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Research Protocol

Physiotherapy Section

Development, Validation and Reliability of Comprehensive Primary Dysmenorrhoea Scale: A Research Protocol

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ABSTRACT

Introduction: Primary Dysmenorrhoea (PD) is a common disorder in both young and adult females which is characterised by cramps that start immediately before or at the beginning of menstruation in the lower abdomen and are spasmodic and painful in nature, without any pelvic pathology. PD has a serious detrimental effect on quality of life and productivity in terms of health.

Need of the study: To the best of author's knowledge, there is no specific scale meant to extensively assess the overall physical, social, psychological and nutritional status of females with PD and evaluate the quality of life, therefore, a comprehensive tool is required to resolve these issues and capture a comprehensive overview of the typical distress encountered during menstruation.

Aim: To develop the items and domains, estimate its content and concurrent validity as well as assess intra-rater and test-retest reliability of the scale, which comprehensively assesses physical, social, psychological and nutritional status of females with PD and determine their quality of life.

Materials and Methods: The present study is a cross-sectional study, that will be conducted at General Outpatient Department (OPD), Maharishi Markandeshwar Institute of Physiotherapy and Rehabilitation, Maharishi Markandeshwar (Deemed to be University), Mullana, Ambala, Haryana, India from April 2023 to March 2024. It consists of three phases. First phase comprises of the scale development procedure which includes generation of domains and items. Second phase is to validate the scale. This phase includes content validation through Delphi method as well as evaluation of criterion (concurrent) validity. Third phase consists of assessing intra-rater and test-retest reliability of the scale.

Keywords: Delphi method, Menstruation, Nutritional status, Quality of life, Test-retest reliability

INTRODUCTION

Dysmenorrhoea is one of the most prevailing gynaecological conditions characterised by excruciating menstrual cramps that have a uterine origin [1]. Due to widespread social expectations about the inconvenience of menstruation and popular societal assumptions about the absence of effective therapies, dysmenorrhea may be the most underdiagnosed gynaecologic illness [2].

There are two distinct forms of dysmenorrhea: primary and secondary. PD, which typically starts in adolescence and affects women with normal pelvic anatomy, is described as painful menstruation. Menstrual pain associated with underlying pathology such as endometriosis, pelvic inflammatory disease, ovarian cysts, adenomyosis, uterine myomas, or polyps is known as secondary dysmenorrhea, and it might begin years after menarche [3].

Dysmenorrhoea, often known as painful menstruation, is characterised by intense, excruciating cramping in the lower abdomen that is frequently accompanied by additional symptoms like sweating, headaches, nausea, vomiting, diarrhoea, and trembling that appear just before or during menses [4]. It generally appears during adolescence, 6-24 months after menarche. During the first day of menstruation, dysmenorrhoeal discomfort frequently gets stronger and might linger up to 72 hours, following a clear and cyclic pattern [1,5].

The prevalence of dysmenorrhea according to the World Health Organisation ranges from 1.7% to 97% [6]. Among females of reproductive age, PD affects 45% to 95% of the population, and between 2% and 29% of those affected report severe discomfort [7]. Teenagers with PD may experience pain that is so severe as to be completely incapacitating, which has a considerable impact on the person's mental health and is the main reason for absenteeism from work or school, eventually leading to an adverse impact on overall performance and productivity [8]. Compared to their peers, these adolescents exhibit lower sleep quality, increased levels of inattention, hyperactivity-impulsivity, and various psychological symptoms including somatic complaints, negative self-image, anxiety, sadness, and hostility [9].

According to pertinent studies examining the effects of dysmenorrhea on women's lives, those affected are more likely to experience higher degrees of despair, anxiety, somatisation, negative self-perception, and aggression, and exhibit decreased productivity, inventiveness, and performance at work [10-12]. Dysmenorrhoeal pain limits one's ability to engage in daily activities and can be very incapacitating [13].

Literature suggests that dysmenorrhea is associated with poor calcium consumption, deficiency of vitamin D, and significantly lower levels of alpha-tocopherol (vitamin E) [2]. High magnesium foods and a high-fibre diet can lessen the severity of dysmenorrhea by lowering prostaglandin synthesis, which is the primary cause of dysmenorrhea [14].

