

RESEARCH ARTICLE (ORIGINAL) 

Evaluation of the psychometric properties of the Treatment Self-Regulation Questionnaire for chronic diseases

Avaliação das propriedades psicométricas do Questionário de Autorregulação para o tratamento medicamentoso na doença crónica

Evaluación de las propiedades psicométricas del Cuestionario de Autorregulación para el tratamiento con medicamentos en enfermedades crónicas

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Abstract

Background: The promotion of the management of the therapeutic regimen in people with chronic disease implies reliable and valid measures to assess motivation for treatment.

Objective: To assess the psychometric properties of the Portuguese version of the Self-Regulation Questionnaire (SRQ) of the medication treatment in a sample of people with chronic disease.

Methodology: A methodological study was conducted using the Confirmatory Factor Analysis (CFA). The sample was comprised of 189 people with chronic disease.

Results: A three-factor solution of the SRQ showed poor fit to the model, thus a four-factor solution was suggested. The convergent validity was confirmed by associations between autonomous motivation, perceived competence and perception of a therapeutic environment that promotes autonomy, and adherence to medication. The reliability analysis showed satisfactory internal consistency values ranging between 0.56 and 0.90.

Conclusion: The instrument shows good reliability and validity to assess self-regulation of the treatment regimen in people with chronic disease.

Keywords: validation studies; factor analysis, statistical; chronic disease; self-regulation

Resumo

Enquadramento: A promoção da gestão do regime terapêutico em pessoas com doença crónica, requer medidas fiáveis e válidas, para avaliação da motivação para o tratamento.

Objetivo: Avaliar as propriedades psicométricas da versão portuguesa do Questionário de Autorregulação (QAR) para o tratamento medicamentoso, numa amostra de pessoas com doença crónica.

Metodologia: Estudo metodológico, com recurso à análise fatorial confirmatória (AFC). Participaram 189 pessoas com doença crónica.

Resultados: A solução trifatorial do QAR não mostrou bom ajustamento ao modelo, pelo que é proposta uma solução de quatro fatores. A AFC mostrou um ajuste muito satisfatório nos índices de adequação do modelo. A validade convergente foi confirmada por associações entre a motivação autónoma, competência percebida e perceção de um ambiente terapêutico promotor da autonomia, e com a adesão aos medicamentos. A análise de confiabilidade mostrou valores de consistência interna que variam entre 0,56 e 0,90.

Conclusão: O instrumento demonstra ser uma medida fiável e válida para a avaliação da autorregulação ao tratamento medicamentoso em pessoas com doença crónica.

Palavras-chave: estudos de validação; análise fatorial; doença crónica; autorregulação

Resumen

Marco contextual: La promoción de la gestión del régimen terapéutico en personas con enfermedad crónica requiere de medidas fiables y válidas para evaluar la motivación hacia el tratamiento.

Objetivo: Evaluar las propiedades psicométricas de la versión portuguesa del Cuestionario de Autorregulación (*Questionário de Autorregulação - QAR*) para el tratamiento con medicamentos en una muestra de personas con enfermedad crónica.

Metodología: Estudio metodológico, en el que se recurrió al análisis factorial confirmatorio (AFC). Participaron un total de 189 personas con enfermedad crónica.

Resultados: La solución trifatorial de QAR no mostró un buen ajuste al modelo, por lo que se propone una solución de cuatro factores. El AFC mostró un ajuste muy satisfactorio en los índices de adecuación del modelo. La validez convergente se confirmó por asociaciones entre la motivación autónoma, la competencia percibida y la percepción de un ambiente terapéutico que promueve la autonomía, y con la adhesión a los medicamentos. El análisis de fiabilidad mostró valores de consistencia interna que oscilan entre 0,56 y 0,90.

Conclusión: El instrumento demuestra que es una medida fiable y válida para la evaluación de la autorregulación al tratamiento con medicamentos en personas con enfermedad crónica.

