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Original Article

Assessing the reliability and validity of a newly developed insomnia treatment satisfaction questionnaire (ITSAT-Q)

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ABSTRACT

Purpose: To produce a valid insomnia treatment satisfaction questionnaire (ITSAT-Q) to assess treatment satisfaction with pharmacotherapy for use in patients with insomnia.

Patients and methods: Items developed for a self-administered questionnaire were analyzed using exploratory factor analysis (EFA), which produced 5 dimensions. Confirmatory factor analysis was used to verify results from EFA, and structural equation modeling was used to test the hypothesized relationship among the dimensions. Data were collected from patients as part of a Sleep Research Project from January 2008 until October of 2008.

Results: Approximately 69.8% of the sample ($n = 298$) was female. Item-to-total correlations were 0.66 for convenience, ranged from 0.52 to 0.62 for expectations, from 0.54 to 0.69 for value, from 0.50 to 0.57 for effectiveness, and from 0.58 to 0.72 for treatment satisfaction. All standardized parameter estimates from confirmatory factor analysis were significant ($p < 0.01$). Goodness of fit measures for the final structural equation model were $\chi^2 = 45.2$ (d.f. = 45); $p = 0.465$; CFI = 1.00; TLI = 1.00; and RMSEA = 0.004. Treatment satisfaction was a strong and significant predictor of value, and effectiveness was a strong predictor of treatment satisfaction ($p < 0.01$). Expectations were a strong and equal predictor of both treatment satisfaction and value ($p < 0.001$).

Conclusion: The ITSAT-Q provided acceptable results for instrument reliability and validity. Findings from this study will provide additional insight regarding patient perceptions of treatment satisfaction and other related therapeutic dimensions to help prescribers assess pharmacotherapy.

1. Introduction

Insomnia affects approximately 20–35% of the general population [1–3]. Sleep disorders and diseases that influence sleep habits exhibit a broad impact on health-related quality of life (HRQL) [4–6]. Although numerous strategies such as behavioral modifications, exercise, dietary changes, and prescribed medications are used widely with some success to help patients cope with these symptoms [7,8], there is a paucity of information that relates patient perceptions of pharmacotherapy to patient-reported outcomes (PRO) such as treatment satisfaction.

In this study, we developed a self-report questionnaire to measure treatment satisfaction for patients with insomnia. For the purposes of this study, treatment satisfaction was conceptualized as an accumulation of treatment experiences related specifically with pharmacotherapy [9–11]. Although questionnaires exist to assess the impact of sleep disturbances on quality of life, sleep quality, satisfaction in general and specific disease states [12–22], additional information is needed to determine which dimensions, if any, relate to treatment satisfaction for patients with insomnia and how patients perceive pharmacotherapy with respect to treatment satisfaction and the value of treatment. Given the numerous treatment options available for patients diagnosed with insomnia and the detrimental impact that symptoms have on patient lifestyle, it is important to develop a questionnaire that allows physicians and other prescribers to assess the progress of pharmacotherapy. Thus, the goal of this research was to develop and validate the insomnia treatment satisfaction questionnaire (ITSAT-Q), an instrument to assess treatment satisfaction with pharmacotherapy for patients with insomnia.

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2. Methods

2.1. Questionnaire development

An extensive search through MEDLINE, sociology, clinical, and other Internet-based literature was conducted to generate items for the study. Items considered for inclusion were related to treatment satisfaction, satisfaction with medication use, and treatment efficacy or value. An expert panel consisting of six individuals representing physicians, educators, pharmacists, and researchers with expertise in psychometrics, psychology, and sociology reviewed the pertinent literature and retained items appropriate for questionnaire development. After revisions, there was consensus among members of the expert panel that items selected were consistent with the relevant literature and study objectives. The study to conduct research in humans was approved by the Institutional Review Board at the University of Alabama, Tuscaloosa, Alabama.

