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Research Article

Keywords: Ménière's disease, self-management, scale, psychometric testing

Posted Date: October 28th, 2026

DOI: https://doi.org/10.21203/rs.3.rs-11098794/v1

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Additional Declarations: No competing interests reported.

Development and Psychometric Evaluation of the Self-Management Behaviour Scale for Patients with Ménière's Disease

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Abstract

Background

Ménière's disease (MD) is a persistent disorder affecting the inner ear. Its primary clinical features include episodic vertigo attacks, progressive hearing loss, and an increased risk of accidental falls. Long-term self-management is critical for symptom control, yet no theory-based, disease-specific tool exists to comprehensively assess self-management behaviours for adult patients with MD. The present research was carried out to construct and psychometrically verify a specialized scale measuring self-management behaviors in adult individuals diagnosed with MD. The scale aims to provide support for outcome evaluation and routine monitoring within chronic vestibular medical service.

Methods

Guided by social cognitive theory and chronic disease self-management frameworks, a two-phase mixed-method design was adopted. A preliminary set of scale items was compiled based on thorough literature retrieval and one-on-one semi-structured interviews with affected patients. Two rounds of expert consultation and small-scale pilot testing refined item wording and structure. A total of 504 outpatients with MD from two tertiary hospitals completed the initial scale. Five statistical strategies were applied for item screening. Internal consistency coefficients, split-half analysis and a two-week retest trial were adopted to estimate the scale's reliability. Multiple psychometric analytical methods were further applied to examine its content, structural and convergent validities.

Results

After multi-step item screening, a final 26-item scale covering six dimensions was retained, explaining 56.69% of total variance. The full-scale Cronbach's α coefficient reached 0.877, split-half reliability was 0.843, and test-retest intraclass correlation coefficient hit 0.965. The overall content validity index of the whole scale was measured at 0.960, while the content validity coefficients for individual items ranged from 0.860 to 1.000. Revised confirmatory factor analysis presented ideal fitting indicators, and composite reliability values of all six dimensions surpassed 0.70 despite partial average variance extracted values being slightly below 0.50.

Conclusions

The final self-management behaviour scale for patients with MD exhibits good reliability and validity. It fills an existing measurement gap for this chronic vestibular disorder and can be utilised both for routine clinical monitoring and as an outcome measure in health-service and interventional research.

Keywords
Ménière's disease; self-management; scale; psychometric testing;

Background

Ménière's disease (MD) is a persistent inner ear disease with unknown etiology, and its core pathological feature is endolymphatic hydrops. It is estimated that the global prevalence rate of MD is 34 to 190 cases per 100,000, and the peak incidence rate is 30 to 70 years old, and the incidence rate of women is higher [1]. There are four typical clinical symptoms of the disease: recurrent rotational vertigo, fluctuating sensorineural hearing loss, tinnitus and ear fullness [2]. At present, the treatment methods include drug therapy, intratympanic administration and surgery. However, there is still a lack of widely recognized long-term maintenance treatment programs for patients in remission. This treatment gap may be part of the reason for the high recurrence rate of this inner ear disease [3]. Acute onset of vertigo will significantly increase the risk of fall-related injuries, especially in the elderly. The long-term physical discomfort caused by MD is often accompanied by anxiety and depression. Because the course of the disease can be delayed for years or even decades, patients need continuous intervention such as long-term medication and regular follow-up. Such long-term care needs will bring a heavy economic burden to families [4]. To sum up, multiple physical, psychological and economic injuries will seriously affect patients' daily self-care ability and social participation ability [5].

Self-management is the core component of chronic disease management system. If implemented in place, this kind of behavior can delay disease progression, improve patients' health-related quality of life (HRQOL), and control medical expenses, thus providing the clinical team with a direction to intervene and adjust in practical work [6]. Studies on common chronic diseases such as hypertension and diabetes have confirmed that individualized intervention measures based on verified standardized questionnaires can enhance patients' self-management confidence and achieve a better long-term prognosis [7,8]. In MD patients, more and more clinical evidence shows that self-management measures such as sodium-restricted diet and regular vestibular rehabilitation training can reduce the frequency of dizziness, reduce the risk of falls and improve the HRQOL [9,10].

Nevertheless, the research on self-management practice specifically for MD is still in the early stage and has obvious limitations. Most assessment tools developed abroad often only focus on a single dimension, such as vertigo-related functional decline, disease prognosis or vestibular exercise compliance [11-13]. In contrast, domestic research often uses self-made questionnaires to collect data [14,15]. Although these tools are convenient for clinical use, they have some problems, such as weak theoretical basis, nonstandard item compilation, and no strict psychometric test. The above defects greatly restrict its wide application and scope of application in different patient groups. Current mainstream assessment tools present distinct limitations for MD evaluation. Generic self-management scales designed for chronic diseases [16], despite their broad application in clinical research, cannot capture the unique self-management needs of MD patients, including vestibular rehabilitation and fall risk prevention. Meanwhile, the MD-Specific Quality of Life Questionnaire [17] centres solely on patients' subjective quality-of-life perceptions and lacks objective indicators to quantify adherence to daily self-care practices. In summary, no theory-based, standardised scale has been developed to cover all exclusive self-management dimensions of MD. The lack of quantitative clinical evaluation tools prevents medical workers from accurately detecting patients' self-management

deficiencies, obstructs the implementation of tiered, personalised transitional care, and restricts refined chronic disease management for MD patients.

To fill the abovementioned research vacancies and resolve unmet clinical practical demands, the current research constructed a self-management behavior questionnaire for adult MD patients based on two mature theoretical frameworks, namely social cognitive theory and chronic disease self-management theory, before conducting complete psychometric verification of the newly developed tool. This original scale makes up for the shortage of disease-specific assessment instruments for MD. It can be used as a unified and standardised measurement tool for MD-related clinical patient evaluation, clinical intervention effect evaluation and follow-up clinical research.

