Development of a Treatment Burden Scale for Elderly Patients with Multimorbidity (Post-Print)

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Abstract

Background: Older patients with multiple chronic conditions experience treatment burden during chronic disease management. When treatment burden becomes excessive, it leads to adverse outcomes. Therefore, assessment of treatment burden in older patients with multiple chronic conditions is necessary, but currently no localized treatment burden scale for this population exists in China. Objective: To develop a treatment burden scale for older patients with multiple chronic conditions and test its reliability and validity, providing a suitable assessment tool for scientifically evaluating the effectiveness of interventions for this population. Methods: An item pool was constructed through literature analysis and patient interviews, and an initial scale was developed via expert consultation. A pre-test was conducted to revise item semantics and optimal expression. From September to November 2021, 294 older patients with multiple chronic conditions were selected using convenience sampling. Item analysis and exploratory factor analysis were used to screen items from the initial scale, forming a test version of the scale. From November 2021 to January 2022, 316 older patients with multiple chronic conditions were selected using convenience sampling. The test version was scientifically evaluated for reliability, validity, and feasibility, resulting in the final formal version of the scale. Results: The formal version of the Treatment Burden Scale for Older Patients with Multiple Chronic Conditions comprises 33 items and 7 dimensions: financial burden, self-management burden, healthcare access burden, medication management burden, adverse drug reaction burden, social burden, and psychological burden. Confirmatory factor analysis results showed: c2/df=1.506, Comparative Fit Index (CFI)=0.933, Tucker-Lewis Index (TLI)=0.925, Standardized Root Mean Square Residual (SRMR)=0.054, and Root Mean Square Error of Approximation (RMSEA)=0.040. The Cronbach' s α coefficient for the total scale was 0.895, split-half reliability was 0.938, and test-retest reliability was 0.939 ($P<0.01$). Item-level Content Validity Index (I-CVI) ranged from 0.833~1.000, Scale-level Content Validity Index (S-CVI/Ave) was 0.939, and correlation coef-

ficients between items and their respective dimensions ranged from 0.522~0.897 (P<0.01). The scale response rate was 95.758%, completion rate was 100%, and completion time was 10~15min. Conclusion: The Treatment Burden Scale for Older Patients with Multiple Chronic Conditions developed in this study demonstrates good reliability and validity, and is suitable for assessing treatment burden among older patients with multiple chronic conditions in China.

Full Text

Development of a Treatment Burden Scale for Older Adults with Multimorbidity

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Abstract

Background: Elderly patients with multimorbidity experience treatment burden during chronic disease management, which can lead to adverse consequences when excessive. Assessing this burden is essential, yet no localized treatment burden scale exists for this population in China. **Objective:** To develop and validate a Treatment Burden Scale for older adults with multimorbidity, providing a suitable assessment tool for evaluating intervention effectiveness. **Methods:** An item pool was constructed through literature analysis and patient interviews, with an initial scale developed via expert consultation. Pretesting refined item semantics and optimal expression. From September to November 2021, 294 older adults with multimorbidity were recruited through convenience sampling. Item analysis and exploratory factor analysis were used to screen items, forming a test version. From November 2021 to January 2022, another 316 patients were selected to evaluate the test version' s scientific properties (reliability, validity, feasibility), resulting in the final scale. **Results:** The final scale comprises 33 items across 7 dimensions: economic burden, self-management burden, healthcare access burden, medication management burden, adverse drug reaction burden, social burden, and psychological burden. Confirmatory factor analysis showed: ^{2}/df = 1.506, CFI = 0.933, TLI = 0.925, SRMR = 0.054, RMSEA = 0.040. Cronbach' s α was 0.895 for the total scale, split-half reliability was 0.938, and test-retest reliability was 0.939 (P < 0.01). Item-level content validity index (I-CVI) ranged 0.833–1.000, scale-level content validity index (S-CVI/Ave) was 0.939, and correlations between items and dimensions ranged 0.522–0.897 (P < 0.01). The response rate was 95.758%, completion rate was 100%, and comple-

tion time was 10–15 minutes. **Conclusion:** The developed scale demonstrates good reliability and validity, making it suitable for assessing treatment burden among older adults with multimorbidity in China.

