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The Self – Efficacy for Appropriate Medication Use Scale (SEAMS) – Evaluation of Its Psychometric Properties Among Greek Chronic Disease Patients: A Pilot Study

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Abstract

Background: *In order to evaluate the patients' medication compliance various measures have been performed.*

Aim: *The aim of the current study is the assessment of the psychometric properties (reliability and convergent validity) of the Self Efficacy for Appropriate Medication Scale (SEAMS)in a group of Greek chronic disease patients.*

Method: *Thirty-six patients participated voluntarily in the pilot study. Based on the data which have been collected at initial assessment, item analysis of SEAMS was conducted. In order to test the psychometric properties of the specific instrument, we used the following tests: repeatability, internal consistency, convergent validity and test-retest reliability.*

Results: *Item analysis confirmed that all items of the questionnaire indicated satisfactory variability. SEAMS internal consistency was very good presenting a value of Cronbach's a at 0.880. Spearman's r and intraclass correlation coefficient (ICC) revealed strong correlations between initial assessment and re-assessment. SEAMS convergent validity analysis indicated that the items were also related to the same construct.*

Conclusion: *The findings of this study show that the Greek version of SEAMS provided excellent reliability and validity supporting that it can be used within chronic disease populations and in the context of national medication compliance measurement. These findings are confirmed by other relevant studies.*

Keywords: SEAMS; chronic disease patients; medication compliance; psychometric properties; internal consistency; convergent validity

Introduction

The term "compliance" reflects the degree to which the patient follows the dose, while its interval of medication is measured over a period of time and is a percentage. It is often referred to in studies as the reason for medication possession ratio (MPR) and defined as the number of administered doses in relation to the administration period. Generally, an MPR greater than 80% is considered "good compliance" (Lyritis, 2013).

The term "stay on treatment" is defined as the time interval from the start of the pharmaceutical treatment until treatment is stopped. The assessment of adherence to treatment should include a predetermined time interval between doses (permissible gap), which defines when non-compliance becomes non-adherence to treatment. The specific period of time it depends on the type of treatment and essentially it is the maximum time a patient may not receive his treatment and at the same time not to disturb the effectiveness of the treatment (Cramer et al., 2008).

By "agreement" is meant a sincere one exchange of information, consultation and a spirit collaboration between patient and health professional. The dichotomy between patient and health scientist is as follows goals: on the one hand, the patient aims to determine his own beliefs about health issues to the doctor, who in turn must receive them into account, while on the other hand, the goal of the doctor or someone else's health professional is to transmit and to make his views clear. The definitions "adherence" and "compliance" are considered synonymous by nurses, while most use the definition of the World Health Organization to describe them (Alikari & Zyga, 2014).

According to the (American College of Preventive Medicine

[ACMP], 2011) the term "noncompliance" encompasses a variety of voluntary and involuntary behaviors, which lead either to a higher or to a lower one receiving the recommended treatment.

Low compliance rates in the context of pharmaceutical treatment are an increasing problem, particularly in chronic diseases (Claesson et al., 2015). The compliance rate in long-term drug therapy is on average 50% in developed countries, while still more is appraised low in developing countries. In the age groups which are over 60, the compliance rate varies from 41% to 74%, while many patients state that they consider it as difficult to follow the proposed medical instructions (Gold, 2006). When the disease is without symptoms or when the treatment presents effects which are adverse, the level of compliance is usually lower (Weycker et al., 2007).

(Jin et al., 2008) in their related study that concerned the factors that influence patient compliance based on the beliefs of the patients themselves of patients, identified the following types of non-compliance: a) taking medication, but not completing it, b) taking the wrong dose, c) taking treatment at the wrong time, d)reduction or increase in the frequency of doses, e) interruption of treatment too early, g) delay in seeking health care, h) omission of medical visits, i) failure to comply with medical instructions, j) interruption of the treatment for some time and its resumption and f) compliance with treatment only intime intervals close to scheduled visits to the health professional.

The early recognition of patients who are suspected of not following the therapeutic treatment correctly is of utmost importance to the health professional as the first step in addressing the issue of non-compliance and achieving better therapeutic outcomes (Cole, 2011).