Methods

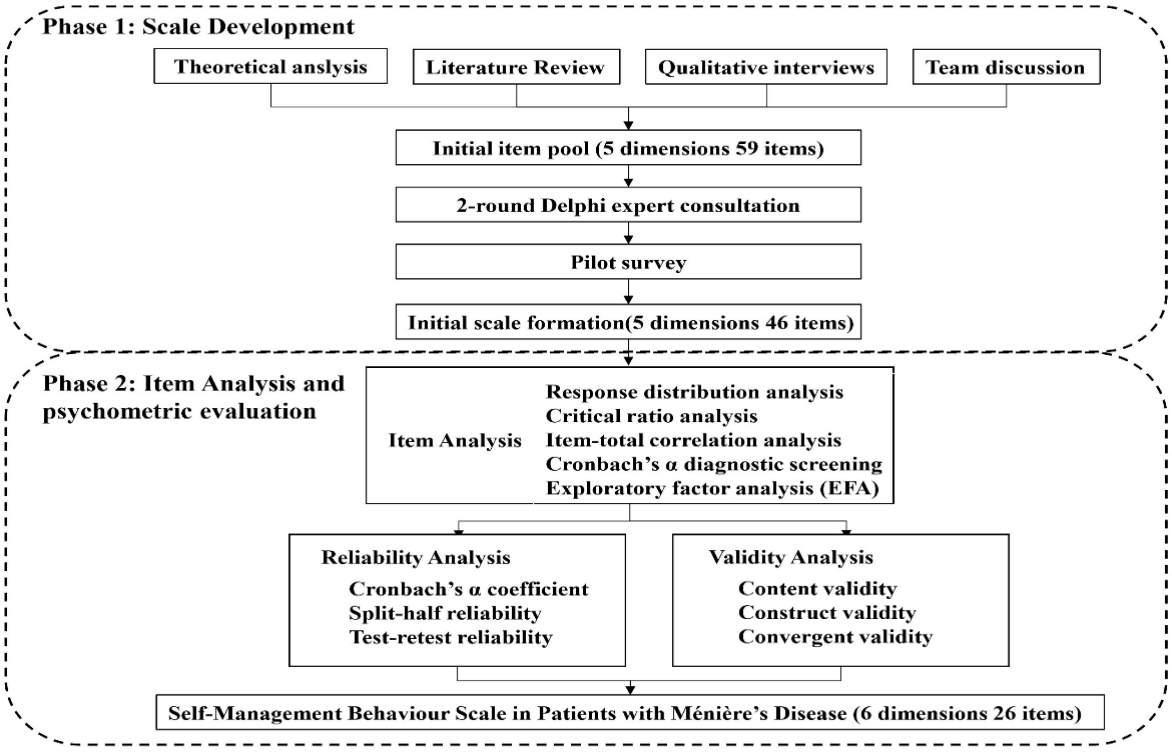
Theoretical Framework

Two core theories underpinned scale construction: social cognitive theory and chronic disease self-management theory. Social cognitive theory posits that individuals formulate behavioral expectations by evaluating personal capabilities and external environmental conditions under goal-oriented motivation, then implement tailored action plans. Throughout behavioral execution, individuals continuously conduct self-reflection, assess their capacity to perform target health behaviors, foster self-efficacy, and dynamically adjust expected outcomes, self-management tactics, and implementation rhythm to iteratively refine health behavioral patterns [18-20]. According to Lorig and Holman, chronic disease self-management comprises three key components: medical-oriented illness management, sustaining social-role function, and reduction of undesirable emotional strain. They further outlined six essential self-management competencies: problem-solving, autonomous medical decision-making, acquisition of external support resources, collaborative communication with medical providers, structured health action planning, and adaptive behavioral adjustment [21,22]. Integrating the two theoretical frameworks, prior published literature, and clinical characteristics of MD, five preliminary dimensions were extracted: lifestyle management, role adaptation management, disease medical management, safety management, and psychological coping management.

Study Design

The research was divided into two sequential phases: (1) scale development; (2) item analysis and psychometric evaluation incorporating comprehensive reliability and validity testing (Fig.1).

Fig.1 Flow diagram of the study design



Phase 1: Scale Development

Systematic Literature Retrieval

In this study, literature retrieval was carried out in six mainstream databases, including three Chinese databases (CNKI, Wanfang data and CBM) and three English databases (Web of Science, PubMed and Cochrane Library). The search keywords included MD, self-management, self-care, management behavior, scale development, psychometric characteristics, vestibular rehabilitation and vertigo nursing. The time range of document retrieval was all publicly included documents from the establishment of the database to June 2022. Qualified literatures included clinical research related to MD clinical practice guidelines and peer-reviewed papers focusing on self-management of chronic diseases. A total of 193 documents were obtained in the initial examination. After systematic full-text screening, 55 documents finally met the pre-set inclusion and exclusion criteria.

Semi-structured Interviews

Based on a thorough review of existing literature, the researcher compiled a semi-structured interview outline. In order to collect qualitative data, this study recruited 10 clinically diagnosed MD patients from a vertigo clinic in a tertiary hospital in Jinan for face-to-face interviews. The research team carried out group brainstorming discussion based on systematic literature research results, evaluated the rationality and applicability of the initial scale items, deleted redundant items and merged synonymous items. After rigorous screening, an initial item library with 59 items in 5 dimensions was formed.

