส้ อาเจียน, เวียนศีรษะ มึนงง O ไม่พบ ระยะเวลาที่ใช้ยานี้(โปรดระบุ).....ปี
O Protaxos® 2 g (Strontium renelate)  	ท่านพบอาการข้างเคียงจากการใช้ยานี้หรือไม่ O พบอาการข้างเคียง เช่น คลื่นไส้, ท้องเสีย, ปวดหัว O ไม่พบ ระยะเวลาที่ใช้ยานี้(โปรดระบุ).....ปี
O แคลเซียม (Calcium carbonate)	ท่านพบอาการข้างเคียงจากการใช้ยานี้หรือไม่ O พบอาการข้างเคียง เช่น ท้องผูก, ปวดท้อง O ไม่พบ ระยะเวลาที่ใช้ยานี้(โปรดระบุ).....ปี

Appendix D

Table 17 Frequency and percentage of each choice of Qualeffo41 item

A. Pain

Item	Valid					
1. How often have you had back pain in the last week?	never	1 day per week or less	2-3 days per week	4-6 days per week	every day	Total
	36 (26.87%)	23 (17.16%)	29 (21.64%)	15 (11.19%)	31 (23.13%)	134 (100.00%)

Item	Valid					
	never	1-2 hours	3-5 hours	6-10 hours	all day	Total
2. How long did you have back pain in daytime?	36 (26.87%)	73 (54.48%)	13 (9.70%)	3 (2.24%)	9 (96.72%)	134 (100.00%)

Item	Valid					
	no back pain	mild	moderate	severe	unbearable	Total
3. How severe is your back pain at its worst?	36 (26.87%)	32 (23.88%)	20 (14.93%)	5 (3.73%)	41 (30.60%)	134 (100.00%)

Item	Valid					
	no back pain	mild	moderate	severe	unbearable	Total
4. How is your back pain at other times?	72 (53.73%)	32 (23.88%)	19 (14.18%)	5 (3.73%)	6 (4.48%)	134 (100.00%)

Item	Valid					
	less than once per week	once a week	twice a week	every other night	every night	Total
5. Has the back pain disturbed your sleep in the last week?	112 (83.58%)	8 (5.97%)	1 (0.75%)	3 (2.24%)	10 (7.46%)	134 (100.00%)

B. Physical function

Activities of daily living

Item	Valid					
	no difficulty	a little difficulty	moderate difficulty	may need some help	impossible without help	Total
6. Do you have problems with dressing?	102 (76.12%)	14 (10.45%)	12 (8.96%)	2 (1.49%)	4 (2.99%)	134 (100.00%)

Item	Valid					
	no difficulty	a little difficulty	moderate difficulty	may need some help	impossible without help	Total
7. Do you have problems with taking a bath or shower?	108 (80.60%)	15 (11.19%)	5 (3.73%)	2 (1.49%)	4 (2.99%)	134 (100.00%)

Item	Valid					
	no difficulty	a little difficulty	moderate difficulty	may need some help	impossible without help	Total
8. Do you have problems with getting to or operating a toilet?	98 (73.13%)	22 (16.42%)	8 (5.97%)	1 (0.75%)	5 (3.73%)	134 (100.00%)

Item	Valid					
	sleep undisturbed	wake up sometimes	wake up often	sometimes I lie awake for hours	sometimes I have a sleepless night	Total
9. How well do you sleep?	9 (6.72%)	60 (44.78%)	15 (11.19%)	34 (25.37%)	16 (11.94%)	134 (100.00%)

Jobs around the house

Item	Valid					
	without difficulty	with a little difficulty	with moderate difficulty	with great difficulty	impossible	Total
10. Can you do the cleaning?	43 (32.1%)	35 (26.1%)	18 (13.4%)	20 (14.9%)	18 (13.4%)	134 (100.00%)

