Adaptation and validation of the Measuring of Treatment Adherence for mental health

Letícia de Oliveira Borba, Fernanda Carolina Capistrano, Aline Cristina Zerwes Ferreira, Luciana Puchalski Kalinke, Maria de Fátima Mantovani, Mariluci Alves Maftum

\(^{1}\) Universidade Federal do Paraná. Curitiba, Paraná, Brazil.

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ABSTRACT

Objective: to adapt culturally and validate the Measuring Instrument of Treatment Adherence for mental health. Method: methodological study, carried out with 300 individuals with mental disorders, in two Psychosocial Care Centers in Curitiba, state of Paraná, Brazil, from April to June 2014. The cross-cultural adaptation was developed according to international recommendations, the construct validation was made by exploratory factor analysis, and internal consistency was verified by Cronbach’s alpha. Results: through the evaluation of a committee of experts and completion of the pre-testing, face and content validation was achieved. From the factor analysis, we identified two factors of the instrument’s construct: involuntary action and voluntary action, with a total explanation variance of 55.7%. The value of Bartlett’s test of sphericity was p<0.001. Cronbach’s alpha was 0.74. Conclusion: the adapted and validated instrument proved to be trustworthy to be applied to the verification of adherence to drug therapy for individuals with mental disorders.

Descriptors: Mental Health; Medication Adherence; Mental Disorders; Validation Studies; Nursing.

RESUMO

Objetivo: adaptar culturalmente e validar o instrumento de Medida de Adesão ao Tratamento para saúde mental. Método: estudo metodológico, realizado com 300 portadores de transtorno mental, em dois Centros de Atenção Psicossocial em Curitiba, Paraná, de abril a junho de 2014. Realizou-se a adaptação transcultural segundo recomendações internacionais, a validação de constructo por meio da análise fatorial exploratória e a verificação da consistência interna pelo alfa de Cronbach. Resultados: mediante avaliação de comitê de especialistas e realização do pré-teste, foi alcançada a validação de face e conteúdo. A partir da análise fatorial, foram identificados dois fatores do constructo do instrumento: ação involuntária e ação voluntária, com total da variação de explicação de 55,7%. No teste de esfericidade de Bartlett obteve-se p<0,001. O alfa de Cronbach geral foi de 0,74. Conclusão: o instrumento adaptado e validado mostrou-se fidedigno para ser aplicado na verificação da adesão à terapêutica medicamentosa por portadores de transtorno mental.

Descritores: Saúde Mental; Adesão à Medicação; Transtornos Mentais; Estudos de Validação; Enfermagem.

RESUMEN

Objetivo: adaptar culturalmente y validar el instrumento de Medida de Adhesión al Tratamiento para la salud mental. Método: estudio metodológico, realizado con 300 portadores de trastorno mental, en dos Centros de Atención Psicosocial en Curitiba, Paraná, de abril a junio de 2014. Se realizó la adaptación transcultural según recomendaciones internacionales, la validación de constructo a través del análisis factorial exploratorio, y la verificación de la consistencia interna por el alfa de Cronbach. Resultados: mediante evaluación de comité de especialistas y realización del pre-test, se logró la validación de cara y contenido. A partir del análisis factorial, se identificaron dos factores del constructo del instrumento: acción involuntaria y acción voluntaria, con total de la varianza de explicación del 55,7%. En la prueba de esfericidad de Bartlett se obtuvo p < 0,001. El alfa de Cronbach
INTRODUCTION

Mental disorders are a chronic health condition, manifested by different symptoms originated from a combination of atypical thoughts, emotions, and behaviors that can negatively impact the personal, familiar, and social spheres of individuals regardless of their socioeconomic class.1-2.

Treatment to individuals with mental disorders requires multiple interventions, such as psychotherapy, psychoeducation, occupational therapy, and use of medication. In this context, drug therapy, when properly prescribed, corresponds to the clinical needs of the individual, minimizing suffering, limitations, and the experienced physical and emotional wear.3-4.

Drug therapy in mental health, guided by the principle of rational use of medication, presents indisputable benefits, since its purpose is to recover the best state of health, reduce risks related to chronic diseases, relief symptoms, and reduce incapacities and relapses.4-5. However, the non-adherence to drug treatment is a real and worrying fact in clinical practice. Studies have shown the low adherence to drug treatment in mental health.6-8.

Adherence can be verified by direct and indirect methods. Direct methods are those that measure the concentrations of the medication or its metabolite in the blood, detecting a biological marker added to the medication.7-9. As for indirect methods, they include assessing the clinical response, counting of pills, and self-report with questioning the patient through interviews or questionnaires.7-9.