The PD is one of the most prevalent gynaecological disorders in young women, which has a serious inimical effect on quality of life. Numerous generic pain measures (such as single-item numerical rating scales, visual analogue scales, and the McGill Pain Questionnaire), dysmenorrhea-specific measures (including the Menstrual Symptom (MS) questionnaire, retrospective symptom scale, and daily symptom scale), perimenstrual symptom measuring scales (like the Menstrual Distress Questionnaire and daily rating form), and menstrual leave estimating measures (WALIDD Scale) have been developed to assess the working ability, location, intensity and days of pain suffered by the menstruating females. However, there is no distinct outcome measure specifically designed for PD that comprehensively assesses the various affected domains of PD [15,16]. A validated outcome measure to comprehensively assess the physical, social, psychological, and nutritional status of females with PD, evaluate their quality of life, and examine the psychometric properties of the scale using appropriate methodology, as well as

aids to estimating there is any effect treatment interventions provided for its management in clinical settings. The aim of the present study is to develop a scale that comprehensively assesses the physical, social, psychological, and nutritional status of females with PD and evaluate their quality of life.

The primary objective of the study is to generate the items and domains of the scale. Secondary objectives include content validation using the Delphi method, evaluation of concurrent validity, as well as assessing intra-rater and test-retest reliability.

REVIEW OF LITERATURE

A cross-sectional observational study was conducted at Careggi University Hospital in Florence, Italy, from June 2019 to May 2020. The study enrolled 418 healthy women aged between 18 and 50 years, excluding those with known uterine or psychiatric disorders. A novel questionnaire, named the Menstrual Distress Questionnaire (MEDI-Q), was developed and administered to participants. The MEDI-Q consisted of 25 items covering a range of menstrual-related experiences, including pain, discomfort, psychological or cognitive changes, gastrointestinal symptoms, and alterations in physiological functions. The MEDI-Q yielded robust findings, demonstrating good internal consistency, as well as convergent and concurrent validity. Total scores on the MEDI-Q, along with its subscales-MS, Menstrual Symptoms Distress (MSD), and Menstrual Specificity Index (MESI)-showed positive correlations with general psychopathology and premenstrual symptoms [17].

The English version of the MEDI-Q displayed outstanding psychometric attributes, boasting high levels of internal consistency and test-retest reliability. It stands as a validated and dependable instrument for gauging menstrual distress and its ramifications on psychological well-being [18].

A mixed methods study was conducted at Thammasat University in Thailand with the goal of developing a questionnaire tailored for women of reproductive age. This study introduced an innovative tool, based on Thai traditional medicine principles, to assess women's health. The resulting instrument, known as the Menstrual-Cycle-Related Signs and Symptoms Questionnaire (MCSQ), is a self-assessment questionnaire featuring 49 items segmented into two sections: menstrual-cycle-related signs and symptoms and associated factors. Within these sections, 35 items were structured as rating-scale questions, while the remaining 14 were presented as multiple-choice questions. The MCSQ demonstrated moderate to high content validity for individual items and notably high content validity for the overall questionnaire. Internal consistency for each component ranged from moderate to good [19].

Up to this point, numerous questionnaires have been utilised in gynaecological settings to evaluate quality of life and perceived stress in pathological conditions [20,21]. However, many of these instruments were not specifically crafted for gynaecological disorders and did not explore the impact of menstruation on physical, social, psychological, and nutritional health. Likewise, certain questionnaires were created to gauge menstrual pain and bleeding or to measure quality of life and psychopathology associated with uterine disorders; yet, none of them were explicitly designed for a comprehensive assessment of primary dysmenorrhea [22,23].

MATERIALS AND METHODS

This cross-sectional study will be conducted at the General OPD, Maharishi Markandeshwar Institute of Physiotherapy and Rehabilitation, Maharishi Markandeshwar Deemed to be University, Mullana, Ambala, Haryana, India, from April 2023 to March 2024. Ethical clearance permission has been taken from the Institution's Ethics Committee (IEC) (IEC-2664), as well as registration in the open-access public domain at ClinicalTrials.gov (CTRI/2024/01/061303) has been completed. The research will strictly adhere to ethical guidelines, including the Helsinki Declaration espoused by the World Medical Association, the International Ethical Guidelines for Health-related Research Involving Humans (Revised 2017) adopted by the Council for International Organisations of Medical Sciences (CIOMS), and the National Ethical Guidelines for Biomedical and Health Research involving human participants as espoused by the Indian Council of Medical Research. All participants will be asked to complete a written informed consent before participating in the research.

Sample size: Donner A and Eliasziw M, and Terwee CB et al., recommended a minimum sample size ranging from 15 to 50 participants, given an expected Intraclass Correlation Coefficient (ICC) of 0.8. Consequently, the observed ICC should ideally be atleast 0.70. Therefore, a total of 51 patients diagnosed with primary dysmenorrhea will be recruited [24,25].