Item	Valid					
	without difficulty	with a little difficulty	with moderate difficulty	with great difficulty	impossible	Total
11. Can you prepare meals?	77 (57.5%)	22 (16.4%)	14 (10.4%)	11 (8.2%)	10 (7.5%)	134 (100.00%)

Item	Valid					
	without difficulty	with a little difficulty	with moderate difficulty	with great difficulty	impossible	Total
12. Can you wash the dishes?	90 (67.2%)	16 (11.9%)	5 (3.7%)	13 (9.7%)	10 (7.5%)	134 (100.00%)

Item	Valid					
	without difficulty	with a little difficulty	with moderate difficulty	with great difficulty	impossible	Total
13. Can you do your day to day shopping?	59 (44.03%)	29 (21.64%)	14 (10.45%)	17 (12.69%)	15 (11.19%)	134 (100.00%)

Item	Valid					
	without difficulty	with a little difficulty	with moderate difficulty	with great difficulty	impossible	Total
14. Can you lift a heavy object of 20 lbs (e.g. a crate of 12 bottles of milk, or a one year old child) and carry it for at least 10 yards?	5 (3.73%)	3 (2.24%)	14 (10.45%)	12 (8.96%)	100 (74.63%)	134 (100.00%)

Mobility

Item	Valid					
	without difficulty	with a little difficulty	with moderate difficulty	with great difficulty	impossible	Total
15. Can you get up from a chair?	70 (52.24%)	32 (23.88%)	16 (11.94%)	8 (5.97%)	8 (5.97%)	134 (100.00%)

Item	Valid					
	easily	fairly easily	moderately	very little	impossible	Total
16. Can you bend down?	49 (36.57%)	34 (25.37%)	23 (17.16%)	17 (12.69%)	11 (8.21%)	134 (100.00%)

Item	Valid					
	easily	fairly easily	moderately	very little	impossible	Total
17. Can you kneel down?	14 (10.45%)	14 (10.45%)	11 (8.21%)	16 (11.94%)	79 (58.96%)	134 (100.00%)

Item	Valid					
	without difficulty	with a little difficulty	with at least one rest	with help only	impossible	Total
18. Can you climb stairs to the next floor of a house?	33 (24.63%)	59 (44.03%)	16 (11.94%)	13 (9.70%)	13 (9.70%)	134 (100.00%)

Item	Valid					
	fast without stopping	slowly without stopping	slowly with at least one stop	only with help	impossible	Total
19. Can you walk 100 yards?	39 (29.10%)	55 (41.04%)	21 (15.67%)	9 (6.72%)	10 (7.46%)	134 (100.00%)

Item	Valid					
	every day	5-6 days/week	3-4 days/week	1-2 days/week	less than once/week	Total
20. How often have you been outside in the last week?	41 (30.60%)	4 (2.99%)	20 (14.93%)	32 (23.88%)	37 (27.61%)	134 (100.00%)

Item	Valid					
	without difficulty	with a little difficulty	with moderate difficulty	with great difficulty	only with help	Total
21. Can you use public transport (bus)?	32 (23.88%)	25 (18.66%)	12 (8.96%)	11 (8.21%)	54 (40.30%)	134 (100.00%)

Item	Valid					
	not at all	a little	moderately	quite a bit	very much	Total
22. Have you been affected by the changes of your figure due to osteoporosis (for example loss of height, increase of waist measurement, shape of your back)?	26 (19.40%)	38 (28.36%)	27 (17.91%)	24 (13.43%)	18 (99.25%)	133 (99.25%)

C. Leisure, social activities

Item	Valid			
	yes	yes with restrictions	not at all	Total
23. Do you play any sport now?	14 (10.45%)	1 (0.75%)	119 (88.81%)	134 (100.00%)

Item	Valid				
	yes	yes with restrictions	not at all	not applicable	Total
24. Can you do your gardening?	30 (22.39%)	14 (10.45%)	24 (17.91%)	66 (49.25%)	134 (100.00%)

