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Brazilian adaptation of the questionnaire to assess adherence to treatment for arterial hypertension

ABSTRACT

OBJECTIVE: To describe the cross-cultural adaptation of the questionnaire evaluating adhesion to treatment for arterial hypertension from its original Spanish version to a Portuguese version, to be applied in Brazil.

METHODS: In order to establish conceptual, semantic and operational equivalents of the items, two independent translations to Portuguese, and two back-translations into Spanish were performed. The translations and back-translations were assessed for changes in referential and general meanings. The synthesis of the translations was applied in pre-tests with patients with arterial hypertension and/or diabetes, which were important to identify different problems and confirm earlier decisions.

RESULTS: In general, the second translation and back translation were evaluated more positively because the translation process did not affect the meanings in five of the twelve items of the questionnaire. Operational changes were made and a vignette with response options and an example included in the instrument facilitated application in interviews.

CONCLUSIONS: The results obtained in the process of evaluating the items' conceptual, semantic and operational equivalence allowed the construction of a Portuguese version of the MBG questionnaire to assess adherence to treatment which can be applied in the Brazilian context.

DESCRIPTORS: Hypertension, drug therapy. Medication Adherence. Translations.Questionnaires. Validation Studies.

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INTRODUCTION

Arterial hypertension and diabetes mellitus are among the most serious preventable health problems in Brazil. According to the Ministry of Health, 11% of the Brazilian population suffer from diabetes and 35% of the population aged over 40 have arterial hypertension.[a,b] These health problems are risk factors for cerebrovascular disease and ischemic heart disease and, if not properly treated, may lead to vascular, renal and cardiac complications, significantly reducing the subject's quality of life.[8]

Proper treatment for diabetes and hypertension may reduce or delay the appearance of these complication. However, once started, these are lifelong treatments which the patient needs to follow in order not to negatively affect their quality of life.

Failure to adhere to treatment for chronic illness is a worldwide public health problem. It is estimates that in developed countries the rate of adhering to treatment for chronic illnesses is as low as 50%.[12] Failure to follow treatment, as well as affecting the health of the individual, has an economic impact on the health system. In many cases, low adherence to treatment results in higher costs due to hospital admissions, including treating long term complications.[12] Failure to control a disease cannot be attributed solely to the failure to follow medical treatment. It can be assumed that this has a significant contibution,[7] and that it leads to an increase in direct costs for treating complications. However, in a country such as Brazil, with a public health system which needs to provide care for a population of almost 200 million people, it is essential that strategies are adopted to help improve adherence to medical treatment.

There are various methods of measuring adherence to treatment, but the lack of a gold standard makes it difficult to compare results found in the literature.[12] Structured interviews, usually in the form of questionnaires,[6] are one of the most common methods, due to the lower cost.

There is also a lack of consensus on the concept of adherence to treatment, whether this means simply complying with doctor's orders or whether the definition should be broader and include the individual's behavior during treatment.[2,6,11]

In 2003, the World Health Organization (WHO) proposed that adherence to long-term therapy be viewed as the "degree to which a person's behavior – taking medicine, following a diet and/or making lifestyle changes – corresponds to the doctor's recommendations"[12] which would indicate the patient's participation.

The aim of this article is to describe the stages of the transcultural adaptation of the adherence to arterial hypertension treatment questionnaire, developed in Spanish, for application in the context of Brazil.

METHODS

In order to evaluate adherence to treatment for arterial hypertension, the Martín-Bayarre-Grau (MBG) questionnaire, developed and validated by Alfonso et al,[5] was used.

The MBG questionnaire underwent an adaptation process in order for it to be applicable to the Brazilian context in the evaluation study of the the "Remédio em Casa Project" of the Prefeitura of Rio de Janeiro, in 2010, which aimed to study hypertension and diabetes patients' adherence to treatment, considered from the WHO perspective.

An operational system based on the model developed by Herdman et al,[3] described in Reichenheim & Moraes,[10] for the transcultural adaptation of instruments. The steps require the verification of six types of equivalence, including: conceptual, item, semantic, operational, measurement and functional. This last dispenses with specific tests or procedures, as their equivalents are found in the other stages of the assessment.

