ORIGINAL ARTICLE

VALIDATION OF AN INSTRUMENT TO EVALUATE THE SIGNS AND SYMPTOMS OF BENZODIAZEPINE WITHDRAWAL

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Highlights: (1) This study provided a validated instrument to identify signs and symptoms of benzodiazepine withdrawal during the deprescription process in elderly Brazilians. (2) This is, to the best of our knowledge, the first instrument validated in Brazil to identify signs and symptoms of benzodiazepine withdrawal in elderly people.

PRE-PROOF

(as accepted)

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ABSTRACT

Objective: to develop and validate an instrument to evaluate signs and symptoms that may occur during the process of deprescribing benzodiazepines in elderly Brazilian people. **Methods:** A study was carried out in three stages; the first consisted of developing an instrument to identify signs and symptoms arising from the gradual deprescription of benzodiazepines in the elderly. The instrument was created based on information from literature and from previously developed and validated scales. In the second, the instrument was validated by referees, who completed a questionnaire with seven questions, with answers scaled from 0 to 10 (Likert scale), according to the judge's degree of agreement with the content of the instrument. They evaluated it regarding the instructions to the interviewer and the interviewee, the language of the questionnaire, clarity of statements for application by 36 health professionals, among other points. The responses to the forms were subjected to verification of agreement using the content validity coefficient (CVC). In the third stage, the understanding of the terms contained in the instrument by the target population (elderly users of primary health care) was assessed. Each of the signs and symptoms were presented to the elderly who responded regarding understanding as: “completely understands”, “partially understands” and “does not understand”. **Results:** The instrument was validated in the first round of evaluation by 36 reviewers (pharmacists, nurses, and physicians). All items obtained a final corrected CVC greater than 0.8. Thirty elderly individuals participated in the assessment of the instrument's comprehension. All questions that were less understood by the elderly individuals in the comprehension assessment (such as photophobia, increased sensitivity to smell, increased sensitivity to touch, involuntary movements, among others) were updated with terms for better understanding. **Conclusion:** The constructed instrument was validated and approved and can be used by health professionals. It is considered that the adequate identification of the signs and

symptoms of benzodiazepine deprescription will be useful in building an effective and safe process.

Keywords: Validation study. Substance Withdrawal Syndrome. Benzodiazepines. Elderly Health. Prescription Drugs.

INTRODUCTION

Benzodiazepines are central nervous system depressants that bind to inhibitory neurotransmitters in the central nervous system, generating hyperpolarization of the neuronal plasma membrane, thus reducing their excitatory capacity. (1) These medications are indicated for the treatment of anxiety and mood disorders, sleep disorders, epilepsy, and muscle spasms. (2). Chronic administration of these medications causes compensatory changes in GABA receptors. Cessation of the drug exposes all the adaptations accumulated due to its presence, causing a rebound effect of activity involving many neurotransmitters and their receptors, thus leading to withdrawal (3). The use of these medications should be avoided in the elderly due to the potential for dependence and tolerance, the high risk of falls and fractures, cognitive impairment, delirium, and increased incidence of car accidents (4,5). Even with contraindications, the use of these medications remains prevalent in the elderly population(6).

Due to the potential for harm, the literature has proposed protocols for deprescribing benzodiazepines, with gradual reduction, associated with behavioral approaches, such as cognitive-behavioral therapy(7,8,9). In Canada, there is a proposal that suggests removing 25 % of the dose every two weeks, with a 12.5 % reduction in the last weeks of the process(7). In Brazil, a protocol was published for deprescribing clonazepam in the elderly with a gradual reduction of 25 % of the dose every 14 days and with the distribution of information leaflets with guidance on the deprescription process and sleep hygiene(10).

The use of protocols that help in the gradual reduction of benzodiazepines increases the possibility of successful deprescription, as this minimizes withdrawal symptoms(11). The signs and symptoms of abstinence, or withdrawal symptoms, can complicate the process of deprescribing benzodiazepines(12), as during withdrawal patients may experience restlessness,

agitation, increased anxiety, loss of appetite, nausea, fatigue, lethargy, insomnia, dizziness, tinnitus, depersonalization, derealization, poor concentration, lack of memory, irritability, depressed dysphoric mood, headaches, palpitations, weakness, muscle pain, stiffness, paresthesia, photophobia, sensory changes, confusion, psychosis, and epileptic seizures[13,14]; however, although they are often mild, transient, and occur in the short term, experiencing these signs and symptoms can harm the withdrawal process[7,15]. It is worth noting that withdrawal symptoms occur earlier in patients using short-acting benzodiazepines; however, switching to long-acting benzodiazepines has not been shown to reduce the incidence of these symptoms or improve deprescription success rates [7,16]

In view of the above, we can see the importance of knowing the characteristics of the signs and symptoms present during the deprescription of benzodiazepines, however, instruments designed to evaluate these signs and symptoms are scarce in the literature[17] and to the best of our knowledge, there are no instruments validated in Brazil. Therefore, this study sought to develop and validate an appropriate instrument for evaluating the signs and symptoms of the benzodiazepine deprescription process in Brazilian elderly people.