Palabras clave: estudios de validación; análisis factorial; enfermedad crónica; autorregulación



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Introduction

Patients with chronic diseases have difficulties in adhering to prescribed therapeutic regimens (Chase, Bogener, Ruppert, & Conn, 2016). In chronic disease, the low adherence to treatment is associated with poor symptom control, deterioration of the clinical condition, increased hospital admissions, and higher costs for the health system. In Portugal, two of the most common chronic diseases are type 2 diabetes and heart disease (Ministério da Saúde, 2018). These chronic diseases have a complex therapeutic regimen with similar characteristics, particularly because it includes both a pharmacological and a non-pharmacological component. This study focuses on the medication regimen for chronic diseases.

Motivation has been studied as a relevant factor for therapeutic adherence in chronic diseases, with the Self-Determination Theory (SDT) being the most relevant framework (Levesque et al., 2007).

In order to determine the type of motivation underlying a given behavior, the authors of SDT built the Treatment Self-Regulation Questionnaire (TSRQ). This instrument allows for the collection of relevant data for the implementation of nursing diagnoses, thus leading to the development of adherence-promoting interventions. TSRQ is often used in international research studies on the motivation of people with chronic diseases (Kálczai-Jánosi, Williams, & Szamosjőzi, 2017), thus being important to validate this instrument for the Portuguese population. The objective of this study is to evaluate the psychometric properties of the Portuguese version of the TSRQ (*Questionário de Autorregulação para o Tratamento - QAR*) in a sample of people with chronic diseases.

Background

The medication regimen in people with chronic diseases is generally required for life. Medication adherence is defined as the person's behavior of taking medication as prescribed. There is evidence of medication non-adherence in people with coronary artery disease (Chase et al., 2016) and in people with type 2 diabetes (Giugliano, Maiorino, Bellastella, & Esposito, 2019), with a negative impact on the progression of these diseases. The intervention for improving medication adherence is a need identified in these studies; however, it is not an easy task. For example, a study on the effectiveness of the Medicare Shared Savings Program (MSPP) found that the adherence to oral antidiabetic drugs in patients with cardiovascular disease and diabetes has remained unchanged for six years (McWilliams, Najafzadeh, Shrank, & Polinski, 2017). Given the complexity of the treatment adherence process in chronic illness, SDT can offer new perspectives on evaluation and intervention. According to this theoretical model, it is important to attend to the patient's experience and motivation because the maintenance of behaviors over time requires that patients internalize values and skills for change, and experience determination (Ryan, Patrick, Deci, & Williams, 2008). For example, a sys-

tematic review of SDT-based interventions in patients with type 2 diabetes concluded that the majority of the interventions resulted in health benefits, even though the behaviors tended to maintain over time when motivation is autonomous (Phillips & Guarnaccia, 2017).

SDT provides an integrated conception of motivation. This theory proposes a continuum of three types of motivation: autonomous motivation, behaving with a sense of volition and choice; controlled motivation, behaving in response to an external or internal pressure; amotivation, which reflects a lack of intent to act because the person does not value the behavior or does not feel competent to perform it (Deci & Ryan, 2008). According to SDT, there are two forms of regulation in controlled motivation: external regulation, in which the behavior occurs in response to external pressure to get a reward or avoid negative consequences, and introjected regulation, in which the behavior results from internal pressures such as guilt, anxiety, or to receive praise (Deci & Ryan, 2008; Denman, Baldwin, Marks, Lee, & Tiro, 2016). When people are autonomously motivated, they commit more to behavioral changes, are more persistent and efficacious than when they are externally motivated (Deci & Ryan, 2012). One aspect that complicates therapeutic adherence in chronic diseases is that the behaviors that people are advised to adopt are not inherently pleasurable (Phillips & Guarnaccia, 2017).

In order to assess motivation, Ryan and Connell built the TSRQ, which has been modified and adapted to assess various health behaviors (Levesque et al., 2007). It was also adapted to the Portuguese population for different types of health behaviors, such as healthy eating in people from the community (Almeida & Pais Ribeiro, 2013), physical exercise in patients with chronic fatigue (Marques, De Gucht, Maes, Gouveia, & Leal, 2012), and smoking cessation in patients with heart disease (Rocha, Guerra, Lemos, Maciel, & Williams, 2017).