Keywords: elderly; multimorbidity; treatment burden; scale; reliability; validity

Introduction

Global population aging is intensifying, with individuals aged 60 and above comprising 18.70% of China' s population [1], marking a transition from rapid to deep aging. China' s large elderly population, combined with age-related physiological decline and reduced disease resistance, results in many older adults suffering from multiple chronic conditions simultaneously. Systematic reviews show multimorbidity prevalence among community-dwelling adults aged 65+ is 33.1% internationally [2-3] and 6.4%–76.5% among Chinese adults aged 60+ [3]. Compared with other countries, China' s older adults with multimorbidity face unique challenges: a large patient base, rapid growth, and high medical resource consumption, making treatment burden a significant public health concern.

Treatment burden refers to the workload of healthcare activities and their impact on patient functioning and health. Workload includes disease management (e.g., medical appointments, medication adherence) and self-care behaviors (e.g., health monitoring, diet, exercise). Impacts include effects on cognition, behavior, and physical/psychological well-being [4]. Excessive treatment burden leads to poor medication adherence [5-9], disease recurrence, declining health and well-being, reduced treatment satisfaction [10], lower quality of life [11-15], and in severe cases, non-compliance or treatment discontinuation [6,9,16], ultimately affecting treatment outcomes. Accurately assessing treatment burden is crucial for developing and evaluating targeted interventions and reducing inefficient resource utilization.

Currently, China lacks a domestically developed treatment burden scale for older adults with multimorbidity. Existing tools are primarily imported, including the Multimorbidity Treatment Burden Questionnaire (MTBQ) [17-18] and Treatment Burden Questionnaire (TBQ) [19,31]. However, these require adaptation for three key reasons: First, translated scales are not age-specific; TBQ does not exclude patients with single chronic conditions. Second, they focus primarily on physical, economic, and time burdens while neglecting psychosocial aspects. Third, MTBQ and TBQ were developed within specific healthcare, cultural, insurance, and social welfare contexts (e.g., free healthcare in their countries of origin), which differ substantially from China' s system. Therefore, guided by the COSMIN (COnsensus-based Standards for the selection of health Measurement INstruments) checklist recommended by JBI (Joanna Briggs Institute) [20], this study developed a comprehensive scale to assess treatment burden among Chinese older adults with multimorbidity, incorporating cultural,

healthcare system, and social welfare perspectives to inform individualized interventions.

Methods

This study followed COSMIN guidelines [20] to develop the Treatment Burden Scale for Older Adults with Multimorbidity, dividing the process into three stages: initial scale development, item optimization, and psychometric validation.

Initial Scale Development

1.1.1 Research Team Formation The research team comprised seven members: two deputy chief nurses from geriatrics, one attending physician from geriatrics, one statistics expert, and three master' s students. The clinical and statistics experts guided scale structure and item development, while graduate students conducted scale development and field surveys.

1.1.2 Theoretical Framework Sav et al. [10] used Rodgers' concept analysis to establish a treatment burden framework encompassing attributes, antecedents, and consequences. Attributes include dynamic, multidimensional, and subjective/objective burden components. The dynamic nature reflects temporal changes; multidimensionality includes economic, self-management, psychosocial, time, and medication burdens. Subjective burden refers to psychological burden, while objective burden encompasses medication management and time costs. Antecedents include patient characteristics, disease status, treatment features, family environment, and healthcare system factors. Primary consequences include treatment non-adherence, poor health/well-being, inefficient resource utilization, and impacts on employment and family caregivers. Based on this framework, we initially categorized treatment burden into economic, self-management, time, psychosocial, and medication burdens.

1.1.3 Item Pool Development Guided by the treatment burden framework, we conducted a comprehensive literature review using search terms including "treatment burden," "multimorbidity," "multiple chronic conditions," and their Chinese equivalents across CNKI, Wanfang, VIP, CBM, PubMed, Web of Science, Medline, and Embase databases. To understand treatment burden in Chinese older adults, we conducted semi-structured interviews with patients aged $ $60 years diagnosed with $ $2 chronic conditions for >6 months across tertiary, secondary, and primary hospitals in Chengdu. Interviews explored experiences, self-management strategies, perceived burdens, impacts, coping mechanisms, life changes, and additional needs. Colaizzi's phenomenological analysis [21] was applied to interview data. The item pool was then drafted based on the conceptual framework, literature review, and qualitative findings [22].