Delphi Expert Consultation

Twenty-three multidisciplinary experts from seven tertiary hospitals in five provinces (Shandong, Fujian, Guangdong, Zhejiang and Liaoning) conducted two rounds of consultation through on-site questionnaires or emails. Inclusion criteria of experts: (1) doctors or specialized nurses who have been engaged in clinical work related to vestibular diseases for at least 10

years; (2) experts in the field of chronic disease care or health management education; (3) intermediate and above titles; (4) bachelor degree or above. The consulting information package includes filling instructions, expert information form, item importance rating questionnaire and modification suggestion form. The response rate, authority coefficient, importance score, full score rate, Kendall's W coefficient and coefficient of variation (CV) were calculated for each round of consultation [23]. Retention criteria of scale items [24]: (1) full score rate > 20%; (2) average importance score > 3.5; (3) CV < 0.25. Combined with statistical indicators and written feedback from experts, the entries were revised through addition, deletion, division and optimization of wording. After two rounds of consultation, the expert opinion tends to be unified and then the consultation process is terminated.

Pilot Survey

Thirty MD outpatients from the same tertiary hospital in Jinan were recruited and included in the pre-test of the scale. The trained researchers standardized the study purpose before filling in the questionnaire and guided each subject to report their self-management behavior in the past month retrospectively. After all the items were compiled, the subjects were invited to evaluate the clarity and readability of each topic in the pre-investigation stage. Combined with the feedback from the subjects, all the vague or misleading items were collectively revised to improve the overall intelligibility, and the initial scale was ultimately finalised.

Phase 2: Item Analysis and Psychometric Evaluation

Cross-sectional Questionnaire Survey

We used convenient sampling method in the formal investigation to recruit MD patients diagnosed clinically from two tertiary hospitals in Jinan. Qualified subjects who meet all the preset inclusion criteria need to fill in the first edition of the scale to collect cross-sectional research data. Then the standardized analysis process is used to analyze the obtained data, which includes strict item screening, reliability test and validity verification. The sample size was calculated following the relevant guidelines of classical factor analysis, which suggested that the number of subjects recruited should be 5 to 10 times of the total number of scale items [25]. To guard against potential invalid or incomplete responses, we additionally recruited an extra 10% of the target number. Since the preliminary scale contained 46 items, at least 253 valid cases were required to support a reliable exploratory factor analysis (EFA). 270 valid questionnaires were finally retrieved and included for EFA in this study. By contrast, confirmatory factor analysis (CFA) requires no fewer than 200 valid study cases. With an extra 10% sample reserve for invalid data exclusion, the required minimum sample size for CFA was set at 220 cases, and 234 valid participants were ultimately incorporated for CFA statistical analysis. For test-retest reliability assessment, 30 participants from the CFA cohort were conveniently sampled to complete the scale twice with a two-week interval between administrations.

Patient inclusion criteria: (1) a definitive diagnosis of MD, which was strictly verified based on the diagnostic guidelines [1]; (2) age of 18 years or older; (3) a disease course of no less than six months; (4) sufficient cognitive ability for self-completion of the survey, and voluntary written informed consent obtained ahead of formal study participation. Patient exclusion criteria: (1) other concurrent vestibular disorders; (2) severe comorbidities of cardiac, cerebral, or renal systems limiting independent self-management behaviors; (3) psychiatric illness or cognitive impairment precluding valid questionnaire completion.

Item Analysis

Five item screening procedures were performed: (1) response distribution analysis eliminating items with >80% respondents choosing one single option [26], (2) critical ratio analysis comparing the top and bottom 27% score subgroups to remove items with insignificant intergroup differences [27], (3) item-total Spearman correlation analysis excluding items with Spearman's $r < 0.30$ and non-significant correlations [28], (4) Cronbach's α screening discarding items whose removal substantially increased the overall scale α [29], (5) EFA implemented exclusively when the Kaiser-Meyer-Olkin (KMO) index ≥ 0.8 and Bartlett's sphericity test produced $p < 0.05$ [30]; principal component analysis with varimax orthogonal rotation was used for factor extraction, with pre-defined item elimination thresholds including factor loading < 0.40, cross-loading across ≥2 factors with a loading difference < 0.10, any factor containing fewer than three retained items, and item grouping inconsistent with the pre-established theoretical framework; EFA was iteratively re-conducted after each item deletion until all residual items met the pre-specified retention criteria.

Reliability Analysis

Reliability was assessed via Cronbach's α, split-half reliability and test-retest reliability [31]. A full-scale Cronbach's $\alpha > 0.8$ reflected excellent internal consistency, while 0.7-0.79 was deemed acceptable. To calculate split-half reliability, all scale items were divided into two subsets according to odd and even serial numbers. Coefficients above 0.7 were treated as the cut-off for satisfactory internal homogeneity. To assess test-retest reliability, we adopted the intraclass correlation coefficient (ICC), which was calculated by two rounds of independent evaluation. An ICC coefficient greater than 0.7 meant that the measurement stability was at an acceptable level over time.

Validity Analysis

Content validity

To evaluate the content validity, the experts were invited to score each item with a 4-point Likert scale, and the scoring anchor point was 1 (completely irrelevant) to 4 (highly relevant). Based on the experts' scoring results, this study calculated the item content validity index (I-CVI) and the scale content validity index (S-CVI) respectively. According to accepted methodological standards, I-CVI was greater than 0.75 and S-CVI was higher than 0.90, which meant that the content validity was good [32].

Construct validity

We used CFA and referred to a set of widely recognized fitting indexes to test the construct validity. The standardized factor loadings were between 0.50 and 0.95, which indicated that there was a solid correlation between the items and their corresponding latent constructs. When χ^2/df was less than 2, the model fitting effect was excellent, and when the ratio was between 3 and 5, it was considered acceptable. In terms of root mean square error (RMSEA), a value lower than 0.05 meant that the fitting was good, and 0.05 to 0.08 meant that the fitting was acceptable. In addition, all the four commonly used comparative fitting indexes, including normed fit index (NFI), comparative fit index (CFI), Tucker-Lewis index (TLI), and incremental fit index (IFI), needed to be greater than 0.90, which proved that the theoretical model had a good matching degree with the observed data [33].

