

# Optimization and Validation of the Core Module for the TCM Spleen-Stomach Disorders PRO Scale (SSD-PRO)

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## 1. Research innovation

- (1) Innovative integration and application of various measurement theories and methods in quantitative research of TCM
- (2) The second edition of TCM spleen and stomach disease PRO scale was optimized and evaluated for the first time under the guidance of CLIPROM standard

## 2. Contribution of our work

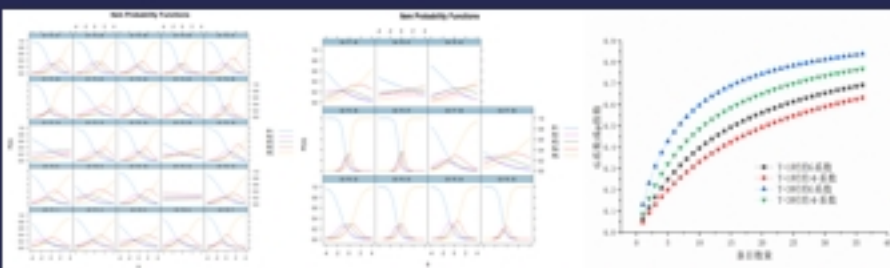
In this study, on the basis of the PRO scale, and further optimized under the guidance of CLIPROM (Clinimetric Criteria for Patient-Reported Outcome Measures) standard, on the basis of classical measurement theory, the subject of sensitivity and reliability validity selection and generalization theory to supplement a set of standardized medical scale optimization and evaluation process.

## 3. Methods

- This study was conducted in China and divided into two phases:
- a. Pilot Survey: Initial screening of scale items;
- b. Formal Survey: Evaluation of scale items using classical test theory, Item Response Theory (IRT), and Generalizability Theory (GT). A cross-sectional survey was administered to 1,243 patients with spleen-stomach disorders for psychometric assessment. The TCM Spleen-Stomach Disorders PRO Scale was further optimized under CLIPROM criteria, and the minimal clinically important difference (MCID) was established.

## 4. Results

- Pilot Survey: Exploratory factor analysis (EFA) indicated a better fit of the second-order confirmatory factor analysis (CFA) model. A preliminary version with 4 domains, 8 facets, and 36 items was developed after screening.
- Formal Survey: EFA showed acceptable model fit for the 4-domain structure:  
 $\chi^2(df = 582, N = 1,243) = 4,189.487, P < 0.001, CFI = 0.937, TLI = 0.932, RMSEA = 0.071, SRMR = 0.062$ . IRT analysis revealed good item discrimination, appropriate difficulty levels, and high information values across the trait interval of -2 to +2, confirming good construct validity. GT analysis demonstrated that the interaction effect of participants, items, and time points ( $P \times I \times T$ ) accounted for 59.90% of total variance, indicating significant item discrimination. MCID results suggested a minimum total score change of 20.678 between two administrations for clinically meaningful improvement.



## 5. Conclusion

An optimized version with 4 domains, 8 facets, and 34 items was developed, suitable for measuring health outcomes in TCM spleen-stomach disorder patients.