With regards to conceptual and item equivalence, the first step consists of exploring the construct in question in the place of origin and in the population with which the instrument will be used. This process includes a bibliographical revision of the processes involved in constructing the source instrument, as well as assessing the relevance of the items to capture each of these domains.[10]

The bibliographical references used by the authors of the original questionnaire, in the Cuban culture, were compared with those which underpin the concept of adherence used in the study applied in the Brazilian culture. This process also aimed to observe the relevance of the items in the MBG questionnaire to be applied in the context of hypertension and diabetes patients' adherence to treatment.

In addition to the researchers responsible for the transcultural adaptation of the instrument, specialists in the study of adherence also participated and thus

[a] Ministério da Saúde, Secretaria de Atenção à Saúde, Departamento de Atenção Básica. Diabetes Mellitus. Brasília (DF); 2006. (Cadernos de Atenção Básica, 16).
[b] Ministério da Saúde, Secretaria de Atenção à Saúde, Departamento de Atenção Básica. Hipertensão arterial sistêmica para o Sistema Único de Saúde. Brasília (DF); 2006. (Cadernos de Atenção Básica, 15).

broadened the discussion during the investigation of the instrument's conceptual and item equivalence. In another stage, representatives of the target population were consulted on their experiences of caring for arterial hypertension and diabetes and their general understanding of the instrument, these consultations, carried out by the principal researcher, served as the first contact with the target population, whose contributions would be more systematically collected and analyzed later in the pre-test stage.

The process of evaluating semantic equivalence involved translation, back-translation, evaluation of the back-translations and a pre-test of the synthesized version. It is recommended that the translation is carried out by someone bilingual whose mother tongue and culture are that into which the instrument is being translated.[10]

Two, independent translations of the MBG questionnaire from Spanish into Portuguese were carried out by Brazilians with a good mastery of Spanish, resulting in two versions translated into Portuguese (T1 and T2).

Next, T1 and T2 were back-translated into the original language, also independently. Respecting the recommendations with regards to the profile of the translators, this was done by translators whose mother tongue was Spanish and who had a good mastery of Portuguese, thus obtaining two back-translations into Spanish, R1 and R2, respectively.

The back-translated versions went through a formal evaluation in which a new, bilingual translator, a public health care professional, whose mother tongue was Spanish and with mastery of Portuguese, judged the equivalence of each with the original instrument. The evaluator was provided with two forms, in which they had to evaluate the semantic equivalence of the original instrument and each of the back-translations. Each form consisted of pairs of statements (one from the back-translation and one from the original instrument), for which the evaluator had to assess the semantic equivalence between the pair. In order to maintain the autonomy of the evaluation with regards to the translators and back-translators, the form did not indicate which statement was from the original version and which from the back-translation. Moreover, the pairs of statements appeared in random order.

This assessment covered referential and general meanings. The former refers to the denotative meaning of the words/expressions. If the referential meaning in the original instrument is the same as in the respective translation, it is presumed that there is a literal correspondence between them. The latter refers to the connotative meaning of each item in the original instrument, which was contrasted with that of the translation into the target language.[9,10]

The correspondence of the general or connotative meaning transcends the literal meaning of those terms and takes into account more subtle aspects, such as the impact the expression has in the cultural context of the target population, in contrast to the aim of analyzing the referential of denotative significance of the items. This analysis of general meaning is necessary as the literal correspondence of a term does not necessarily mean that the same emotional impact will be evoked in different cultures.[10] At the beginning of the evaluation form, there was an explanation for the translator on the difference between denotative and connotative meaning.

In order to evaluate the agreement between the items with regards to referential (denotative) meaning, the evaluator gave each pair of items a mark between zero and ten, which was directly proportional to their opinion as to the agreement between the pairs of statements. To evaluate the level of change in the general (connotative) meaning, the evaluator had to choose between the following options: unaltered, little altered, significantly altered or completely altered. Next, they had to justify in writing the score given for agreement, with regards to referential meaning and the classification of alteration of general meaning for each pair of statements.

