

How to Cite:

Siahbazi, S., Taghizadeh, Z., Montazeri, A., & Maasoumi, R. (2022). Design and psychometric evaluation of a specific tool for measuring the quality of life of women with premenstrual syndrome: A sequential exploratory study. *International Journal of Health Sciences*, 6(S7), 6271-6290. Retrieved from <https://sciencescholar.us/journal/index.php/ijhs/article/view/13514>

Design and psychometric evaluation of a specific tool for measuring the quality of life of women with premenstrual syndrome: A sequential exploratory study

Shiva Siahbazi

Department of Midwifery, School of Nursing and Midwifery, Guilan University of Medical Sciences, Rasht, Iran

Email: shiva_siahbazi@yahoo.com

Ziba Taghizadeh*

Department of Reproductive Health, School of Nursing and Midwifery, Tehran University of Medical Sciences, Tehran, Iran.

Correspondence email: zibataghizadeh@yahoo.com

Ali Montazeri

Health Metrics Research Center, Iranian Institute for Health Sciences Research, ACECR, Tehran, Iran

Email: montazeri@acecr.ac.ir

Raziyeh Maasoumi

Department of Reproductive Health, School of Nursing and Midwifery, Tehran University of Medical Sciences, Tehran, Iran and Nursing and Midwifery Care Research Center, School of Nursing and Midwifery, Tehran University of Medical Sciences, Tehran, Iran

Email: r.masoomie@gmail.com

Abstract---Background: Premenstrual syndrome (PMS) is one of the most common disorders and challenges in women lives that can affect their quality of life. Therefore, the present study was conducted to design and psychometrically evaluate a specific tool for measuring the quality of life of women with premenstrual syndrome. Methods: This is a combined exploratory study of tool design. This study in two phases (qualitative and tool psychometric evaluation) was conducted in 2017-2018 in Tehran. In the first phase, a qualitative content analysis with a contractual approach was carried out by in-depth and semi-structured individual interviews with 21 women affected by premenstrual syndrome. Then, the pool of items extracted from the qualitative stage was completed by reviewing the existing texts and

tools. The second phase of the study involved reducing the overlapped items and validating the tools. In order to investigate the construct validity, a cross-sectional study was conducted with the participation of 440 women with premenstrual syndrome. Data analysis was performed by SPSS-19 software using exploratory factor analysis and reliability tests (Cronbach's alpha and intraclass correlation coefficient). Results: In the qualitative phase, after reviewing the existing texts and tools by the research team, a 55-item questionnaire was developed and entered into the psychometric evaluation phase. Then, after the psychometric evaluation process (validity and reliability), a specific questionnaire was developed to measure the quality of life of women with premenstrual syndrome with 41 items in six dimensions, which explained 73.99% of the total variance. The stability of the tool was confirmed with Cronbach's alpha (0.887) and the interclass correlation coefficient (0.892) for the whole questionnaire. Then, the questionnaire was finalized with six areas of mental health, physical health, concern, compatibility, social-familial functioning, and support. Conclusion: The 41-item self-reporting tool for the quality of life of women with premenstrual syndrome had acceptable validity and reliability. Therefore, it could be used for research, and educational and therapeutic purposes.

Keywords---*Premenstrual Syndrome - Psychometric-Quality of Life- Tool Design-(PMS-QOLQ).*

Introduction

Premenstrual syndrome (PMS) is a condition that periodically occurs in some women before menstruation and disappears with the onset of menstruation; it also has physical, mental, and emotional symptoms [1, 2]. Approximately, 90-70% of women of childbearing age experience some of the most painful symptoms of PMS, with 3 to 8% of them experiencing severe and debilitating symptoms [3]. The prevalence of premenstrual syndrome (PMS) varies according to the diagnosis and classification. The prevalence of premenstrual syndrome in most studies in Iran is estimated to be between 10% and 54% [4, 5]. All age groups are affected by this syndrome, but the most common age of onset is 25 to 45 years [6]. The cause of premenstrual syndrome is unknown and seems to be multifactorial, but the imbalance between estrogen and progesterone that affects the neurotransmitters serotonin and gamma aminobutyric acid has been considered more than other causes [7, 8]. The symptoms of PMS are varied [9] and difficult to diagnose due to their variation. There are several tests and questionnaires that are used for diagnosis of PMS, the most common of which are DRSP [10] and PSST [11].

In recent years, PMS has often prevented women from achieving their full potential, and has affected their social relationships and private lives, imposing great economic costs for society [8]. A great deal of attention has been paid to PMS in recent years [12]. In addition, this syndrome is considered a contributing factor in inactivity, lack of motivation, and low accuracy as well as disintegration of marital life. During this period, women with PMS are more likely to require

hospitalization and be absent from work. They sometimes have psychological distress and even suicidal thought. On average, women's performance scores while experiencing PMS can drop by an average of 10% [13]. This syndrome can affect the health of women and their quality of life, but it is not the same for all suffers. In the last century, the study of chronic diseases and disorders, and the recording of health-related quality of life in therapeutic interventions and counseling have become increasingly important [14]. One of the goals of health for all policy in 21st century is to improve the quality of life, so that maintaining a normal life would not be considered a desirable objective, and improving the quality of life in many areas would be achieved through the fundamental effort of societies, so it is important to measure the quality of life [15].