Item	Valid			
	yes	yes with restrictions	not at all	Total
25. Do you perform any hobby now?	127 (94.78%)	1 (0.75%)	6 (4.48%)	134 (100.00%)

Item	Valid				
	yes	yes with restrictions	not at all	no cinema, or theatre within a reasonable distance	Total
26. Can you visit a cinema, theatre?	59 (44.03%)	50 (37.31%)	14 (10.45%)	11 (8.21%)	134 (100.00%)

Item	Valid				
	once a week or more	once or twice a month	less than once a month	never	Total
27. How often did you visit friends or relatives during the last 3 months?	35 (26.12%)	30 (22.39%)	32 (23.88%)	37 (27.61%)	134 (100.00%)

Item	Valid				
	once a week or more	once or twice a month	less than once a month	never	Total
28. How often did you participate in social activities (clubs, social gatherings, church activities, charity etc.) during the last 3 months?	36 (26.87%)	30 (22.39%)	37 (27.61%)	31 (23.13%)	134 (100.00%)

Item	Valid			
	not at all	a little	not applicable	Total
29. Does your back pain or disability interfere with intimacy (including sexual activity)?	19 (14.18%)	4 (2.99%)	111 (82.84%)	134 (100.00%)

D. General health perception

Item	Valid					
	excellent	good	satisfactory	fair	poor	Total
30. For your age, in general, would you say your health is	12 (8.96%)	38 (28.36%)	48 (35.82%)	33 (24.63%)	3 (2.24%)	134 (100.00%)

Item	Valid					
	excellent	good	satisfactory	fair	poor	Total
31. How would you rate your overall quality of life during the last week?	26 (19.40%)	60 (44.78%)	27 (20.15%)	17 (12.69%)	4 (2.99%)	134 (100.00%)

Item	Valid					
	much better now	slightly better now	unchanged	fair	much worse now	Total
32. How would you rate your overall quality of life compared with 10 years ago quality of life during the last week?	9 (6.72%)	21 (15.67%)	53 (39.55%)	42 (31.34%)	9 (6.72%)	134 (100.00%)

E. Mental function

Item	Valid					
	in the morning	in the afternoon	only in the evening	after strenuous activity	almost never	Total
33. Do you tend to feel tired?	25 (18.66%)	5 (3.73%)	10 (7.46%)	48 (35.82%)	46 (34.33%)	134 (100.00%)

Item	Valid					
	almost every day	three to five days a week	one or two days a week	once in a while	almost never	Total
34. Do you feel downhearted?	4 (2.99%)	2 (1.49%)	10 (7.46%)	52 (38.81%)	66 (49.25%)	134 (100.00%)

Item	Valid					
	almost every day	three to five days a week	one or two days a week	once in a while	almost never	Total
35. Do you feel lonely?	3 (2.24%)	4 (2.99%)	5 (3.73%)	35 (26.12%)	87 (64.93%)	134 (100.00%)

Item	Valid					
	almost every day	three to five days a week	one or two days a week	once in a while	almost never	Total
36. Do you feel full of energy?	81 (60.45%)	36 (26.87%)	10 (7.46%)	2 (1.49%)	5 (3.73%)	134 (100.00%)

Item	Valid					
	never	rarely	sometimes	quite often	always	Total
37. Are you hopeful about your future?	4 (2.99%)	10 (7.46%)	50 (37.31%)	20 (14.93%)	49 (36.57%)	133 (99.25%)

Item	Valid					
	never	rarely	sometimes	quite often	always	Total
38. Do you get upset over little things?	25 (18.66%)	34 (25.37%)	57 (42.54%)	17 (12.69%)	1 (0.75%)	134 (100.00%)

Item	Valid					
	never	rarely	sometimes	quite often	always	Total
39. Do you find it easy to make contact with people?	6 (4.48%)	6 (4.48%)	21 (15.67%)	33 (24.63%)	68 (50.75%)	134 (100.00%)