The measure of adherence by self-report is of easy applicability, since the direct methods of assessment are costly from an economic point of view and that the counting of pills involves at least two visits to individuals’ homes, depending on them to have kept the packaging of the medication in use.7-9.

Within this context is the Measuring Instrument of Treatment Adherence (MITA), adapted and validated by Artur Barata Delgado and Maria Luisa Lima in Lisbon, Portugal, in a study with 167 patients with chronic diseases.10 This instrument applies to many clinical and therapeutic contexts, as a result of its flexibility and adaptability, as well as being able to provide an outline of the profile of adherence to drug treatment to health professionals.10.

Thus, we identified that having an instrument to verify the adherence of individuals with mental disorders to drug therapy is essential to plan actions of care and deploy intervention strategies to prevent the costly complications arising from non-adherence. In addition, in the Brazilian context, we did not find studies that have adapted and validated the MITA for use in individuals with mental disorders. Therefore, it was considered appropriate to carry out this study.

OBJECTIVE

To adapt culturally and validate the Measuring Instrument of Treatment Adherence for mental health.
initiative, after feeling worse?; 5 – have you ever taken one or more pills for your disease, by your own initiative, after feeling worse?; 6 – have you ever interrupted the treatment for your disease for running out of the medication?; 7 – have you ever stopped taking the medication for your disease for any other reason but indication of the physician?

The answers to the seven items are obtained through a six-point Likert scale. The degree of adherence is obtained by adding the values of each answer (ranging from 1 to 6) and dividing by the total number of items. The obtained value is converted into a dichotomous scale (adherence and non-adherence). We considered as non-adherent to drug treatment individuals who obtain in the calculation of the arithmetic mean values from 1 to 4, concerning the answers “always”, “almost always”, “often”, and “seldom”. As for the ones who achieve in the calculation of total amount and division of the items values between 5 and 6, concerning the answers “rarely” and “never”, are considered adherents to the drug treatment.¹⁰

The original MITA, when participants answer the seven items in Likert scale, presents an acceptable internal consistency of 0.74 (Cronbach’s alpha). This consistency is maintained when converting the Likert scale to a dichotomous scale (Cronbach’s alpha of 0.75). However, when the answers to the seven items are given dichotomously, the internal consistency is lower (Cronbach’s alpha of 0.54). In addition, the responses on Likert scale showed higher values of specificity (0.73) and sensitivity (0.77), when compared to the dichotomous scale (0.53 of specificity and 0.73 of sensitivity).¹⁰

To culturally adapt the MITA, the international recommendations that seek to produce semantic, idiomatic, cultural, and conceptual equivalence between the original instrument and the adapted one were followed. Five steps are recommended for the cross-cultural adaptation of an instrument, namely: translation, synthesis of the translations, retranslation, evaluation by a committee of experts, and pre-test, depending on the scenario in which the instrument shall be applied. However, cross-cultural adaptation of the instrument in a pre-test must be performed, which involves the analysis of the adapted instrument on aspects of semantic, idiomatic, cultural, and conceptual equivalence by a committee of experts and the implementation of the instrument in a pre-test.¹¹

Thus, after authorization of its creators, the MITA was adapted for use in individuals with mental disorders, in the Brazilian context, being submitted to a committee of experts for analysis as to face validity. Ten experts were invited via e-mail, and we sent them a letter of invitation with the relevant clarifications, the original instrument, and the adapted version for evaluation. Ten experts accepted to participate in this phase, all with consolidated practical or academic experience in the area of mental health.

After the experts’ suggestions were gathered and analyzed, the items of MITA were rewritten and the instrument was sent again to the same experts for consensus. As they did not request new changes, the adapted version of the MITA, validated by the committee of experts, was applied to individuals with mental disorders through a pre-test.

The pre-test aimed to ensure the validity of the content of the adapted instrument. It was applied in March 2014 by ten trained interviewers to 30 people with mental disorders, aged over 18 years, who had prescriptions for medical products for their mental health treatment and resided in Curitiba or its metropolitan region.

It should be noted that during the pre-test the participants received a ruler with the six possibilities of reply contained in the MITA to facilitate the understanding and visualization of the options.