The synthesized version of the instrument, obtained after evaluating the translations, was tested in order to fine tune it, as in this process of cultural adaptation, it is essential that a correspondence between the perception and the impact on the respondent is reached.[10]

Operational equivalence refers to the comparison between the aspects of using the instrument with the target and the source population, so that the efficacy is similar even if the modus operandi is not the same.[10]

The pre-tests were carried out through face to face interviews with 12 diabetic and/or hypertensive patients who were approached while waiting to be seen in the pharmacy of a health center in Rio de Janeiro, Southeastern Brazil, in 2010. The intention, therefore, was for the socio-demographic characteristics to be as similar as possible to those of the population to be interviewed in the study.

The items in the questionnaire were presented, one by one, to the participant. Special attention was paid to those items that raised doubts or ambiguities. After the first test, the items which caused the most doubts or hesitation on the part of the interviewees were reformulated and tested again. The interviews lasted between 20 and 40 minutes, depending on how difficult the items were to understand. Contributions were noted down during the interviews. The systemized data were compiled in tables to produce the results for the operational equivalence of the instrument. The interviewee's level of understanding was assessed by their agreement, doubts and responses provided for each item of the instrument.

Table 1. Assessment of semantic equivalence between the Martín-Bayarre-Grau instrument in the Spanish original and two translations into Portuguese. Rio de Janeiro, Southeastern Brazil, 2010.

Original instrument	Semantic evaluation[a] (exponent)							
	T1	R1	Ref	Ger	T2	R2	Ref	Ger
a) Toma los medicamentos en el horario establecido - take medication at the correct time	Toma as medicações no horário estabelecido	Tomar los medicamentos en el horário establecido	10	LA	No horário marcado toma os remédios	En el horario marcado toma los remedios	7	LA
b) Se toma todas las dosis indicadas - take all prescribed doses	Devem-se tomar todas as dosagens indicadas	Se deben de tomar todas las dosis indicadas	10	SA	Se tomam todas as doses indicadas	Se toma toda las dosis indicadas	5	SA
c) Cumple las indicaciones relacionadas con la dieta - follow recommendation on diet	Cumpre as indicações relacionadas com a dieta	Cumplir las indicaciones relacionadas con la dieta	10	LA	Segue as regras da dieta	Sigue las reglas de la dieta	10	UN
d) Asiste a las consultas de seguimiento programadas - attend all follow up appointments	Acompanha as consultas ambulatoriais programadas	Acompañar las citas programadas	3	CA	Vai a consultas periódicas	Asiste a consultas periódicas	10	UN
e) Realiza los ejercicios físicos indicados - Do recommended exercise	Realiza os exercícios físicos indicados	Realice los ejercicios físicos indicados	10	LA	Faz os exercícios físicos indicados	Hace los ejercicios médicos indicados	0	CA
f) Acomoda sus horarios de medicación, a las actividades de su vida diaria - Fit schedule for taking medicine in with day-to-day life	Adequa seus horários de tomada dos medicamentos às atividades de sua vida diária	Adaptar sus horários de la toma de sus medicamentos con los de sus actividades diárias	8	LA	Encaixa os horários do remédio no seu dia a dia	Los horarios de sus remédios encajan en su dia a dia	8	LA
g) Usted y su médico, deciden de manera conjunta, el tratamiento a seguir - You and your doctor made a joint decision as to what treatment to follow	O senhor e seu médico decidem de maneira conjunta o tratamento a ser seguido	Usted con su médico deciden como llevar a cabo su tratamiento	10	UN	Senhor/Senhora e seu médico decidem juntos o tratamento que vai fazer	Señor/Señora y su médico deciden juntos el tratamiento que va hacerce	8	UN
h) Cumple el tratamiento sin supervisión de su familia o amigos - Follow treatment without supervision by family or friends	Cumpre o tratamento sem supervisão de sua família ou amigos	Cumpla con el tratamiento sin la ayuda de familiares o amigos	10	SA	Cumpre o tratamento sem supervisão de sua família ou amigos	Cumple el tratamiento sin supervicion de sus familiares o amigos	10	UN
i) Lleva a cabo el tratamiento sin realizar grandes esfuerzos - Follow the treatment without major effort	Leva até o fim o tratamento sem realizar grandes esforços	Termine su tratamiento sin hacer mayores esfuerzos	10	LA	Leva o tratamento sem grandes esforços	Lleva el tratamiento sin grandes esfuerzos	9	UN

