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Development and Preliminary Psychometric Testing of a Brief Tool to Measure Medication Adherence in Older Populations

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Purpose: Chronic diseases in older age are major sources of burden for healthcare systems. Compliance with medications is the key to treatment success for these patients, especially for frail individuals living in community settings. However, adherence to long-term medications in this population is not optimal, which leads to the need for frequent screening of compliance within large-scale public health surveys. In this context, a brief, simple and valid measure capturing medication adherence is not yet available. This study aims to develop and psychometrically test the Therapeutic Adherence Scale, a brief four-item tool that measures medication adherence in community-dwelling older adults affected by chronic diseases.

Methods: We conducted a three-phase process of instrument development, content validity assessment and psychometric testing.

Results: Of the candidate nine items derived from a review of the literature, only four were deemed essential to capture intentional and nonintentional nonadherence. These items underwent structural validity, convergent and known-groups validity, and internal consistency on a sample of 269 participants (mean age = 7.91 years, SD = 7.26). Confirmatory factor analysis confirmed satisfactory fit indices (RMSEA = 0.000, CFI = 1.00, TLI = 1.00). Scores of the TAS were higher for those perceiving loneliness ($\rho = 0.33$, $p < 0.001$), those declaring memory loss in the last year ($\rho = 0.29$, $p < 0.001$), and those exhibiting worse mental quality of life ($\rho = -0.15$, $p = 0.03$) compared with the other groups. Cronbach's alpha and split-half reliability coefficients were acceptable, with values of 0.68 and 0.77, respectively.

Conclusion: The Therapeutic Adherence Scale is a brief, valid and reliable self-report measure of medication adherence that can be used in practice and research to screen patients living in community settings. This tool is also free to use, which contributes to advancing knowledge on the field of medication adherence of older adults affected by chronic diseases.

Keywords: aged, factor analysis, medication adherence, patient-reported outcome, psychometrics, self-report, statistical, questionnaire

Introduction

Chronic diseases have become a major source of burden worldwide, with more than 40 million individuals dying prematurely each year.[1] Ageing strongly increases the risk of suffering from chronic diseases,[2] reflecting the cumulative effects of various biological and psychosocial risk factors.[3] Estimates from the World Health Organization indicate that older individuals, aged over 60 years, will increase from 600 million in 2000 to 2 billion within 2050, which will inevitably lead to an alarming expansion of chronic disease burden.[4]

Chronic diseases in older age have complex consequences, especially when in combination. First, the physical limitations typical of this population tend to worsen, which ultimately increases the risk of having permanent disabilities,

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and loss of autonomy in activities of daily living. The difficulties in mobility function expose the older individual to sarcopenia and undernutrition, which ultimately lead to falls and incidents, and acute and chronic wounds.[5] Second, disability and unmet needs can impact mental health, causing or worsening anxiety and depression, and cognitive status dysfunction, and ultimately affecting the quality of life.[6,7] Finally, the absence of proactive interventions may lead to an increase in demand for healthcare services and medications, leading to further pressure on the healthcare systems, and related economic burden.[8]

Multimorbidity is the simultaneous coexistence of more than one chronic condition in a single individual. It is common, particularly in older adults with prevalence estimates of 62–81.5% for those >65 years of age.[9] Older adults with multiple chronic conditions more often show a history of frequent hospitalization, especially when they are frail[10–12] due to the coexistence of social isolation, multimorbidity and service fragmentation that make adherence to therapies difficult. Such hospitalizations are associated with high cost[13,14] and increased risk of declines in mobility, function, and cognition following discharge.[15]

Compliance with medications is key to treatment success in chronic disease. A document issued by the World Health Organization reports "adherence enhancing" as the main strategy to counteract chronic diseases.[16] Indeed, optimal adherence to medications is important to ensure that their therapeutic benefits are transmitted to patients. Notwithstanding, it is estimated that the rate of adherence to long-term medication treatments in older adults is about 50%, with even lower rates found in those with multimorbidity and polypharmacy.[17] This nonadherence is a significant factor for morbidity and mortality, which demands more and more effective strategies to promote medication adherence to this population.[18] Common causes of non-compliance in the elderly include cognitive impairment, multimorbidity, and concerns. To some extent, these factors can lead to forgetfulness and refusal to comply with treatment recommendations.[19,20]

The first step to promoting medication adherence is its assessment. So far, many strategies have been implemented, from direct estimates (eg, pill counts, and pharmacy refill records) to self-report measures,[21] with the latter approach resulting more informative and flexible than the objective measures.[22,23] The self-report approach allows researchers to collect information on possible barriers of adherence, such as intentional and nonintentional adherence, which accounts for up to 50% of all nonadherent behaviors in patients over the age of 65 years.[24]