The four-factor structure of TSRQ was confirmed by Levesque et al. (2007) in different contexts and health behaviors (smoking, diet, and exercise), with factor loadings ranging from 0.33 to 0.97. In their study, the confirmatory factor analysis (CFA) found absolute and relative indices, which reflect an excellent fit: the Comparative Fit Index (CFI) ranged from 0.94 to 0.97, the Goodness of Fit Index (GFI) ranged from 0.89 to 0.94, and the Root Mean Square Error of Approximation (RMSEA) ranged from 0.60 to 0.09. However, to date, it is unknown whether a study has been conducted to validate this questionnaire for medication adherence in Portuguese adults with chronic diseases. Several changes have been suggested by different authors since its initial version developed with healthy adults and a four-factor structure. A recent perspective has considered that external regulation and introjected regulation are part of a single dimension, called controlled motivation (Marques et al., 2012). Another factor that varied across the multiple versions of the questionnaire is associated with the amotivation subscale, which was eliminated in several versions of the questionnaire (Denman et al., 2016; Marques et al., 2012). However, this subscale tends to be used when the

analyzed behaviors are associated with the initiation or maintenance of a medical treatment (Życińska, Januszek, Jurczyk & Syska-Sumińska, 2012).

In view of the above, this study used the four-factor version: Autonomous Motivation, External Regulation, Introjected Regulation and Amotivation.

The person's confidence in their ability to maintain the prescribed treatment (perceived competence) and their perception of the autonomous support provided by health professionals (perception of the therapeutic environment) are essential in promoting their autonomy and treatment adherence (Deci & Ryan, 2008; Phillips & Guarnaccia, 2017; Rocha et al., 2017). For this reason, these variables are also studied in this study, more specifically in the assessment of the convergent validity of TSRQ.

Research hypothesis

The factor structure of TSRQ has satisfactory psychometric properties for assessing motivation for medication adherence in chronic disease.

Methodology

A methodological study was conducted with people with chronic diseases (type 2 diabetes and heart disease). Taking into account Maroco's recommendations (2014) on sample size requirements for structural equation modeling (to ensure sufficient variability for estimating the model's parameters), 10 to 15 observations are required for each variable and at least five observations for each parameter. Thus, it is estimated a sample size of at least 150 participants, although the total sample was composed of 189 subjects.

The sampling method was accidental. People with diabetes were recruited through an endocrinology consultation at a university hospital in Porto and people with heart disease were recruited through a cardiology consultation at a university hospital in Porto and a private hospital unit in the northern region of Portugal. The following inclusion criteria were applied: diagnosis of type 2 diabetes or heart disease for at least one year, aged over 18 years, knowing how to read and write in Portuguese, and agreeing to participate in the study. Participants with cognitive impairment preventing them from understanding and completing the questionnaire were excluded from the study.

The following four instruments were used in this study: The TSRQ was adapted by Almeida and Pais Ribeiro (2013) based on the TSRQ version made available by the author, Edward Deci, at <http://selfdeterminationtheory.org/>. The questions were adapted to the treatment of diabetes and heart diseases. This instrument assesses the person's motivation to maintain their medication treatment based on three types of motivation: Autonomous Motivation, Controlled Motivation, and Amotivation. The questionnaire is composed of 15 items (statements) rated on a Likert scale ranging from 1 (*not at all true*) to 7

(*very true*). Almeida and Pais Ribeiro (2013) obtained the following Cronbach's alpha values for the three subscales: 0.84 for Autonomous Motivation, 0.79 for Controlled Motivation, and 0.56 for Amotivation.

The Perceived Competence Scale was developed by Edward Deci (available at <http://selfdeterminationtheory.org/>) and adapted to the Portuguese population by Almeida and Pais Ribeiro (2013). This instrument assesses the extent to which individuals feel confident in their ability to maintain a given behavior, in this case, to carry out the prescribed treatment. This scale is composed of four statements rated on a Likert scale ranging from 1 (*not at all true*) to 7 (*very true*). It has a unidimensional structure, where the total score is obtained through the mean of the scores obtained in the four items. The higher the score, the more confident the person feels to maintain that behavior. Almeida and Pais Ribeiro (2013) found a Cronbach's alpha coefficient of 0.90.