METHODS

This is a validation study, carried out in three stages: I) the first was the development of an instrument to identify signs and symptoms arising from the gradual deprescription of benzodiazepines in Brazilian elderly people; ii) the second stage consisted of validating the instrument's content through evaluation by health experts and/or experts in elderly health; iii) the third stage was to carry out a pre-test to assess the understanding of terms contained in the instrument by the target population: Brazilian elderly users of primary health care.

Step 1: Preparation of the instrument.

The instrument was created based on information from literature and from previously developed and validated scales[17,18,19] and is intended to assess the presence of symptoms within a regular period of two weeks for reapplication. In the initial proposal, it was divided

into five parts: symptoms related to the senses, symptoms of the musculoskeletal system, gastrointestinal symptoms, symptoms of the central nervous system, and other symptoms[20]. In constructing the instrument, terms in language accessible to the elderly were used and synonyms were included in order to facilitate its compression.

However, the proposal was created so that health professionals directly involved in the patient deprescription process apply the questionnaire. The instrument should not be used in a decontextualized manner or by self-application.

Step 2: Content Validation.

After its development, the instrument was sent by email to health professionals and/or specialists in the area of elderly health for validation. These were chosen for convenience, according to the place of work and/or title of specialist in the area. The professionals who agreed to participate filled out a seven-question questionnaire, with answers scaled from 0 to 10 (Likert scale), according to the reviewer's degree of agreement regarding the instrument's content.

The evaluation took place using an electronic form available on the Google Docs® platform and the single round took place within 14 consecutive days.

The reviewers evaluated the instrument and responded regarding 1) the instructions for the interviewer; 2) instructions to the interviewee; 3) language of the questionnaire (for the elderly to understand); 4) clarity of the statements for the application of the questionnaire by the health professional; 5) the depth and scope of the information included to identify the signs and symptoms of the deprescription process; 6) arrangement and logical sequence of statements; and 7) adequate division regarding the categories of signs and symptoms.

The responses to the forms by the reviewers were subjected to verification of agreement using the content validity coefficient (CVC). Items with a final corrected CVC (CVCc) greater than or equal to 0.8 were considered validated[21].

The CVC was calculated based on the reviewers' scores (0 to 10), and the average of the scores for each item was calculated. Then, based on the average, the initial CVC was calculated for

each item, dividing it by the maximum value that the question could receive. Then, the error was calculated to discount possible biases by the evaluating judges, for each question (divide 1 by the number of evaluating reviewers, raised by the same number of evaluators). With this, the final CVCc of each item/question can be calculated by subtracting the initial CVC from the error.

Stage 3: Assessment by the elderly (Pre-test).

To carry out the evaluation, the instrument was applied through interviews, to a population group with characteristics similar to the target population of the questionnaire, being elderly people (60+ years old), and users of primary health care. Thirty elderly people evaluated the instrument, according to recommendations in the literature[22]. The elderly participants were not users of benzodiazepines.

Recruitment was carried out by active search in primary health care units in two municipalities in the Brazilian state of Minas Gerais: Divinópolis and Pitangui.

The evaluation was carried out using a form on the Google Forms® platform. At this stage, two interviewers participated who were previously trained by project researchers. The instrument, which contains 29 questions, was prepared in three parts:

a) Sociodemographic data: gender, age, and education.

b) Cognition assessment of the Functional Clinical Vulnerability Index questionnaire – 20 (*Índice de Vulnerabilidade Clínico Funcional – 20* - IVCF-20)[23]. Three questions were used that aim to provide information about the cognitive health conditions of the elderly, namely:

a) Sociodemographic data: gender, age, and education.

b) Cognition assessment of the Functional Clinical Vulnerability Index questionnaire – 20 (*Índice de Vulnerabilidade Clínico Funcional – 20* - IVCF-20)[23]. Three questions were used that aim to provide information about the cognitive health conditions of the elderly, namely:

• Has a family member or friend told you that you are becoming forgetful?

• Is this forgetfulness getting worse in recent months?

• Is this forgetfulness preventing you from carrying out any daily activities?