Convergent validity

In order to evaluate the convergent validity, we calculated the average variance extraction (AVE)

and composite reliability (CR) of each latent variable dimension. According to mature psychometric norms, when the AVE of a factor was greater than 0.50 and the CR was higher than 0.70, it was considered that the factor had ideal convergent validity [34].

Statistical Analysis

Data entry and initial organisation of raw questionnaire responses were performed in Microsoft Excel 2019. Descriptive statistics, item screening, EFA and all reliability examinations were conducted applying SPSS version 25.0, while CFA was conducted with AMOS 24.0. Continuous measurement data were reported in the form of mean ± standard deviation; categorical counting data were summarised through frequencies and constituent proportions. A two-sided significance level of $\alpha = 0.05$ was adopted throughout this research, and $p < 0.05$ was regarded as statistically meaningful.

Ethical Approval

All collected data were exclusively used for statistical analysis within this research project, and all personal identifying information was fully de-identified. Every respondent held the privilege to terminate their participation at any stage of the investigation, and declining participation would not bring any negative consequences to their routine clinical diagnosis and treatment. The research scheme obtained official ethical authorisation from the Ethics Committee of the School of Nursing and Rehabilitation, Shandong University (Approval Number: 2022-R-148).

Results

Outcomes of Scale Development Phase

Delphi expert consultation outcomes

Table 1 summarises the demographic profiles of experts enrolled in the two-round Delphi consultation.

Table 1 Demographic characteristics of the experts in the Delphi consultation (N=23)

Item	Category	Number	Proportion (%)
Gender	Female	16	69.6%
	Male	7	30.4%
Age（years）	30-40	1	4.3 %
	40-50	12	52.2%
	≥50	10	43.5%
Education	Bachelor	4	17.4 %
	Master	8	34.8 %
	Doctor	11	47.8%
Professional title	intermediate	2	8.7 %
	Associate senior	14	60.9 %
	senior	7	30.4%
Years of work experience	10-20	7	30.4%
	20-30	6	26.1 %
	≥30	10	43.5 %
Current field of work	Vertigo Department	10	43.5 %
	Neurology	2	8.7%
	Traditional Chinese Medicine	1	4.3 %
	Nursing	8	34.8 %
	Otorhinolaryngology	2	8.7%

Table 2 lists key Delphi indicators across both rounds, including questionnaire response rate, expert authority coefficient, item importance score, full-mark proportion, Kendall's W coefficient and CV. Throughout the two-round consultation procedure, high levels of expert agreement regarding the relevance of individual items were achieved. Detailed information regarding items and dimensions revised or eliminated during the Delphi expert consultation is provided in Supplementary S1.

Table 2 Summary and statistical table of expert opinions

Item	Response rate (%)	Authority coefficient	Full score Rate (%)	Importance scores	Coefficient of variation	Kendall's W coefficient
Round 1	92.0%	0.866	0-91.3%	2.57-4.91	0.06-0.70	0.299**
Round 2	100%	0.927	30.0%-100%	3.96-5.00	0-0.22	0.168**

Note: ** indicates $P < 0.001$

Pilot testing results

Thirty patients with MD completed the pilot version, with completion time consistently controlled within 20 minutes. Only Item 15 ("I actively learn the pharmacological mechanism of my prescribed drugs") contained overly specialized terminology that confused participants. To improve intelligibility, the research group rephrased this item into the statement "I actively learn what my medications do". Every retained item was expressed in plain, readily understandable language. The initial scale contained 5 dimensions and 46 items (see Supplementary S2).

Sociodemographic characteristics of cross-sectional participants

Convenience sampling was utilised for questionnaire distribution; in total, 535 surveys were dispatched, and 504 valid responses were finally obtained, corresponding to an effective response rate of 94.2%. Complete demographic characteristics of the study sample are summarised in **Table 3**.

Table 3 Demographic characteristics of the participants (N=504)

Variables	EFA sample (N=270) n (%)	CFA sample (N=234) n (%)
Gender		
Male	109 (40.4)	102 (43.6)
Female	161 (59.6)	132 (56.4)
Age (years)		
18–40	46 (17.0)	34 (14.5)
41–60	120 (44.5)	102 (43.6)
>60	104 (38.5)	98 (41.9)
Residence		
Urban	154 (57.0)	147 (62.8)
Rural	116 (43.0)	87 (37.2)
Marital status		
Unmarried	3 (1.1)	7 (3.0)
Married	247 (91.5)	214 (91.5)
Divorced	6 (2.2)	4 (1.7)
Widowed	14 (5.2)	9 (3.8)

