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# Comprehensive Assessment and Validation of an Integrated Premenopausal Symptom Questionnaire

**Research Article**

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## Abstract

Pre-menopause indicates a period before menopause where a woman undergoes a transitional period where several symptoms come into existence due to the fluctuating ovarian hormones. The symptoms are quite complex with the involvement of different systems, making it difficult for health providers to diagnose and advise management aptly. The study aims to develop an integrated pre-menopausal questionnaire to assess premenopausal symptoms. The integrated pre-menopausal questionnaire was developed by including confounding factors and symptoms available in Ayurvedic literature, contemporary textbooks, and clinical observations by *Prasoothi Tantra* and *Stree roga* (Obstetrics and Gynaecology) experts. Premenopausal symptoms and confounding factors were incorporated into the questionnaire in the form of 36 questions under five sections and were assigned a score from 0 to 4 based on the strength of literature evidence and expert opinion. The questionnaire was subjected to validation i.e. face validation, content validation; and construct validation followed by factor analysis and reliability statistics. This tool is believed to be an important landmark in diagnosing pre-menopausal symptoms in pre-menopausal women so that an early intervention can be implemented. The questionnaire, finalized after expert committee review and recommendations, was also validated for its sensitivity and specificity to detect pre-menopausal symptoms in Palakkad District through a pilot study.

**Keywords:** Face validation, Premenopausal symptoms, Screening questionnaire, Integrated premenopausal questionnaire.

## Introduction

Premenopausal symptoms are a group of symptoms affecting pre-menopausal women that arise due to the fluctuation in ovarian hormones. The average age of menopause is 47.5 years in Indian women, with an average life expectancy of 71 years. (1) The physiological symptoms before menopause (the final menstrual period) can start ten years before this and may continue after menopause too. There are dynamic neuro-endocrinal changes associated with clinical symptoms affecting different systems of the body, namely the vasomotor system (hot flashes, sleep disturbances), urogenital system (urinary urgency, stress incontinence), and central nervous system (anxiety, memory loss, insomnia, irritability, and depression). The pre-menopausal period is much more challenging than the menopausal period, as it is a transitional period. Menopausal symptoms are more prominent during this pre-menopausal period due to the deficient ovarian hormones impacting the functions of different systems of the body. Women around the world suffer from ailments characteristic of the menopausal period, regardless of ethnic origin, skin color, or socio-demographic factors. (2) Factors assessed in the proforma, such as age, medical history, diet, exercise, infertility treatments, exposure to hormonal supplements, postpartum conditions, the attitude of the family and the subject towards menopause, and *Prakruti* (constitution), have an important role in altering the clinical conditions during the pre-menopausal period according to Ayurveda. An early diagnosis with a detailed assessment of these factors will help the health provider decide the best solution for the subject, whether dietetic, lifestyle changes, or the prescription of suitable medication or treatment. Pre-menopausal symptoms, if neglected, impact the quality of life immensely, which adversely affects the family and career of the woman.

In India, especially, a large portion of cases of premenopausal symptoms go undiagnosed as timely assessments are not widely practiced and are often disregarded as a physiological transition and not a clinical condition. Pre-menopausal symptoms are also neglected due to large variations in clinical presentation and the absence of symptom specificity. There are many tools accepted worldwide, like the MRS (Menopause Rating Scale) and the Greens Climacteric Scale (3), and these tools are exclusively used to decide whether a subject needs hormone replacement therapy or not based on the assessment score calculated for each subject. However, the integrated pre-menopausal questionnaire in the current study intends to assess pre-

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menopausal symptoms based on confounding factors and menopausal symptoms. Since hormone replacement therapy (4- 6) is not a permanent solution to conquering pre-menopausal or menopausal symptoms due to its adverse effects, a reasonable solution will be to provide a holistic approach in Ayurveda by giving diet and lifestyle advice and, if necessary, Ayurvedic treatment after a thorough examination of the subject by an expert.

**Lacuna in previous existing questionnaire**

The menopausal symptoms are greatly influenced by cultural, environmental, psychosocial backgrounds, lifestyle, constitution etc.

· The available scale universally accepted for the analysis of menopause symptoms is the MRS (Menopause Rating Scale) (7), the assessment of which is affected by each subject's understanding of hormonal changes and the attitude of the subject towards the choices of management strategies.

· MRS is used exclusively to assess the presence or absence of symptoms and factors influencing symptoms are not accessed.

· MRS is developed to assess whether a patient is eligible for HRT (Hormone Replacement Therapy).