A literature review conducted in PubMed/Medline indicated that, in instruments related to the medication compliance, the only tool specifically aimed at measuring this dimension giving emphasis to self - efficacy level is the self - efficacy for appropriate medication use scale (SEAMS). There are no studies concerning the investigation of the psychometric properties of this specific instrument for chronic disease patients in Greece. Based on the fact that there is a lack of studies regarding this form of tool in a Greek sample, the current research aimed to measure the psychometric properties (reliability and convergent validity) of the SEAMS.

Methods

Cultural Adaptation

SEAMS has been translated from English (the foundation language) to Greek (the aim language). Guidelines for adapting tools to several languages and cultures as well as translation were performed (Hambleton et al., 2002). Translators, who were aware of both the source and target languages and who also demonstrated skills in cross-cultural adaptation of the instruments, performed two independent forward and two independent backward translations. The final version was independently reviewed and translated by a bilingual health psychologist without having previously seen the original version of the SEAMS. The very close agreement between the back-translation and the SEAMS original was confirmed by a specialized linguist fluently speaking in both English and Greek. The final language normalization step was performed by a health scientist who knew both languages. This step involved the editing of the target language version of the instrument in a reliable way of writing. This contributed to the confirmation that patients could easily understand the modified version of the SEAMS. The final version of the instrument was examined in case of omissions by a social expert. By interviewing the participants, we performed semantic validation contributing to the understanding of the existing SEAMS items. This phase aimed to find problems which were related to the acceptance and understanding of the terms by the participants in the study. As part of this stage of the acculturation process, 10 patients diagnosed with end-stage renal disease responded to the items of the SEAMS as well as the General Body Scorer, indicating very satisfactory results (Theofilou , 2023).

Study Population

The study that was conducted is a pilot study. A sample consisting of 65 chronic disease patients was selected from different health centers in the area of Rhodes. There were some selection criteria: a. above 18 years old; b. Capability to communicate in the Greek language; c. Having a diagnosis of a chronic disease; d. Sufficient level of perceived ability and cooperation. Out of these 65 patients, 36 patients completed 2 times the SEAMS questionnaire taking part in this way in the process of assessment and re-assessment of the tool.

The total sample includes all patients, consisting of 26 males (40.0%) and 39 females (60.0%), with a mean age of 71.92 years ± 8.59. Thirty-nine patients (60.0%) were married, 1 (1.5%) single, 7 (10.8%) divorced and 18 (27.7) widowed. Moreover, the majority of patients had elementary andsecondary education (35,4% and 35,4% respectively) and 29.2% (19 patients) had university education. Forty-three patients (66,2%) were pensioners, 14 patients (21,5%) private employees, 6 (9,2%) house wives and only 2 patients (3,1%) public servants. The mean duration in taking medication was 16,77 years ± 8.71 while 33 patients (50,8%) were taking <5 pills per day and 32 patients (49,2%) were taking 5 pills and above per day.

Greek adults, who decided to participate in the current study, signed a relevant consent form. All individuals were aware of the right they had to discontinue or refuse their participation in the context of the ethical standards of the Helsinki Declaration. Ethical permission for this study was gained from the health centers. The study was conducted between March 2023 and April 2023.

Procedure

Day-1 was the initial assessment in which all participants completed the Greek version of the SEAMS questionnaire under the direction of one of the individuals of the research

team. Seven days after the first appointment day, the SEAMS was re-completed by all the participants. Between the two assessments, no variation was recorded in individuals' clinical condition and no therapeutic interventions took place (Theofilou et al., 2013).

Data Analysis

A $p<0.05$ was considered to be a statistically significant value. All statistical analyses were performed with the use of the Statistical Package for the Social Sciences (SPSS 25.0 for Windows). Shapiro Wilk test was conducted so as to check if the values of the sample present a normal distribution.

To examine which the variability is among the 16 items and the total score and to recognize if any of these items of the questionnaire did not indicate a positive monotonic trace when they plotted compared to the total score, item analysis of the SEAMS was used based on the mean and standard deviation data of the SEAMS items from day-1 (the initial assessment) (Theofilou et al., 2013).