Two strategies were used to examine face validity, which ensured there was conceptual consistency between experts and study participants with respect to the interpretation of items. For the first strategy, two focus groups consisting of seven and five individuals with insomnia and currently using a number of strategies to control their symptoms were recruited. Focus group participants were recruited from the Sleep Research Project (SRP), a research and clinical training program within the Department of Psychology at the University of Alabama (UA). Participants in the focus group were randomly selected from a compiled list of 2042 potential participants who responded to media announcements of a study to treat hypnotic-dependent insomnia and lived in the Tuscaloosa area. Individuals were recruited if they satisfied the International Classification of Sleep Disorders, Second Edition [ICSD-II] criteria [23], which included a 19-item measure to determine sleep hygiene (SH) and a variety of activities characteristic of poor SH [24,25], and if they consented to participate in future studies. In addition, participants had to be at least 19 years of age, had to perceive that a physician or other prescriber would provide a diagnosis of insomnia, defined as problems falling or staying asleep three nights a week for a least 1 month, having an adequate opportunity to attain sleep (i.e., not working a late-night shift), and having current complaints of daytime functioning impairment, where complaints of impaired daytime functioning had to meet at least one of the above ICSD-II criteria. Participants were excluded if they already had a physician-confirmed diagnosis of a sleep disorder other than insomnia or were evaluated and during the initial screening process were determined to be at high risk for the presence of other sleep disorders such as sleep apnea, restless legs syndrome, or narcolepsy.

Participants were contacted by telephone, given a brief description of the study, and asked if they would be interested in participating in a focus group. Participants meeting the study criteria were offered their choice of times for participation and mailed a consent and payment form. A protocol consisting of several open-ended questions was developed. First, participants were asked to describe aspects of treatment strategies that worked or did not work. Second, they were asked about treatment satisfaction and what aspects of treatment they found to be satisfying and worthwhile compared to those that were not satisfying. Third, responses were elicited about the value of medication use and whether medication provided value that contributed to monetary and non-monetary aspects of treatment. Fourth, participants were asked to distinguish, if possible, between treatment satisfaction and treatment value. Each session was recorded, lasted 1.5 h, and participants had the opportunity to provide additional responses to questions outside the standard protocol. Following the focus group session, participants completed the questionnaire consisting of 43 specific items, eight global items, demographic information, and measures of symptom severity. Participants were asked to provide feedback verbally and to write notes and comments directly on the questionnaire.

For the second strategy, the questionnaire was distributed to a convenience sample and pre-tested with 22 individuals, of which eight were used for test retest. These individuals also reviewed the instrument for clarity, readability, and applicability to insomnia. The final preliminary questionnaire consisted of 43 items, demographic information, measures of symptom severity, and open-ended questions for comments to ensure the relevance of items to study objectives. Results from the eight individuals from the test, retest group indicated consistent response patterns, with variations in response no greater than one level when considering responses of two and higher. Modifications included changing the directions to bring attention to the entire medication use experience, rewording items to improve interpretability, and removing redundant and vague items. All participants were required to provide a response to each of the final 34 items regarding their perceptions of the item's relational importance to treatment satisfaction ranging from 1 = not important at all to 5 = extremely important. Global measures were included for treatment satisfaction, value, and effectiveness. Other information elicited from participants included age, gender, and symptom severity before and after any type of treatment, over-the-counter (OTC) and prescribed medication use, other chronic conditions, and self-reports of anxiety or depression.

2.2. Sample

For the main study, a larger group of new participants was randomly recruited from the same database of individuals in the Sleep Research Project. If participant behaviors regarding sleep quality met the ICSD-II criteria, they were mailed a copy of the questionnaire with two copies of an informed consent (one to return and one for their records), a payment form, a cover letter explaining the study procedures, and a return envelope. Follow-up calls were made 2 weeks after the questionnaire was mailed to determine if the participant had received the questionnaire and to answer any questions. If the participant could not be reached after two follow-up attempts, they were left a voice message. A total of 430 participants met the criteria for the study and were sent a questionnaire. Once the completed questionnaires were received from participants, they submitted a payment form and received a mailed check for $25.00.

2.3. Statistical approach

Descriptive data were analyzed using SPSS 16.0 Windows; SPSS Inc., Chicago, IL. We used (AMOS) version 16.0 software and user's guide (James L. Arbuckle, 1995–2006) to perform the confirmatory factor analysis and structural equation modeling. Summary statistics for descriptive data included means, standard deviations and *t*-tests to obtain information for demographic variables and to determine if OTC and prescribed medications contributed to a treatment effect with respect to symptom severity. Exploratory factor analysis (EFA) using Varimax rotation to increase interpretability was performed to reduce the number of items and to identify underlying dimensions of relevance. Items with acceptable loadings ($\geqslant 0.3$) on 1 factor and without extensive cross-loading on other factors were retained in the factor structure [26]. Item-to-total correlations were examined with items having Cronbach alphas of 0.70 or higher retained for scale development [27]. Discriminant validity was acceptable if the Cronbach alphas (scale reliabilities) were greater than the interscale correlations and if the average correlations between scale and non-scale items were lower than the correlation between scale and scale items [27]. After discriminant