Literature reports a myriad of self-reported measures of medication adherence, each of which has distinctive characteristics in terms of number of items, question phrasing, and response scale formats.[25] Despite this, the need for a brief, standardized, and validated questionnaire persists for some specific patient populations. This is particularly the case for older adults living in community settings and affected by chronic diseases. Often, these patients are involved in large-scale public health studies where numerous surveys are administered in order to collect data to assess multi-dimensional frailty and improve health and well-being.[26] In this context, a brief and simple but at the same time valid measure would be ideal to address the rapidity of data collection within the framework of large-scale surveys. Unfortunately, the characteristics of the available self-reported measures of medication adherence hinder this process. First, a significant percentage of these measures offer assessments based on complex multi-items tools; although these scales ensure a more comprehensive coverage of the nuances of reasons for adherence, they may be a source of burden, for patients, healthcare providers and researchers. Second, some instruments have double-barreled or ambiguous questioning that can reduce the accuracy of the measures;[25,27] this may be an even more sizeable problem in older adults, due to their decline in cognitive function and memory loss increase. Third, some instruments have copyrighted restrictions and impose licensing fees for their use, thereby limiting the advancement of scientific knowledge.[28]

This article describes the development and preliminary psychometric testing of the Therapeutic Adherence Scale (TAS), a brief four-item tool to measure medication adherence in older patient populations.

Methods

We conducted a three-phase process to develop the TAS. First, we identified the constructs of interest and generated the items based on the related theoretical frameworks. Second, we assessed the content validity of the items. Finally, we used the baseline data from a multicenter study to test the psychometric properties of the newly developed instrument.

Instrument Development

In this step, we conducted a literature search to identify all the measures of medication adherence and related constructs covered in the context of older adults' care. This analysis was conducted by three researchers who identified the scales considering multiple criteria, including the main focus on oral medications, whether they were generic or condition-specific, and their psychometric properties. After discussing these criteria, the group selected a pool of indicators that incorporated both aspects of intentional and nonintentional nonadherence, ease of use and comprehensibility. Subsequently, a pool of new items was written de novo and refined to avoid unclear structure, double-barreling, and use of vague terms. Finally, the items were translated into Italian by two expert bilinguals, and independently checked for accuracy by a third bilingual.

Content Validity Assessment

The selected items were tested for content validity (ie, degree of relevance of the items as being representative of the construct). A multidisciplinary team of experts in public health (n = 5) who included family and community nurses (n = 2), geriatricians (n = 2), and a general practitioner (n = 1) were asked to judge the relevance of the items by indicating whether they considered each of them as "essential", "useful but not essential", or "unnecessary". This process aimed at creating a brief questionnaire composed of up to four candidate items. Five items were judged "useful but not essential" and were eliminated, while four were deemed "essential" due to their representativeness in capturing intentional and nonintentional nonadherence in the elderly population. Then, the four remaining items were pilot tested on a group of twelve patients over 65 years who judged whether the items were easily understood and conveyed the intended meaning. No issues were detected during this step.

Psychometric Testing

After instrument development and content validity procedures, the items underwent psychometric testing. Specifically, we tested structural validity, convergent and known-groups validity, and internal consistency of the scale.

Sample

Participants were older adults enrolled as part of the SUNFRAIL plus study, whose protocol has already been published.[29] Briefly, the data from this study were collected through convenience sampling of older adults recruited from different health-care settings in Northern, Central, and Southern Italy. To be included, the subjects had to be at least 65 years of age, living at home, regularly access the healthcare settings of the participating centers, and be able to sign the informed consent. Subjects admitted at the hospital or resident in nursing homes, with overt frailty or disability, unable to understand the study's aims and sign the informed consent form were excluded.

Data Collection

Following approval of the mother study by the Institutional Review Board of the Federico II University and A. Cardarelli Hospitals in Southern Italy (Protocol number: 284–SUNFRAIL+), eligible participants were approached in each center by trained research assistants who explained them the purposes of the study and asked to sign the informed consent to participate. After this step, the participants filled in the questionnaires autonomously or were helped by the research assistants if needed. This study complies with the ethical guidelines stated by the Declaration of Helsinki. All the participants provided written informed consent before participation.