Item	Valid					
	never	rarely	sometimes	quite often	always	Total
40. Are you in good spirits most of the day?	- -	1 (0.75%)	36 (26.87%)	56 (41.79%)	41 (30.60%)	134 (100.00%)

Item	Valid					
	never	rarely	sometimes	quite often	always	Total
41. Are you afraid of becoming totally dependent?	72 (53.73%)	8 (5.97%)	38 (28.36%)	8 (5.97%)	8 (5.97%)	134 (100.00%)

Appendix E

Table 18 Frequency and percentage of each dietary calcium and protein intake item

Type of calcium and protein diet	Frequency and percentage of dietary calcium and protein intake (days/week)				
	everyday	4-6 days/week	2-3 days/week	1 day	not take
1. milk product	57 (42.54%)	15 (11.19%)	17 (12.69%)	4 (2.99%)	41 (30.60%)
2. dried prawn or fish product	11 (8.21%)	23 (17.16%)	41 (30.60%)	32 (23.88%)	27 (20.15%)
3. vegetable	83 (61.94%)	21 (15.67%)	20 (14.93%)	5 (3.73%)	5 (3.73%)
4. nut product	30 (22.39%)	30 (22.39%)	40 (29.85%)	16 (11.94%)	18 (13.43%)
5. meat	86 (64.18%)	23 (17.16%)	20 (14.93%)	4 (2.99%)	1 (0.75%)

Appendix F

Table 19 Output of multiple regression analysis in the factor affecting the quality of life in postmenopausal women with the risk of osteoporosis

Descriptive Statistics

	Mean	Std. Deviation	N
Quality of life	34.50	15.49	130
BMI	24.31	3.83	130
Occupation(Z1)	.22	.42	130
Occupation(Z2)	.43	.50	130
Duration of menopause	22.16	10.24	130
Energy expenditure (Kcal/d)	157.97	131.88	130
Dietary score	17.89	3.61	130
Alcohol drinking	.05	.21	130
Caffeine taking	.70	.46	130
Smoking	.00	.00	130
Duration of osteoporosis drugs taking	39.38	31.43	130
Duration of calcium taking	62.06	45.83	130
Side effect of osteoporosis drugs	.13	.34	130
Side effect of calcium	.10	.30	130

Correlations

		Quality of life	BMI	Occupation(Z1)	Occupation(Z2)	Duration of menopause	Energy expenditure (Kcal/d)	Dietary score	Alcohol drinking	Caffeine taking	Smoking	Duration of osteoporosis drugs taking	Duration of calcium taking	Side effect of osteoporosis drugs	Side effect of calcium
Pearson Correlation	Quality of life	1.000	.064	.031	-.292	.367	-.553	-.265	-.011	-.085	.	.024	-.091	.069	.065
	BMI	.064	1.000	.141	-.148	-.065	-.042	-.054	.194	.071	.	-.076	-.030	.009	-.061
	Occupation(Z1)	.031	.141	1.000	-.466	-.075	-.003	-.082	-.118	.069	.	-.076	.026	-.043	.129
	Occupation(Z2)	-.292	-.148	-.466	1.000	-.049	.015	.069	.031	-.041	.	.354	.314	-.153	-.135
	Duration of menopause	.367	-.065	-.075	-.049	1.000	-.308	-.079	-.075	.002	.	.064	-.022	.049	.089
	Energy expenditure (Kcal/d)	-.553	-.042	-.003	.015	-.308	1.000	.160	-.051	-.002	.	-.070	-.033	-.119	.009
	Dietary score	-.265	-.054	-.082	.069	-.079	.160	1.000	-.075	.107	.	.024	-.004	.120	-.004
	Alcohol drinking	-.011	.194	-.118	.031	-.075	-.051	-.075	1.000	-.016	.	.082	.054	.023	.049
	Caffeine taking	-.085	.071	.069	-.041	.002	-.002	.107	-.016	1.000	.	-.034	-.021	-.194	.050
	Smoking	.	.	.	.	.	.	.	.	.	1.000	.	.	.	.
	Duration of osteoporosis drugs taking	.024	-.076	-.076	.354	.064	-.070	.024	.082	-.034	.	1.000	.633	-.078	-.167
	Duration of calcium taking	-.091	-.030	.026	.314	-.022	-.033	-.004	.054	-.021	.	.633	1.000	-.132	-.048
	Side effect of osteoporosis drugs	.069	.009	-.043	-.153	.049	-.119	.120	.023	-.194	.	-.078	-.132	1.000	.099
	Side effect of calcium	.065	-.061	.129	-.135	.089	.009	-.004	.049	.050	.	-.167	-.048	.099	1.000
Sig. (1-tailed)	Quality of life	.	.233	.362	.000	.000	.000	.001	.452	.167	.000	.394	.152	.217	.231
	BMI	.233	.	.054	.046	.233	.319	.273	.013	.210	.000	.194	.368	.460	.244