**Chart 1 – Scenarios that require cross-cultural adaptation**

<table>
<thead>
<tr>
<th>Need to use a questionnaire on a new population</th>
<th>Results in changes in:</th>
<th>Necessary adjustments:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Culture</td>
<td>Language</td>
</tr>
<tr>
<td>A. To use in the same population. Without any change in culture, language, or country of origin.</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>B. To use in immigrants established in the country of origin.</td>
<td>✓</td>
<td>-</td>
</tr>
<tr>
<td>C. To use in another country, but with the same language.</td>
<td>✓</td>
<td>-</td>
</tr>
<tr>
<td>D. To use in new immigrants who do not speak English, but in the same country of origin.</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>E. To use in another country and with another language.</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>

Source: Beaton; Bombardier; Guillemin; Ferraz.¹¹
After the respondents answered the seven items, we asked if they had some difficulty in understanding the questions, if they had any suggestions for change, and how they assessed the use of the ruler during the application of the adapted MITA. With the pre-test completed, a meeting was held between the interviewers and researchers responsible for the cross-cultural adaptation of the instrument, to evaluate the suggestions provided by the respondents and make the necessary changes in the final version of the MITA.

Analysis of results and statistics

After the application of the adapted MITA to 300 individuals with mental disorders, construct validity was carried out, by the exploratory factor analysis technique, and internal consistency was verified by Cronbach’s alpha. For the statistical tests, the data were organized in Microsoft Excel® and analyzed with the aid of the software IBM SPSS Statistics, v.20.0® for Windows®.

The method chosen for extraction of factors was principal components with rotation by the Varimax orthogonal method, extracting the factors corresponding to eigenvalues greater than or equal to 1. More than 42 individuals were used for each MITA item, higher number than the methodological recommendation of five patients per item, since the bigger the sample, the more reliable is the exploratory factor analysis.40-15

To verify the adjustment of the data to the exploratory factor analysis, the Kaiser-Meyer-Olkin test (KMO) and Bartlett’s test of sphericity were used. Reasonable values of KMO range between 0 and 1; the closer to 1 the better, with 0.5 being an acceptable limit. Bartlett’s test of sphericity is based on the chi-square statistic distribution, resulting in a significance value of less than 0.05.

After the data was adjusted to the exploratory factor analysis, the results of the variance explained by the extracted factors, the values of the KMO measures, the communalities, and the factor loadings were presented. The analysis of construct validity is ensured when the total variance explanation represents more than 50%.16

The proportion of explanation variance of the indicator by the identified factors (commonalities) must present acceptable values of at least 0.50.16,17. The correlation between the indicator and the extracted factor is represented by the factor loadings: values between 0.30 and 0.40 are considered minimal; between 0.50 and 0.70 are significant; and greater than 0.70 are indicative of a well-defined structure. As for residues, they are represented by the questions whose variance was not explained by the indicators, thus, it is not desirable that they are greater than 50%.16,17

The internal consistency of the instruments’ questions was evaluated by estimating the Cronbach’s alpha coefficient. As the internal consistency values vary according to each author, we considered satisfactory the value of 0.7. Values over 0.8 were considered of high internal consistency.14-15

RESULTS

Regarding the face validity of the instrument, there was consensus among the ten experts as to the items, ensuring its semantic, idiomatic, cultural, and conceptual coherence. Thus, few changes were made to the MITA regarding its written form. To facilitate the understanding, the insertion of the phrase “your mental disorder” was suggested, replacing “disease”, present in the original instrument items, as study participants could present comorbidities that also require the use of continuous medication, causing them to associate the questions about the use of medication to all drugs they used, and not exclusively to those prescribed for the treatment of mental health.

In item 3, “Have you ever stopped taking the medication for mental disorders, by your own initiative, due to feeling better”, it was suggested to add the term “by your own initiative”; and in item 5, “Have you ever increased the dosage of the medication for mental disorders, by your own initiative, after feeling worse?”, it was proposed to change the term “one or several pills” to “increased the dosage of the medication”, since the respondents could use medication in oral solutions as well as pills.

Regarding content validity, during the pre-test the respondents stated that they did not have any problems understanding the questions, and also evaluated the use of the rule as positive, as a facilitator of MITA implementation process. However, they requested that the term “your mental illness” was replaced by “mental disorder”, since the first could connote a matter of prejudice historically built concerning the people affected by this disease.

Thus, the MITA adapted, in its final version, is presented in Chart 2.

Regarding construct validity, from the model of exploratory factor analysis, two factors were extracted: involuntary action (2.81 eigenvalue) and voluntary action (1.08 eigenvalue), with 40.2% and 15.5% of variance, respectively, implying a total explained variance of 55.7%.