1.1.4 Delphi Expert Consultation Two rounds of Delphi consultation were conducted with 15 experts specializing in geriatric chronic disease research [23]. Inclusion criteria were: expertise in geriatric chronic disease care, chronic disease nursing, nursing management, or instrument development; bachelor' s degree or higher; $ $5 years of relevant experience; intermediate or higher professional title; and willingness to participate. Expert feedback was analyzed for active participation coefficient, authority coefficient (Cr), and variation coefficient. In Round 1, items meeting both CV < 0.25 and mean importance score > 3.5 were retained. Items meeting only one criterion were discussed by the research team based on clinical utility. Suggested new items were included in Round 2. Round 2 incorporated Round 1 feedback and followed the same retention criteria.

1.1.5 Pretesting Pretesting with 20 patients refined item wording and clarity. For example, Item 13 was revised to "Difficulty using transportation to access medical care" for clearer expression. Inclusion criteria were: diagnosed with $ $2 chronic conditions for >6 months; age $ $60 years; normal communication ability; and voluntary participation. Exclusion criteria were: participation in other clinical studies or severe illness preventing cooperation.

Scale Item Optimization

Convenience sampling was used to recruit older adults with multimorbidity from tertiary, secondary, and primary hospitals in Chengdu (same inclusion/exclusion criteria as pretesting). Participants completed a questionnaire including basic demographics and the initial scale. Item analysis (critical ratio method, correlation coefficient method, dispersion trend method, Cronbach' s alpha method) and exploratory factor analysis were employed for item selection.

Psychometric Validation

1.3.1 Participants Using convenience sampling, older adults with multimorbidity meeting the same inclusion/exclusion criteria were recruited from tertiary, secondary, and primary hospitals in Chengdu.

1.3.2 Reliability Assessment Reliability was evaluated through test-retest reliability, split-half reliability, and Cronbach' s alpha. Thirty participants were randomly selected for retesting 2–3 days post-discharge using Pearson correlation coefficients: >0.75 indicates excellent, 0.40–0.75 good, and <0.40 poor test-retest reliability. Split-half reliability required correlation $ $0.7. Internal consistency was assessed via Cronbach' s alpha for the total scale and each dimension, with $\alpha \geq 0.7$ considered acceptable.

1.3.3 Validity Assessment Validity was evaluated through content validity and construct validity. Six experts in geriatric chronic disease care (same inclusion criteria as above) rated items. Item-level content validity index (I-CVI) and scale-level content validity index (S-CVI/Ave) were calculated: I-CVI =

number of experts rating 3 or 4 / total experts; S-CVI/Ave = mean of all I-CVI values. Acceptable thresholds were I-CVI $\geq$ 0.78 and S-CVI/Ave $\geq$ 0.9 [36]. Construct validity was assessed through item-dimension correlations (0.3-0.8 indicating good validity) and confirmatory factor analysis. Model fit indices were: RMSEA $<$ 0.05 (good), 0.05-0.08 (acceptable); ^{2}/df $<$ 3; IFI, CFI, TLI $>$ 0.9 (better fit as values approach 1); GFI $>$ 0.85 and AGFI $>$ 0.8 (acceptable).

1.3.4 Feasibility Assessment Feasibility was evaluated through acceptance rate, completion rate, and completion time. Acceptance rate (response rate) and completion rate should each exceed 85%. Completion time should be <20 minutes to avoid participant burden.

Statistical Analysis

Data were double-entered in Excel and cross-verified. SPSS 21.0, QSR NVivo 12.0, and Mplus 14.0 were used for analysis. Descriptive statistics included means, standard deviations, medians, quartiles, frequencies, and percentages. Item screening employed critical ratio, correlation coefficient, dispersion trend, Cronbach' s alpha, and factor analysis. Reliability was tested via test-retest, Cronbach' s alpha, and split-half reliability. Validity was assessed through content and construct validity. Feasibility was evaluated via response rate, completion rate, and completion time. Significance level was set at $\alpha = 0.05$.

Results

Item Pool Development and Delphi Consultation

Based on the treatment burden framework, literature analysis, and interview findings [22], a 49-item pool was developed across six dimensions: economic burden, medication burden, self-management burden, healthcare access burden, social burden, and psychological burden. The original time burden dimension was integrated into healthcare access burden, encompassing time/travel burden and difficulty accessing medical resources.