	Occupation(Z1)	.362	.054	.	.000	.199	.489	.178	.091	.219	.000	.195	.383	.312	.071
	Occupation(Z2)	.000	.046	.000	.	.291	.434	.217	.364	.323	.000	.000	.000	.041	.063
	Duration of menopause	.000	.233	.199	.291	.	.000	.186	.197	.490	.000	.235	.404	.291	.157
	Energy expenditure (Kcal/d)	.000	.319	.489	.434	.000	.	.034	.283	.493	.000	.213	.355	.089	.460
	Dietary score	.001	.273	.178	.217	.186	.034	.	.198	.114	.000	.394	.483	.088	.481
	Alcohol drinking	.452	.013	.091	.364	.197	.283	.198	.	.428	.000	.178	.273	.396	.290
	Caffeine taking	.167	.210	.219	.323	.490	.493	.114	.428	.	.000	.348	.407	.013	.285
	Smoking	.000	.000	.000	.000	.000	.000	.000	.000	.000	.	.000	.000	.000	.000
	Duration of osteoporosis drugs taking	.394	.194	.195	.000	.235	.213	.394	.178	.348	.000	.	.000	.190	.029
	Duration of calcium taking	.152	.368	.383	.000	.404	.355	.483	.273	.407	.000	.000	.	.067	.293
	Side effect of osteoporosis drugs	.217	.460	.312	.041	.291	.089	.088	.396	.013	.000	.190	.067	.	.132
	Side effect of calcium	.231	.244	.071	.063	.157	.460	.481	.290	.285	.000	.029	.293	.132	.
N	Quality of life	130	130	130	130	130	130	130	130	130	130	130	130	130	130
	BMI	130	130	130	130	130	130	130	130	130	130	130	130	130	130
	Occupation(Z1)	130	130	130	130	130	130	130	130	130	130	130	130	130	130
	Occupation(Z2)	130	130	130	130	130	130	130	130	130	130	130	130	130	130
	Duration of menopause	130	130	130	130	130	130	130	130	130	130	130	130	130	130
	Energy expenditure (Kcal/d)	130	130	130	130	130	130	130	130	130	130	130	130	130	130
	Dietary score	130	130	130	130	130	130	130	130	130	130	130	130	130	130

Alcohol drinking	130	130	130	130	130	130	130	130	130	130	130	130	130	130
Caffeine taking	130	130	130	130	130	130	130	130	130	130	130	130	130	130
Smoking	130	130	130	130	130	130	130	130	130	130	130	130	130	130
Duration of osteoporosis drugs taking	130	130	130	130	130	130	130	130	130	130	130	130	130	130
Duration of calcium taking	130	130	130	130	130	130	130	130	130	130	130	130	130	130
Side effect of osteoporosis drugs	130	130	130	130	130	130	130	130	130	130	130	130	130	130
Side effect of calcium	130	130	130	130	130	130	130	130	130	130	130	130	130	130

