# Postprint: Development of a Traditional Chinese Medicine Patient-Reported Outcome Scale for Perimenopausal Depressive Disorder and Its Theoretical Model

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## Abstract

Background: Perimenopausal depressive disorder (PDD) is a serious mood disorder occurring around menopause. Traditional Chinese Medicine (TCM) treatment for PDD has advantages such as holistic regulation and treatment based on syndrome differentiation; however, there is currently a lack of dedicated efficacy evaluation tools for TCM treatment of PDD. Objective: To introduce Patient-Reported Outcomes (PROs) and construct a PDD-PROs scale and its theoretical model under the guidance of TCM theory. Methods: From April to June 2022, literature on TCM treatment of PDD published from database inception to April 17, 2022 was retrieved via computer searches of CNKI, Wanfang Data Knowledge Service Platform, VIP, SinoMed, PubMed, Web of Science, and the Cochrane Library, followed by literature analysis. From September to November 2022, medical records of 136 PDD patients who visited outpatient clinics at Shenzhen Hospital (Longgang) of Beijing University of Chinese Medicine and Dongfang Hospital of Beijing University of Chinese Medicine between January 2017 and August 2022 were retrospectively analyzed, and one-on-one semi-structured interviews with PDD patients were conducted using a self-designed interview outline to establish an item pool. A multidisciplinary expert consultation group for PDD was formed, and three rounds of Delphi expert consultation were initiated in December 2022. Results: A total of 123 articles were ultimately included, encompassing 5 categories and 12 PDD outcome evaluation scales. Retrospective medical record analysis and patient interview results demonstrated that PDD clinical symptoms accumulated 1,465 occurrences, involving 176 distinct clinical symptoms. Following three rounds of Delphi expert consultation, a TCM PROs scale for PDD containing 4 dimensions (psychological dimension, physiological dimension, social dimension, overall evaluation)

and 43 items was finalized, along with its theoretical model. Conclusion: This study introduced internationally established PROs, utilized literature analysis, medical record review, patient interviews, and other methods to construct an item pool, and through three rounds of Delphi expert consultation, successfully developed a PDD-PROs scale and its theoretical model under the guidance of TCM theory, which can be referenced and utilized in efficacy evaluation research on TCM treatment of PDD.

## Full Text

# The Construction of the Traditional Chinese Medicine PROs Scale for Perimenopausal Depressive Disorder and Its Theoretical Model

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### Abstract

**Background:** Perimenopausal depressive disorder (PDD) is a serious mood disorder that occurs before and after menopause. Traditional Chinese medicine (TCM) offers advantages such as holistic regulation and syndrome differentiation and treatment in managing PDD, but currently lacks a specialized efficacy evaluation tool for TCM treatment of PDD. **Objective:** To introduce patient-reported outcomes (PROs) and construct a PDD-PROs scale and its theoretical model under the guidance of TCM theory. **Methods:** From April to June 2022, computer searches were conducted on databases including CNKI, Wanfang Data, VIP, SinoMed, PubMed, Web of Science, and the Cochrane Library for literature on TCM treatment of PDD published up to April 17, 2022, followed by literature analysis. From September to November 2022, a retrospective analysis was performed on medical records of 136 PDD patients who visited outpatient departments at Shenzhen Hospital (Longgang) and Dongfang Hospital of Beijing University of Chinese Medicine between January 2017 and August 2022. Based on a self-designed interview outline, one-to-one semi-structured interviews with PDD patients were conducted to establish an item pool. A multidisciplinary expert consultation group related to PDD was selected and established, and three rounds of expert consensus using the Delphi method began in December 2022. **Results:** A total of 123 articles were included, involving 5 categories and 12

postmenopausal depression outcome evaluation scales. Retrospective medical record analysis and patient interviews showed that the cumulative frequency of clinical symptoms of PDD was 1,465 times, involving 176 clinical symptoms. After three rounds of expert consensus using the Delphi method, the Traditional Chinese Medicine PROs Scale for PDD and its theoretical model were ultimately formed, including 4 dimensions (psychological dimension, physiological dimension, social dimension, and overall evaluation) and 43 items. **Conclusion:** This study introduced internationally mature PROs, used literature analysis, medical record review, and patient interview methods to construct an item pool, and successfully constructed the PDD-PROs scale and its theoretical model through three rounds of expert consensus using the Delphi method under the guidance of TCM theory, which can be used in research on efficacy evaluation of TCM treatment for PDD.