Many women experience PMS over the years, even from menarche, which leads to chronic problems in relationships, impaired quality of life and negative attitudes toward femininity [16]. According to a survey, no questionnaire exists to assess the quality of life of women with PMS. In a study by Valenstein et al (2008), the PMSIS questionnaire was developed, which is a tool for predicting the effects of premenstrual symptoms [17]. There is another questionnaire designed by Kues et al in Germany with the name of "PMS-IQ" that examines severe premenstrual complaints [18]. These tools do not fully assess the quality of life, because examining symptoms is only part of the quality of life. Researchers have also used the general quality of life questionnaires or health-related tools to measure the quality of life of women with PMS in Iran and other countries. However, unfortunately these general tools cannot cover all information related to psychological and functional aspects of suffers' lives, have a low sensitivity, do not show changes that result from treatment, often include questions that are not related to a specific disease, and ignore important issues [19].

Given that PMS is a serious problem in women of childbearing age and affects their quality of life [20-23], and taking into account that PMS is influenced by social and cultural factors and also since our knowledge in this field is limited to only few studies with low sample size, in which quality of life has been measured by general quality of life questionnaires [24, 25], we decided to take a qualitative approach and use content analysis to examine the quality of life from the perspective of affected women, and accordingly, develop a questionnaire with psychometric characteristics. Therefore, this study was conducted to design and psychometrically evaluate a quality of life assessment tool in women with premenstrual syndrome.

Methods

This is a combined exploratory study that was conducted between September 2017 and June 2018. This type of study begins with a qualitative step and is followed by a quantitative study. This method was introduced by Cresol and Clark-Plano as one of the five main types of combined studies. This type of study is divided into two categories; theory design and tool design. The present study is a tool design study [26]. To design the tool, it was necessary to know the concept of quality of life using the experience of participants in the study, because having a conceptual framework is the first step towards building a tool. Therefore, the qualitative part of this study was grounded and implemented to design a tool

based on it, and then during a quantitative study, the psychometric properties of the tool were evaluated and confirmed.

Step 1: Qualitative study

In the qualitative phase, 21 semi-structured individual interviews, face to face, were conducted with women suffering from premenstrual syndrome (10 single women and 11 married women). The interviews were conducted by a female researcher with a PhD in Reproductive Health who had sufficient information and experience in the field of reproductive health and health literacy. Before conducting the interview, the interviewer introduced her personal and educational characteristics, study objectives, and research questions.

The participants were selected by purposive sampling. The inclusion criteria were; being a 15-45 years old woman with PMS confirmed by PSST questionnaire, having minimal education in reading and writing, having normal menstruation cycle, and having no chronic mental or physical illnesses. The samples had to be able to express their experiences and willing to participate in the study. The interview was conducted with the agreement of the researcher and the participants in any place where the participants could easily recall their experiences. Interview questions were asked with the help of an interview guide questions such as: What effect does premenstrual syndrome have on your life and its quality? Can you tell us about your experiences with premenstrual syndrome? How do you feel about having premenstrual syndrome? How does your life change during these periods? What is bothering you during this time? As the study progressed, corrective or new questions were asked. Probing questions such as "What do you mean?" or "If you can please explain more" were also used in the interviews as needed (the interview guide developed for this study is provided as Additional File 2).

With the permission of the participants, the interview was recorded and then transcribed. To further validate the information, the interviews were re-checked with the participants. At the end of each interview, participants were asked to express anything else they wish to say. Analysis of the qualitative phase was performed using contractual content analysis through MAXQDA-10 software. After analyzing the findings of qualitative phase and reviewing the existing texts and tools, a pool of items was created and then, members of the research team reviewed the items and initial draft of the specialized quality of life questionnaire for women with premenstrual syndrome (PMS-QOLQ), which had 55 items. A 5-option Likert's scales (never, often, sometimes, most of the time, and always) was used in the designed questionnaire. At this stage, the psychometric evaluation phase began, which included the assessment of validity (face, content, construct, and criteria) and reliability (internal consistency and stability) of the tool.

Step 2: Tool's Psychometric evaluation

Validity

Content validity: The opinions of 15 experts (5 experts of reproductive health, 2 experts of obstetrics and gynecology, 1 expert of psychology, 2 tool developers, 2

psychiatrists, 2 midwives and 1 nurse) were considered in the qualitative content validity, and they were asked to carefully examine the tool and present their corrective views and suggestions regarding content coverage, grammar, use of appropriate phrases, and appropriate location of the items. Then, to ensure that the items have been designed for content measurement, two validity indices were used, including content validity ratio (CVR) and content validity index (CVI). The Lawshe's model was used to calculate the CVR. First, to determine the content validity ratio, the experts were asked to review each item based in the three-option Likert's spectrum (necessary, useful but not necessary, not necessary). In the present study, according to the number of experts (12 persons) and the above table, items with the CVR coefficient of more than 0.56 were preserved. To determine the CVI, the Waltz and Basel validity index [27] was used. In order to determine the content validity index, items were examined with three options (relevance or specificity, clarity and simplicity). If the validity index of each item was higher than 0.790, the validity of that item was accepted [28].

Face validity: To determine the qualitative face validity, 15 married and 15 single women with premenstrual syndrome were selected by available sampling method with different age range, occupation and education. Then, factors such as the level of difficulty, the degree of appropriateness and the ambiguity of the items were discussed with the selected women, and based on their comments and suggestions, necessary changes were made to the items. After that, the impact score method was used to determine the quantitative face validity so that, the items with the score of 5.1 or higher were preserved and other items were removed [27]. Also, 15 married and 15 single women with premenstrual syndrome were asked to rate the importance of each item.

