

Assessment Tool of Thai Menopause-Specific Quality of Life in Surat Thani Province, Thailand

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Objective: To develop an assessment tool of Thai menopause-specific quality of life in Surat Thani Province, Thailand.

Material and Method: The present study divided research design into three phases. Phase I Concept clarification, a thorough study of related literature was conducted to search for the concept of menopause-specific quality of life and its existing instruments to guide developing instrument. Phase II Item development, in-depth interviews with 30 Thai menopausal women in Surat Thani was conducted and an initial pool of items relating to menopause-specific quality of life was generated to develop the instrument, then, tested with 399 menopausal women. Phase III psychometric test, the developed questionnaire was tested for validity and reliability with 402 menopausal women.

Results: The Thai Menopause-Specific Quality of Life instrument was well developed with 63 items, internal consistency reliability coefficient obtained 0.952, comprised of three domains including physic-psychological well-being (51 items), sexual-socio-economic well-being (9 items) and vasomotor well-being (3 items).

Conclusion: The present study was directed to develop an effective instrument with integrity of psychometric property. This instrument was more meaningful to detect quality of life specific to Thai menopausal women.

Keywords: Menopause, Health-specific quality of life, Measurement tool

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Studies in menopausal Asian women demonstrated that physical, psychological and sociocultural circumstances of mid-life Asian women lead to experience of menopausal symptoms and other related health outcome different between countries and different from experiences reported by Western women⁽¹⁾. Furthermore, the pattern of menopausal symptoms experienced by Asian women also appears to differ when compared to their Western counterparts. Conflicting findings reflect some of the methodological difficulties inherent in studies of the menopause as well as specific issues pertaining to the measurement of symptoms and quality of life according to menopause⁽²⁾. Most of the studies carried out so far, climacteric symptoms were analyzed using scales, which had originated in the West, without taking into consideration the socioeconomic factors and

cultural background of this region. Another important example if the application of health related quality of life (HRQOL) instruments is that the prevalence of individual menopausal symptoms was different among ethnic groups of Asian women⁽³⁾. It has been suggested that utilizing the same quality of life (QOL) measurement may not be applicable to worldwide populations or across regional ethnicities unless linguistic and cultural adaptation is provided. Thus, the purpose of the present study was to develop the menopause-specific quality of life instrument as a self-administered condition specific tool to measure health-related quality of life in Thai middle-aged women. Ethics approval to conduct the present study was obtained from The Ethical Review Committee for Research Involving Human Research Subjects, Health Science Group, Chulalongkorn University, Thailand.

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Material and Method

The present descriptive study was designed to develop a menopause-specific quality of life instrument for Thai menopausal women.

Population and Samples

The present study was conducted in urban and rural areas of Surat Thani Province in Southern Thailand. The population was Thai menopausal women aged 45-59 years currently living in Surat Thani Province. The inclusion criteria included Thai middle-aged women (45-59 years old) who had ceased menstruation at least for 1 year, had not had a hysterectomy, and had never taken hormonal therapy during the preceding six months. The exclusion criteria were contraindications to estrogen use which currently has had unstable medical or social problems, and had other chronic disease that might affect health related quality of life. Participants of each phase would not be allowed to involve in the other step of the questionnaire development.

Sample size

According to the study design, samples of the present study were drawn differently in each phases of the study as: Qualitative study to guide item generation by 30 participants who met the inclusion criteria were invited to in-depth interviews; 400 menopausal women who had never been involved in the previous steps were asked to complete the developed questionnaire for Item reduction and 402 menopausal women were tested for reliability and validity.

The process of instrumental development comprised of three phases covering nine steps as the following summary:

Phase I is covering step1-2: Step 1-Identification of the population, and Step 2-Definition of the construct to be measured.

Phase II is covering step 3-7: Step 3-Qualitative research to guide item generation; Step 4-Generation of items to represent construct dimensions; Step 5-Design and scale format; Step 6-Content validity check by expert judges and Step 7-Item reduction (pre-test the result on the sample of potential respondents).