**Keywords:** Depression; Perimenopause; Mental disorders (TCM); Patient-reported outcome measures; Models; Theory

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## 1. Methods

### 1.1 Literature Search Strategy

From April to June 2022, we conducted computer searches of Chinese and English databases for literature on TCM treatment of PDD published up to April 17, 2022. Chinese databases included CNKI, Wanfang Data Knowledge Service Platform, VIP, and SinoMed, searched using keywords: "perimenopausal," "menopausal," "depression," "depressive disorder," "depressive episode," "TCM," "Chinese medicine," and "integrated Chinese and Western medicine." English databases included PubMed, Web of Science, and the Cochrane Library, searched using keywords: "Perimenopausal Depression," "Permenopausal Medicine," "TCM," "Herbal Medicine," "Chinese Medicine," and "CM."

### 1.2 Literature Inclusion and Exclusion Criteria

Inclusion criteria: Studies with clear TCM syndrome differentiation and pattern identification for PDD. Exclusion criteria: (1) Duplicate literature; (2) Reviews or animal experiments.

### 1.3 Retrospective Medical Record Analysis and Patient Interviews

From September to November 2022, we retrospectively analyzed medical records of 136 PDD outpatients at Shenzhen Hospital (Longgang) and Dongfang Hospital of Beijing University of Chinese Medicine from January 2017 to August 2022. Clinical symptoms were collected using a self-designed PDD clinical symptom information form. Simultaneously, trained researchers conducted one-to-one semi-structured interviews with PDD patients using a self-designed interview outline

to understand psychological and somatic discomfort symptoms and their impact on patients' lives, work, and families. Based on the principle of information saturation, 30 PDD patients were interviewed. This study was approved by the Clinical Research Ethics Review Committee of Shenzhen Hospital (Longgang), Beijing University of Chinese Medicine (Approval No.: SZLDH2022LSYM-128).

### 1.4 Patient Inclusion and Exclusion Criteria

Inclusion criteria: (1) Age 45-55 years; (2) Female; (3) Accompanied by menstrual disorders, typical hot flash and sweating symptoms, or emotional irritability, anger, irritability, insomnia, etc., with modified Kupperman Index (KI) score >15 points; (4) Persistent low mood for more than 2 weeks, with Hamilton Depression Scale (HAMD)-17 score $ $17 points; (5) Ability to understand and answer relevant questions; (6) Voluntary participation. Exclusion criteria: (1) Accompanied by severe language impairment or mental illness; (2) Post-hysterectomy menopause and currently undergoing hormone therapy.

### 1.5 Delphi Method Expert Consultation

The results of retrospective medical record analysis and patient interviews were summarized and merged. After repeated discussion and preliminary screening by the research team, 51 items were initially formed. Based on PDD clinical efficacy evaluation methods, clinical characteristics of PDD, and the connotation of PROs, the research team preliminarily determined that the PDD TCM PROs scale should include 4 dimensions: psychological dimension, physiological dimension, social dimension, and satisfaction. The 51 items were categorized into these 4 dimensions to design the "First Edition PDD TCM PROs Questionnaire." A Likert-5-point scale was used to score the importance of each item: "very important," "important," "generally important," "not very important," and "unimportant" were assigned 5, 4, 3, 2, and 1 points, respectively.

Following principles of authority, expert representativeness, and broad geographic distribution, a multidisciplinary expert consultation group related to PDD was selected and established. All members were from tertiary hospitals, with basic information shown in Table 1 . A pre-survey was conducted before the first round of Delphi expert consultation to evaluate the rationality and operability of the "First Edition PDD TCM PROs Questionnaire." Delphi expert consultation began in December 2022, with questionnaire links sent to members of the PDD multidisciplinary expert consultation group via email and collected within 15 days.