· Lacuna of MRS (8) - A study published in which bias measurements are presented when a differential response pattern is observed, according to an external characteristic of the instrument (age, education, ethnic group, etc.), it is concluded that the items of the psychological domain of the MRS show differential functioning according to the ethnic group. The finding could produce a systematic mistake in the measurement of the construct or lack of adjustments to the linguistic and semantic distinctive features of each Colombian ethnic group. A careful assessment of this dimension of the scale is required.

**Need of the study**

This study aims to develop a valid integrated pre-menopausal questionnaire with sensitivity and specificity to detect pre-menopausal symptoms and their confounding factors by integrating both *Ayurvedic* and modern views of this physiological transition period in a woman's life.

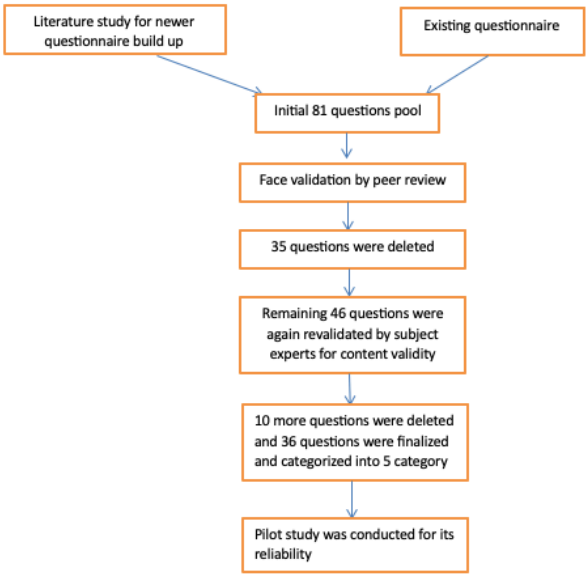
## Materials and methods

There are three main phases of questionnaire preparation 1) Pre-menopausal symptom selection and questionnaire construction were based on the literature survey 2) Face validation of questionnaire 3) Pilot study on targeted patients.

Pre-menopausal symptom selection and questionnaire construction were based on the literature survey; 81 questions were finalized.

Ayurvedic Literary Review on *Jara Nidana / Rasayana prayoge varjya*, i.e., all the predisposing factors that contribute to aging *Jara* (ageing) *nidana* mentioned in *charak samhita* (9) was considered feasible to apply as a confounding factor of menopause, as menopausal symptoms were not separately

**Figure 1: Overview of questionnaire development and validation procedure**




mentioned for male and female in *Ayurvedic* texts. However, menopause in women is always related to aging and is considered *swabhavaja* (10) (physiological difficulties), which happen due to *kala* or time. It is an inevitable physiological process that paves the way to a progressive decline in physiological functions. Considering age as a physiological process affecting both genders, the factors mentioned as diet, lifestyle, and medicines are prescribed in the concerned chapter to bring about equilibrium in the body for healthy living. The milestones in a woman's life like menarche, lactation, and menopause occur at a particular age as per the time factor (*kala*) (11). The Confounding factors of aging and the importance of diet (12,13), lifestyle, and psychological factors (14) affecting the formation and function of *Arthava Dosha* predominance, *Srotho dushti* (15) *lakshanas*, *Dathu kshaya lakshanas* and *dhatu pradoshaja lakashanas* (16, 17, 18) as symptoms related to menopause and included in the questionnaire to assess the pre-menopausal symptoms. A proforma or case sheet was constructed with basic information like age, area, economic status, religion, occupation, marital status, BMI, medical, surgical, obstetric, menstrual, and family history, personal habits, psychological attitudes, and *Prakruti* (Constitution).

***Prakruti* analysis tool:**

Understanding the *Prakruti* of the subject is a part of Ayurvedic clinical practice. Studies show that there can be symptomatic variations in subjects depending on the *Prakruti* of the woman. (19) The *Prakruti* assessment tool (20) was used to assess the *Prakruti* of the subjects.

Scoring method (general scoring pattern as per the severity of the complaint): The answers to each question were scored in a pattern of 0 to 4. As per the severity of the symptoms from mild to severe in all questions uniformly. The scoring was as follows: No complaints [0]; Mild complaints [1]; Moderate

complaints but no difficulty in routine work [2]; severe complaints and difficulty in routine work, but subside by rest [3]; Very severe complaints of being unable to do routine work do not subside with rest and seeking medical help. [4]

Face validation was done by peer review from physicians of different disciplines of Ayurveda specialties, namely *Kriya Sharir* (Physiology), *Rachana Sharir* (Anatomy), *Samhitha Siddhant* (Department concerned with basic principles of ayurveda), *Swastha Vrittha* (Preventive medicine), *Roga Nidhana evum vikruit vigyana* (Pathology), *Kaya Chikitsa* (General Medicine), and *Prasoothi tantra evum stree roga* (gynecology and obstetrics) consultants. After their validation out of 81 questions, 35 were deleted and 46 remained after face validity.