Educational level		
Primary school and below	48 (17.8)	57 (24.4)
Junior high school	75 (27.7)	64 (27.4)
Senior high school / Technical secondary school	62 (23.0)	56 (23.9)
Junior college	47 (17.4)	27 (11.5)
Bachelor's degree and above	38 (14.1)	30 (12.8)
Occupation		
Farmer	112 (41.5)	88 (37.6)
Worker	55 (20.4)	57 (24.4)
Teacher	10 (3.7)	12 (5.1)
Civil servant	33 (12.2)	25 (10.7)
Others	60 (22.2)	52 (22.2)
Employment status		
Employed	98 (36.3)	75 (32.1)
Unemployed	172 (63.7)	159 (67.9)
Monthly household income (CNY)		
<2500	68 (25.2)	65 (27.8)
2500–5000	101 (37.4)	78 (33.3)
5000–7500	54 (20.0)	60 (25.6)
7500–10000	26 (9.6)	17 (7.3)
>10000	21 (7.8)	14 (6.0)
Medical expense payment type		
Medical insurance	236 (87.4)	215 (91.9)
Self-paid	17 (6.3)	17 (7.3)
Others	17 (6.3)	2 (0.8)
Living arrangement		
Living alone	13 (4.8)	17 (7.3)
Living with parents	7 (2.6)	7 (3.0)
Living with spouse	157 (58.2)	156 (66.6)
Living with spouse and children	78 (28.9)	41 (17.5)
Living with children only	13 (4.8)	13 (5.6)
Others	2 (0.7)	0 (0)
Age at first vertigo onset (years)		
<18	8 (3.0)	2 (0.9)
18–40	87 (32.2)	68 (29.0)
41–60	137 (50.7)	125 (53.4)
>60	38 (14.1)	39 (16.7)
Vertigo attacks in the past year		
1–4 times	161 (59.6)	120 (51.3)
5–10 times	56 (20.8)	48 (20.5)
>10 times	53 (19.6)	66 (28.2)
Vertigo attacks in the past month		
0	59 (21.9)	65 (27.8)
1–4 times	149 (55.2)	129 (55.1)

5–10 times	9 (3.3)	24 (10.3)
>10 times	53 (19.6)	16 (6.8)
Accompanied cochlear symptoms		
Left ear	79 (29.3)	79 (33.8)
Right ear	77 (28.5)	58 (24.8)
Bilateral ears	105 (38.9)	85 (36.3)
None	9 (3.3)	12 (5.1)
Disease course (years)		
<1	53 (19.7)	51 (21.8)
1–5	94 (34.8)	91 (38.9)
6–10	53 (19.6)	38 (16.2)
>10	70 (25.9)	54 (23.1)
Number of comorbidities		
0	138 (51.1)	123 (52.6)
1	85 (31.5)	77 (32.9)
2	31 (11.5)	22 (9.4)
3	9 (3.3)	8 (3.4)
>3	7 (2.6)	4 (1.7)

Item analysis outcomes

From January to March 2023, 270 MD patients were enrolled for systematic item screening using five statistical methods.

(1) Response distribution analysis: none of the 46 initial items had a single response option selected by over 80% of participants, with no severely skewed items identified. All items were therefore temporarily retained.

(2) Critical ratio analysis: Mann-Whitney U tests showed no significant intergroup differences in item 33 and item 46 ($p > 0.05$), and these two items were excluded accordingly.

(3) Item-total Spearman correlation analysis: ten items (items 2, 6, 15, 21, 23, 33, 36, 39, 40, 46) exhibited weak correlations with the overall scale score ($r < 0.3$), indicating poor construct representativeness, and were all removed.

(4) Cronbach's α screening: The preliminary 46-item scale yielded an overall Cronbach's α coefficient of 0.876. The deletion of items 6, 15, 33, 36 and 46 markedly improved the scale's overall internal consistency coefficient. This result demonstrated that the five problematic items weakened the scale's internal homogeneity, thereby supporting their elimination from the initial item bank.

(5) EFA: After deleting ten items that failed to meet quality standards, we performed EFA on the remaining 36. The KMO value was 0.830, and Bartlett's test reached significance ($\chi^2 = 3643.029$, $p < 0.001$), confirming that the dataset was adequate for factor extraction. The principal component analysis with varimax orthogonal rotation was adopted to extract factors with eigenvalues greater than or equal to 1. In accordance with pre-defined elimination criteria, problematic items were iteratively excluded and EFA was repeatedly reperformed. This iterative procedure resulted in the further elimination of ten additional items (items 20, 22, 12, 4, 30, 34, 1, 19, 29, 31). As illustrated in the scree plot (Fig. 2), a six-factor structure was statistically well-fitted for the scale. The final EFA yielded six latent factors comprising a total of 26 items, which could explain 56.690% of total variance. All retained items exhibited standardised factor

loadings within the acceptable range, and the extracted factor structure was highly consistent with the pre-established theoretical framework (Table 4). The six validated factors were correspondingly named Lifestyle Management, Psychological Coping Management, Role Adaptation Management, Safety Management, Disease Medical Management, and Information Communication Management.

Fig.2 The scree plot for the self-management behaviour scale in patients with Ménière's disease