Questionnaire recovery rate was used to reflect expert enthusiasm coefficient. Cronbach's $\alpha$ coefficient was used to reflect questionnaire reliability. Mean ($\bar{x}$) and full-mark ratio (K) were used to evaluate expert opinion concentration degree. Kendall's W and coefficient of variation (CV) were used to evaluate expert coordination degree. Expert authority degree (Q) was related to familiarity and judgment basis, calculated as Q = (mean familiarity + mean judgment basis)/2.

Items with K <30% or CV $ $0.3 were deleted.

### 1.6 Statistical Methods

Microsoft Excel 2019 and SPSS 25.0 statistical software were used to establish databases and conduct descriptive analysis.

### 1.7 Quality Control

For included literature, two researchers independently extracted information on PDD clinical symptoms, pattern types (decomposed into pathogenic location and nature elements), and outcome evaluation scales. For retrospective medical record analysis data, two researchers independently entered data.

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## 2. Results

### 2.1 Literature Search and Analysis Results

A total of 123 articles were included, with the literature screening process shown in Figure 1 [Figure 1: see original paper]. Based on the included literature, common clinical symptoms of PDD included insomnia, depressive mood, irritability, and lack of energy. Pathogenic location elements for PDD were liver, kidney, heart, spleen, and gallbladder, with frequencies of 57, 46, 12, 9, and 1, respectively. Pathogenic nature elements were qi stagnation, yin deficiency, yang deficiency, blood stasis, qi deficiency, phlegm-heat, blood deficiency, phlegm-dampness, qi stagnation transforming into fire, essence deficiency, melancholy injuring spirit, and phlegm-qi stagnation, with frequencies of 47, 22, 15, 11, 3, 2, 2, 2, 2, 1, 1, and 1, respectively. PDD outcome evaluation scales involved 5 categories and 12 scales: (1) Depression evaluation: HAMD, Beck Depression Inventory (BDI), Self-Rating Depression Scale (SDS); (2) Perimenopausal symptom evaluation: Modified KI score, Greene Climacteric Scale; (3) Sleep evaluation: Pittsburgh Sleep Quality Index (PSQI); (4) Anxiety evaluation: Hamilton Anxiety Scale (HAMA), Self-Rating Anxiety Scale (SAS); (5) Quality of life evaluation: Menopause-Specific Quality of Life Questionnaire (MENQOL), WHO Quality of Life-BREF (WHOQOL-BREF), 36-Item Short Form Survey (SF-36), Social Functioning Rating Scale (SFRS).

### 2.2 Retrospective Medical Record Analysis and Patient Interview Results

Retrospective medical record analysis showed that PDD clinical symptoms appeared with a cumulative frequency of 1,465 times, involving 176 clinical symptoms. Among them, 32 symptoms appeared with frequency $ $10 times, ranked from high to low as follows: insomnia (114 times), depressive mood (102 times), lack of energy (77 times), decreased appetite (74 times), pessimism and easy crying (60 times), palpitations (51 times), hot flashes and night sweats (43 times),

forgetfulness (40 times), menopause (40 times), dizziness (37 times), frequent sighing (30 times), loss of interest (29 times), chest and hypochondriac distending pain (27 times), soreness and weakness of waist and knees (27 times), bitter taste (26 times), tinnitus (23 times), scanty menstruation (22 times), loose stools (22 times), dry mouth (19 times), tension (19 times), headache (19 times), chest tightness (18 times), five-center heat (17 times), excessive thinking (17 times), delayed menstrual cycle (16 times), anxiety (15 times), suspiciousness and worry (14 times), dark purple menstrual blood (14 times), slow reaction (10 times), many menstrual blood clots (10 times), dry stools (10 times). Patient interview results are shown in Table 2 .

### 2.3 Delphi Method Expert Consultation Results

The first round of Delphi consultation sent 40 questionnaires, with 33 valid responses recovered (expert enthusiasm coefficient 82.5%). Cronbach's $\alpha$ coefficient was 0.956, Kendall's W was 0.241, and Q value was 0.851. The second round sent 33 questionnaires, with 27 valid responses (81.8%). Cronbach's $\alpha$ was 0.970, Kendall's W was 0.213, and Q value was 0.862. The third round sent 32 questionnaires, with 29 valid responses (90.6%). Cronbach's $\alpha$ was 0.953, Kendall's W was 0.351, and Q value was 0.865. All three rounds showed high expert enthusiasm, good questionnaire reliability, acceptable coordination, and high expert authority.