Again the Content validation was done by 9 experts in *Prasoothi Tantra evum Stree roga* department from different parts of India, namely, Kerala, Karnataka, Gujarat, Rajasthan, Punjab, Assam, Meghalaya, and Orissa.

**Pilot study**

36 subjects (as the number of items in the questionnaire was 36, the same number of subjects were selected randomly from the General OPD of Santhigiri Ayurveda Medical College, Palakkad). The subjects who gave their voluntary consent were assessed with a validated questionnaire satisfying the inclusion criteria. After that the questionnaire was subjected to reliability statistics.

**Inclusion criteria**

36 women between the age group of 42 to 52 years who are menstruating selected randomly.

**Exclusion criteria**

women with induced menopause or who have achieved menopause, simple hysterectomy, receiving any kind of hormone therapy, and the and the presence of medical conditions such as diabetes, hypertension, cardiac disease, and thyroid disorders.

**Statistical Analysis**

The original format of the data file was in Excel. In order to design a classical test, exploratory factor analysis (EFA) was used, and this approach incorporated the "not relevant" responses. EFA is a statistical process that makes it possible to estimate an instrument's underlying dimensions. Principal component analysis (PCA), a method used to condense a large number of questionnaire items into a smaller number of dimensions by analyzing the correlations between the individual items, is one example of how complex sets of data are simplified into factors. As a result, every factor that is generated serves as a signal for the connections among a group of variables. (21) PCA was employed, utilizing varimax rotation (orthogonal rotation) to find interpretable dimensions. The values of the Kaiser Meyer- Olkin and Bartlett's Test of Sphericity were computed in order to assess whether the sample size was sufficient for conducting factor analysis. It is recommended to use values of $p<0.0001$ and 0.5 or higher, respectively. (22) Tests were also utilized to look at the instrument's item pool and domain structure. This study calculated the Cronbach's alpha reliability coefficient, which is the measure most commonly used to determine a questionnaire's internal consistency reliability (i.e., the degree to which items within a scale are associated with each other or the homogeneity of the items). (23) Cronbach's alpha results in a number from 0 to 1, but it can be negative numbers as well. A negative number indicates that something is wrong with your data, perhaps forgot to reverse score some items. The general rule of thumb is that a Cronbach's alpha of 0.70 and above is good, 0.80 and above is better and 0.90 and above is best.

## Results and Discussion

For filling up the lacuna in the existing scale to access premenopausal symptoms and to incorporate the unique concept of Ayurveda regarding premenopausal symptoms newer questionnaire was developed and validated. From the Ayurveda literature survey and study of existing premenopausal scale the total 81 items were pooled for the questionnaire to access pre-menopausal symptoms. The Ayurveda refernces for menopause were collected from the *Jara nidana/ Rasayana prayoge varjya*. When describing the advantages of *rasayana, acharya charaka* stated in his *Chikitsa Sthana* that *rasayana* is primarily utilized to inhibit the aging process, or *tarunam vayah*. (24) Menopause is rarely mentioned in Ayurvedic literature. On the other hand, women's menopause is always associated with age and is seen as *swabhavaja* (physiological challenges), which arise because of *kala*, or time. Menarche, breastfeeding, and menopause are among the life milestones that occur at specific ages based on the time factor (*kala*). Aging and other confounding factors were chosen. All the questions were scored uniformly of 0 to 4 as per the severity of the symptoms from mild to severe. The questionnaire was validated i.e. face validation, content validation; construct validation followed by factor analysis and reliability statistics. Subjected items were face validated by peer review found 35 questions were not suitable and were deducted. During the refinement process of the questionnaire, 35 questions were removed from the initial 81-question set. The primary reasons for their exclusion were twofold. Firstly, these questions were found to be region-specific, meaning they did not consistently apply across different parts of the country, potentially affecting the questionnaire's generalizability. Secondly, peer reviews indicated that some of these questions did not align well with the overarching aim of the questionnaire, as they either lacked direct relevance to premenopausal symptom assessment or introduced variables that could confound the intended analysis. The decision to omit these questions was made to enhance the questionnaire's applicability and ensure a more standardized and focused approach to assessing premenopausal symptoms. After peer review the items

were subjected to subject experts for the content validity revealed more 10 questions were not suitable for the questionnaire on the basis of appropriateness of it content, design (structure). The data from these experts were further checked for its content validity index. Table 1 shows content validity index of all 46 questions. The questions with an I-CVI of 0.78 or higher were considered evidence of good content validity and 36 questions satisfied this I-CVI out of 46 questions.