Construct validity: In the present study, the initial reliability (correlation between items) was performed before determining the construct validity. To assess the initial reliability, convenience sampling was performed among 30 women with premenstrual syndrome. The internal consistency of the whole questionnaire was 0.92 and the correlation between the scores of each item and the whole questionnaire was in the range of 0.71-0.96, as a result, the high-reliability tool entered the construct validity stage. Exploratory factor analysis approach was used for construct validity. In this study, considering that the number of items in the "quality of life of women with premenstrual syndrome questionnaire" was 42 items, the sample size for performing exploratory factor analysis was estimated to be 10 times of each item ($n=440$). According to the PSST questionnaire, the criteria for entering the study included; being a 15-45 years old woman with PMS, having the minimum education to read and write, having normal menstruation cycle, and having no chronic mental or physical illness. Their exclusion criteria were; unwilling to continue answering the questions and having a stressful event in the last 6 months, such as the loss of loved ones, etc. For the validity of first construct, the KMO sample adequacy test and the Bartlett's test were performed. Then, the analysis of main components was determined by performing a varimax rotation and exploratory factor analysis of the questionnaire.

Criterion validity: Criterion validity is done by comparing scale scores with one or more external variables or criteria that are believed to measure the trait under

study. This criterion can be the predicted outcome of the tool or a valid and stable tool that has already been designed. It is said that a tool is valid when its scores match the scores of the criterion tool. There are two types of criterion validity; prediction validity and simultaneous validity. One of the problems with checking the validity of a criterion is finding a valid and reliable criterion. If there is an appropriate criterion, it is possible to estimate the validity by calculating the correlation coefficient. This coefficient can vary between zero and one variable, so that the closer it is to one, the higher the correlation [29, 30]. In this study, simultaneous criterion validity was used. In the present study, the Persian version of the health-related quality of life tool (SF-36) was used as a simultaneous criterion for the quality of life tool for women with premenstrual syndrome. In order to determine the criterion validity, 60 participants in this study in addition to completing the researcher-made questionnaire, completed the SF-36 questionnaire as a criterion and then, using the statistical test, the correlation between the six factors extracted from factor analysis of PMS-QOLQ and 8 factors of the SF-36 questionnaire was compared.

Reliability

After confirming the validity of the questionnaire, reliability methods of internal consistency (Cronbach's alpha) and stability determination (test-retest) were used. In the present study, Cronbach's alpha was performed using SPSS-22 software with a coefficient of 0.7 as the lower limit. In this study, to determine the stability of the questionnaire, 30 women with premenstrual syndrome (15 single and 15 married) were asked to complete the final questionnaire twice in two weeks. The Intraclass Correlation Coefficient (ICC) was then calculated for all domains as well as for the whole questionnaire. A minimum score of 0.7 is acceptable for ICC [31].

Ethical statement

In order to observe ethical considerations in this research, permission was obtained from the Faculty of Nursing and Midwifery of Tehran University of Medical Sciences and the Deputy for Research with the No: IR.TUMS.UCR.REC.1395.01846). Also, to participate in the research, written informed consent was obtained from the individuals and the confidentiality of personal information in all stages of the study was considered. The informed consent was obtained from parents/guardians of the minors (anyone under the age of 16 years) included in this study.

Results

Qualitative phase

In the qualitative phase, to obtain the required samples, first demographic and PSST questionnaires were distributed among 137 women, 129 of whom completed the questionnaires and 48 of them had premenstrual syndrome. Of the 48 women, 34 were willing to participate in the qualitative phase of the study, and at the end, the data saturation was reached with 21 interviews. Participants' age ranged from 15 to 45 years, and the interviews lasted from 34 to 75 minutes with an average of 56 minutes. The education level of participants varied from high

school to doctorate. Major and minor themes extracted from the qualitative stage include the effects of the syndrome on various health dimensions (physical, psychological, behavioral, and family-social consequences), syndrome-related concerns (feelings of danger and insecurity, and ambiguous nature) and coping with the syndrome (adaptive approaches and factors Was intensifying). Using the findings of qualitative phase and review of texts and tools, a pool of item was created with 98 items, which were reviewed by the research team in several stages in terms of writing, repetition, overlap and importance of the topics. Finally, the items were reduced to 55 items.

Quantitative phase

Content validity: In this study, content validity was performed in both qualitative and quantitative phases. In the qualitative review of the content, the tool was sent to 12 well-known experts and they were asked to present their corrective views after a careful study of the tool. According to the comments and suggestions of them regarding the content coverage, observance of the grammar, use of appropriate phrases and appropriate location of the items, the tool was revised. According to the experts, the quality of life tool in women with premenstrual syndrome had an appropriate comprehensiveness.

In the quantitative content validity, 12 experts were used to determine the CVR and CVI. The minimum accepted CVR is 0.56 based on the Lawshe's table and experts. In the content validity index, items with a score of above 0.79 are acceptable, between 0.70 and 0.79 need to be corrected, and less than 0.7 are unacceptable. Finally, 11 items that their CVR and CVI scores were less than the specified values were removed. Another two items were removed due to the CVI score of below acceptable level. Therefore, the final questionnaire with 42 items entered the next stage.

Face validity: Face validity was done in both qualitative and quantitative phases.

To determine the qualitative face validity, 30 women with premenstrual syndrome (15 single and 15 married) were interviewed face-to-face. The items had no problem in terms of difficulty level. Corrections were made to the ambiguity of the statements, and regarding the Likert's spectrum, the participants' suggested that for a better understanding, the Likert's spectrum should be changed to never, rarely, sometimes, most of the time, and always, which we did. In the quantitative section, to calculate the impact score, 30 participants were asked to rate the importance of each item. At the end of this section, no items were removed (due to the score of above 1.5) and the questionnaire entered the next step with 42 items.

Construct validity

The sample characteristic: The results showed that about 60% of the participants were under 30 years old and 39.7% were over 30 years old. Also, the most education level was bachelor's degree among the participants and most of them were students.