In the psychological dimension, experts in the first round suggested merging item 1 "low mood" with item 2 "sadness and easy crying," and adding items 4 "poor concentration," 9 "feeling worthless," and 10 "self-harm and suicide." These items were included after the second and third rounds.

In the physiological dimension: experts suggested merging items 11 "difficulty falling asleep," 12 "dream-disturbed sleep," and 13 "early awakening" into one item "sleep disorder"; merging items 36 "irregular menstrual cycle" and 37 "light or dark purple menstrual color" into "menstrual disorder"; merging items 39 "constipation," 40 "dry hard stools," 41 "loose stools," and 42 "diarrhea" into "abnormal bowel movements"; and adding items 45 "foreign body sensation in throat," 46 "abnormal eye sensation," and 47 "abnormal vaginal discharge." Based on K and CV values, items 38 "dark complexion" and 44 "abnormal sensation" were deleted after the first round; items 20 "tinnitus" and 47 "abnormal vaginal discharge" after the second round; and items 15 "frequent sighing," 22 "slow reaction," 35 "dry skin and itching," and 34 "sweaty palms and soles" after the third round. All other items were included.

In the social dimension, based on K and CV values, item 53 "medical burden" was deleted after the first round, with all other items included and no new items added.

In the satisfaction dimension, experts suggested adding items 58 "satisfaction with relationships with others" and 59 "self-evaluation of current psychological status" in the first round, which were included after the second and third rounds.

Results of the three rounds of Delphi expert consultation on the "First Edition PDD TCM PROs Questionnaire" are shown in Table 3 .

### 2.4 PDD TCM PROs Scale and Its Theoretical Model

Integrating literature search and analysis results, retrospective medical record analysis and patient interview results, and Delphi expert consultation results, this study ultimately formed a PDD TCM PROs scale containing 4 dimensions (psychological dimension, physiological dimension, social dimension, overall evaluation) and 43 items (Table 4 ). Referencing previous studies, the psychological, physiological, social, and overall evaluation dimensions of the PDD TCM PROs scale correspond to "emotion theory," "syndrome differentiation and treatment," "correspondence between human and nature," and "treatment according to individual differences" in TCM theory, respectively. The theoretical model is shown in Figure 2 [Figure 2: see original paper].

The PDD TCM PROs scale theoretical model places the "psychological dimension" first to highlight attention to PDD patients' psychological states. Based on PDD outcome evaluation scales, patient interview results, and Delphi expert consultation results, it forms 9 items covering two aspects: "core depressive disorder symptom cluster" (Q1-Q3) and "other psychological symptoms" (Q4-Q9). In the "physiological dimension," common PDD clinical symptoms were first summarized and organized from literature search results, retrospective medical record analysis, and patient interview results. Then, through Delphi expert consultation, somatic symptoms that could reflect TCM therapeutic advantages were selected, forming 23 items covering two aspects: "symptoms related to pathogenic location elements (liver, kidney, heart, spleen)" and "symptoms related to pathogenic nature elements (qi stagnation, yin deficiency, yang deficiency, blood stasis, etc.)" (Q10-Q32), which have good correspondence with the "13th Five-Year Plan" textbook *TCM Diagnostics* (Figure 3 [Figure 3: see original paper]). In the "social dimension," patient interviews first explored their functional independence, work ability, social ability, social role function, economic level, and understanding/respect, then Delphi expert consultation formed 6 items covering "functional independence" (Q33-Q36) and "social support" (Q37-Q38). In "overall evaluation," patient interviews first explored satisfaction with their own health, life, work, and treatment, then Delphi expert consultation formed 5 items covering "satisfaction evaluation" (Q39-Q42) and "psychological status self-evaluation" (Q43).