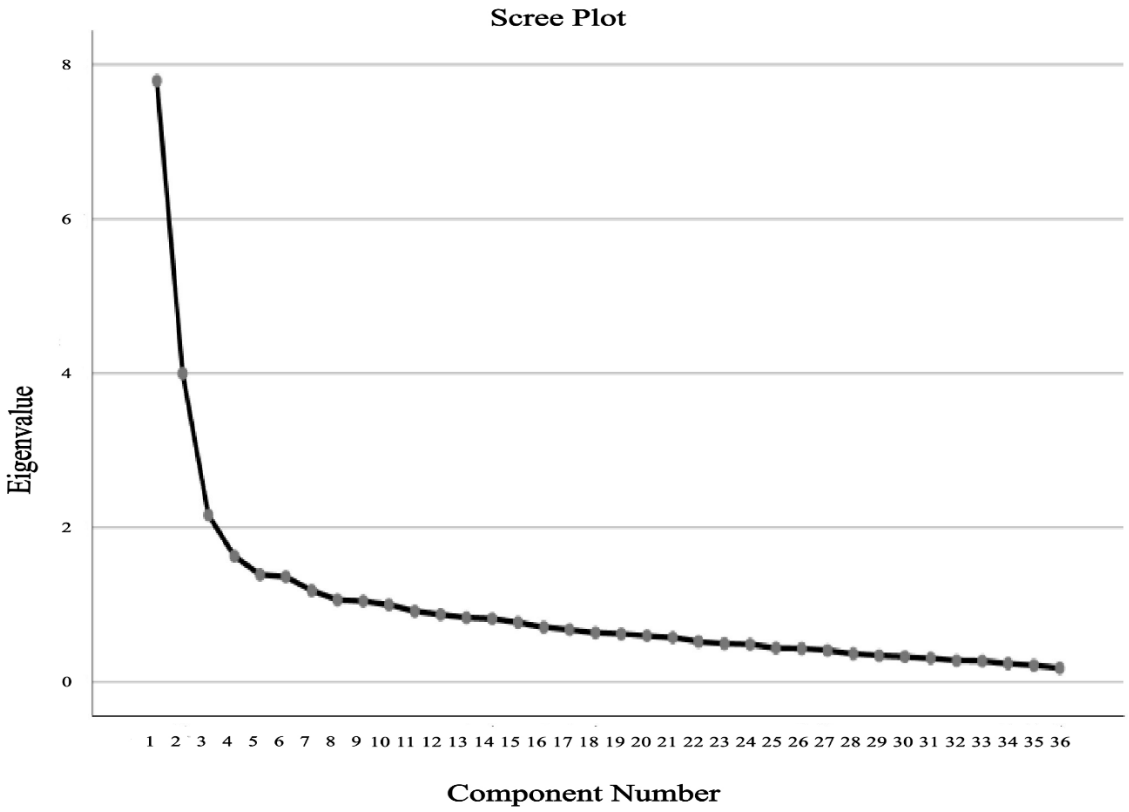


Table 4 Results from exploratory factor analysis of the final scale (N = 270)

Items	Factor1	Factor2	Factor3	Factor4	Factor5	Factor6	Eigenvalues	Explained Variation (%)
Item 5	0.802							
Item 8	0.799							
Item 7	0.785						6.124	23.554
Item 9	0.726							
Item 3	0.522							
Item 44		0.715						
Item 42		0.704						
Item 41		0.684					2.937	11.297
Item 45		0.612						
Item 43		0.561						
Item 10			0.719					
Item 11			0.643					
Item 17			0.628				1.733	6.665
Item 16			0.583					
Item 14			0.567					

Item 37	0.737				
Item 35	0.732			1.557	5.988
Item 32	0.641				
Item 38	0.634				
Item 27		0.794			
Item 26		0.745		1.22	4.691
Item 25		0.599			
Item 28		0.571			
Item 18			0.744		
Item 24			0.590	1.168	4.494
Item 13			0.470		

Reliability analysis

An independent sample of 234 MD outpatients, recruited from May to July 2023, was enrolled for comprehensive psychometric reliability evaluation of the final scale. All results obtained from the reliability analyses are systematically presented in Table 5. The final scale achieved an overall Cronbach's α coefficient of 0.877, with the α values for its six dimensions ranging from 0.803 to 0.865. All coefficients exceeded the commonly adopted threshold of 0.8, indicating excellent internal consistency of the scale. The overall split-half reliability was 0.843, and subdimension split-half coefficients varied between 0.765 and 0.820. All indices were above the acceptable cutoff value of 0.7, demonstrating stable and robust inter-item correlations of the developed instrument. Thirty participants completed the scale again after a two-week interval for test–retest reliability assessment. The overall ICC of the scale was 0.965, and the subdimension ICC values ranged from 0.956 to 0.987. All these values were considerably higher than the conventional cutoff of 0.7, confirming the robust temporal stability of the developed scale.

Table 5 Results of the internal consistency, split-half reliability and test–retest reliability (N=234)

Dimensions	Cronbach's α	Split-half reliability	Test-retest reliability
Lifestyle management	0.803	0.784	0.984
Psychological Coping Management	0.811	0.765	0.968
Role Adaptation Management	0.822	0.811	0.956
Safety Management	0.865	0.820	0.987
Disease Medical Management	0.851	0.813	0.983
Information Communication Management	0.852	0.776	0.962
Total	0.877	0.843	0.965

Validity analysis

Content validity

The S-CVI was calculated as 0.960, while the I-CVI values ranged from 0.860 to 1.000. All indicators fully met the recognised methodological criteria, with S-CVI exceeding 0.90 and I-CVI above 0.75. These findings verified satisfactory content validity, which was well consistent with the underlying theoretical measurement framework of the scale.