In the first step, the KMO test and the Bartlett's test (BT) were used to assess the adequacy of sampling and to investigate the sufficient relationship between the

variables to allow for factor analysis. The KMO sampling index of 0.860 in the factor analysis model indicated that, the research sample was adequate for factor analysis. Also the Bartlett's test was significant, which indicated sufficient correlation between variables for factor analysis (Table 1).

Then, to determine the number of constituent factors of the questionnaire, Scree Plot and Eigenvalue Diagrams were used. The Scree Plot confirmed the choice of seven factors (Fig. 1). In the next step, after calculating the correlation matrix between the variables, the extraction of factors was performed by analyzing the main components using an orthogonal rotation with Eigen values of greater than one.

Factor loading of each question was considered at least 0.4 in the factor matrix and the rotation matrix. In this study, based on specific value, 7 factors were extracted, which together explained 76% of the total variance. It means that, according to the variance index, the predictive power of the model was 76.579. To ensure the structure of items, the structure of 3 to 7 factors was tested with different rotations, which according to the results of the diagram, nature of the questions, opinion of the research team, and also the factor period, the best case was 6 factors, which together explained 73.99% of the total variance.

Out of a total of 42 questions, only 1 question was removed in the construct validity section and the number of questions reached 41 item. Finally, after performing factor analysis, 6 factors with 41 items, explained 73.999% of the total variance of the tool. The first factor entitled; "mental health" had 9 questions with a variance of 16.827, the second factor called; "physical health" included 9 questions with a variance of 15.92, the third factor called; "concern" had 7 questions with a variance of 12.728, the fourth factor called; "compatibility" included 5 questions with a variance of 10.789, the fifth factor entitled; "socio-familial functioning" had 5 questions with a variance of 9.325, and the sixth factor called; "support" had six questions with a variance of 8.939. Thus, the questionnaire was finalized with 41 items (Table 2).

Criterion validity: In order to determine the criterion validity, the 60 participants of this study in addition to completing the researcher-made questionnaire, completed the quality of life questionnaire as a criterion. Then, using the Pearson linear correlation statistical test for 6 factors extracted from the factor analysis, the 8-factor quality of life questionnaire was compared with the short version of SE-36 quality of life questionnaire (Table 3). There was a significant statistical relationship between the aspects of our specialized quality of life questionnaire and SF-36 quality of life questionnaire, which was related to common items. However, in some aspects such as concern, compatibility and support, there was no significant statistical relationship between the two questionnaires.

Internal consistency: In this study, in order to determine the internal consistency after construct and criterion validities, Cronbach's alpha coefficient in the sample of 440 people was calculated to be 0.887 (Table 4). In order to determine the stability of the questionnaire in the aspect of repeatability, the intraclass correlation coefficient (ICC) for the whole tool was calculated to be 0.892 (Table 4). The results showed that, the intraclass correlation coefficient and

the test retest score were higher than the acceptable range. Finally, the questionnaire was finalized with 41 items in six dimensions (the questionnaire developed for this study is provided as Additional File 4).

Discussion

The aim of present study was to design and psychometrically evaluate a specialized quality of life questionnaire in women with premenstrual syndrome. The initial questionnaire was designed based on the data extracted from a qualitative study of women with premenstrual syndrome, the use of expert opinions, and a review of existing studies on quality of life. The results of present study in the design and psychometric sections led to the production of final version of the quality of life questionnaire in women with premenstrual syndrome with 41 items in 6 dimensions, the validity and reliability of which were confirmed.

According to surveys, there is no questionnaire to measure the quality of life of women with premenstrual syndrome. Only two similar tools were found, one designed by Valenstein et al (2008) called PMSIS, which is a groundbreaking tool for the effects of premenstrual symptoms [17], and another one is the PMS-IQ questionnaire designed by Kues et al in Germany, that examines the effects of severe premenstrual complaints [18]. These tools do not fully assess the quality of life because examining the symptoms of this syndrome is only part of quality of life, not all of it. In addition, both questionnaires have been designed using deductive rather than inductive methods, meaning that in order to collect items, tools such as pain management questionnaire, dealing with pain questionnaire, and premenstrual syndrome diagnostic questionnaire have been used.

In the Kues et al. PMS-IQ questionnaire, the KMO and the Bartlett (BT) tests were adequate to assess the adequacy of sampling and relationship between the variables to allow for factor analysis. The exploratory factor analysis and the varimax rotation showed two factors from which, the first factor measures the psychological distress caused by the symptoms, which is why is called the "psychological effect." The second factor is the functional impact that examines the impact on daily and social activities. The Cronbach's alpha of 0.9 and 0.9 were found for the psychological factor and functional factor, respectively. Convergent validity with the Pain Disability Index questionnaire was also desirable [18]. The Valencia PMSIS questionnaire also includes six items, including unpleasant feelings about symptoms, mood swings due to symptoms, limited ability to concentrate, stress due to symptoms, fatigue at work due to symptoms, and avoiding the community due to symptoms. In this questionnaire, psychometric details are not well expressed [17]. Therefore, only some of the above steps to determine validity and reliability are in line with our study. While in our study, face and content validities were performed completely while the initial reliability was also used.

Quality of life is a multidimensional concept, but there are tools that measure only one dimension of quality of life, and clinical specialists consider their output as a quality of life that does not seem to be correct [32]. In order to accurately assess the quality of life, it is necessary to design a specific questionnaire

consisting of different dimensions to provide a good view of the quality of life in these patients. On the other hand, considering the role of culture in shaping the concept of quality of life, this concept should be defined in terms of culture and accordingly, a credible and valid tool should be designed to measure the quality of life of patients with a specific disease or disorder [33]. The Quality of Life Questionnaire for Women with Premenstrual Syndrome in the present study includes 41 items in six dimensions, including mental health (9 items), physical health (9 items), concerns (7 items), compatibility (5 items), familial-social functioning (5 items) and support (6 items), which seem to be necessary in the questionnaire.