From July to September 2021, 15 experts were invited from 10 provinces/municipalities (Chongqing, Hebei, Shanxi, Henan, Jiangsu, Sichuan, Guangdong, Fujian, Zhejiang, Shandong). Expert characteristics: age 42–59 years, work experience 22–41 years, 10 senior, 4 associate senior, and 1 intermediate title; 2 doctoral, 7 master' s, and 6 bachelor' s degrees. Round 1 distributed 20 questionnaires (15 valid, 75.00% response); Round 2 distributed 15 questionnaires (15 valid, 100% response). Expert authority coefficient (Cr) was 0.897. Kendall' s W coordination coefficients were 0.144 (Round 1) and 0.293 (Round 2), with ^{2} values of 103.454 and 175.684 (both P $<$ 0.001), indicating good consensus. Round 1 importance means were 3.200–4.800 (CV: 0.086–0.377); Round 2 means were 3.530–4.800 (CV: 0.086–0.205). Items with CV $\geq$ 0.25 or mean $\leq$

3.5 were deleted [24], along with expert-recommended deletions (Items 8, 10, 13, 29, 30, 32, 37, 38, 49). One item was added: "Long-term medication makes me dependent on drugs." The resulting initial scale contained 41 items across six dimensions.

Item Analysis and Exploratory Factor Analysis

From September to November 2021, 310 questionnaires were distributed, yielding 294 valid responses (94.839% response rate). Participants (n = 294) had a mean age of 70.59 ± 6.53 years (range 60–93); 144 were male and 150 female. Detailed characteristics are shown in Table 1 .

Item Analysis: 1. **Critical ratio method:** The top 27% (high group) and bottom 27% (low group) were compared via t-tests. All 41 items showed $P < 0.05$, indicating good discriminability [25]. 2. **Correlation analysis:** Items 15, 22, 23, 29, 31, 32, 33, 34, 35, and 36 had item-total correlations < 0.4 [26], flagged for deletion. 3. **Dispersion trend method:** Items with standard deviation < 0.8 were deleted [27]; Items 3, 6, 7, 8, 9, 22, and 36 met this criterion. 4. **Cronbach' s alpha method:** Deleting Items 32, 33, 34, and 35 would increase overall α [28].

Deletion criterion: Items failing $ $2 criteria were deleted, resulting in removal of Items 22, 32, 33, 34, 35, and 36, leaving 35 items across six dimensions.

Exploratory Factor Analysis: The 35-item scale underwent exploratory factor analysis. Items with factor loadings < 0.4 or similar loadings on $ $2 factors were removed [29]. First analysis: KMO = 0.844, $P < 0.001$, eight factors extracted (eigenvalue > 1) explaining 62.058% variance. Item 10 loaded < 0.4 on all factors; Factor 8 contained only Item 15 (insufficient for factor interpretation, as each factor should have $ $3 items [30]). After deleting Items 10 and 15, second analysis: KMO = 0.838, $P < 0.001$, seven factors extracted explaining 60.659% variance. The rotated component matrix (Table 2) showed appropriate factor loadings with no further deletions.

The final structure comprised seven dimensions with 33 items: economic burden (4 items), self-management burden (6 items), healthcare access burden (9 items), medication management burden (3 items), adverse drug reaction burden (3 items), social burden (3 items), and psychological burden (5 items).

Psychometric Validation Results

From November 2021 to January 2022, 330 questionnaires were distributed, yielding 316 valid responses (95.758% response rate). Participants (n = 316) had a mean age of 69.09 ± 6.13 years (range 60–82); 156 male, 160 female; 83.861% married; insurance types: 34.810% employee, 35.759% resident, 27.215% rural cooperative, 2.215% commercial/self-pay; 40.506% had three chronic conditions; 66.139% had disease duration >10 years.

Reliability: Cronbach' s α was 0.895 for the total scale and 0.740–0.840 across dimensions. Split-half reliability was 0.938 overall and 0.673–0.860 for dimensions. Test-retest reliability was 0.939 overall and 0.753–0.953 across dimensions (all $P < 0.01$).