**Table 1: Content validity index of all 46 questions**

| Question No | Expert 1 | Expert 2 | Expert 3 | Expert 4 | Expert 5 | Expert 6 | Expert 7 | Expert 8 | Expert 9 | Experts in Agreement | I- CVI | UA |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 9 | 1 | 1 |
| 2 | 0 | 0 | 1 | 1 | 0 | 0 | 0 | 1 | 1 | 4 | 0.44444 | 0 |
| 3 | 0 | 1 | 1 | 1 | 0 | 0 | 0 | 1 | 1 | 5 | 0.555555 | 0 |
| 4 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 9 | 1 | 1 |
| 5 | 1 | 0 | 1 | 1 | 1 | 0 | 1 | 1 | 1 | 7 | 0.777777 | 0 |
| 6 | 0 | 1 | 1 | 0 | 0 | 0 | 0 | 1 | 1 | 4 | 0.444444 | 0 |
| 7 | 0 | 0 | 1 | 0 | 1 | 0 | 0 | 1 | 1 | 4 | 0.444444 | 0 |
| 8 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 9 | 1 | 1 |
| 9 | 1 | 0 | 1 | 1 | 1 | 0 | 1 | 1 | 1 | 7 | 0.777777 | 0 |
| 10 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 9 | 1 | 1 |
| 11 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 9 | 1 | 1 |
| 12 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 9 | 1 | 1 |
| 13 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 9 | 1 | 1 |
| 14 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 9 | 1 | 1 |
| 15 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 9 | 1 | 1 |
| 16 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 9 | 1 | 1 |
| 17 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 9 | 1 | 1 |
| 18 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 9 | 1 | 1 |
| 19 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 9 | 1 | 1 |
| 20 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 9 | 1 | 1 |
| 21 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 9 | 1 | 1 |
| 22 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 9 | 1 | 1 |
| 23 | 0 | 1 | 1 | 1 | 0 | 0 | 0 | 1 | 1 | 5 | 0.555555 | 0 |
| 24 | 0 | 0 | 1 | 0 | 1 | 1 | 1 | 1 | 1 | 6 | 0.666666 | 0 |
| 25 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 9 | 1 | 1 |
| 26 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 9 | 1 | 1 |
| 27 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 9 | 1 | 1 |
| 28 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 9 | 1 | 1 |
| 29 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 9 | 1 | 1 |
| 30 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 9 | 1 | 1 |
| 31 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 9 | 1 | 1 |
| 32 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 9 | 1 | 1 |
| 33 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 9 | 1 | 1 |
| 34 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 9 | 1 | 1 |
| 35 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 7 | 0.777777 | 0 |
| 36 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 9 | 1 | 1 |
| 37 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 9 | 1 | 1 |
| 38 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 9 | 1 | 1 |
| 39 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 9 | 1 | 1 |
| 40 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 9 | 1 | 1 |
| 41 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 9 | 1 | 1 |
| 42 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 9 | 1 | 1 |
| 43 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 9 | 1 | 1 |
| 44 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 7 | 0.777777 | 0 |
| 45 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 9 | 1 | 1 |
| 46 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 9 | 1 | 1 |
| | | | | | | | | | | 380 | 42.22222 | 36 |
| | | | | | | | | S-CVI/Ave | | 0.9178744 | 0.9178744 | |
| | | | | | | | | S-CVI/ UA | | | | 0.782609 |

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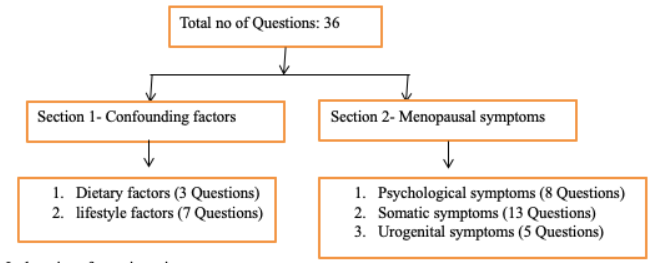
Factor analysis was done through exploratory analysis and the 36 questionnaire was divided into 2 domains and 5 subgroups.