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## 3. Discussion

PROs are outcome indicators that measure and evaluate disease and its development and prognosis directly from the patient's perspective, emphasizing patients' subjective feelings. Any changes in health status that patients can clearly perceive and describe can serve as PROs measurement objects. In recent years,

with changes in modern medical models, indicators that can comprehensively evaluate patients' subjective feelings, functional status, and quality of life have become research hotspots in clinical efficacy evaluation. Studies have found that depression occurrence in perimenopausal women is related to biological, psychological, and social factors. PROs scales cover four dimensions: physiological, psychological, social, and satisfaction. Advantages of using PROs in PDD clinical efficacy evaluation include: (1) PDD diagnostic criteria are based on psychological symptoms such as low mood, decreased interest, pessimism, and low self-evaluation, making patients' subjective feelings more diagnostically significant than biological indicators; (2) PDD patients' main clinical symptoms, such as depression or irritability, hypochondriac distending pain, hot flashes, palpitations, and migraines, are entirely subjective symptoms. Clinical doctors must inquire about patients to understand depressive emotions, and patients experience these symptom improvements most genuinely; (3) Clinical doctors evaluating PDD efficacy usually focus only on main clinical symptoms, signs, or laboratory indicators, easily overlooking abnormalities in patients' life, work, and interpersonal relationships; (4) PDD is a typical psychosomatic disease with complex conditions and diverse symptoms. Patients often have obvious somatization discomfort, severely affecting quality of life while causing stigma and economic burden. Psychological and social factors play important roles in PDD treatment and prognosis. Therefore, this study constructed a PDD-PROs scale and its theoretical model under TCM theory guidance.

Currently, domestic PDD clinical efficacy evaluation scales are mostly single psychological or physiological domain scales or generic scales. Although MENQOL focuses on quality of life, it only includes one item related to depression evaluation. Meanwhile, due to the lack of specialized scales for evaluating PDD clinical efficacy, clinicians often need to use two or more scales, making the evaluation process cumbersome and burdensome for researchers and participants. Moreover, most PDD clinical efficacy evaluation scales are imported from abroad and used after translation and debugging. However, due to differences in cultural backgrounds, thinking patterns, and health perceptions between East and West, they are not fully applicable and lack TCM characteristics, limiting their use in evaluating TCM treatment efficacy for PDD. Therefore, forming a TCM-characteristic PDD-PROs scale that can comprehensively evaluate physiological, psychological, and social dimensions and is convenient to operate is essential.

Although TCM literature does not contain the disease name "PDD," based on its clinical manifestations and characteristics, it can be classified under "depression syndrome," "lily disease," "visceral agitation," etc. *Suwen • Shanggu Tianzhen Lun* states, "Women at age 49… the Ren meridian becomes deficient, the Chong meridian declines, Tian Gui is exhausted, the earth channel is blocked, thus the body deteriorates and childbearing ceases." "Age 49" corresponds to the perimenopausal period. TCM theory holds that when the Chong and Ren meridians become deficient and Tian Gui is exhausted, women's reproductive function declines, leading to menstrual disorders, soreness and weakness of waist and knees, decreased libido, and other physical discomforts. When kidney qi grad-

ually declines and kidney essence is deficient, brain marrow formation becomes insufficient, and brain spirit loses nourishment, resulting in impaired mental consciousness activities that manifest as depression, anxiety, and emotional indifference. The "liver and kidney share the same origin"; when kidney water cannot nourish liver wood, kidney deficiency can lead to liver blood deficiency. Since "the liver is yin in substance but yang in function," liver blood deficiency can cause liver failing to disperse, eventually leading to liver depression manifested as low mood and pessimism with easy crying. *Lin Zheng Zhi Nan Yi An* states, "Women take the liver as congenital… prone to depression; when depressed, qi stagnates and blood also stagnates," suggesting that women with liver depression and qi stagnation easily have concurrent blood stasis. Some scholars believe that deficiency can lead to stasis, and stasis can cause depression, thus manifesting as chest and hypochondriac distending pain and frequent sighing. Additionally, kidney yin deficiency cannot ascend to nourish heart fire, leading to heart spirit losing nourishment and heat disturbing heart spirit, causing tidal fever, sweating, irritability, and insomnia. Moreover, *Qian Zhai Yi Xue Jiang Gao* states, "Liver and spleen dual deficiency, wood failing to dredge earth… thus forming depression syndrome," indicating that PDD is also related to middle-jiao spleen and stomach abnormalities. When liver depression overacts on the spleen and spleen fails to transform and transport, it cannot ascend clear qi, leading to lack of energy, excessive thinking, and decreased appetite.