Phase III is covering step 8-9: Step 8-Establish reliability and Step 9-Establish validity.

PHASE I - Concept clarification (step 1-step 2)

Step 1 - Identification of population

The specific purpose of this instrument is to evaluate the menopause specific quality of life of Thai menopausal women. Participants representing the experiences symptoms of menopause were identified.

Step 2 - Definition of the construct to be measured

A thorough study of related literature was conducted to search for definition of menopause-specific quality of life. Researchers reviewed existing measurements related to menopause and quality of life and critically analyzed to obtain the integrity of instruments. Based on the obtained information from the literature review, specific domains were selected to guide the developing instrument. Possible questions that belong to each domain were derived.

PHASE II - Item development (step 3-step 7)

Step 3 - Qualitative study to guide item generation

The primary reason for including this qualitative study step is to provide guidance on the appropriateness of the language to be used in initial scale development. In addition, respondents are able to provide a level of detail in explaining or justifying their opinions. The interviews were performed in private settings in the communities. Researchers applied the four forms of interviews useful for qualitative research⁽⁴⁾. The interviews were conducted by using the interview guide approach. During the interview, participants were asked to identify their experiences of menopause symptoms that affected their quality of life. They were asked specifically about each of the domains. New respondents were interviewed with consecutive interviews, a technique termed interviewing to redundancy until no new information was identified.

The interview guide approaches were as the following:

1. What are the natural menopause transitions and when do they occur?

2. What sign or symptoms accompany the transitions?

Did your urinary system change and how?

Did your skin change and how?

Did your pulse change and how?

Did your extremity sensory change and how?

Did your power change and how?

Did your dietary system change and how?

Did your mood change and how?

Did your memory system change and how?

Did your genital organ change and how?

Did your sexual intercourse change and how?

3. Can you describe how these symptoms affected you/and persons around you?

4. Did you have satisfaction on your menopause transition and how?

5. Which symptoms related to menopause did you experience during this period and seek for help and how?

6. Which symptoms related to menopause did your family or your friends experience during this period and were they the same as yours? What factors affect the transitions?

7. Did you worry about your economic status?

8. Did you have an image about yourself by self-esteem and how?

Step 4 - The generation of items to represent construct dimensions

After reviewing a thorough understanding of the literature/theoretical framework and qualitative study, this step was to generate statements/questions for the questionnaire. An initial pool of related items to menopause-specific quality of life was derived.

Step 5 - Design and scale format

The heart of the scale construction was the scaling method used for selecting items. Several methods were described, grouped according to the type of scale (stimulus-centered, subject-centered, or response). The present study used Subject-Centered Scale Methods. Subject-Centered scales are probably the kind of scale with the most frequent use in counseling psychology research. Individual differences in both the clients and the counselors were thought to account for significant portions of counseling outcomes variance. Also possibly, because individual different variables were among the most easily accessible to researchers, much effort had been put into constructing and developing subject-centered scales.

Step 6 - Content validity checks by expert judges

The first version of Thai menopause-specific quality of life was refined and edited for validated content by expert judges who were healthcare professionals on menopause. Means for each of the dimensions were obtained by asking respondents to indicate the degree of agreement with each of statements describing the dimensions of menopause-specific quality of life. Those expert judges included gynecologists and nurses.

Step 7 - Item reduction (pre-test)

Pre-testing was conducted to determine if the interpretation of the questions was consistent and

the questions were unambiguous and jargon free. The questionnaire was administered to a group of 400 menopausal women who had not been involved in the previous steps of the questionnaire development. They were asked to describe what each question meant to them, if there were any problems with the question, or if there were any omissions from the instrument.