**Figure 2: Domains of questionnaire**




The results obtain by factor analysis using KMO and Bartlett's Test are as follow table 2.

**Table 2: KMO and Bartlett's Test analysis**

| | | | | |
|---|---|---|---|---|
| Kaiser-Meyer-Olkin Adequacy. | | Measure of Sampling | | 0.274 |
| Bartlett's Sphericity | Test | of | Approx. Chi-Square | 943.077 |
| | | | Df | 630 |
| | | | Sig. | 0.000 |

This table shows two tests that indicate the suitability of our data for structure detection. The Kaiser-Meyer-Olkin Measure of Sampling Adequacy is a statistic that indicates the proportion of variance in your variables that might be caused by underlying factors. High values (close to 1.0) generally indicate that a factor analysis may be useful with our data. If the value is less than 0.50, the results of the factor analysis probably will not be very useful. In our sample study, the Kaiser- Meyer-Olkin Measure of Sampling Adequacy is 0.274 and this indicates that sampling adequacy is less. The results obtained by using Cronbach's alpha reliability coefficient, which is the measure most commonly used to determine a questionnaire's internal consistency reliability for both MSR and Integrated Questionnaire shows the value of 0.752 (table 3) indicating the questionnaire has good items.

Principal component analysis (PCA) is a technique that examines the correlations between the different items in a questionnaire to help reduce the number of dimensions from an enormous amount. (Table 4). To determine interpretable dimensions, PCA was used together with varimax rotation, also known as orthogonal rotation. Here we have 13 principal components. In the table 5 Eigen values, which represent the amount of standardized variance that has been captured by each of the components. The first component accounts for the largest possible amount of variance and it explains 17.010 % of the variance and the second component explains 8.3% of variance. varimax rotation (orthogonal rotation) to find interpretable dimensions converged in 21 iterations (table 6).

**Table 3: Cronbach's alpha reliability coefficient**

| Item | Cronbach's Alpha | | Scale Mean if Item Deleted | Scale Variance if Item Deleted | Cronbach's Alpha if Item Deleted |
|---|---|---|---|---|---|
| MSR | 0.713 | MSR 1 | 9.109 | 21.432 | 0.699 |
| | | MSR 2 | 9.696 | 24.794 | 0.717 |
| | | MSR 3 | 9.783 | 24.174 | 0.711 |
| | | MSR 4 | 9.043 | 18.887 | 0.631 |
| | | MSR 5 | 9.370 | 20.949 | 0.654 |
| | | MSR 6 | 9.087 | 20.881 | 0.658 |
| | | MSR 7 | 9.739 | 21.753 | 0.666 |
| | | MSR 8 | 10.435 | 26.696 | 0.719 |
| | | MSR 9 | 9.891 | 22.855 | 0.699 |
| | | MSR 10 | 10.109 | 27.210 | 0.739 |
| | | MSR 11 | 8.739 | 22.553 | 0.699 |
| Integrated Questionnaire | 0.752 | 1-Q1 | 60.9565 | 116.443 | 0.743 |
| | | 2-Q4 | 61.7826 | 117.641 | 0.745 |
| | | 3-Q8 | 62.0435 | 120.220 | 0.751 |
| | | 4-Q10 | 61.9348 | 122.596 | 0.753 |
| | | 5-Q11 | 61.2391 | 118.453 | 0.758 |
| | | 6-Q12 | 62.6522 | 122.321 | 0.747 |
| | | 7-Q13 | 62.6739 | 126.580 | 0.756 |
| | | 8-Q14 | 61.5435 | 123.187 | 0.765 |
| | | 9-Q15 | 61.2826 | 123.407 | 0.763 |
| | | 10-Q16 | 61.3478 | 121.521 | 0.751 |
| | | 11-Q17 | 61.6957 | 115.594 | 0.737 |
| | | 12-Q18 | 62.1739 | 115.080 | 0.733 |
| | | 13-Q19 | 61.9348 | 114.151 | 0.737 |
| | | 14-Q20 | 61.8696 | 122.383 | 0.749 |
| | | 15-Q21 | 61.9565 | 117.509 | 0.740 |
| | | 16-Q22 | 62.0217 | 116.644 | 0.738 |
| | | 17-Q25 | 62.0217 | 115.533 | 0.739 |
| | | 18-Q26 | 62.0217 | 118.688 | 0.745 |
| | | 19-Q27 | 61.3913 | 108.110 | 0.722 |
| | | 20-Q28 | 61.5870 | 113.003 | 0.740 |
| | | 21-Q29 | 61.7174 | 110.918 | 0.728 |
| | | 22-Q30 | 62.0435 | 117.287 | 0.741 |
| | | 23-Q31 | 62.5000 | 121.056 | 0.746 |
| | | 24-Q32 | 62.3913 | 120.110 | 0.743 |
| | | 25-Q33 | 62.0435 | 116.176 | 0.737 |
| | | 26-Q34 | 62.4565 | 118.476 | 0.742 |
| | | 27-Q36 | 62.1522 | 118.976 | 0.742 |
| | | 28-Q37 | 62.1739 | 117.391 | 0.739 |
| | | 29-Q38 | 61.9565 | 123.687 | 0.767 |
| | | 30-Q39 | 62.6087 | 124.421 | 0.754 |
| | | 31-Q40 | 62.6522 | 124.810 | 0.753 |
| | | 32-Q41 | 62.5870 | 119.270 | 0.741 |
| | | 33-Q42 | 62.4565 | 125.320 | 0.754 |
| | | 34-Q43 | 62.3261 | 123.647 | 0.753 |
| | | 35-Q45 | 60.5000 | 124.478 | 0.765 |
| | | 36-Q46 | 62.1739 | 125.169 | 0.755 |