Validity: - **Content validity:** Six experts (3 geriatric nursing, 2 geriatric physicians, 1 instrument development specialist) rated the scale. I-CVI ranged 0.833–1.000, S-CVI/Ave was 0.939. - **Construct validity:** Item-dimension correlations ranged 0.522–0.897 ($P < 0.01$). Confirmatory factor analysis using maximum likelihood estimation showed initial fit: $^2/df = 1.727$, CFI = 0.903, TLI = 0.892, SRMR = 0.065, RMSEA = 0.048. After correlating error terms for Items 32 and 33 based on modification indices, final fit improved: $^2/df = 1.506$, CFI = 0.933, TLI = 0.925, SRMR = 0.054, RMSEA = 0.040. All standardized factor loadings > 0.4, indicating good model fit (Figure 1 [Figure 1: see original paper]).

Feasibility: Response rate was 95.758%, completion rate was 100%, and average completion time was 10–15 minutes.

Discussion

Clinical Applicability and Feasibility

Currently, China primarily uses imported scales (TBQ [29] and MTBQ [18]) to assess treatment burden in multimorbidity, lacking a domestically developed tool. Treatment burden is a multidimensional concept deeply influenced by cultural background, healthcare systems, and social welfare policies. Comparative analysis reveals limitations: both TBQ and MTBQ are unidimensional, inadequately capturing treatment burden' s complexity. TBQ, developed in France as a generic chronic disease scale, is not age-specific and includes single-condition patients. French patients receive free healthcare [31-32], so TBQ initially omitted economic burden, though a subsequent item was added, its assessment remains limited. In contrast, economic burden is critical in China' s context. MTBQ, though comprehensive for multimorbidity, overlooks psychosocial burden. Like TBQ, MTBQ was developed in the UK' s free healthcare system [18], considering only additional disease management costs without addressing hospitalization, examination, or transportation expenses, differing from China' s healthcare system.

Our study, grounded in Sav et al.' s [10] concept analysis and enriched by literature and qualitative research, developed a 33-item scale covering seven dimensions: economic, self-management, healthcare access, medication management, adverse drug reactions, social, and psychological burden. This scale addresses gaps in existing tools by incorporating economic burden and psychosocial aspects, offering a more comprehensive, culturally appropriate assessment. With good psychometric properties and a 15–20 minute completion time, it demon-

strates strong clinical applicability and feasibility among older adults with multimorbidity.

Reliability

For a scale, internal consistency should exceed 0.7 [33], split-half reliability should exceed 0.7 [34], and test-retest correlation should reach 0.7 [35]. Our scale achieved Cronbach' s $\alpha = 0.895$ overall and 0.740–0.840 across dimensions, indicating good internal consistency. Split-half reliability was 0.938 overall and 0.673–0.860 for dimensions; the adverse drug reaction dimension' s lower split-half reliability (0.673) likely reflects its odd number of items (3) preventing equal split. Test-retest reliability was 0.939 overall and 0.753–0.953 across dimensions (all $P < 0.01$). These results demonstrate excellent reliability.

Validity

Content validity requires I-CVI ≥ 0.78 and S-CVI/Ave ≥ 0.9 [36]. Our scale achieved I-CVI = 0.833–1.000 and S-CVI/Ave = 0.939, indicating strong content validity. For construct validity, item-dimension correlations should be 0.3–0.8 [37]; our results (0.522–0.897, $P < 0.01$) confirm good construct validity. Confirmatory factor analysis criteria include ^{2}/df < 2, TLI > 0.90, CFI > 0.9, SRMR < 0.08, RMSEA < 0.08 [26]. Our final model met all criteria (^{2}/df = 1.506, TLI = 0.925, CFI = 0.933, SRMR = 0.054, RMSEA = 0.040) with all standardized factor loadings > 0.4, confirming excellent structural validity.

Conclusion

This study developed a 33-item Treatment Burden Scale for Older Adults with Multimorbidity encompassing seven dimensions: economic burden, self-management burden, healthcare access burden, medication management burden, adverse drug reaction burden, social burden, and psychological burden. The scale demonstrates strong psychometric properties and is suitable for assessing treatment burden among Chinese older adults with multimorbidity. Limitations include convenience sampling from three hospitals in Chengdu, Sichuan, suggesting need for further validation to enhance generalizability.

Author Contributions

Bai Dingxi conceptualized the study, collected and analyzed data, and drafted the manuscript. Gao Jing supervised quality control, reviewed the manuscript, provided funding, and assumed overall responsibility. Yang Zhi conducted surveys and integrated data. Wu Chenxi analyzed results. All authors approved the final manuscript.

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Conflict of Interest Statement: The authors declare no conflicts of interest.

Note: Figure translations are in progress. See original paper for figures.