Continuation

Continuation

Original instrument	Semantic evaluation[a] (exponent)							
	T1	R1	Ref	Ger	T2	R2	Ref	Ger
j) Utiliza recordatorios que faciliten la realización del tratamiento - Used reminders to make it easier to follow the treatment	Utiliza lembretes que facilitem a realização do tratamento	Utilice papelitos recordatorios para facilitar la realización de su tratamiento	8	SA	Faz uso de lembretes para realização do tratamento	Hace uso de recordatorios para la realizacion del tratamiento	10	UN
k) Usted y su médico analizan, cómo cumplir el tratamiento - You and your doctor analyzed how to follow the treatment	O senhor e seu médico analisam como cumprir o tratamento	Usted con su médico deciden como realizar su tratamiento	6	SA	Senhor/Senhora e seu médico analisam como cumprir o tratamento	Señor/Señora y su médico analizan como cumplir el tratamiento	8	LA
l) Tiene la posibilidad de manifestar su aceptación del tratamiento que ha prescripto su medico - You had the opportunity to show your agreement to the treatment your doctor prescribed	Tem a possibilidade de manifestar sua concordância com o tratamento prescrito pelo seu medico	Tiene la posibilidad de manifestar que está de acuerdo con el tratamiento que le dejó su médico	10	UN	Tem como dar a sua opinião no tratamento que o médico prescreveu	Tiene como dar su opinion en el tratamiento que le médico prescribio	10	UN

[a] Ger: general; T1: translation 1; T2: translation 2; R1:back-translation 1; R2: back-translation 2 CA: completely altered; MA: significantly altered; PA: little altered; UN: unchanged

This study was approved by the Committee for Ethical Research of the *Escola Nacional de Saúde Pública Sérgio Arouca* (Process n° CAAE 0157.0.031.000-09 5/8/2009) and the Committee for Ethical Research of the *Secretaria Municipal de Saúde e Defesa Civil do Rio de Janeiro* (Process nº CAAE 0257.0.314.000-09 14/12/2009).

RESULTS

When assessing the conceptual equivalence, equivalence is deemed to exist between the construct of adherence to therapy in the original culture and the construct of adherence to therapy in the target culture as the Brazilian study, in which the translation of this instrument would be used, also considers adherence to treatment to be understood as a process in which the individual actively participates.

It was possible to identify the equivalence of items in the instrument, as the cultural context of the original population is similar to that of the target population. The results referring to semantic equivalence are shown in Table 1.

It is noteworthy that translation 2 scored better that translation 1, as it received a score of 10 for referential meaning and unaltered (UN) for general meaning for a greater number of items, indicating they were perfectly translated.

Two items (h, k) were translated in the same way into Portuguese (T1=T2). However, T1 and T2 received different evaluations, due to problems with the back-translation R1 of these items into Spanish.

The translation of item (b) in both T1 and T2 were not well done. The assessment of the referential meaning for T2 received a score of 5 due to an error in agreement which occurred upon back-translating this sentence into Spanish, which impacted directly on the general meaning. In the case of T1, in spite of the referential meaning remaining unaltered, the use of the term '*se deben'* in back-translation 2 modified the general meaning of this item.

Doubts and problems of understanding of the questions identified in both pre-tests are shown in Table 2. The alterations resulting from analyzing the respondents' problems in understanding and doubts are shown in Table 3. Modifications made to items (b) and (f) make these sentences clearer for the interviewees, who showed no more doubts when responding to them.