The reliability of the SEAMS was measured by assessing the internal consistency, repeatability, and test-retest reliability of the instrument. Internal consistency assesses how well different questions (items) testing the latent construct of the instrument should yield consistent results. The internal consistency of the psychometric tool was assessed with the use of the Cronbach's alpha coefficient (Cronbach's a) and based on the data obtained from the initial assessment. A threshold value of 0.70 was chosen, indicating sufficient reliability for research purposes. In the present study, "Cronbach's a if item deleted" was additionally used to assess the internal consistency of the SEAMS. Repeatability can be defined as the presented stability regarding participants' replies over time. Consequently, it refers to the ability of the tool to give reliable outcomes whenever it is used.

SEAMS repeatability was determined by using the Spearman correlation coefficient (Spearman's r) between baseline and re-assessment total scores of the psychometric tool. Spearman correlation coefficient values were determined as follows: 0.00-0.19 = very weak correlation.0.20-0.39 = weak correlation.0.40-0.69 = moderate correlation.0.70-0.89 = strong correlation and 0.90-1.00 = very strong correlation. Test–retest reliability of the instrument was defined as the extent to which participants maintained their opinion on repeated measurements of the SEAMS questionnaire, accounting for measurement error as a percentage of total variance. Test–retest reliability was assessed using the intraclass correlation coefficient (ICC) with 95% confidence interval (CI). The ICC, which is the most appropriate statistical test for assessing reliability, ranges from 0 to 1, with 1 indicating perfect reliability. Cronbach's a and ICC correlations were characterized as follows: 0.00-0.25 = little reliability, if any, correlation.0.26-0.49 = low reliability; 0.50-0.69 = moderate reliability; 0.70-0.89 = high reliability and 0.90-1.00 = excellent reliability. In addition, the scores of the two assessments were tested for systematic differences using the paired t-test, because the ICC does not correct for systematic differences and agreement by chance (Theofilou et al., 2013). Finally, the convergent validity of the SEAMS was assessed by examining the correlations between the scale's total score and item scores at baseline. Acceptable convergent validity should be indicated by high or excellent (0.70 to 1.00) domain correlations for all pairs of items. This would provide evidence that all SEAMS items relate to the same construct (Theofilou et al., 2013).

Results

Descriptives

The values of the total cohort did not pass the test of the normality distribution ($p<0.05$). At first assessment (day 1) and the reassessment (day 7), 36 individuals completed the questionnaire. The mean SEAMS total score (day 1) was 45.38 (SD ± 3.97), ranging from 29.00 to 48.00. There were no missing values for the SEAMSscore. At the second assessment (day 7), all participants completed again the questionnaire and the mean SEAMS total score was found to be 45.33 (SD±4.42), ranging from 29.00 to 48.00.

Item Analysis

Item analysis for the SEAMS instrument confirmed that all items indicated a positive monotonic trace when they were plotted in contradiction of the total score. Item analysis statistics are presented in table 1, with item means (average response for each item) ranging from -2.69 (item 5) to 2.97 (items 1 and 2 respectively). There was also a good variability in relation to the means (SDs ranged from 0.167 to 0.577) (table 1).

	N	Minimum	Maximum	Mean	Std. Deviation
SEAMS 1	36	2	3	2,97	,167
SEAMS 2	36	2	3	2,97	,167
SEAMS 3	36	2	3	2,83	,378
SEAMS 4	36	2	3	2,86	,351
SEAMS 5	36	1	3	2,69	,577
SEAMS 6	36	1	3	2,81	,401
SEAMS 7	36	2	3	2,72	,454
SEAMS 8	36	2	3	2,78	,485
SEAMS 9	36	1	3	2,81	,467
SEAMS 10	36	1	3	2,75	,500
SEAMS 11	36	1	3	2,92	,368
SEAMS 12	36	1	3	2,86	,424
SEAMS 13	36	1	3	2,78	,540
SEAMS 14	36	1	3	2,92	,280
SEAMS 15	36	2	3	2,83	,447
SEAMS 16	36	1	3		

Table 1: Item Analysis of the SEAMS

Reliability

The internal consistency of the SEAMS was very satisfactory, with an overall Cronbach's a reaching 0.880, ranging between 0.861 (item 11) and 0.890 (item 15) (table 2). All the values

were higher than the chosen threshold value of 0.7, indicating that all SEAMS items are interdependent and homogeneous in terms of the construct they measure.