PHASE III - Psychometric test (step 8-step 9)

The Thai menopause-specific quality of life tested the reliability and validity in menopause women who met the inclusion criteria as follows: 1) ability to communicate in the Thai language, 2) ability to respond to questions and 3) willing to participate in the present study. The sample size was based on DeVellis⁽⁶⁾ where the number of subjects need is equal to the multiplication of the number of items and levels of answers. Tinsley⁽⁷⁾ noted that it is sometimes difficult to estimate the number of expected factors. In that event, they extended the recommendation to include 5 to 10 subjects per item for up to 300 subjects.

Step 8 - Establish reliability

Test-retest reliability was determined by comparing domain and summary scores using intraclass correlation coefficients. Domain internal consistency was calculated using Cronbach's alpha. To test reliability, this measurement tool was administered at two time points. Ideally, the time interval should not exceed six months because most measures were not stable over long periods of time⁽⁸⁾. Correlations of 0.8 or higher are excellent⁽⁹⁾. The time period for test-retest reliability was chosen (two weeks) in the present study because it was long enough for individuals not to remember specific responses and not too long so that maturation and learning was most likely to not occur in this time frame, affecting the answers.

Step 9 - Establish validity

In the initial development of a scale, it is more important to determine what the measure actually measures than whether it predicts accurately or not. Measuring construct validity, on the other hand, requires ensuring that the instrument is actually measuring what it intends to measure⁽¹⁰⁾. Factor analysis is one way of establishing construct validity⁽¹¹⁾. According to Nunnally and Berstein⁽¹²⁾, the most appropriate method for assessing the construct validity is to investigate the coefficient alphas for each of the dimensions. Additionally, a factor analysis will run on items into the identified dimensions to provide

further insight into whether or not items should be dropped. Therefore, factor analysis was cautiously conducted to obtain instrument construct validity of the present study.

Results

The goal of the instrument was to evaluate the menopause specific quality of life of Thai menopausal women. An initial pool of related items of menopause-specific quality of life was generated by a critical review from the literature, the existing menopause-specific quality of life measures and information from in-depth interviews. Therefore, 80 potential items were generated in Thai to form an initial draft of the Thai Menopause-Specific Quality of Life instrument (TMSQOL). Items of the TMSQOL were supposed to be indicators of quality of life in Thai menopausal women.

A list of items was generated into a questionnaire format and item scaling was performed. A 5-point Likert-type scaling procedure was utilized for the instrument. The 5-point scale was scored as degree of menopausal women's perception. Scoring weights from 1 to 5 were assigned to the five rating-scale points (not at all to very much). The questionnaire consisted of two sections. The first section was demographic information. The second section comprised 80 items related to menopause-specific quality of life.

After obtaining content validity and face validity by experts who were gynecologists and nurses, the preliminary instrument with 80 items of eight domains ($CVI = 0.96$) was ready for pre-test. The Kaiser-Meyer-Olkin measure of sampling adequacy was 0.935, indicating excellent sampling adequacy and relatively compact patterns of correlation, such that factor analysis should produce distinct and reliable factors remaining 77 items were formed for Thai Menopause-Specific Quality of Life (TMSQOL).

To examine the underlying structure of the relationships among the 77 items with in the Thai Menopause-Specific Quality of Life (TMSQOL), the 402 sample data was used to analysis the factors. The KMO value of 0.895 and the high significant level value = 0.000 in examining the data from the rotated factor analysis, investigators set a criterion level of greater than 0.40 as the factor loading criterion. Fourteen items had factor loadings less than 0.40. Consequently, 14 items were discarded and the remaining 63 items for the TMSQOL. After examining the various factor solutions, investigators found that a three-factor

solution provided the most meaningful factor pattern and accounted for 69.03% of the total variance. Items within each factor were analyzed and named based on the item description. There were totally 63 items within three factors. These factors and their loading are explained in the following:

The first factor with an Eigen value of 18.32 emerged significant with 51 items. This factor contributed a variance of 23.80% to the total variance. The factor loading ranged from 0.427 to 0.711. This factor related to the subject's perception of well-being that derived from menopause transition which composes of physical, psychological, urinary and vaginal symptoms. Factor 1 was labeled physio-psychological well-being.