In case of a positive answer to any of the three questions, the interviewer thanked them and ended the interview.

c) Evaluation of terms that describe signs, symptoms and their synonyms, previously validated by experts and evaluated between three alternatives depending on the elderly person's response: “completely understands”, “partially understands”, and “does not understand”.

The results obtained underwent normality assessment and were described by absolute and relative frequencies. Terms that reached a percentage greater than or equal to 80 % were considered validated as “completely understood”[24]. The analysis took place using the Excel application to calculate percentages and assess understanding of terms.

The study was approved by the Research Ethics Committee of the Federal University of São João Del-Rei (UFSJ), Campus Centro-Oeste Dona Lindu, by CAAE: 30688320.0.0000.5545, opinion 4.049.528.

RESULTS

To construct the instrument, scales previously developed and validated[17,18,19] outside Brazil were translated and adapted, and commonly used terms were added. It was divided into five parts according to symptoms[20] and designed for application by health professionals, and not for self-application.

To validate the questionnaire “Signs and symptoms of benzodiazepine withdrawal”, after it was developed, an invitation was sent to health professionals, including doctors, nurses, and pharmacists. After sending invitations to participate in the validation of the instrument, 36 responses were obtained. Among the professionals who participated in the survey, the majority were pharmacists (72.2 %), followed by nurses (25.0 %) and doctors (2.8 %).

After the evaluators' responses, the results on the instrument were explored and, based on the analysis of the responses, it was possible to calculate the CVC for each item (Table 1).

Table 1. Final corrected content validity coefficient (CVCc) of the reviewers' assessments of the instrument's content.

Items relating to the instrument	CVCc
Adequacy of instructions for the interviewer	0.89
Adequacy of instructions to the interviewee	0.93
Clarity of language for the elderly	0.85
Clarity of statements for applying the questionnaire	0.95
Depth and scope for identifying signs and symptoms of the deprescription process	0.96
Arrangement and logical sequence of statements	0.97
Adequacy in the division regarding the categories of signs and symptoms	0.97

CVCc: Final corrected content validity coefficient

It can be seen that all items presented satisfactory content validity coefficient values, that is, above 0.818. The criterion "clarity of language for the elderly" was the one that presented the lowest value (CVCc= 0.85) and the criteria arrangement and logical sequence of statements and adequacy in the division between the categories of signs and symptoms, were the criteria which obtained the highest values (CVCc = 0.97).

Even considering the instrument validated in the first round, some items were modified, considering the suggestions sent by the reviewers, allowing for better adaptation in each item.

Among the changes that were made, the following stand out: a) the inclusion of instructions for the interviewer and the interviewee in the initial part of the questionnaire, and b) the items "Dizziness (loss of balance, dizziness)" and "Cephalalgia (headaches")" which were classified as other signs and symptoms, were transferred to the Central Nervous System signs and symptoms section.

In addition to these changes, explanations were included in parentheses after each question to improve understanding of the content and some terms (e.g. profuse sweating (a lot of sweat)), as well as the formatting of the instrument, were adapted for better understanding by the patient and application by the professional of health.

In the third stage, 30 elderly people were interviewed, 24 of whom were female (80 %), aged between 60 and 102 years old and with predominantly incomplete primary education (46.7 %).

Among the 29 terms present in the validation, 20 reached 80 % as completely understood by the study population. Table 2 details the terms of the questionnaire with the respective results.

Table 2. Evaluation of the terms used in the questionnaire based on responses from elderly people who do not use benzodiazepines in the city of Divinópolis, Minas Gerais, Brazil (n=30).

Questionnaire Terms	Completely understands	Partially understands	Does not understand
Greater sensitivity to noise OR being sensitive/bothered by noise OR noises seem to be louder.	86.67%	3.33%	10.00%
Tinnitus OR whistle in the ear.	86.67	0.00%	13.33%
Photophobia OR sensitive/bothered by light in the eyes OR light/brightness seems to be stronger in the eyes.	70.00%	0.00%	30.00%
Increased sensitivity to smell OR sensitive/bothered by smell OR smell seems stronger.	73.33%	6.67%	20.00%
Greater sensitivity to touch OR sensitive/bothered by touch.	46.67%	3.33%	50.00%
Different taste in the mouth.	83.33%	3.33%	13.33%
Muscle pain or contractions OR pulling the muscle.	80.00%	0.00%	20.00%
Involuntary movements OR unintentional pulling on the arms.	70.00%	3.33%	26.67%
Tremors OR trembling.	83.33%	0.00%	16.67%