Table 2. Problems identified in the pre-tests and their respective suggested solutions. Rio de Janeiro, Southeastern Brazil, 2010.

Item[a]	Problem	Suggested solution
b	Some people did not understand the meaning of "dose of medicine."	Introduced an explanation of the concept of doses in the fieldworker manual. Other proposed changes to this item were to conjugate the verb "take" instead of leaving it in the infinitive and replace "as stated" for "indicated."
F	Understood by respondents as: "take medications on schedule."	Added the term "activities" to the sentence.
i	The term "great efforts" was not clearly understood.	Replaced the term "great efforts" by "great difficulty."
K	The term "analyze" in item k was understood by the respondent as clinical analysis of your health and not as establishing a partnership relationship with the doctor.	The term "analyze" was replaced by "discuss" the sentence of item (k).
g, k	Were understood the same way by the respondents, who even asked if it was a repeated question.	Although "discuss" is not a synonym for "analyze" in Portuguese, it emphasizes the active role of the patient in relation to the doctor more than the term "analyze".
g, k, l	Nuanced understanding of items that comprise the same category.	The term "be able to give your opinion" replaced by "have the opportunity to give your opinion" in the sentence in item (l).
c, e	Did not apply to some patients because they received no recommendation on diet or physical exercise.	Insert a filter question into the questionnaire to identify whether the patient received recommendations on diet and exercise in the treatment of hypertension and / or diabetes.

[a] The letters refer to the question items in the instrument.

It was noted that there was a problem in understanding items (g), (k) and (l). In the original instrument, these items composed the category 'Interrelationship', in other words, they investigated the patient's active and passive role in relation to the doctor. However, the majority of responses to items (g) and (k) were positive (always and almost always), whereas as those to item (l) were negative (never or almost never). Moreover, respondents only commented on item (l) saying "accept everything the doctor says as s/he's the doctor", showing a passive attitude to treatment and indicating that only this item led to the interpretation sought by all three items on the interrelationship between patient and doctor.

Substituting the term 'analyze' for 'discuss' in item (k) emphasized the patient's active position in relation to the doctor, as respondents then understood that this sentence referred to their participation in their consultations with the doctor.

Despite the fact that no ambiguity was noted in item (l) during the pre-test, it was suggested that the expression "be able to" could be understood to be the respondents' technical capacity to give an opinion on the treatment. Therefore, in the final version of the instrument, this item was reformulated to include the expression "have the possibility of" arising from T1 of this item.

Substituting "effort" for "difficulties" in item (i) made the sentence clearer for some, but was understood by others to mean financial difficulties. In order to avoid ambiguities, this change was not included.

After the alterations resulting from the second pre-test the final version, shown in Table 4, was arrived at.

As regards operational equivalency, during both of the pre-tests it was observed that there were difficulties in applying the Likert scale in the interviews, due to both the lack of objectivity in choosing one of the five frequency options as well as a natural tendency to agree or disagree with the statement, responding 'yes' or 'no' to each item.

When faced with the difficulty of responding objectively using one of the five frequency options on the scale, it was proposed that an explanation be given in order to familiarize the interviewee with the way in which the questions should be answered before they encountered the items themselves. Moreover, it was also proposed that a written explanation with the five options from the response scale be given to the interviewee in order to help them respond objectively.

These modifications to the way the instrument was carried out were tested in the second pre-test.

Two interviewees were given the instrument without having been shown the written explanation, as had been done in the first pre-test. In spite of the example making the instrument easier to apply, the

Table 3. Modifications to the synthesized version of the Martín-Bayarre-Grau instrument after the pre-tests. Rio de Janeiro, Southeastern Brazil, 2010.