Measures

A questionnaire designed ad hoc by the research team was used to collect the sociodemographic characteristics of the sample. In addition, we collected the following variables:

The degree of perceived loneliness and memory loss was investigated with two open-ended questions taken from the SUNFRAIL tool.[30] The first question asked whether the patient felt lonely most of the time, and the second question asked whether the patient had experienced memory decline during the last years. These items were in a yes or no binary response format.

The level of mental quality of life was collected with the mental component summary of the SF-12 health survey.[31] This subscale includes the aspects of vitality, social functioning, role emotional and mental health. Scores are standardized 0–100, with higher scores representing better mental quality of life.

Statistical Analysis

Descriptive statistics were used to describe the participants' and item's characteristics. Since the TAS was developed to represent the construct of medication adherence, and considering that this scale has only four indicators, we used a confirmatory factor analysis (CFA) to test the unidimensional structural validity. The items of the TAS are binary; therefore, we used the diagonally weighted least square estimator (WLSMV), which is the best choice for modelling categorical or ordered data.[32] The following indices were used to judge model fit: $\chi 2$ statistics (p values higher than 0.05 are indicative of good fit), comparative fit index (CFI: values above 0.95 are supportive), Tucker and Lewis Index (TLI: values above 0.95 are supportive), root mean square error of approximation (RMSEA: values less than 0.05 indicate a well-fitting model), and standardized root mean square residual (SRMR: values less than 0.08 are indicative of good fit).[33] Factor loadings above |0.32| were considered adequate to represent the construct.[34]

The sample was split into two subsamples: the first was used for a preliminary evaluation of factor loadings and fit indices, and the second subsample was used to confirm replicability of the previous solution and obtain parameter estimates more stable in dimensionality and reliability. Internal consistency reliability was estimated with Cronbach's alpha and split-half reliability coefficients, with values above 0.70 considered adequate.[35]

Convergent validity was ascertained by correlating the scores of the TAS with the Short Form 12 (Mental Component Summary score). Known groups validity was ascertained by correlating the scores of the TAS with those who declared to be lonely most of the time and noticed memory loss during the last year.

Results

The sample comprised a total of 269 participants with an average age of 77.91 years (SD = 7.26) (Figure 1). Most of them were female (60.2%) and declared memory loss problems during the last year (52.4%). The most frequent problem declared was forgetfulness (47.6%). Item-total correlations were all above 0.30 (Table 1).

The CFA performed on the subsample yielded unsatisfactory fit indices: $\chi 2$ (2), N = 130 = 12.69, P = 0.002, CFI = 0.94, TLI = 0.83, RMSEA = 0.203 (90% CI, 0.106–0.316), P = 0.007, SRMR = 0.080. Inspection of the modification indices revealed that the misfit was due to an excessive covariance between items 1 and 3. This covariance is plausible because both specifically capture nonintentional adherence. Therefore, the model was respecified by releasing this parameter, after which the fit indices were excellent: $\chi 2$ (1), N = 130 = 0.534, P = 0.465, CFI = 1.00, TLI = 1.00, RMSEA = 0.000 (90% CI, 0.000–0.208), P = 0.533, SRMR = 0.016. All factor loadings were significant and above 0.60, except for the loading of item 1, which was 0.47. The same factor solution was replicated on the whole sample with the following fit indices: $\chi 2$ (1), N = 269 = 0.035, P = 0.852, CFI = 1.00, TLI = 1.00, RMSEA = 0.000 (90% CI, 0.000–0.090), P = 0.894, SRMR = 0.003. Factor loadings were high and significant (Table 2). The Cronbach's alpha coefficient of the TAS was 0.68 and the split-half reliability coefficient was 0.77, confirming acceptable internal consistency.

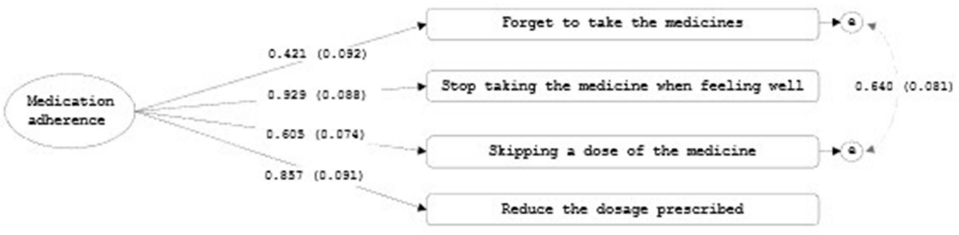

Figure 1 Confirmatory factor analysis of the Therapeutic Adherence Scale on the whole sample (n=269).