Weakness/fatigue OR tiredness.	86.67%	0.00%	13.33%
Nausea and vomiting OR feeling sick.	97.67%	0.00%	3.33%
Loss of appetite OR no desire to eat.	90.00%	3.33%	6.67%
Sensing that things move when they are still.	53.33%	0.00%	46.67%
Hallucinations/derealization OR seeing/hearing things that are not real.	83.33%	0.00%	16.67%
Memory loss OR forgetfulness.	96.67%	0.00%	3.33%
Insomnia OR difficulty sleeping.	93.33%	0.00%	6.67%
Nightmares OR bad dreams.	90.00%	3.33%	6.67%
Irritation OR nervousness.	100.00%	0.00%	0.00%
Dysphoria OR anxiety/depression.	90.00%	0.00%	10.00%
Agitation OR being unable to sit still.	86.67%	6.67%	6.67%
Lethargy OR sluggishness/slow thinking.	76.67%	13.33%	10.00%

Difficulty concentrating OR not being able to concentrate when doing something.	70.00%	3.33%	26.67%
Mental confusion OR confused thoughts.	73.33%	3.33%	23.33%
Seizures.	66.67%	6.67%	26.67%
Dizziness OR loss of balance OR dizziness.	93.33%	3.33%	3.33%
Cephalgia OR headaches.	96.67%	0.00%	3.33%
Sweating OR a lot of sweating.	93.33%	0.00%	6.67%
Palpitations OR heart pounding OR racing heart.	90.00%	0.00%	10.00%
Uncontrolled pressure OR unchecked pressure OR high or low pressure OR drop in pressure.	93.33%	3.33%	3.33%

After evaluating the elderly's understanding, terms or phrases were added to explain those who did not reach 80 % in the “completely agree” category. The terms and phrases in parentheses were added after the pre-test: Photophobia (when looking at sunlight, the eyes hurt more than normal); Greater sensitivity to smell (you are smelling odors more easily); Greater sensitivity to touch (when something touches your skin it causes greater discomfort); Involuntary movements (your arms or legs move without you telling them to); Perception that things move when they are still (objects around you seem to be moving, but you know they are still); Lethargy (laziness to think); Difficulty concentrating (easily distracted and forgetting what you were doing); Mental confusion (confused thoughts/difficulty reasoning/cannot think straight);

and Convulsions (falling to the floor and fainting, with the body struggling, making involuntary movements).

Thus, in Chart 1 we can see the final version of the questionnaire, signs and symptoms of benzodiazepine withdrawal during the deprescription process, where the patient will respond about the frequency of symptoms they have presented in the last two weeks.

Chart 1: Final version of the Signs and Symptoms of benzodiazepine withdrawal questionnaire during the deprescription process.

Instructions for the interviewer: Before starting the dialogue, introduce yourself. Always call the interviewee by name. Be receptive and greet them by saying "good morning, Mr./Ms. (name)", "good afternoon Mr./Ms. (name)" or "good evening Mr./Ms. (name)" depending on the time. Be gentle and speak in a friendly tone of voice, be patient and calm to explain any questions and/or repeat any phrase. When mentioning each symptom, make it clear that you will repeat it if necessary and that you will read the options at the end of each situation. Use the terms in parentheses, if necessary, for adequate understanding by the patient. **Instructions to the interviewee:** Mr./Ms. (say the patient's name), now I'm going to talk about some symptoms about the gradual withdrawal (in this process of gradually reducing the dose/quantity of the medication) of (say the name of the benzodiazepine) and I ask you to tell me how often you have felt these symptoms in the last two weeks. Your answer will be: never, rarely, sometimes, almost always, or always. Remembering that these are new symptoms that you did not feel before starting to reduce the dose. **How often (how many times) did you feel, in the last 2 (two) weeks:**

Signs and Symptoms related to the senses:	**0***	**1****	**2*****	**3******	**4*******
Greater sensitivity to noise (sensitive/bothered by noise, noises seem to be louder).					
Tinnitus (whistling in the ear).					
Photophobia (sensitive/annoyed by light in the eyes, light/brightness seems to be stronger in the eyes/when looking at sunlight the eyes hurt more than normal).					
Greater sensitivity to smell (sensitive/bothered by smell, the smell seems to be stronger/you are smelling odors or bad smells more easily).					
Greater sensitivity to touch (sensitive/annoyed by touch/when something touches your skin it causes greater discomfort).					
Different taste in the mouth.					
Signs and Symptoms of the musculoskeletal system:					
Pain or muscle contractions (pulling the muscle).					
Involuntary movements (example: accidentally jerking your arms/your arms or legs move without you telling them to).					
Tremors (shaking).					
Weakness/fatigue (tiredness).					
Gastrointestinal Signs and Symptoms:					
Nausea and vomiting (sickness).					
Loss of appetite (no desire to eat).					
Central Nervous System Signs and Symptoms:					
Sensation of things are moving when they are still (objects around you appear to be moving, but you know they are still).					