The Portuguese version of the 6-item Health Care Climate Questionnaire which was adapted to the Portuguese population by Lemos and Garrett (2013) was used in this study. This questionnaire assesses the individual's perception of the support provided by the healthcare practitioners, that is, if the health care provider uses mostly an autonomy-supporting or controlling approach. The scale is composed of six statements rated on a Likert scale ranging from 1 (*strongly agree*) to 7 (*strongly disagree*). The authors of the Portuguese adaptation found a Cronbach's alpha coefficient of 0.91 (Lemos & Garrett, 2013).

The Reported Adherence to Medication Scale was adapted to the Portuguese population by Pereira and Silva (1999). This instrument measures the levels of medication adherence, including the frequency by which patients adjust or change the prescribed dosages (Pereira & Silva, 1999). In the study of adaptation of this instrument, the Cronbach's alpha coefficient was 0.71 (Pereira & Silva, 1999). This 4-item instrument is rated on a 5-point Likert scale. The first two items, after item inversion, are rated from 1 (*strongly agree*) to 5 (*strongly disagree*). The last two items are rated from 5 (*never*) to 1 (*almost always*). The total medication adherence score is obtained by summing the answers to the four items, with the total scores ranging from 4 to 20 and the higher scores indicating higher levels of adherence.

The participants were contacted while waiting for their hospital appointment. They were informed about the objective of the study and the voluntary nature of their participation. They were also informed that they could withdraw at any time and that their care would not be compromised if they decided not to participate. The questionnaires were completed in the waiting room. The study was approved by the ethics committees of the institutions involved, under reference nº4143 and permission dated 3/11/2014. Data were analyzed using IBM SPSS Statistics, version 24. To check if the three-factor model fits the type of motivation to treatment among chronic patients, confirmatory factor analyzes were performed using its covariance matrix and a multivariate analysis using AMOS (version 24.0, IBM SPSS). The reflexive model under analysis included 15 observed variables and

four latent variables. To estimate the parameters of each item, the variance was set at 1.

Univariate and multivariate normality was determined by analyzing the skewness and kurtosis values and the existence of outliers was assessed using Mahalanobis distance. The maximum likelihood estimation method was used. Local fit was assessed by examining factor loadings and the reliability coefficients of each item. Composite reliability and mean extracted variance for each factor were assessed as described by Maroco (2014). In addition to modification indices, model fit was based on the underlying theoretical considerations and recommendations of Kline (2010).

Fit indices used in this study were: GFI, CFI, RMSEA, normed chi-square (χ^2/df), Root Mean Square Residual (RMR), and the Expected Cross-Validation Index (ECVI). A p -value less than 0.05 was considered statistically significant. The internal consistency of the instruments was determined using Cronbach's alpha coefficient. Convergent validity was assessed through the correlation with two other measures of motivational variables, the perception of an autonomy-supportive therapeutic environment, and perceived competence, as well as through the association with medication adherence. Discriminant validity was assessed through intercorrelations between subscales (Denman et al., 2016).

Results

The sample included 143 participants (75.6%) with a diagnosis of type 2 diabetes and 46 participants (24.4%)

with a diagnosis of heart disease, mostly males ($n = 107$; 57%) and married ($n = 133$; 70%). Participants were aged between 21 and 84 years, with around half of the sample being under 57 years of age ($M = 55.86 \pm 14.22$). Most of the participants did not work and 20.3% of the 66 (34.9%) participants who had a professional activity were on medical leave. Participants had attended school on average for eight years ($M = 7.97 \pm 4.64$), ranging from 2 to 21 years.

Confirmatory Factor Analysis

A CFA was conducted to test if the three-factor model (as described in the Methodology section) fit the empirical model. No skewness values $< |3|$ and kurtosis values $< |10|$ values were found, thus multivariate normality was accepted. The results represented in model 1 showed a poor fit (Table 1).

The analysis of parameter estimates revealed that only the Amotivation and Controlled Motivation factors were highly correlated and that some standardized indices did not load on the respective factor. Item 2 ("because I would feel guilty or ashamed if I did not follow treatment") and item 7 ("because I would feel bad about myself if I did not follow treatment") showed low factor loadings (0.21 and 0.09, respectively) and residuals of the standardized covariance matrix with values above 2.58. Although these items could have been deleted, their clinical value was acknowledged and the four-factor model (Amotivation, External Regulation, Introjected Regulation, and Autonomous Motivation) described by Levesque et al. (2007) and represented in model 2 (Figure 1) was tested.

