

P10 Optimization and validation of the Core Module for the TCM Spleen-Stomach Disorders PRO Scale (SSD-PRO)

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Objective: To optimize the Core Module of the TCM Spleen-Stomach Disorders Patient-Reported Outcome (SSD-PRO) Scale system under the guidance of CLIPROM (Clinimetric Criteria for Patient-Reported Outcome Measures) using multiple modern measurement theories.

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.

Results: a. 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.

b. Formal Survey: EFA showed acceptable model fit for the 4-domain structure: $X^2(df = 582, N = 1,243) = 4,189.487, P < 0.001, CFI = 0.937, TLI = 0.932, RMSEA = 0.071, SRMR = 0.062$. 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.

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