Bartlett’s test of sphericity indicated that the factor analysis of questions 1 to 7 can be performed properly (p < 0.001), i.e., the data obtained in the application of the instrument are adjusted to the exploratory factor analysis.

The questions that compose each of the factors, the values of the KMO measures, the communality, and factor loadings are shown in Table 1. The general value of KMO was 0.77 and, separately, all were above 0.5, considered an acceptable value, indicating that the applicability of the exploratory factor analysis to the existing data set is adequate. As for communality, item 6 of factor 1 and item 5 of factor 2 are slightly below the indicated value, and other items are above the indicated value as the minimum accepted by the literature (0.5). Regarding factor loading, items 1, 2, and 7 showed a well-defined structure (> 0.70) and items 3, 4, 5, and 6 were significant (from 0.50 to 0.70).

Concerning the method of extraction of the residues main components, we found 42.8% of residues greater than 0.10 and 57.1% greater than 0.05.

As for the reliability test, Table 2 presents the Spearman correlation coefficients between each two questions and between each question and the total points obtained from the sum of the points from the seven items. The item-item correlation ranged from 0.13 to 0.51, and item-total from 0.47 to 0.70.

The general estimated Cronbach’s alpha was 0.74. For the questions of factor 1, the coefficient was 0.63; for factor 2, 0.70, demonstrating good internal consistency.
**Chart 2 – Adapted version of the Measuring Instrument of Treatment Adherence**

<table>
<thead>
<tr>
<th>Construct</th>
<th>1 – Have you ever forgotten to take any of the medication for mental disorders?</th>
<th>2 – Have you ever neglected the time to take the medication for mental disorders?</th>
<th>3 – Have you ever stopped taking the medication for mental disorders, by your own initiative, due to feeling better?</th>
<th>4 – Have you ever stopped taking the medication for mental disorders, by your own initiative, after feeling worse?</th>
<th>5 – Have you ever increased the dosage of the medication for mental disorders, by your own initiative, after feeling worse?</th>
<th>6 – Have you ever interrupted the treatment for mental disorder for running out of the medication?</th>
<th>7 – Have you ever stopped taking the medication for mental disorders for any other reason but indication of the physician?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Always</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Almost always</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Often</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Sometimes</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Rarely</td>
<td>5</td>
<td>5</td>
<td>5</td>
<td>5</td>
<td>5</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>Never</td>
<td>6</td>
<td>6</td>
<td>6</td>
<td>6</td>
<td>6</td>
<td>6</td>
<td>6</td>
</tr>
</tbody>
</table>

**Table 1 – Analysis of the construct of the Measuring Instrument of Treatment Adherence (N = 300), Curitiba, Paraná, Brazil, 2014**

<table>
<thead>
<tr>
<th>Construct</th>
<th>KMO*</th>
<th>Communality</th>
<th>Factor loading</th>
</tr>
</thead>
<tbody>
<tr>
<td>Factor 1: involuntary action</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 – Have you ever forgotten to take any of the medication for mental disorders?</td>
<td>0.75</td>
<td>0.65</td>
<td>0.76</td>
</tr>
<tr>
<td>2 – Have you ever neglected the time to take the medication for mental disorders?</td>
<td>0.73</td>
<td>0.63</td>
<td>0.78</td>
</tr>
<tr>
<td>6 – Have you ever interrupted the treatment for mental disorder for running out of the medication?</td>
<td>0.85</td>
<td>0.40</td>
<td>0.60</td>
</tr>
<tr>
<td>7 – Have you ever stopped taking the medication for mental disorders for any other reason but indication of the physician?</td>
<td>0.74</td>
<td>0.69</td>
<td>0.82</td>
</tr>
</tbody>
</table>

| Factor 2: involuntary action                                              |      |             |                |
| 3 – Have you ever stopped taking the medication for mental disorders, due to feeling better? | 0.77 | 0.56 | 0.69 |
| 4 – Have you ever stopped taking the medication for mental disorders, by your own initiative, after feeling worse? | 0.82 | 0.50 | 0.70 |
| 5 – Have you ever increased the dosage of the medication for mental disorders, by your own initiative, after feeling worse? | 0.80 | 0.48 | 0.69 |

Note: general *KMO: 0.77
The validation of the instrument is characterized by the degree to which it measures what it intends to measure. It allows for verifying if there is adequacy between the studied phenomenon and the theoretical concept to be measured. Therefore, it is of vital importance for the effectiveness of the instrument in the sociocultural and language contexts, as well as for abstraction. In this sense, Bartlett’s test of sphericity pointed out that the analyzed data are favorable and well suited to the exploratory factor analysis. The suitability test of the sample with KMO values were considered very good for items 4, 5, and 6 of the MITA, and good for items 1, 2, 3, and 7, which indicates that the results of the exploratory factor analysis are suitable and capable of generalization.