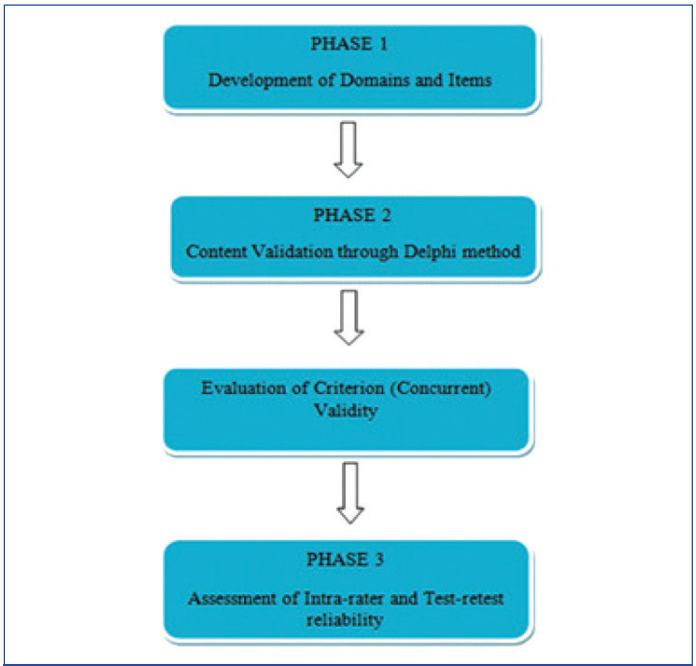
Inclusion criteria: The inclusion criteria states females suffering from painful menstruation after the onset of menses without any underlying pelvic pathology, with a regular menstrual cycle, and experiencing pain in the lower back, abdomen, and pelvic region with pain intensity of >=3 according to the Numeric Pain Rating Scale (NPRS) [26].

Exclusion criteria: The exclusion criteria consist of secondary dysmenorrhoeal conditions like Polycystic Ovarian Disease (PCOD), Polycystic Ovarian Syndrome (PCOS), endometriosis, amenorrhea, etc., and females with any type of abdominal surgery, females who have given birth, patients with Urinary Tract Infection (UTI), females with abnormal vaginal discharge, or those suffering from any endocrine or chronic diseases.

Scale Development Procedure

The participants will be females between 14 to 28 years of age. This study will consist of three major phases. The initial item generation pertaining to the impact of PD on physical, social, psychological, and nutritional status of females will be derived from an extensive literature search and direct interviews with patients and experts. Secondly, these items will be assessed using the Delphi approach for content validation [27].

Thereafter, concurrent validity will be calculated. The third step includes reliability study in which intra-rater and test-retest reliability of the scale will be evaluated [Table/Fig-1].



[Table/Fig-1]: Scale development procedure.

Phase 1:

- **Systematic development of domains and items:** During this phase, items will be generated for the domains of physical,

social, psychological, and nutritional status. This phase will be divided into three sub-phases.

1. **Extensive literature search:** English language databases such as PubMed, Scopus, Google Scholar, and the Cochrane Library will be used to search for relevant material from 1990 to 2023. Literature search items will include PD, physical activities, social problems, nutrition, quality of life, psychological effects, and PD questionnaires.
2. **Direct interview with experts:** Two physiotherapists and one gynaecologist with more than a decade of experience will have in-depth discussions to identify domains associated with primary dysmenorrhea to produce related items.
3. **Direct patient interview:** Face-to-face interviews will be conducted with females suffering from PD. They will be asked to discuss the difficulties and limitations they face during and before menstruation due to PD and its impact on their overall health.

Phase 2:

- **Content validation through Delphi method:** To establish content validity, this scale will be provided online to a panel of 6-10 specialists and professional experts in the field of physiotherapy and gynaecology with more than 5 years of experience, holds academic qualification of master's degree or higher in their field, and interacting with patients suffering from primary dysmenorrhoea from different geographical locations within India.

A Google form will be generated and electronically sent to experts through an email or the WhatsApp mobile application to invite them to participate in the content validation via Delphi method. Their responses will be documented. The experts will be asked to assess the relevance and clarity of the items using a four-point rating scale (where 4=highly relevant, 3=quite relevant, 2=somewhat relevant, and 1=not relevant for relevance, and 4=very clear, 3=clear but needs minor revision, 2=item needs some revision, and 1=not clear for clarity). The experts' decisions hold prime significance as the entire documentation will be based on their responses, which are made by serious catechisation, including questions such as: Are these items needed in the questionnaire and relevant in the context of the given condition? Are these items clear and not confusing to the person administering this questionnaire?