The second factor has nine items with significant loading, which ranged from 0.439 to 0.623. This factor contributed a variance of 7.13% to the total variance with an Eigen value of 5.49. The items described as a subject's perception of well-being that derived from menopause transition and composes of sexual, economic, and self-esteem. This factor was called sexual-socioeconomic well-being.

The Eigen of the third factor was 4.24. The variance contributed by this factor was 5.51% the three items in this factor describes a subject's perception of well-being that was derived from menopause transition, which is composed of vasomotor symptoms. Factor 3 was labeled vasomotor well-being.

Finally, the Thai Menopause-Specific Quality of Life instrument had 63 items with three factors namely, physio-psychological well-being, sexual-socio-economic well being, and vasomotor well-being.

Discussion

The conceptual framework of menopause-specific quality of life, of the present study was defined as a subject's perception of well-being that derived from menopause transition which was composed of three factors that were based on the main supported following:

1. The conclusion of the present study of the impact of menopause in different cultures is that there were large differences in the experience of menopause by perception of women of the same culture and among different cultures. Menopausal symptoms appear to be caused by a combination of physical changes, cultural influences and individual perceptions⁽¹³⁾.

2. The psychosocial model looks at the menopausal transition as a natural part of development, which should not be treated by medication such as

estrogens. This model can lead to personal development with new knowledge and self-esteem. On the other hand, in women with severe climacteric symptoms, this model may lead to a conflict and a feeling of failure and loss of self-esteem⁽¹⁴⁾.

3. Thai women viewed menopause as a natural life process and accepted it as a normal physiological changed⁽¹⁵⁾. Many Thai women expressed positive views about menopause⁽¹⁶⁾. A National study of health behavior of pre and post-menopausal Thai women⁽¹⁷⁾ found that approximately 78% of women believed that menopause is a natural process. However, about 65% and 60% of women also believed that menopause accelerate ageing process and caused emotional changes, respectively.

4. Thai postmenopausal women reported sexual symptoms more frequently than women with pre-or perimenopausal. These sexual symptoms were the main causes for postmenopausal women with lost quality of life⁽¹⁵⁾.

5. Thai women had more likely satisfaction with personal domains of life (*e.g.*, spiritual life, family life, and self) whereas they were less satisfied with environmental domains of life were (*e.g.*, life in Thailand, Thai government). Additionally, the significant determinants of overall life satisfaction were education and household income. The results suggested that both human capital (education) and economic well-being are important to overall life satisfaction of Thais⁽¹⁸⁾.

The scales that have stems with both positive and negative wording are less reliable than those where all the stems are worded in the same direction⁽¹⁹⁾. The scales of the present study have stems with both positive and negative wording. However, the majority of items (93.70%) have negative wording and few (6.3%) have positive wording. Thus, it concluded that the majority are worded in the same direction.

Longer test yield higher estimates of reliability. This phenomenon can be best explained through an examination of the Spearman Brown prophecy equation, which indicates that as number of items increase, there is a direct increase in the reliability estimate. However, one must consider the reliability gains earned in such situations, as infinitely long tests are not necessarily desirable⁽²⁰⁻²²⁾. In the present study, Thai Menopause-Specific Quality of Life instrument has a 63-item and internal consistency reliability coefficient of 0.952, which indicated that test length was appropriate.

Limitation of the present study was confined to a single area (Surata thani Province) cover regions in Thailand and cross menopausal status will help to develop a comprehensive, sensitive tool.

Conclusion

The present study was designed to develop a menopause-specific quality of life instrument for Thai menopausal women. The Thai Menopause-Specific Quality of Life instrument was well developed with 63 items, internal consistency reliability coefficient obtained 0.952, comprised of three domains including physic-psychological well-being (51 items), sexual-socio-economic well-being (9 items), and vasomotor well-being (3 items).

This first factor was related to the subject's perception of well-being that derived from menopause transition, which composes of physical, physical, psychological, urinary, and vaginal symptoms. Factor 1 was labeled physic-psychological well-being and consisted of 51 items.