	Scale Mean if Item Deleted	Scale Variance if Item Deleted	Corrected Item-Total Correlation	Cronbach's Alpha if Item Deleted
SEAMS 1	42,42	14,879	,685	,874
SEAMS 2	42,42	14,879	,685	,874
SEAMS 3	42,56	14,025	,572	,871
SEAMS 4	42,53	14,313	,509	,873
SEAMS 5	42,69	13,418	,482	,877
SEAMS 6	42,50	13,743	,638	,868
SEAMS 7	42,58	13,393	,760	,863
SEAMS 8	42,67	13,829	,519	,873
SEAMS 9	42,61	14,416	,309	,883
S E A M S 10	42,58	14,136	,408	,878
S E A M S 11	42,64	12,809	,762	,861
S E A M S 12	42,47	13,628	,744	,864
S E A M S 13	42,53	13,913	,535	,872
S E A M S 14	42,61	12,759	,709	,863
S E A M S 15	42,47	15,856	-,066	,890
S E A M S 16	42,56	13,797	,539	,872

Table 2: Internal consistency of the SEAMS

The Wilcoxon Signed Ranks Test (non parametric of paired samples t-test) between the SEAMS total score at the first and the second assessment indicated no statistically significant difference, (p=0.888, table 3). The tests of Spearman's r and the ICC respectively showed excellent correlations between the two stages of the first assessment and the second one (table 3). Our results indicated that the total score of the SEAMS was remarkably consistent between the two measurements.

Property	Measure	Value	Significance
Internal consistency	Cronbach's *a*	0.880	-
Repeatability	Spearman's *r*	0.967	<0.001
Test-retest reliability I	ICC (95%CI)	0.964	<0.001
Test-retest reliability II	Wilcoxon Signed Ranks Test	45.38±3.97a 45.33±4.42b	NS (p=0.888)

Table 3: Reliability properties of the SEAMS

ICC=intraclass correlation coefficient; [a]SEAMS at initial assessment; [b]SEAMS at re-assessment; NS= non-Significant

Convergent Validity

Table 4 summarizes the correlations between the SEAMS total score and the item scores of the questionnaire at the first assessment (items - total score correlations). All items showed acceptable correlation coefficients, extending from 0.004 (item 15) to 0.813 (item 11), indicating that SEAMS items were related to the same construct.

	Spearman's *r*
SEAMS 1	0.00
SEAMS 2	0.00
SEAMS 3	0.00
SEAMS 4	0.00
SEAMS 5	0.00
SEAMS 6	0.00
SEAMS 7	0.00
SEAMS 8	0.00
SEAMS 9	0.01
SEAMS 10	0.00
SEAMS 11	0.00
SEAMS 12	0.00
SEAMS 13	0.00
SEAMS 14	0.00
SEAMS 15	0.98
SEAMS 16	0.00

Table 4: Convergent validity of the SEAMS (item-total score correlations)

Discussion

This is the first study to examine the psychometric properties of the SEAMS questionnaire in a Greek population cohort. The constructed Greek version of the SEAMS was tested in chronic disease patients and was found to have excellent repeatability, very high test-retest reliability, very good internal consistency and satisfactory convergent validity properties.

The standardized methods used in all phases during the cross-cultural adaptation of the original SEAMS scale and the random selection of participants from a well-defined and homogeneous target population are important strengths of this study. Further, exploring the reliability of the SEAMS instrument using four

standard statistical measures added statistical strength to the results of the current study.

Conclusion

The findings of the study indicate that the Greek version of SEAMS showed very good psychometric properties supporting that it can be used within not healthy populations and in the context of national medication compliance measurement. These findings are confirmed by other relevant studies (Jessica Risser et al., 2007; Dong et al., 2016; Sjoe et al., 2019; Pratama et al., 2022).

Nevertheless, a potential limitation takes place associated with the present study. The SEAMS was examined for reliability and validity in a small number of patients. Therefore, it is necessary to lengthen the study of the instrument's psychometric properties to more groups and participants. An ongoing study by the same research team will aim at the documentation of the validity properties of the SEAMS questionnaire.

Ethic Approval and Consent to Participate

Permission was obtained from the health centers to conduct the research.

Human and Animal Rights

No animals were used for studies that are the basis of this research. All the humans were used in accordance with the ethical standards of the committee responsible for human experimentation (institutional and national), and with the Helsinki Declaration of 1975, as revised in 2013 (http://ethics.iit.edu/ecodes/node/3931).

Consent for Publication

Informed consent was obtained from all participants of this study.

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