On the other hand, there are numerous and reputable general tools available to measure quality of life and some researchers use general quality of life questionnaires to assess the quality of life of women with premenstrual syndrome. Unfortunately, these tools alone cannot cover all aspects of life in women with this syndrome, which also seems very important. In general tools, the quality of life in all dimensions varies. For example, the dimensions of SF-36 questionnaire include physical functioning (10 questions), limitations caused by physical problems (4 questions), physical pain (2 questions), general health perception (5 questions), mental health (5 questions), limitations caused by emotional problems (3 questions), social functioning (2 questions), and vitality (4 questions), [34]. The World Health Organization's (WHOQOL-BREF) General Quality of Life Questionnaire also has four dimensions, including physical health, psychological health, social relationships, and living environment [35].

Research has shown that, the quality of life of each person is influenced by the person's background characteristics and his/her social, cultural and environmental status [36, 37]. Therefore, data obtained from the patient himself as well as the use of statistical methods such as factor analysis are the strongest and best determinants of quality of life [38] which can be one of the reasons for the existence of different dimensions in our questionnaire compared to other quality of life questionnaires. The main difference in the items of PMSQOLQ-41 questionnaire is that, these items specifically assess the impact of premenstrual syndrome on the quality of life of affected women, while the items of general quality of life questionnaires assess their quality of life in general, and measures their life situation.

In examining the dimensions of our questionnaire, we can refer to the dimension of "concern". In this dimension, questions are related to the concerns of women with PMS and its impact on their quality of life, which includes 7 items. The general quality of life questionnaires and even two other tools do not address this dimension (concern) and even do not mention it in other dimensions. One reason for this difference may be that, the questionnaire designed in this study not only addresses the impact of disease on quality of life, but also on other aspects of quality of life, such as outcomes and concerns. Of course, the cultural, religious, and social context of women in society and its impact on their quality of life should be a cause for concern.

The other dimensions in the present questionnaire include support and compatibility. None of the quality of life tools that we examined had dimension of

"dealing with the disease". Such dimension can provide a more comprehensive questionnaire and this is one of the strengths of our questionnaire. Because studies have shown that there is a close connection between the quality of life and parameters such as lifestyle [39], level of awareness [40], spirituality [41], support and counseling [40], adaptive behavior [10] and background context of families [42]. Another noteworthy point is that, general tools do not pay attention to treatments and cannot provide a good understanding of the quality of life of patients. Therefore, in designing quality of life tools in a particular disorder or disease, in addition to focusing on those dimensions of life that are affected by the disease, good evaluation of the effectiveness of different therapies should also be considered [32]. In the present questionnaire, there are several items in this regard.

One of the strengths of present study is that, before determining the construct validity, the initial reliability of the instrument was assessed by internal consistency method. In many quality of life questionnaires, the initial reliability has not been calculated. Our findings showed that, the internal consistency of the whole questionnaire (0.92) and correlation between the scores of each item and the whole questionnaire (0.71 – 0.96) were in the acceptable range (0.91 - 0.96). These criteria should be considered when selecting a tool [43].

In regard to the SF-36 questionnaire, the statistical analysis showed a significant correlation between the SF-36 and present questionnaires, which indicates that the PMSQOLQ-41 questionnaire has some common constructs and concepts with the SF-36 questionnaire. This confirms the criterion validity and on the other hand, the correlation is not very high in some dimensions, indicating that the two questionnaires are not exactly the same, and our questionnaire measures items that do not exist in the SF-36 questionnaire.

One of the essential features of quality of life questionnaires is to have an overview of the quality of life. The availability of quality of life in a numerical manner can enable policymakers to detect changes in the quality of life. However, this number should be able to be divided and reported by the scope of domains [44]. In this study, the type of score for the quality of life questionnaire of women with premenstrual syndrome was standardized based on 100. The advantage of this method is that, it helps each person to compare him or herself with a score of 100. Each scale is given a separate score, and it is possible to calculate the total score of the tool.

One of the limitations of this study may be its reminiscence bias. Reminiscences of past events may be somewhat forgotten, as it is possible for people not to remember the symptoms well. On the other hand, the voluntary participation of the participants may have led to the elimination of experiences of those who were not willing to participate in this study. In designing the PMSQOLQ-41 questionnaire, we found that, the quality of life in women with PMS is a multidimensional concept that is related to cultural and social context. By comparing the PMSQOLQ-41 questionnaire with the PMS-IQ and PMSIS questionnaires, we found that our questionnaire has several strengths in comparison to them. It also assesses other aspects of life that are influenced by premenstrual syndrome, such as family problems, etc. The designed

questionnaire also assesses how to deal with the syndrome (including dimensions of support and compatibility) as well as concerns that affect the quality of life of these people, while the two aforementioned tools do not address these variables. Based on this, the PMSQOLQ-41 questionnaire seems to be the preferred choice for measuring the quality of life of women with premenstrual syndrome.

It is suggested that, our questionnaire should be validated in other parts of Iran to confirm its reliability and other characteristics in other studies. In order to facilitate the use of PMSQOLQ-41 questionnaire, further studies are suggested to provide a short version of PMSQOLQ-41 questionnaire, and validate it. Moreover, the confirmatory factor analysis of the PMSQOLQ-41 questionnaire and the confirmatory factor analysis in different women with different severity of syndrome are recommended in order to compare their quality of life.