In summary, TCM theory considers PDD occurrence and development closely related to liver, kidney, heart, and spleen. Abnormalities in these organs cause qi and blood deficiency, yin-yang imbalance, and mixed deficiency-excess patterns, ultimately forming PDD pathological characteristics dominated by liver-kidney deficiency and qi-blood disharmony. It should be noted that PDD has diverse clinical symptoms and numerous pattern types, mostly based on individual experience, with no unified TCM pattern differentiation standard. Syndrome elements are basic unit elements in TCM diagnosis, and pattern differentiation using syndrome element combinations has advantages such as dimension reduction, simplification, and promoting standardization of patterns/types. This study first used syndrome element pattern differentiation to combine numerous PDD clinical symptoms, then formed the PDD TCM PROs scale, giving it certain TCM pattern differentiation characteristics.

The TCM concept of "correspondence between human and nature" emphasizes that humans and social environment form an integral whole. Women play important roles in families and society, and perimenopausal women often face multiple stressors and life events, such as retirement, unemployment, changes in social roles, children leaving home requiring family relationship readjustment, marital crises, and serious illnesses. Therefore, perimenopausal women's emotional fluctuations caused by physiological factors are more difficult to self-regulate. Studies show that perimenopausal depressed women receive lower family support, friend support, and other social support. Social support mainly includes two categories: objective visible support, including economic material assistance and social group support; and subjective experiential support, namely emotional

experiences and satisfaction of being respected, understood, and supported in society. Good social support and utilization can help improve perimenopausal women's psychological resilience, enabling them to correctly face various stressors and life events and reduce PDD occurrence.

TCM theory holds that "treatment according to individual differences" not only emphasizes syndrome differentiation and individualized strategies but also "people-oriented" humanistic care. Patients' satisfaction with their own health, life, work, and interpersonal relationships are subjective experiences determining their quality of life. Most PDD patients are sensitive and suspicious, paying more attention to their own physical discomfort. Satisfaction with medical services and treatment interventions is an important factor affecting treatment compliance. *Huangdi Neijing· Lingshu· Shi Chuan* states, "Tell them what leads to failure, tell them what is good, guide them to what is convenient, and relieve them from what is bitter," indicating that physicians should not only treat physical discomfort but also provide psychological comfort and support, enhance patients' confidence in overcoming disease, enable optimistic and active cooperation with treatment, treat both body and mind, and thereby improve quality of life.

In conclusion, this study introduced internationally mature PROs, used literature analysis, medical record review, and patient interview methods to construct an item pool, and successfully constructed the PDD-PROs scale and its theoretical model through three rounds of Delphi expert consultation under TCM theory guidance, which can be used as a reference in TCM treatment efficacy evaluation research for PDD. Study limitations include: (1) Limited research on TCM treatment efficacy evaluation for PDD, resulting in a limited number of included literature; (2) Retrospective case analysis and patient interviews were single-centered. Although a geographically broad PDD multidisciplinary expert consultation group was established and three rounds of Delphi expert consultation were conducted, the sample size was limited with certain selection bias. Multi-center, large-sample clinical surveys are needed to validate the validity (reliability, validity, responsiveness), measurement performance, and further optimize and improve the PDD TCM PROs scale and its theoretical model, potentially making it a specialized efficacy evaluation tool for TCM treatment of PDD.

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**Author Contributions:** MA Huaping was responsible for study conception, design, and manuscript writing. MA Huaping, LI Hongpei, HU Yuli, and MOU Lei were responsible for collecting and organizing Delphi expert consultation materials, statistical processing, and figure/table preparation. MA Huaping, HU Wenyue, WU Yue, and CHEN Runming were responsible for study implementation, retrospective case analysis, and patient interviews. HAN Zhenyun was responsible for quality control, review, revision, and overall supervision of the manuscript.

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