Item[a]	Synthesized version	Origin	Modifications after the first pre-test	Modifications after the second test
A	Toma as medicações no horário estabelecido - *Take medication at the set time*	T1	–	–
B	Tomar todas as doses dos medicamentos como indicado - *Take all doses as indicated*	T1 + T2 modificado	Toma todas as doses indicadas	–
C	Segue as regras da dieta - *Follow a diet*	T2	–	–
D	Vai a consultas marcadas - *Attend appointments*	T2 modificado	–	–
E	Realiza os exercícios físicos indicados - *Do exercise as recommended*	T1	–	–
F	Encaixa os horários do remédio no seu dia a dia - Fit *schedule for taking medicine in with day-to-day life*	T2	Encaixa os horários do remédio nas atividades do seu dia a dia	–
G	O senhor e seu médico decidem juntos o tratamento a ser seguido - *You and your doctor made a joint decision as to what treatment to follow*	T1 + T2	–	–
H	Cumpre o tratamento sem supervisão de sua família ou amigos - *Follow treatment without supervision by family or friends*	T1 = T2	–	–
I	Leva até o fim o tratamento sem realizar grandes esforços - *Follow the treatment without major effort*	T1	Leva até o fim o tratamento sem grandes dificuldades	Leva o tratamento sem grandes esforços
J	Faz uso de lembretes para realização do tratamento - *Used reminders to make it easier to follow the treatment*	T2	–	–
K	O/a senhor/senhora e seu médico analisam como cumprir o tratamento - *You and your doctor analyzed how to follow the treatment*	T1 = T2	O(a) senhor(a) e seu médico discutem como cumprir o tratamento	–
L	Tem como dar a sua opinião no tratamento que o médico prescreveu -*You had the opportunity to show your agreement to the treatment your doctor prescribed*	T2	–	Tem a possibilidade de dar a sua opinião no tratamento que o médico prescreveu

[a] The letters refer to the question items in the instrument.
T1: translation 1; T2: translation 2

Table 4. Final version of the Martín-Bayarre-Grau instrument, adapted for use in Brazil. Rio de Janeiro, Southeastern Brazil, 2010.

Item[a]	Final version
A	Take medication at the set time
B	Take all doses as indicated
C	Follow a diet
D	Attend appointments
E	Do exercise as recommended
F	1.1.1 Fit schedule for taking medicine in with day-to-day life
1.1.2	1.1.3 You and your doctor made a joint decision as to what treatment to follow
1.1.4	1.1.5 Follow treatment without supervision by family or friends
1.1.6	1.1.7 Follow the treatment without major effort
1.1.8	1.1.9 Used reminders to make it easier to follow the treatment
1.1.10	1.1.11 You and your doctor analyzed how to follow the treatment
1.1.12	1.1.13 You had the opportunity to show your agreement to the treatment your doctor prescribed

[a] The letters refer to the question items in the instrument.

interviewees still did not respond one of the five options on the Likert scale.

Two other interviewees were given the written explanation in the following order: always, almost always, sometimes, almost never, never. The understanding of the scale was better as, as well as the example, the written explanation also enabled them to choose one of the five options objectively.

Two other individuals were given the written explanation, but in the following order: never, almost never, sometimes, almost always and always. The aim in starting the explanation with the lowest frequencies was to minimize possible bias in positive. When the explanations were given in the order never to always, it was observed that there was greater diversity in the responses.

However, it was established that before completing the questionnaire, an example would be given and that there would also be a written explanation of the options written in the order never, almost never, sometimes, almost always and always.

DISCUSSION

The drawing up of the MBG instrument by Martin Alfonso et al[5] was preceded by an analysis of the different definitions which appeared in the literature referring to the behaviour of complying with medical treatment. These authors agreed with the criticism of the term 'compliance', as it was limited in its coverage of the complexity of the phenomenon in question.

It was also observed that the term 'compliance' is one which is frequently used in medical and pharmaceutical practice, and is frequently encountered as a synonym of adherence.[4]

Finally, Martin Alfonso[4] consider adherence to treatment to be a behavioral matter and to depend as much on the behavior of the patient as of the doctor. In this sense, adherence to treatment was considered to be the most appropriate term for its psychological meaning. It was proposed that for adhesion to treatment to occur the following must be observed in the process: acceptance of the treatment agreed between patient and their doctor; following the treatment; active participation in the treatment and the voluntary character of the actions of following the treatment.[4] Based on this proposal, the operational definition of adherence to treatment adopted by Alfonso et al[5] in drawing up the MBG questionnaire was: "patient's voluntary and active involvement in behavior related to following the treatment mutually agreed upon with their doctor".