Conclusion

In the present study, the concept of quality of life was determined and a questionnaire with acceptable validity and reliability was designed and validated based on data obtained from in-depth interviews with women with premenstrual syndrome. Researchers acknowledge that designing and validating a new questionnaire is a difficult and time-consuming process, so it is hoped that in future research, our questionnaire would be used repeatedly and potential problems that will arise would be solved.

Abbreviations

Not applicable.

Declaration

Ethical statement

In order to observe ethical considerations in this research, permission was obtained from the Faculty of Nursing and Midwifery of Tehran University of Medical Sciences and the Deputy for Research with the No: IR.TUMS.UCR.REC.1395.01846). Also, to participate in the research, written informed consent was obtained from the individuals and the confidentiality of personal information in all stages of the study was considered. The informed consent was obtained from parents/guardians of the minors (anyone under the age of 16 years) included in this study.

Consent for publication

Not applicable.

Availability of data and materials

All relevant data are within the paper and its supporting information files.

Competing interests

The authors declare that they have no competing interests.

Funding

The authors received no specific funding for this work.

Authors' contributions

ZT supervised all stages of the study, analyzed and interpreted the data and wrote the manuscript. SS, AM and RM participated in the planning and supervised all stages of the study. and writing the manuscript. All authors critically reviewed and revised the manuscript for important contents. All the authors have read and approved the final manuscript.

Acknowledgments

This study with the code of ethics: IR.TUMS.UCR.REC.1395.01846). We would like to thank all the experts and participants who helped us in this research with care and patience.

Author details

Department of Midwifery, School of Nursing and Midwifery, Guilan University of Medical Sciences, Rasht, Iran

Department of Reproductive Health, School of Nursing and Midwifery, Tehran University of Medical Sciences, Tehran, Iran

Health Metrics Research Center, Iranian Institute for Health Sciences Research, ACECR, Tehran, Iran.

.Nursing and Midwifery Care Research Center , School of Nursing and Midwifery ,Tehran University of Medical Sciences,Tehran ,Iran.

References

1. Ryu A, Kim TH. Premenstrual syndrome: A mini review. *Maturitas*. 2015; 82(4):436-40.
2. American Psychiatric Association. Diagnostic and statistical manual of mental disorders: DSM-5, 5th edition. Arlington: American Psychiatric Publishing. 2013.
3. Ginsburg KA. Premenstrual syndrome. In: Ransom SB, editor. *Practical strategies in obstetrics and gynecology*. Philadelphia: WB Saunders; 2000. 10.
4. Shahpoorian F, Mahmoodi Z, Hosseini F, Bastani F, Parsay S. Premenstrual Syndrome and the Related Symptoms Among Students of Iran University of Medical Sciences. *Iran Journal of Nursing*. 2007; 44:57-67.

5. Talaei A, Bordbar F, Nasiraei MR, Pahlavani A, Dadgar M, Samar S. Epidemiology of Premenstrual Syndrome in Students of Mashhad University of Medical Sciences. *Iranina Journal of Obstetrics Gynecology and Infertility*. 2009; 2: 15-20.
6. Lowder milk D L, Perry SE. *Maternity and Womens Health care*. 7th edition. Health science Company .2004;161-163.
7. Charles B. *Obstetrics and gynecology for medical student*. Baltimore Lippincott Williams and Wilkins. 2001; 252-3
8. Dickerson LM, Mazyck PJ, Hunter MH. Premenstrual syndrome. *Am Fam Physician* .2003; 67:1743-52.
9. Siahbazi S, Hariri F, Montazeri A. Standardization of premenstrual symptoms screening questionnaire PSST translation and psychometric Iranian species. *Payesh Journal*. 2011;10(4):421-7.
10. Endicott J, Nee J, Harrison W. Daily record of severity of problems (DRSP): reliability and validity. *Arch Womens Ment Health*. 2005; 9:41-49.
11. Steinner M, Macdougall M, Brown E .The premenstrual symptoms screening tool for clinicians .*Archives of Womens menstrual Health* .2003;203-209.
12. Willson JR, Carrington ER. *Obstetrics and Gynecology* .9th edition. 1991;115-120.
13. Heravi F, Badiiei MM, eds. *Premenstrual syndrome*. Tehran: Institute of Elevation of Women Health. 2008.
14. Wit M, Wall HA, Powver F .Monitoring health related quality of life in adolescent. *Arch Dis Child*. 2007; 92(5): 434-439.
15. Maleki F, Pourshahbaz A, Asadi A, Yoosefi A. The Impact of Premenstrual Disorders on Health related Quality of Life. *Research papers* .2014; 2(3): 105 - 111.
16. Henshaw CA. PMS: diagnosis, a etiology, assessment and managemen . *Advances in Psychiatric Treatment* .2007; 13: 139-146.
17. Wallenstein GV, Blaisdell-Gross B, Gajria K, Guo A, Hagan M, Kornstein SG, et al. Development and validation of the Premenstrual Symptoms Impact Survey (PMSIS): a disease-specific quality of life assessment tool. *J Womens Health* .2008; 17:439-450.
18. Kues JN, Janda C, Kleinstäuber M, Weise C. How to measure the impact of premenstrual symptoms? Development and validation of the German PMS-Impact Questionnaire. *Journal Women & Health*. 2016;56(7).
19. Aghabarari M, Ahmadi A. Mohammadi E. Hajizadeh I. Varvani-Farahani A. Effect of Designed Exercise Program on Quality of Life in Women with Breast Cancer Receiving Chemotherapy. *Scand J Caring Sci*. 2010; 24: 251-258.
20. Mishell DR Jr. Premenstrual disorders: epidemiology and disease burden. *The American journal of managed care* .2005; 11: 473-479.
21. Indusekhar R, Usman SB, Obrien S. Psychological aspects of premenstrual syndrome. *Best Pract Res Clinical Obstetr Gynaecol* .2007;21:207-20.
22. Montazeri A, Taghizadeh Z, Taheri S, Siahbazi S, Masoomi R. Domination of premenstrual syndrome on women's quality of life: a qualitative study. *Payesh (Health Monitor)*. 2019; 18 (1): 53-66.
23. Siahbazi S, Montazeri A, Taghizadeh Z, Masoomie R. The consequences of premenstrual syndrome on the quality of life from the perspective of affected women: a qualitative study. *Journal of Research in Medical and Dental Science*. 2018; 6 (2): 284-92.