Table 1

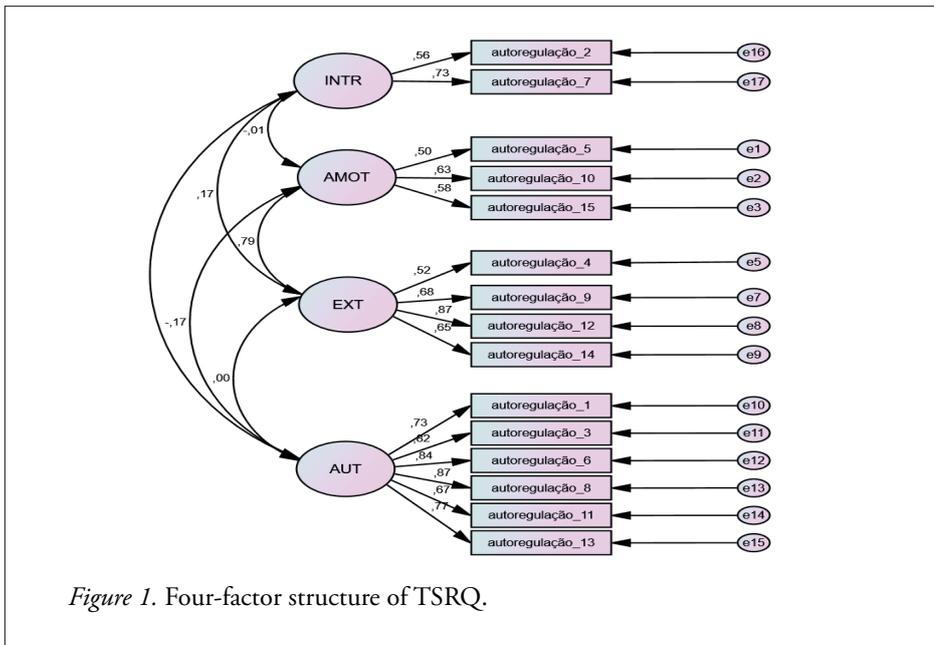
Indices of fit to the tested factor models

	χ^2/df	RMR	GFI	CFI	RMSEA	ECVI
Model 1	3.31	0.42	0.82	0.83	0.11	1.88
Model 2	2.09	0.29	0.89	0.92	0.08	1.48

Note. χ^2/df = Normed chi-square; RMR = Root Mean Square Residual; GFI = Goodness of Fit Index; CFI = Comparative Fit Index; RMSEA = Root Mean Square Error of Approximation; ECVI = Expected Cross Validation Index.

Thus, model 2 obtained good fit indices, as can be seen in Table 1. External Regulation and Autonomous Motivation emerge as independent factors and Amotivation

and Introjected Regulation also tend to become independent factors.



Reliability

Cronbach's alpha coefficients for internal consistency ranged from 0.56 in Introjected Regulation, 0.60 in Amotivation, 0.76 in External Regulation, to 0.90 in Autonomous motivation. Taking into account that the first factor only has two items, it can be assumed that the Portuguese version of TSRQ has acceptable reliability.

Convergent validity

Table 2 shows the analysis of the correlation matrix of

TSRQ with perceived competence, therapeutic environment, and medication adherence. Autonomy had a positive, moderate, and statistically significant correlation with perceived competence ($r = 0.664$; $p = 0.001$) and the perception of an autonomy-supportive therapeutic environment ($r = 0.487$; $p = 0.0001$), and a low to moderate correlation with medication adherence ($r = 0.331$; $p = 0.0001$).

Table 2

Correlations between TSRQ and the perception of the therapeutic environment, perceived competence, and medication adherence, and intercorrelations between the different types of motivation

	Perceived competence	Therapeutic environment	Medication adherence	Introjected	Amotivation	External
Therapeutic environment	0.51**					
Medication adherence	0.38**	0.21**				
Introjected	0.35**	0.27**	0.14			
Amotivation	-0.20**	-0.06	-0.02	-0.04		
External	-0.03	0.04	-0.03	0.20**	0.50**	
Autonomous	0.66**	0.49**	0.33**	0.56**	-0.13	0.07

Note. **Correlation is significant at 0.01 (2-tailed).