The second factor was described as a subject's perception of well-being that derived from menopause transition, which was composed of sexual, economic, and self-esteem. This factor was called sexual-socioeconomic well-being and consisted of nine items.

The third factor was described a subject's perception of well-being that derived from menopause transition, which was composed of vasomotor symptoms. Factor three was labeled vasomotor well-being and consisted of three items.

The present study was done to develop an effective instrument with integrity of psychometric property. This instrument was more likely meaningful to detect quality of life specific to Thai menopausal women.

Potential conflicts of interest

None.

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เครื่องมือประเมินคุณภาพชีวิตสตรีไทยในภาวะหมดระดู จังหวัดสุราษฎร์ธานี ประเทศไทย

ดวงเดือน อินทร์บำรุง, สุรศักดิ์ ฐานิพานิชสกุล, สมรัตน์ เลิศมหาฤทธิ์, สัญญา ภัตราชัย

วัตถุประสงค์: เพื่อสร้างแบบวัดคุณภาพชีวิตสำหรับสตรีไทยวัยหมดระดูในจังหวัดสุราษฎร์ธานี

วัสดุและวิธีการ: การศึกษาครั้งนี้ได้แบ่งวิธีการดำเนินการวิจัยเป็น 3 ระยะคือ ระยะที่ 1 การศึกษากรอบแนวคิดโดยศึกษากรอบแนวคิดและทฤษฎีที่เกี่ยวข้องกับวัยหมดระดูจากเอกสารและงานวิจัย รวมทั้งการกำหนดกรอบในการสร้างเครื่องมือวิจัย ระยะที่ 2 การสร้างแบบสอบถาม เป็นการนำกรอบการสร้างเครื่องมือ ที่ได้ในขั้นระยะที่ 1 ไปใช้ในการสร้างและพัฒนาแบบสอบถาม ซึ่งประกอบด้วยการสัมภาษณ์เชิงลึกสตรีไทยวัยหมดระดูจำนวน 30 คน และการปรับปรุงแบบสอบถาม โดยทดสอบกับสตรีไทยวัยหมดระดูจำนวน 399 คน ระยะที่ 3 เป็นการนำเครื่องมือที่ได้ในระยะที่ 2 ไปใช้ทดสอบคุณภาพด้านความเชื่อมั่นและความเที่ยงตรงของเครื่องมือ (*validity and reliability*) กับสตรีไทยวัยหมดระดูจำนวน 402 คน โดยทดสอบจำนวน 2 ครั้ง ห่างกัน 2 สัปดาห์

ผลการศึกษา: พบร่วมแบบวัดคุณภาพชีวิตสำหรับสตรีไทยวัยหมดระดู มีค่า *reliability* = 0.952 สามารถสกัดองค์ประกอบได้ 3 องค์ประกอบ ได้แก่ 1) ปัจจัยที่มีผลกระทบต่อคุณภาพชีวิตจากการเปลี่ยนแปลงทางด้าน ร่างกาย และจิตใจ (จำนวน 51 ข้อ) 2) ปัจจัยที่มีผลกระทบต่อคุณภาพชีวิตจากการเปลี่ยนแปลงทางด้านการมีเพศสัมพันธ์ อย่างwise แล้วสถานะทางเศรษฐกิจ (จำนวน 9 ข้อ) และ 3) ปัจจัยที่มีผลกระทบต่อคุณภาพชีวิตจากการเปลี่ยนแปลงทางด้านระบบประสาทอัตโนมัติ (จำนวน 3 ข้อ)

สรุป: แบบวัดคุณภาพชีวิตสำหรับสตรีไทยวัยหมดระดูมีความเชื่อมั่น และความเที่ยงตรงอยู่ในเกณฑ์ดี และมีความเหมาะสมที่จะนำไปใช้ในการศึกษาคุณภาพชีวิตสำหรับสตรีไทยวัยหมดระดู