Table 1 Sociodemographic Characteristics of the Sample (n=269)

Characteristic	Mean (± SD) or n (%)
Age	77.91 (7.26)
Gender (female)	162 (60.2)
Education (High school or above)	102 (37.9)
Loneliness most of the time	96 (35.7)
Memory loss during the last year	141 (52.4)
SF-12 (MCS)	48.31 (9.95)

Abbreviations: SD, standard deviation; SF-12, short form 12 health Survey; MCS, mental component summary.

Table 2 Frequency of Positive Responses of Items and Total Score of the Therapeutic Adherence Scale

Items	n (%) or mean (SD), [range]	Item-total Correlation
1. Do you sometimes forget to take your medicines?	128 (47.6)	0.42
1. When you feel well do you sometime stop taking your medicines?	50 (18.6)	0.46
1. Do you sometimes skip a dose of your medicines?	102 (37.9)	0.53
1. Do you sometimes reduce the dosage prescribed by the doctor?	46 (17.1)	0.44
Total score	1.21 (1.26), [0–4]	-

Abbreviation: SD, Standard deviation.

Higher mean scores were found for individuals perceiving loneliness ($\rho = 0.33$, $p < 0.001$) and those declaring memory loss in the last year ($\rho = 0.29$, $p < 0.001$). Moreover, those with poorer mental quality of life were more likely to score higher on the TAS scale compared to the others ($\rho = -0.15$, $p = 0.03$).

Discussion

The aim of this study was to develop and psychometrically test a new measure of medication adherence in older adult populations. We found that the four items composing the TAS scale exhibit satisfactory validity and reliability. Overcoming the limitations of the other instruments, this is a promising measure that, due to its brevity, can easily be included in the battery of self-reported questionnaires used for large-scale public health surveys.

The approach used in this study was prompted by the development of a scale that could be short, simple, and free to use. This was accomplished by our multi-step approach of extensive literature review, and involvement of both experts in the field and patients, who ensured that a synthetic representation of the adherence construct in older adults could be represented. Some authors have discussed whether the introduction of several questions such as medication beliefs or adherence barriers could introduce heterogeneous content that would no longer genuinely represent adherence behaviors.[25] We believe that having a scale that could be easily administered, brief and at a low cost, definitely outweighs these issues.

The CFA implemented confirmed that the items are strong representations of the construct of adherence, with high and significant factor loadings. We found a strong correlation between 2 items that capture forgetfulness. This is justified by the fact that these two behaviors frequently occur together. However, these two items are important because the most common errors reported by the older people taking medications are skipping a dose or taking them irregularly.[36] Older

adults can also be reluctant to take their medications regularly or being at risk of self-adjusting the dosage due to perceived side effects or worries about possible interference of the drugs with specific daily activities.[37]

We found that the TAS has a non-optimal internal consistency reliability according to Cronbach's alpha. We believe this can be due to the few numbers of items of the TAS. It is well known that the shorter the scale, the worse the internal consistency indexes.[38] However, it has also been pointed out that even reliability values as low as 0.50 should not seriously impair the validity of a scale.[39] Future testing of the TAS on a larger population are warranted to investigate this aspect.

Limitations and Strengths

There are a few limitations of this study. First, the validation of the TAS was conducted by collecting data on older patients living in the community without severe disability. This might have limited the generalizability to other samples that are clinically different from the current one. Further investigation of patients with a mixture of disability and illness severity would provide more valuable data regarding the TAS range of usefulness. Second, construct validity of the TAS should be confirmed using objective measures of adherence, such as pill counts and monitoring devices. This process should also be complemented by establishing the score threshold for nonadherence in this population. Finally, this tool is self-reported; hence, there is a likelihood of response bias, especially in those with memory problems. To prevent this, we recommend that patients, if possible, seek support from their family carers, when filling in the questionnaire.

Despite these limitations, our results suggest that the TAS is valid, appropriate and reliable for assessing adherence to medications in community-dwelling older patients. Additionally, this tool overcomes some limitations inherent in other instruments such as complexity, ambiguous question wording, and copyright restrictions, which limit their applicability in clinical practice and research.

Considering that the prevalence of this population is constantly increasing, due to population aging and longer survival, this scale can potentially favor the screening of a wide range of individuals and help identify those who are non-compliant, which, in turn, can be used for targeted education.

Conclusions

In conclusion, the TAS is a brief and valid self-reported measure of medication adherence that can be used in practice and research to screen patients living in community settings. This tool is also free to use to the public, which contributes to advancing knowledge on the field of medication adherence of older adults affected by chronic diseases.

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Disclosure

The authors report no conflicts of interest in this work.

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