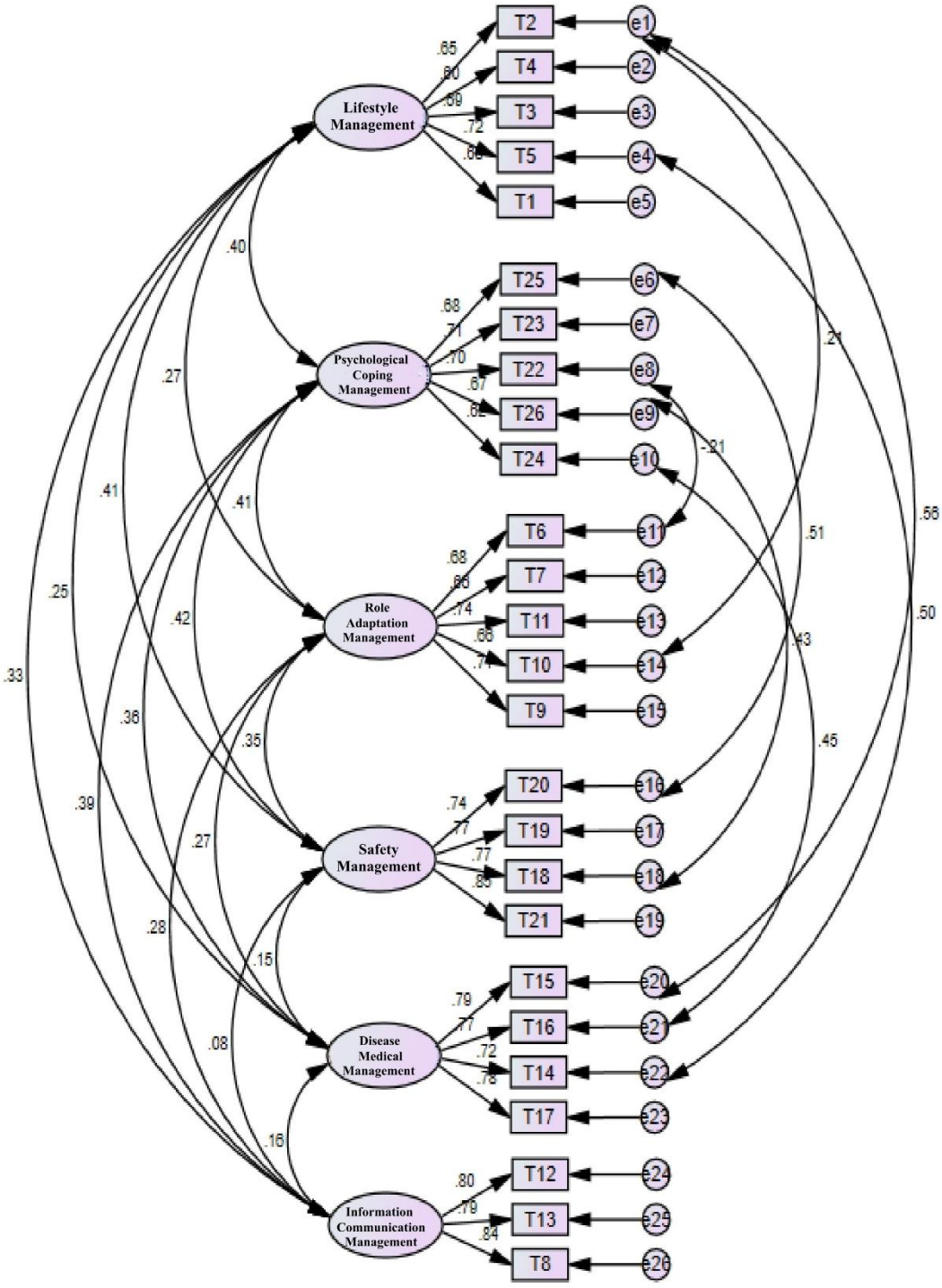
Construct validity

CFA generated standardised item factor loadings spanning 0.601-0.845; each loading was higher than the critical reference value of 0.5. The baseline model exhibited marginally acceptable fit ($\chi^2/df = 2.135$, RMSEA = 0.070), whereas the NFI value of 0.794 failed to reach the optimal threshold of 0.9, indicating suboptimal model fitness despite acceptable IFI, TLI, and CFI values of 0.879, 0.859, and 0.877, respectively. To improve model fitting, the baseline structure was revised by incorporating correlated residual error paths based on modification indices and expected parameter change values. The modified CFA model presented substantially improved psychometric properties, with item loadings ranging from 0.596 to 0.851. All fit indices reached excellent levels: χ^2/df decreased to 1.307, RMSEA reduced to 0.036, and IFI, TLI and CFI increased to 0.968, 0.962 and 0.968 (all > 0.9), while NFI improved to 0.877 (> 0.85). The revised six-factor model thus achieved optimal data-model fit (see Fig.3).

Convergent validity

Across the six latent dimensions, AVE estimates varied between 0.450 and 0.660, whilst corresponding CR coefficients ranged from 0.803 to 0.863. Although three dimensions presented AVE values lower than the conventional cutoff of 0.5, the CR coefficients of all dimensions were above the standard threshold of 0.7. Taken together, these results confirmed adequate convergent validity for all latent dimensions of the scale. The final 26-item scale is provided in Supplementary S3.

Fig.3 Confirmatory factor analysis of the self-management behaviour scale in patients with Ménière's disease



Discussion

Based on social cognitive theory and mature theoretical frameworks for chronic disease self-management, this study developed and psychometrically verified a specialised self-management behaviour scale for adult patients with MD. This tool fills the key gap in targeted quantitative assessment instruments currently unavailable for MD populations.

Methodologically, five complementary statistical screening strategies were utilised to eliminate defective items from the initial 46-item pool. This integrated method effectively prevents over-reliance on subjective expert evaluation or a single quantitative indicator [27]. Four statistical

strategies were applied in the initial phase: response distribution analysis (retaining all items), critical ratio analysis (removing 2 items), item-total Spearman correlation (excluding 10 items), and Cronbach's α-based evaluation (discarding 5 items). Through these steps, a total of 10 items were eliminated. Subsequent EFA removed another 10 items, ultimately yielding a 26-item formal scale organised into six dimensions. In addition, the cross-sectional study design of split samples, coupled with strict data quality control, further enhanced the reliability of the overall methodology of this study. In this study, 270 outpatients were selected as the main sub-samples to carry out EFA and iterative item optimization. An independent sample of 234 subjects was reserved for CFA and integrity reliability evaluation. This two-sample analysis method can effectively curtail the risk of overfitting and help ensure a stable final factor structure [35].