24. Siahbazi S, Behboudi-Gandevani S, Moghaddam-Banaem L, Montazer A. Effect of zinc sulfate supplementation on premenstrual syndrome and health-related quality of life: Clinical randomized controlled trial. *The journal of obstetrics and gynecology research*.2017;43(5):887-894.
25. Delara M, Ghofranipour F, Azadfallah P, Tavafian SS, Kazemnejad A., Montazeri A. Health related quality of life among adolescents with premenstrual disorders: a cross sectional study. *Health and Quality of Life Outcomes*.2012;10: 1-5.
26. Creswell,J.W&Clark,V.L.P.Designing and Conducting Mixed Methods Research .2014.
27. Waltz CF, Strickland OL, Lenz ER. Measurement in nursing and health research. 4 ed. New York: Springer Publishing Company. 2010.
28. Polit, Denise F, Beck, Cheryl Tatano. The content validity index: are you sure you know what's being reported? Critique and recommendations. *Res Nurs Health*.2006; 29(5): pp. 489-497.
29. Grant JS, Davis LL.Focus on quantitative methods selection and use of content experts for instrument development. *Journal of Research in Nursing & Health*. 1997; 20: 269-274.
30. Hulley SB, Cummings SR, Browner WS, Grady D, Newman TB. Designing clinical research: an epidemiologic approach. 4th ed. Philadelphia, PA: Lippincott Williams & Wilkins; 2013;79.
31. Polit Df Beck Ct. *Essentials of Nursing Research: Methods. Appraisal and Utilization*. Lippincott Williams & Wilkins. Philadelphia. Pa. USA. 8th Ed. 2006.
32. Fayers P M, Machin D. *Quality of Life Assessment, Analysis and Interpretation*. Jhon Willy. New york: 2000.
33. Darvishpoor Kakhaki A, Abed Saeedi Z, Yaghmaie F, Alavi Majd H. Instrument Development to Measure Diabetic Clients Quality of Life (DCQOL). *Iranian Journal of Endocrinology and Metabolism*. 2005; 7(2) :149-155.
34. Montazeri A, Vahdaninia M, Mousavi SJ, Omidvari S. The Iranian version of 12-item Short Form Health Survey (SF-12): factor structure, internal consistency and construct validity. *BMC Public Health*2009; 9:31.
- 35.Nussbaum M, Sen A. *The quality of life*. Oxford University Press, 1993.
36. Alonso J, Ferrer M, Gandek B, Ware JE Jr, Aaronson NK, Mosconi P et al. Healthrelated quality of life associated with chronic conditions in eight countries: results from the International Quality of Life Assessment (IQOLA) Project. *Qual Life Res*. 2004; 13: 283-98.
37. Gjersing L, Caplehorn JR, Clausen T. Cross-cultural adaptation of research instruments: language, setting, time and statistical considerations. *BMC medical research methodology*. 2010; 10(1):13.
38. Nejat S. *Quality of Life and its Measurement*. irje. 2008; 4 (2) :57-62.
39. Fallah LT, Najafi A, Fathizadeh N, Khaledian Z. The effect of evening primrose oil on premenstrual syndrome. *Sci J Hamadan Nurs Midwifery Facul* 2008; 16(1):35-45.
400. Fata L, Mootabi F, Mohammadkhani S, Kazemzade M. *Practical guidelines of life skills workshops for students: a guid book for educators*.Tehran:Danjeh Publication; 2006.
41. Boudreau JE DA. Quality of life in end stage renal disease: a concept analysis. *Cannt Journal*. 2014; 24(1): 12-20.

42. Nagata C, Hirokawa K, Shimizu N, Shimizu H. Soy, fat and other dietary factors in relation to premenstrual symptoms in Japanese women. *BJOG*.2004;111(6):594-599.
43. Reneman MF, Dijkstra A, Geertzen JH, Dijkstra PU. Psychometric properties of chronic pain acceptance questionnaires: a systematic review. *European Journal of Pain*. 2010; 14(5):457-65.
44. Hagerty MR et al. Quality of life indexes for national policy: review and agenda for research. *Social Indicators Research*.2001; 55(1): 1-12.

Table 1 Sampling Sufficiency Index (KMO) and Results of Bartlett Test (BT)

Sampling Sufficiency Test of KMO		0.860
Bartlett's test	Approximation of Chi-square	17450.611
	Degree of freedom	861
	Significant level	0.001

Table 2 Factors extracted from the exploratory factor analysis by the main components and Varimax period analysis methods

The item	factor 1	factor 2	factor 3	factor 4	factor 5	factor 6
You feel unwell due to cardio-respiratory symptoms (such as shortness of breath, palpitations, and chest tightness).	0.12	0.863	0.049	0.012	0.036	0.016
Urinary-genital symptoms (such as itching, burning, and dryness of the genital area) are annoying you.	0.002	0.894	0.022	0.029	0.049	0.095
Headaches or dizziness during this time will bother you	0.33	0.898	0.122	0.048	0.006	0.002
Changes in the skin, including facial acne, are unpleasant for you.	0.039	0.705	0.013	0.029	0.042	0.045
Digestive symptoms (such as nausea, heartburn, bloating, diarrhea, or constipation) are annoying you.	0.003	0.868	0.056	0.047	0.066	0.041
Increased sensitivity to touch and breast pain are uncomfortable for you	0.008	0.856	0.046	0.015	0.051	0.012