Model Summary

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate
1	.698[a]	.487	.434	11.65103

a. Predictors: (Constant), Side effect of calcium, Dietary score, Duration of calcium taking, BMI, Duration of menopause, Caffeine taking , Alcohol drinking , Occupation(Z1), Side effect of osteoporosis drugs , Energy expenditure (Kcal/d), Occupation(Z2), Duration of osteoporosis drugs taking

ANOVA[b]

Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	15074.337	12	1256.195	9.254	.000[a]
	Residual	15882.339	117	135.746		
	Total	30956.677	129			

a. Predictors: (Constant), Side effect of calcium, Dietary score, Duration of calcium taking, BMI, Duration of menopause, Caffeine taking , Alcohol drinking , Z1, Side effect of osteoporosis drugs , Energy expenditure (Kcal/d), Z2, Duration of osteoporosis drugs taking

b. Dependent Variable: Quality of life

Coefficients[a]

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.
		B	Std. Error	Beta		
1	(Constant)	51.912	9.603		5.406	.000
	BMI	.190	.282	.047	.676	.500
	Occupation(Z1)	-5.157	2.944	-.139	-1.752	.082
	Occupation(Z2)	-11.113	2.616	-.357	-4.248	.000
	Duration of menopause	.248	.108	.164	2.290	.024
	Energy expenditure (Kcal/d)	-.056	.008	-.473	-6.616	.000
	Dietary score	-.656	.297	-.153	-2.206	.029
	Alcohol drinking	-4.449	5.126	-.060	-.868	.387
	Caffeine taking	-3.053	2.319	-.091	-1.316	.191
	Duration of osteoporosis drugs taking	.086	.044	.174	1.937	.055
	Duration of calcium taking	-.034	.030	-.100	-1.135	.259
	Side effect of osteoporosis drugs	-2.756	3.259	-.060	-.846	.400
	Side effect of calcium	3.323	3.575	.065	.930	.355

Appendix G

Table 20 Coefficients of predictor variables in multiple regression for each domain in Qualeffo 41

Pain domain

Coefficients[a]

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.
		B	Std. Error	Beta		
1	(Constant)	54.914	19.624		2.798	.006
	BMI	.167	.575	.025	.290	.773
	Occupation(Z1)	-14.366	6.015	-.237	-2.388	.019
	Occupation(Z2)	-17.865	5.346	-.351	-3.342	.001
	Duration of menopause	-.112	.222	-.045	-.506	.614
	Energy expenditure (Kcal/d)	-.041	.017	-.215	-2.399	.018
	Dietary score	-.126	.608	-.018	-.208	.836
	Alcohol drinking	8.082	10.475	.067	.772	.442
	Caffeine taking	-6.902	4.739	-.125	-1.456	.148
	Duration of osteoporosis drugs taking	.095	.091	.118	1.049	.296
	Duration of calcium taking	-.090	.061	-.164	-1.481	.141
	Side effect of osteoporosis drugs	-2.766	6.660	-.037	-.415	.679
	Side effect of calcium	5.576	7.306	.066	.763	.447

a. Dependent Variable: Total score pain domain

Physical domain

Coefficients[a]

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.
		B	Std. Error	Beta		
1	(Constant)	35.761	12.719		2.812	.006
	BMI	.709	.373	.128	1.901	.060
	Occupation(Z1)	-3.374	3.899	-.067	-.865	.389
	Occupation(Z2)	-11.069	3.465	-.260	-3.195	.002
	Duration of menopause	.567	.144	.274	3.946	.000
	Energy expenditure (Kcal/d)	-.074	.011	-.463	-6.686	.000
	Dietary score	-.631	.394	-.107	-1.602	.112
	Alcohol drinking	-12.195	6.789	-.121	-1.796	.075
	Caffeine taking	-2.226	3.072	-.048	-.725	.470
	Duration of osteoporosis drugs taking	.087	.059	.129	1.476	.143
	Duration of calcium taking	-.037	.040	-.081	-.942	.348
	Side effect of osteoporosis drugs	-.897	4.317	-.014	-.208	.836
	Side effect of calcium	5.250	4.735	.075	1.109	.270

a. Dependent Variable: Total score physical domain

Social activities domain

Coefficients[a]