**Table 4: Communalities: Extraction Method: Principal Component Analysis.**

| Items | Initial | Extraction |
|---|---|---|
| 1-Q1 | 1 | 0.698 |
| 2-Q4 | 1 | 0.732 |
| 3-Q8 | 1 | 0.798 |
| 4-Q10 | 1 | 0.814 |
| 5-Q11 | 1 | 0.702 |
| 6-Q12 | 1 | 0.784 |
| 7-Q13 | 1 | 0.791 |
| 8-Q14 | 1 | 0.597 |
| 9-Q15 | 1 | 0.718 |
| 10-Q16 | 1 | 0.786 |
| 11-Q17 | 1 | 0.709 |
| 12-Q18 | 1 | 0.818 |
| 13-Q19 | 1 | 0.804 |
| 14-Q20 | 1 | 0.862 |
| 15-Q21 | 1 | 0.767 |
| 16-Q22 | 1 | 0.769 |
| 17-Q25 | 1 | 0.807 |
| 18-Q26 | 1 | 0.78 |
| 19-Q27 | 1 | 0.757 |
| 20-Q28 | 1 | 0.677 |
| 21-Q29 | 1 | 0.796 |
| 22-Q30 | 1 | 0.826 |
| 23-Q31 | 1 | 0.874 |
| 24-Q32 | 1 | 0.794 |
| 25-Q33 | 1 | 0.827 |
| 26-Q34 | 1 | 0.819 |
| 27-Q36 | 1 | 0.817 |
| 28-Q37 | 1 | 0.807 |
| 29-Q38 | 1 | 0.866 |
| 30-Q39 | 1 | 0.899 |
| 31-Q40 | 1 | 0.933 |
| 32-Q41 | 1 | 0.91 |
| 33-Q42 | 1 | 0.733 |
| 34-Q43 | 1 | 0.869 |
| 35-Q45 | 1 | 0.698 |
| 36-Q46 | 1 | 0.835 |