The Item-level Content Validity Index (I-CVI) for each item and Scale level Content Validity Index (S-CVI) using both the Universal Agreement method (S-CVI/UA) and Average method (S-CVI/Ave) will be documented in a tabular form and calculated [28,29]. In the process of content validation, Lynn MR advised a minimum S-CVI of 0.78 for 6-10 experts, and an S-CVI/Ave of 0.90 was regarded as outstanding content validity [30]. If the S-CVI/Ave does not reach 0.80, another round of the Delphi survey will be conducted unless it reaches the same, and new modifications and changes will be done as recommended by the expert panel to meliorate the scale until it achieves the determined values.

- **Pilot test:** After the assessment by professional experts, the comprehension, perception, and feasibility of the scale items will be determined by conducting a pilot test and administering it to 12 patients [31]. The patients will be asked to sign an informed consent and subsequently fill out the scale. Thereafter, an interview session will be held where patients will be asked about their opinions and perceptions of the items in the domains and their selected responses. The procured responses will be delved to discover any flaws in the items and assess the practicality of the questionnaire.
- **Criterion validity:** Concurrent validity signifies the correlation of a newly developed tool with the similar domains of an already established or widely used existing tool at the same point in time. It assesses the degree of agreement in judgments between the two tools under compared, specifically focusing on similar domains or areas of evaluation.

Currently, there is no "gold standard" to assess the quality of life in females with PD. Hence, a fitting and appropriate scale will be used to assess concordance between similar domains in the reference and the newly developed scale. A total of 51 patients will be administered both scales within a difference of 15 minutes, and the scores will be calculated and documented. Furthermore, in cases where discrepancies are noted either within specific domains or in the overall assessment, potential causes will be investigated, and clarifications will be provided.

Phase 3:

- **Reliability:** Intra-rater reliability will be estimated by administering the newly developed scale twice to 51 patients within a time difference of 24 hours and documenting both scores [24]. The patients suffering from PD will be diagnosed by a gynaecologist and recruited according to the inclusion and exclusion criteria. The scale will be administered through printed forms after obtaining written consent, via face-to-face method by the primary researcher. The overall scores for the two occasions will be correlated to estimate the consistency of results produced by the newly developed scale.

Test-retest reliability assesses the consistency and reproducibility of outcomes obtained under similar conditions from the same group of people under the same conditions. It will be evaluated by asking the patients to fill out the form twice with a 48-hour time difference between the initial and final occasions. The primary researcher will ask the patients to fill out the printed forms through face-to-face method. The outcomes of both occasions will be documented, and overall scores will be correlated.

- **Submission of the documented data:** The final step in this process involves the submission of all records and forms to the committee responsible for overseeing the developed scale. This step is essential to verify the ethical conduct of the development and validation, ensuring that all necessary steps were followed to attain the intended objectives. This thorough review aims to validate the entire process, ensuring accurate representation in the reports. The organisation or committee will not intervene to alter the content, and it is assumed that by following the described process, a reasonable scale has been developed.

STATISTICAL ANALYSIS

The content validity of the newly developed scale will be calculated using both I-CVI and S-CVI approaches. After the Delphi survey conducted with 6-10 professional experts, the I-CVI of each item is anticipated to be a minimum of 0.78, and the S-CVI/Ave is expected to achieve excellent content validity by reaching 0.90, affirming the accuracy of the items of the scale.

The concurrent validity of the scale will be calculated and analysed using correlation functions with statistical software International Business Machines (IBM) Statistical Package for Social Sciences (SPSS) version 26.00 (Armonk, NY).

There are two methods to quantify the reliability of the developed tool: Absolute and Relative reliability. Relative reliability is the ability of a tool or an instrument to consistently produce the same outcomes over repeated observations in the same sample, whereas absolute reliability can be understood as the degree of measurement variability [32,33]. Hence, it is advisable to calculate both relative as well as absolute reliability of the newly developed tool before implementing it in clinical settings. The Bland Altman agreement will be applied for absolute reliability [34].

Cronbach's alpha (α) will be employed to compute the internal consistency for the scale. The value of α ranges from 0.00 (indicating no consistent variance) to 1 (indicating all variance is consistent).

Generally, an α value of 0.70 or greater is widely acknowledged as indicative of satisfactory internal reliability [35].

The ICC will be calculated to assess test-retest reliability. The ICC will be used to assess test-retest reliability, and either Spearman's Rank rho or Pearson's product correlation will be applied based on the data's normality [36]. According to Shrout PE and Fleiss JL, the ICC classification states that values below 0.5 suggest poor reliability, values between 0.5 and 0.75 indicate moderate reliability, values between 0.75 and 0.9 suggest good reliability, and values exceeding 0.90 indicate excellent reliability [37].

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