We had carried out a number of reliability evaluations and the reliability of this scale was equivalent to other self-management tools for chronic diseases [36,37]. The overall Cronbach's α coefficient of the scale was 0.877, the α coefficients of each dimension were between 0.803 and 0.865, and the overall split-half coefficient was 0.843. In addition, the test-retest ICC reached 0.867, which was markedly exceeding the conventional benchmark of 0.70, thus demonstrating satisfactory temporal stability. Good repeatability ensures that the scale can continuously reflect patients' long-term self-management behaviours and can be used as a reliable tool to appraisal the long-term outcome of clinical care intervention.

This new scale has good and comprehensive psychometric properties with strong content and construct validity. Content validity is excellent, with the S-CVI reaching 0.960, and all I-CVI being greater than 0.75. The above results were completed by two Delphi rounds involving 23 multidisciplinary experts. In the second round, the expert authority coefficient was 0.927, and Kendall's W coefficient was 0.168 ($p < 0.001$), which indicated that the content bias was effectively reduced and the consistency of expert opinions was reliable [38]. The fitting index of CFA performed well, which supported the structural validity of the scale: $\chi^2/df = 1.307$, RMSEA = 0.036, CFI = 0.968. The above ideal indicators show that the scale is not only suitable for routine clinical evaluation, but also for targeted research on MD. All items are revised carefully to avoid over-fitting. The CR coefficients of all dimensions were higher than the benchmark threshold of 0.70 in aggregation validity. Although the AVE of some dimensions is slightly lower than 0.50, this phenomenon is not uncommon in multidimensional behavior scale. Methodological literature confirms that in this kind of research scenario, only relying on high CR is enough to show that the aggregation validity is up to standard [39].

This scale can offer a standardised and practical method for evaluating the six core self-management dimensions of MD patients. Clinicians can accurately find out the specific shortcomings of patients' self-care ability with the help of this scale, so as to formulate personalized and targeted programs. For instance, individuals scoring low on safety management may benefit from customised fall-prevention education—a particularly meaningful intervention, given that recurrent vertigo and postural instability place this population at considerable risk of falls [40]. Likewise, patients with insufficient psychological coping resources, as reflected by low scores in Psychological Coping Management, can be timely provided with professional cognitive behavioural guidance and mental health support. Notably, the Information Communication Management domain was newly extracted in this scale and was not included in the initial five-dimensional theoretical framework. This newly identified dimension emphasises the essential role of patient-clinician communication and

active health information acquisition in supporting effective self-management among MD patients. Overall, this domain-based individualised assessment strategy overcomes the limitations of conventional one-size-fits-all management models. It allows clinical staff to precisely address the heterogeneous self-management needs of MD patients and delivers personalised management accordingly.

There are some methodological limitations that need to be considered. First, participants were recruited only from vertigo outpatient clinics of two urban tertiary hospitals. Such constrained sampling may introduce bias and limit the scale's generalisability to other healthcare settings and patient populations. Second, Rasch modelling and other item response theory methods were not performed, so further research is needed to investigate the item difficulty, item threshold performance and scale target matching. The test-retest assessment also relied on a limited subsample and ignored dynamic fluctuations in MD symptom severity, which may alter patients' self-reported self-management behaviours over time. Third, all data depended on patient self-report without external cross-validation. Criterion validity was not examined using objective clinical indicators such as vertigo frequency or hearing impairment severity, restricting the scale's capacity to predict actual clinical outcomes.

In conclusion, the final 26-item, six-dimension self-management behaviour scale for patients with MD exhibits satisfactory internal consistency, temporal stability and construct validity, addressing the shortage of standardised quantitative tools for self-care assessment in MD. Clinicians may use this instrument to objectively evaluate self-management competence among people living with MD and implement individualised interventions. The future research work should carry out multi-center sampling covering different geographical and medical environments. Completing cross-cultural adaptation and verification in other language groups will help to expand the international application scope of this tool. At the same time, it is necessary to carry out longitudinal research to test its responsiveness, so that it can be safely used in intervention research and routine service evaluation to measure the change of self-management level.

List of abbreviations

MD: Ménière's disease
HRQoL: health-related quality of life
CV: coefficient of variation
EFA: exploratory factor analysis
CFA: confirmatory factor analysis
ICC: intraclass correlation coefficient
KMO: Kaiser-Meyer-Olkin
I-CVI: item-level content validity index
S-CVI: scale-level content validity index
RMSEA: root mean square error of approximation
CFI: comparative fit index
NFI: normed fit index
IFI: incremental fit index
TLI: Tucker-Lewis index
AVE: average variance extracted
CR: composite reliability

Declarations

Ethics approval and consent to participate

All collected data were exclusively used for statistical analysis within this research project, and all personal identifying information was fully de-identified. Every respondent held the privilege to terminate their participation at any stage of the investigation, and declining participation would not bring any negative consequences to their routine clinical diagnosis and treatment. The research scheme obtained official ethical authorisation from the Ethics Committee of the School of Nursing and Rehabilitation, Shandong University (Approval Number: 2022-R-148). Clinical trial registration: Not applicable. This study was a cross-sectional psychometric scale development study and did not constitute a clinical trial.

Consent for publication

Not Applicable.

Availability of data and materials

All data supporting the findings of this study are available within the paper and its supplementary information.

Competing Interests

The authors declare no competing interests.

Funding

The authors declare that no financial support was received for the research and publication of this article.

Authors' contributions

G.C. and X.R. conceived the whole investigation, including its research framework, statistical analytical strategy and manuscript preparation. X.Z. took part in study design as well as data curation. L.S. undertook participant enrollment and questionnaire-based data acquisition. W.H. carried out data-related analytical work. W.Y. contributed to study conception and secured essential research resources. All authors reviewed the manuscript, provided critical revisions, and approved the submission of completed manuscripts.

Acknowledgements

The authors acknowledge the valuable involvement of Delphi experts, clinical nursing personnel and patients throughout the course of this research.

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