With the exploratory factor analysis for the validation of the seven items that compose the MITA, it was possible to verify that the adapted instrument comprehends two constructs related to adherence to the drug therapy: involuntary action and voluntary action. This indicates that the adherence of not of an individual is not limited to his/her desire to use them or not, corroborating the idea that adherence is a multidimensional phenomenon and that does not depend solely on the patient, as it is a product of the interaction among the dimensions related to the patient, the health team/service, socioeconomic factors, and the proposed therapy.

The appropriate number of factors extracted can be confirmed by the total explained variance, as well as by the Kaiser criterion, in which the eigenvalues of both factors were greater than 1, representing the best way of correlation between the observed variables. Regarding the presence of over 50% of residues with values greater than 0.05, as well as the fact that the communality values of two items being below 0.5, it can be understood that they are not representative in their respective constructs, since they are below the minimum values indicated and, therefore, could be excluded. However, we decided to keep them and suggest that new study be carried out concerning the content of these indicators, because we understand that this is the most appropriate way to explain or understand the instrument’s content.

The general estimated Cronbach’s alpha coefficient was of 0.74, the same found in the original MITA, demonstrating an adequate internal consistency. Other studies that adapted and validated the MITA to be applied to patients with other chronic diseases in the Brazilian context, found alpha coefficients of 0.84 and 0.60.

It is known that the value of this coefficient is sensitive to the number of items, being higher when there is a greater number of them. However, even restricted to seven items, we understand that the reliability of the MITA is homogeneous, therefore, it properly measures what it intends to measure, in the case of this study, the adherence of individuals with mental disorder to drug therapy.

The correlation intensity between the instrument’s items (item-item) presented scores below 2.0, resulting in a low specific performance. However, the correlation between items and the total score highlighted adequate values, ensuring the ability of MITA to measure variations in adherence, making it an instrument with stability and equivalence.

The cross-cultural adaptation and construct validity of a self-report instrument to verify adherence to drug therapy for individuals with mental disorders may contribute to the clinical practice of mental health professionals, as well as to the research in the area, which lacks Brazilian studies of longitudinal design to better explain the associations found in cross-sectional studies.

The use of the adapted MITA in clinical practice can promote early identification of individuals with mental disorders not adhering to drug treatment, since it is easy to apply and to understand and provides reliable data about the use of medication for this clientele. This can directly impact on the quality of life of individuals with mental disorders, since non-adherence to drug treatment can increase hospitalizations/relapses, severity and frequency of crises, suicide risk, impairment of quality of life and cost of health services.

In addition, adherent individuals also require continuous monitoring regarding the use of medication. Adherence to drug therapy at a given time does not guarantee later adherence, since there are factors there are external to the will of the individual with a mental disorder regarding the use or not of the medication. It is not, therefore, a static relationship.

Non-adherence to the use of medication for people with mental disorders, when not properly identified by health professionals, can lead to the inclusion of other drugs in the drug treatment, increase of dosage or even replacement regarding the possible ineffectiveness of the formerly prescribed medication. These unnecessary settings can lead to consequences that compromise patient safety concerning the drug therapy.

Study limitations

As limitation, this study presents the indirect method of verification of adherence, which may result in overestimation of real adherence, since non-adherent individuals with mental disorders may state that they do take their medication, due to the difficulty or fear of making explicit to health professionals a questionable behavior pattern.

Contributions to the fields of nursing, health, or public policy

This study contributes to the fields of nursing, health and public policy in the sense of care and research, since the cross-cultural adaptation and validation of the MITA allow its application to individuals with mental disorders in the clinical context, aiming to identify early those individuals who do not make correct use of their medication, allowing strategies that promote adherence to drug therapy.
treatment and patient safety in drug therapy to be implemented, in addition to guiding towards the rational use of medication.

Regarding scientific research, it can be used as a tool in studies with different designs for verification of adherence to drug treatment in the field of mental health, given its easy application.

**CONCLUSION**

The results found show that the adapted MITA is a valid and reliable instrument to measure adherence to drug therapy of individuals with mental disorders, contributing to guide the practice of mental health professionals and as a research instrument concerning this theme.

The authors previously authorize the application of the adapted MITA to individuals with mental disorders, as long as authorship is mentioned.

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