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.
		B	Std. Error	Beta		
1	(Constant)	81.531	14.896		5.473	.000
	BMI	-.169	.437	-.029	-.387	.700
	Occupation(Z1)	-.606	4.566	-.011	-.133	.895
	Occupation(Z2)	-14.452	4.058	-.324	-3.561	.001
	Duration of menopause	.291	.168	.135	1.730	.086
	Energy expenditure (Kcal/d)	-.066	.013	-.391	-5.039	.000
	Dietary score	-.983	.461	-.160	-2.132	.035
	Alcohol drinking	-13.651	7.952	-.130	-1.717	.089
	Caffeine taking	-4.834	3.597	-.100	-1.344	.182
	Duration of osteoporosis drugs taking	.008	.069	.011	.117	.907
	Duration of calcium taking	-.026	.046	-.053	-.551	.583
	Side effect of osteoporosis drugs	-6.786	5.056	-.104	-1.342	.182
	Side effect of calcium	3.009	5.546	.041	.542	.589

a. Dependent Variable: Total score social domain

General health perception domain

Coefficients[a]

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.
		B	Std. Error	Beta		
1	(Constant)	93.610	13.514		6.927	.000
	BMI	-.763	.396	-.163	-1.925	.057
	Occupation(Z1)	-6.030	4.142	-.141	-1.456	.148
	Occupation(Z2)	-6.204	3.681	-.172	-1.685	.095
	Duration of menopause	-.280	.153	-.160	-1.834	.069
	Energy expenditure (Kcal/d)	-.057	.012	-.421	-4.840	.000
	Dietary score	-.611	.418	-.123	-1.460	.147
	Alcohol drinking	.777	7.213	.009	.108	.914
	Caffeine taking	-2.171	3.263	-.056	-.665	.507
	Duration of osteoporosis drugs taking	.049	.062	.085	.780	.437
	Duration of calcium taking	-.027	.042	-.068	-.634	.527
	Side effect of osteoporosis drugs	-.759	4.586	-.014	-.166	.869
	Side effect of calcium	4.799	5.031	.081	.954	.342

a. Dependent Variable: Total score general domain

Mental function domain

Coefficients[a]

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.
		B	Std. Error	Beta		
1	(Constant)	47.700	11.982		3.981	.000
	BMI	-.216	.351	-.053	-.616	.539
	Occupation(Z1)	-5.480	3.673	-.147	-1.492	.138
	Occupation(Z2)	-7.060	3.264	-.225	-2.163	.033
	Duration of menopause	.007	.135	.004	.048	.962
	Energy expenditure (Kcal/d)	-.023	.010	-.194	-2.189	.031
	Dietary score	-.782	.371	-.181	-2.109	.037
	Alcohol drinking	8.199	6.396	.111	1.282	.202
	Caffeine taking	-1.780	2.894	-.053	-.615	.540
	Duration of osteoporosis drugs taking	.147	.055	.296	2.653	.009
	Duration of calcium taking	-.009	.037	-.025	-.232	.817
	Side effect of osteoporosis drugs	-4.463	4.066	-.097	-1.097	.275
	Side effect of calcium	-1.640	4.461	-.032	-.368	.714

a. Dependent Variable: Total score mental domain

BIOGRAPHY

Isaree Junyasak was born in Suratthani, Thailand, on January 9, 1983. She graduated from Suksanari School in 2001 and received her Bachelor of Science degree in Pharmacy from Mahidol University in February 2006. Isaree worked in Siriraj Hospital from 2006 to 2008, in the position of pharmacist. She entered the Degree of Master of Science in Social and Administrative Pharmacy Program, Faculty of Pharmaceutical Science at Chulalongkorn University in 2008.