**Table 5: Total Variance Explained: Extraction Method: Principal Component Analysis.**

| Component | Initial Eigen values | | | Extraction Sums of Squared Loadings | | |
|---|---|---|---|---|---|---|
| | Total | % of Variance | Cumulative % | Total | % of Variance | Cumulative % |
| 1 | 6.124 | 17.010 | 17.010 | 6.124 | 17.010 | 17.010 |
| 2 | 3.000 | 8.334 | 25.344 | 3.000 | 8.334 | 25.344 |
| 3 | 2.777 | 7.715 | 33.059 | 2.777 | 7.715 | 33.059 |
| 4 | 2.325 | 6.459 | 39.518 | 2.325 | 6.459 | 39.518 |
| 5 | 2.246 | 6.240 | 45.758 | 2.246 | 6.240 | 45.758 |
| 6 | 2.074 | 5.760 | 51.519 | 2.074 | 5.760 | 51.519 |
| 7 | 1.975 | 5.486 | 57.004 | 1.975 | 5.486 | 57.004 |
| 8 | 1.605 | 4.457 | 61.462 | 1.605 | 4.457 | 61.462 |
| 9 | 1.514 | 4.205 | 65.666 | 1.514 | 4.205 | 65.666 |
| 10 | 1.334 | 3.706 | 69.373 | 1.334 | 3.706 | 69.373 |
| 11 | 1.281 | 3.557 | 72.930 | 1.281 | 3.557 | 72.930 |
| 12 | 1.166 | 3.240 | 76.170 | 1.166 | 3.240 | 76.170 |
| 13 | 1.053 | 2.924 | 79.094 | 1.053 | 2.924 | 79.094 |
| 14 | 0.984 | 2.734 | 81.828 | | | |
| 15 | 0.780 | 2.166 | 83.994 | | | |
| 16 | 0.751 | 2.086 | 86.080 | | | |
| 17 | 0.599 | 1.663 | 87.743 | | | |
| 18 | 0.576 | 1.601 | 89.344 | | | |
| 19 | 0.510 | 1.417 | 90.761 | | | |
| 20 | 0.461 | 1.282 | 92.043 | | | |
| 21 | 0.446 | 1.239 | 93.282 | | | |
| 22 | 0.393 | 1.093 | 94.375 | | | |
| 23 | 0.379 | 1.054 | 95.429 | | | |
| 24 | 0.359 | 0.998 | 96.427 | | | |
| 25 | 0.288 | 0.800 | 97.227 | | | |
| 26 | 0.219 | 0.607 | 97.833 | | | |
| 27 | 0.191 | 0.531 | 98.364 | | | |
| 28 | 0.144 | 0.401 | 98.766 | | | |
| 29 | 0.099 | 0.276 | 99.042 | | | |
| 30 | 0.087 | 0.242 | 99.284 | | | |
| 31 | 0.080 | 0.222 | 99.506 | | | |
| 32 | 0.056 | 0.156 | 99.662 | | | |
| 33 | 0.051 | 0.142 | 99.804 | | | |
| 34 | 0.040 | 0.112 | 99.916 | | | |
| 35 | 0.019 | 0.053 | 99.969 | | | |
| 36 | 0.011 | 0.031 | 100.000 | | | |

After all the statistical analysis done for the validation of the questionnaire, it was subjected to 36 subjects (as the number of items in the questionnaire was 36, the same number of subjects were selected randomly from the General OPD of Santhigiri Ayurveda Medical College, Palakkad) for pilot study to check reliability statistics. Interpretation Assessment of the scores for the answer to each question is scored from 0 to 4. The subjects responding to Section 1 (Confounding factors) containing 2 subsections, subsection I, the Dietary Factors contains 3 Questions, a score of more than 6 indicates the subject needs Dietary advice similarly in Subsection II, the Lifestyle Factors contains 7 questions, a score of more than 14 indicates the subject needs Lifestyle advice from an expert. While the subjects responded for Section 2 (Menopausal symptoms) containing 3 subsections, Subsection I, the Psychological Symptoms contains 8 Questions, a score of more than 16 advice for a counseling session.

Similarly in Subsections II and II contain 12 and 5 questions, with scores of more than 26 and 10 respectively recommends consultation with A *Prasoothi Tantra evum Stree roga* expert for appropriate medication or Ayurvedic treatment. 180 (36 x 5) subjects were assessed with the finalized questionnaire and were statistically analyzed. (Sample size: After the development of the draft tool, the sample size was fixed according to the items of the tool. The number of subjects must be 5 times the number of items in the draft tool to ensure an adequate sample size as per Barbara Hazard Munro's method (25)

## Conclusion

The Integrated Pre-menopausal questionnaire was successfully tested for its applicability in clinical setting. The committee designed for face validation agreed that the questions were clear, comprehensible, and consistent in their measurement. Suggestions from

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**Rotated Component Matrix**