Muscle, joint, and bone pain are an annoying experience for you	0.19	0.862	0.056	0.010	0.025	0.061
Changes in sleep patterns (such as sleep deprivation, insomnia, and hyperactivity) can have a negative effect on your life.	0.005	0.793	0.030	0.010	0.013	0.07
You feel tired and bored all the time and you don't have enough energy	0.151	0.796	0.023	0.025	0.167	0.172
Most of the time you are nervous and aggressive	0.825	0.063	0.132	0.035	0.036	0.073
You feel homesick and depressed and this is painful for you.	0.845	0.027	0.004	0.020	0.075	0.027
You become irritable and easily lose control.	0.873	0.049	0.093	0.022	0.080	0.103
You became stubborn and excused.	0.883	0.053	0.034	0.039	0.051	0.084
You have difficulty concentrating on what you need to do.	0.880	0.008	0.061	0.19	0.077	0.086
The symptoms you experience during this period will make you feel bad about the female gender	0.855	0.001	0.100	0.061	0.043	0.088
Feeling restless and anxious during this period is annoying.	0.890	0.005	0.035	0.028	0.011	0.028
You cry for no reason and suddenly.	0.876	0.021	0.011	0.002	0.031	0.051
The feeling of hatred towards those around you (such as your spouse, parents, and other family members) is unpleasant for you.	0.857	0.020	0.045	0.026	0.005	0.017
You have trouble caring for your spouse, children, and other family members	0.007	0.012	0.001	0.007	0.838	0.053
You have trouble interacting with your spouse, children, and other family members.	0.086	0.008	0.081	0.049	0.897	0.080

You feel unable to do business or study.	0.044	0.004	0.059	0.030	0.892	0.102
You do not want to take part in exercise or other entertainments	0.006	0.054	0.07	0.043	0.881	0.063
Your ability to perform daily activities decreases	0.035	0.002	0.015	0.021	0.837	0.117
Don't worry about not being able to perform your duties as a mother, wife, or daughter during these period	0.108	0.138	0.826	0.047	0.112	0.019
You will be upset that you are sometimes labeled a psychic by others	0.039	0.069	0.867	0.059	0.087	0.049
You are worried about having other illnesses in the future due to premenstrual symptoms.	0.075	0.082	0.898	0.024	0.048	0.049
Characteristics of this disorder, such as irregularity and different symptoms, confuse and worry you.	0.049	0.050	0.879	0.063	0.027	0.092
You regret the loss of your life due to this emotional disorder.	0.024	0.027	0.886	0.006	0.014	0.043
You worry that over time, your symptoms may get worse.	0.034	0.048	0.828	0.002	0.097	0.072
Taking certain painkillers can cause side effects and worries and this bothers you.	0.093	0.020	0.854	0.077	0.071	0.093
Exercising is effective in improving your mood.	0.097	0.014	0.127	0.803	0.095	0.117
You can relax by using methods (such as massage, listening to music and resting).	0.060	0.09	0.073	0.881	0.881	0.017
Doing religious duties during this period has a good effect on your condition	0.019	0.024	0.009	0.898	0.057	0.004
Taking some sedatives and supplements (chemical or herbal) will help you get better.	0.027	0.007	0.014	0.868	0.022	0.021

Table 3 Correlation between the extracted factors of the PMS-QOLQ questionnaire and 8 factors of SF-36 criterion tool

SF-36 tool PMS-QOL tool	Physical functioning	Physical problems	Physical pain	General health	Vitality	Social functioning	Emotional problems	Mental health
Mental health	*0.43 **0.001	0.52 0.000	0.40 0.000	0.41 0.000	0.35 0.006	0.45 0.000	0.26 0.032	0.15 0.25
Physical health	0.13 0.34	0.25 0.12	0.21 0.20	0.52 0.000	0.19 0.23	0.41 0.001	0.37 0.02	0.45 0.000
Concerns	0.03 0.8	0.37 0.02	0.05 0.68	0.14 0.26	0.42 0.001	0.27 0.030	0.36 0.004	0.36 0.02
Compatibility	0.14 0.28	0.39 0.002	0.35 0.006	0.45 0.000	0.38 0.002	0.53 0.000	0.41 0.001	0.43 0.001
Social-familial functioning	0.25 0.12	0.28 0.07	0.32 0.01	0.07 0.57	0.4 0.001	0.41 0.001	0.36 0.02	0.09 0.46
Support	0.07 0.58	0.05 0.68	0.18 0.28	0.23 0.16	0.06 0.69	0.14 0.39	0.28 0.02	0.39 0.002

* Correlation coefficient

** Significant level

Table 4 Cronbach's alpha coefficient and ICC levels of factors in the PMS-QOLQ questionnaire

Construct	Number of items	Cronbach's alpha coefficient	*ICC	**CI (95%)	Pvalue
Mental health	9	0.929	0.937	0.863-0.971	0.000
Physical health	9	0.899	0.965	0.927-0.984	0.000
Concerns	7	0.891	0.855	0.690-0.932	0.000
Compatibility	5	0.826	0.846	0.604-0.933	0.000
Social-familial functioning	5	0.782	0.854	0.693-0.930	0.000
Support	6	0.829	0.784	0.552-0.897	0.000
Total	41	0.887	0.892	0.829-0.940	0.000

*ICC: Intraclass correlation coefficient

**confidence intervals