In addition to the wide bibliographical revision on this topic in order to formulate an operational definition for adherence to treatment, the WHO suggestions on adherence to long term treatment were also considered. This was based on following medical recommendations established in agreement with patients and on good communication between patients and health care professionals.[12] Thus the definition of adherence to therapy in the Cuban MBG questionnaire[5] and the construct of adherence proposed by the WHO[12] are shown to be convergent.

In spite of it being considered that for the majority of items on the instrument the cultural context of the original and target populations were similar, the only criticism raised was about the relevance of items referring to following recommended diets and exercise.[1] Although they are mentioned in the Brazilian Hypertension and Diabetes Societies, it is possible that there are patients with hypertension and diabetes who were not recommended to go on a diet and do exercise by their doctor.[a,b]

It is also possible that such recommendations were given by other health care professionals such as nutritionists or nurses[1] which would make it necessary to have an instrument which included these patients' adherence to the recommendations of other health care professionals. In these cases, it is not possible to consider adherence to recommendations which did not exist. To get around this problem, questions on recommendations were added to the questionnaire in the assessment study.

Still, overall, it was considered that specific items in the questionnaire are relevant and acceptable to be applied to the target population.

With respect to semantic equivalence, overall, T2 and R2 scored better, as they were marked as not significantly altered for both referential and general meanings for five of the 12 items (items c, d, h, j, l). In the case of T1 and R1, a perfect translation was only obtained for two of the 12 items. In order to create the synthesized version, the T2 translation of items (c), (h), (j) and (l) was incorporated in full and the T2 translation of item (d) was changed, as the expression "regular consultations" is not commonly used, and replaced with "appointments".

It should be pointed out that items (h) and (k) were translated in the same way in both T1 and T2, but T2 scored better due to problems in the back-translation into Spanish. In the case of item (f), the T1 translation was different to that of T2, but both received the same score for general and referential meaning. The sentence from T2 was eventually chosen for the synthesized version.

Both T1 and T2 translations of item (g) were positively evaluated for both referential and general meaning, but in order to create the synthesized version terms from both translations were included. The opposite was the case for item (b), as neither T1 nor T2 received positive evaluations and, therefore, in the synthesized version, this item originated from both translations and was further modified with the introduction of the expression "as stated".

These results show the problems which often occur when back-translating sentences into the original language and not during the translation into the target language. Thus, it is important that two independent translations are carried out, as this increases the options for creating the synthesized version of the translated questionnaire.

The two pre-tests proved to be important as each of them identified different problems and confirmed decisions made in the previous pre-test.

Among the operational modifications was the introduction of an example in the explanation of the instrument – to train the interviewee to respond – and the provision of a written explanation with the response options – in the order never, almost never, sometimes, almost always, always. These elements, in addition to making the questionnaire easier to administer, also enabled it to become an instrument which could be used as part of an interview as well as self-administered, whilst maintaining the same output as the original scale – a numerical score of five points for each item. This meant the results of the application of the instrument received the same analytical treatment as that suggested in the original instrument and facilitated comparisons of psychometric properties between versions.

In order to conclude the transcultural adaptation, it was also necessary to verify the equivalence of measurement, although this was not an objective of this study and will be presented in specialist publications.

Also, to avoid the effects of fatigue (paying less attention to the responses to the final questions) or learning (responding worse to the first questions as the questionnaire has still not been properly understood), the starting point of the questionnaire was changed regularly. The research group's assessment was that the formulation of the items in the MBG questionnaire was sufficiently independent to allow for alterations in the order in which they are presented without negatively affecting understanding.

Based on the evaluation of conceptual, item, semantic and operation equivalence, we propose a Portuguese version of the MBG questionnaire developed to comprehensively evaluate adherence to treatment, which views individuals undergoing treatment as active subjects, as voluntary participation is as important as following doctor's orders.

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