**Table 6: Rotation Method: Varimax with Kaiser Normalization.**

| | Component | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 |
| 13-Q19 | **0.859** | | | | | 0.130 | | 0.107 | 0.136 | | | | |
| 27-Q36 | **0.705** | 0.307 | -0.129 | -0.133 | 0.107 | | 0.163 | -0.211 | | 0.197 | -0.233 | | |
| 12-Q18 | **0.703** | 0.133 | | 0.109 | | -0.114 | 0.202 | 0.430 | 0.159 | 0.128 | | | |
| 28-Q37 | **0.629** | 0.309 | | | | -0.160 | 0.217 | -0.210 | -0.124 | | 0.349 | 0.221 | |
| 11-Q17 | **0.507** | 0.193 | 0.267 | 0.185 | -0.104 | | 0.282 | 0.424 | | -0.118 | | | |
| 26-Q34 | | **0.851** | | | | | | 0.233 | | 0.125 | | 0.101 | |
| 25-Q33 | 0.328 | **0.744** | | 0.243 | | -0.118 | | | 0.223 | | | 0.140 | -0.105 |
| 21-Q29 | 0.195 | **0.650** | 0.474 | | 0.233 | | 0.135 | | | | | | |
| 4-Q10 | -0.215 | -0.142 | **0.793** | -0.232 | | | -0.102 | | -0.180 | | | 0.101 | |
| 19-Q27 | 0.327 | 0.243 | **0.683** | 0.162 | | | | | | 0.230 | 0.109 | -0.107 | |
| 16-Q22 | 0.131 | 0.133 | **0.492** | | 0.313 | -0.129 | 0.359 | | 0.447 | | | -0.160 | |
| 20-Q28 | -0.126 | | **0.417** | | 0.381 | | | 0.232 | | 0.257 | 0.360 | 0.173 | -0.191 |
| 31-Q40 | | | | **0.939** | -0.103 | | | 0.118 | | | | | |
| 30-Q39 | | | | **0.919** | | | -0.109 | | | 0.121 | | | |
| 14-Q20 | | | | -0.139 | **0.899** | | | | | | | | |
| 18-Q26 | | | 0.137 | | **0.654** | 0.220 | | | -0.238 | 0.134 | -0.299 | 0.304 | |
| 15-Q21 | 0.285 | | 0.264 | -0.109 | **0.564** | -0.366 | | | 0.109 | 0.128 | | -0.336 | |
| 29-Q38 | -0.161 | | | | | **0.829** | 0.258 | 0.135 | | | | | 0.200 |
| 36-Q46 | | | | -0.136 | -0.177 | **0.783** | | -0.250 | | | 0.239 | -0.101 | -0.134 |
| 10-Q16 | -0.138 | 0.156 | 0.311 | 0.282 | | **-0.547** | 0.257 | -0.131 | -0.129 | 0.203 | | 0.166 | -0.302 |
| 23-Q31 | 0.250 | | | | | 0.145 | **0.866** | | 0.145 | | | | |
| 32-Q41 | 0.456 | 0.325 | | | | -0.306 | **0.591** | | 0.181 | 0.126 | 0.236 | | 0.166 |
| 5-Q11 | | 0.251 | | -0.168 | 0.157 | 0.167 | **0.475** | 0.255 | | -0.116 | -0.266 | | -0.414 |
| 2-Q4 | | | | | | | | **0.836** | | | | | |
| 3-Q8 | 0.204 | 0.190 | | -0.143 | | 0.141 | 0.130 | 0.132 | **0.793** | | | | |
| 1-Q1 | 0.338 | 0.205 | 0.209 | -0.280 | | | -0.105 | 0.344 | **-0.531** | | | | |
| 17-Q25 | 0.167 | | 0.179 | | 0.154 | | | | | **0.816** | | -0.178 | -0.129 |
| 22-Q30 | 0.236 | | -0.103 | | | | 0.250 | 0.163 | -0.298 | **0.567** | | 0.299 | 0.391 |
| 35-Q45 | -0.209 | | 0.196 | 0.194 | -0.212 | | -0.381 | | | **0.532** | 0.241 | | 0.175 |
| 24-Q32 | 0.352 | | -0.239 | | 0.134 | 0.188 | | 0.353 | 0.436 | **0.447** | | | -0.169 |
| 34-Q43 | | -0.114 | 0.161 | | | 0.107 | | | | | **0.872** | -0.172 | 0.115 |
| 33-Q42 | | 0.366 | -0.227 | -0.133 | | | | -0.126 | -0.307 | -0.132 | **0.566** | 0.116 | -0.216 |
| 6-Q12 | | | 0.245 | | 0.140 | -0.145 | | 0.367 | -0.138 | | | **0.712** | |
| 8-Q14 | | -0.192 | 0.207 | | 0.171 | | | | -0.170 | | | **-0.656** | |
| 9-Q15 | 0.235 | -0.197 | 0.173 | 0.135 | 0.183 | | | -0.389 | -0.176 | | -0.102 | **0.442** | 0.383 |
| 7-Q13 | -0.181 | | | | | 0.136 | | | | | | | **0.848** |

the committee members have been incorporated, and the questionnaire has been modified for the pilot study is expected to establish the validity of the Integrated Pre-Menopausal Questionnaire as a screening tool and to establish the sensitivity and specificity of the questionnaire to detect the confounding factors and symptoms of pre-menopausal women along with final survey with large number of sample.

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