Discussion

The results of this study do not confirm the validity of the three-factor model of TSRQ for assessing chronic patients' motivation to follow their treatment plan. Based on the analysis of the fit indices obtained for the three-factor model and the behavior of the original items of the Introjected Regulation dimension, a second model was tested with the

structure proposed by Levesque et al. (2007). This second solution added a fourth factor - Introjected Regulation - and proved to have a good fit in absolute fit indexes (RMR and GFI), relative fit indices (CFI), population discrepancy indices (RMSEA), and the expected cross-validation index (ECVI). A review of previous studies found that the items representing Introjected Regulation often raise psychometric problems, for which reason some authors have deleted

them from the questionnaire (Życińska et al., 2012). In a study with people with type 2 diabetes and heart disease whose results did not confirm the three-factor structure, the authors decided to use a two-factor structure: Autonomous Motivation and External Regulation, excluding Introjected Regulation (Życińska et al., 2012). The results of the present study are in line with those found by Levesque et al. (2007), confirming that the four dimensions of motivation are appropriate for assessing the behavior of adherence to the medication regimen in people with chronic disease, namely type 2 diabetes and heart disease.

The analysis of the internal consistency of the four factors in this sample somehow reinforces the adequacy of the solution proposed in previous studies (Levesque et al., 2007) to the extent that the findings revealed suitable values for the subscales of Autonomous Motivation and External Regulation and less satisfactory values for the other dimensions. These results seem to indicate with some robustness that there are two types of motivation regarding the long-term maintenance of the medication regimen in type 2 diabetes and heart disease, namely Autonomous Motivation, which promotes adherence to the medication regimen, in opposition to External Motivation, which complicates this process.

The analysis of the intercorrelations between subscales, which are often used as a measure of divergent validity, obtained more surprising results. Theoretically, it would be expected that Autonomous Motivation would negatively correlate with External Regulation (Życińska et al., 2012), which did not happen. In fact, no statistically significant correlation was found between both types of motivation. Interestingly, introjected regulation showed statistically significant positive correlations with both Autonomous Motivation and External Regulation, which, in our opinion, reinforces the adequacy of the SDT model that suggests various levels of extrinsic motivation along a progressively more self-regulated continuum where introjected regulation is transitioning to a more autonomous motivation (Ryan & Deci, 2000). The motivation to maintain a medication regimen for these pathologies might be influenced by multiple factors: the desire to control the disease that leads the patient to follow the advice of the doctor who prescribes the treatment; the recognition that maintaining a good health is important to the performance of family and occupational roles; and the patient's satisfaction with feeling that they are being able to manage their disease.

Although this study provides a useful tool for clinical practice, there are some limitations such as the fact that the pharmacological treatment of both diseases (type 2 diabetes and heart disease) involves a different set of skills and knowledge. Moreover, only two chronic diseases were studied and the participants were at different stages of treatment, and it is known that motivation to follow treatment may vary depending on the time of diagnosis, the phase of exacerbation, and the presence and severity of symptoms. Hence, this model should be tested with new and more representative samples, preferably randomized samples, in other contexts of chronic disease. Future studies should also analyze the different types of motivation to begin a non-pharmacological treatment.

Conclusion

The TSRQ model with the best fit index was the four-factor model, which allows distinguishing the type of motivation (Amotivation, External Regulation, Introjected Regulation, and Autonomous Motivation) of patients with chronic illness to follow their medication treatment. This study provides a useful tool for healthcare professionals to explore the role of motivation in the adherence to the medication treatment in chronic diseases. The results of the TSRQ application provide relevant data for nursing diagnosis and intervention.

Author contributions

Conceptualization: Lima, L., Bastos, C., Barroso, C., Rocha, A. L., Regufe, V.

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Writing – review & editing: Lima, L., Bastos, C., Santos, C., Barroso, C., Rocha, A. L., Regufe, V., & Martins, T.

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