Hallucinations/derealization (seeing/hearing things that are not real).					
Memory loss (forgetfulness).					
Insomnia (difficulty sleeping).					
Nightmares (bad dreams).					
Irritation (nervousness).					
Dysphoria (anxiety/depression).					
Agitation (not being able to sit still).					
Lethargy (sluggishness/slow thinking/mental tiredness/laziness to think).					
Difficulty concentrating (not being able to concentrate when you are doing something/getting easily distracted and forgetting what you were doing).					
Mental confusion (confused thoughts/difficulty reasoning/can't think straight).					
Convulsions (falling to the floor and fainting, with the body struggling, making involuntary movements).					
Dizziness (loss of balance, dizziness).					
Cephalgia (headaches).					
Other signs and symptoms:					
Sweating (a lot of sweat).					
Palpitations (heart pounding, racing heart).					
Pressure loss control (uncontrolled pressure, high or low pressure, drop in pressure).					

* 0 Never

** 1 Rarely

*** 2 Sometimes

**** 3 Almost always

***** 4 Always

DISCUSSION

From the systematic development and validation with experts experienced in the care of the elderly, it was possible to construct an instrument for the adequate identification of the signs and symptoms of withdrawal present during the process of deprescribing benzodiazepines in Brazilian elderly people. The agreement coefficient found was higher than the established minimum of 0.8 and the critical evaluation of the evaluators allowed the improvement of the questionnaire.

During the benzodiazepine withdrawal process, patients may experience a series of signs and symptoms that may discourage the deprescription process. A gradual reduction can minimize and even avoid the presence of these symptoms, especially in patients who use high doses or for a long period of time[14]. Signs and symptoms are mild in most cases, but it is important that the patient receives appropriate guidance and actively participates in the success of the process[25,26]. It is important to assess the presence of these signs and symptoms every 1-2 weeks during the benzodiazepines [7] withdrawal process.

Validation carried out by a multidisciplinary team included the collaboration of pharmacists as the majority of the reviewers. This professional is responsible for promoting the rational use of medications, offering clinical services in the dispensing of medications and/or pharmacotherapeutic monitoring, with a focus on reducing problems related to the use of medications and encouraging adequate adherence to pharmacotherapy, minimizing the risk of iatrogenic events[27,28].

In addition to pharmacists, nurses and doctors contributed to the validation of the instrument. The doctor is the professional responsible for prescribing psychotropic medications, and is a fundamental player in monitoring patients in Family Health Strategies (FHS), and it is important to highlight that they often do not initiate treatments, but follow up on prescriptions for medications already used by the patient[29]. The nurse provides holistic care to patients with or without psychological distress, which, through nursing consultations, seeks to understand the needs of the patient and family, establishing a bond of trust, which is essential for continuous monitoring of the patient[30].

In this way, the importance of coordinated work among health professionals who work in primary care stands out, aiming beyond the promotion, prevention and treatment of diseases to reduce damage to health[31]. To this end, deprescription must be guided in a planned manner in patients who use benzodiazepines for isolated insomnia or associated with a comorbidity already under treatment. It is essential to combine non-pharmacological strategies that can help patients at the time of deprescription[7], minimizing the signs and symptoms that may be present at that time.

As pointed out during the instrument validation process, some symptoms were appropriate, as they had technical terms that were difficult to understand for patients who had less education, a reality for the majority of Brazilian elderly people[32]. Therefore, they were adapted according to the recommendations of the reviewers.

Among the reviewers' suggestions was the need for guidance for the interviewer regarding the instrument used. This concern with the preparation of the interviewer is common to other instrument validation studies, to avoid possible biases on the part of the instrument[33].

Terms such as “photophobia OR sensitive/bothered by light in the eyes OR light/brightness seems to be stronger in the eyes”, “greater sensitivity to smell OR sensitive/bothered by smell OR the smell seems to be stronger”, “involuntary movements OR unintentional twitching in your arms”, “lethargy OR slowness/slow thinking”, “difficulty concentrating OR not being able to concentrate when doing something”, “mental confusion OR confused thoughts”, and “seizures” reached agreement values between 60-79 % in the evaluation by the elderly, which represents a moderate degree of consensus. Only the terms “greater sensitivity to touch OR sensitive/bothered by touch” and “sensation that things move when they are still” obtained agreement values below 60 %, which shows a low degree of consensus. This result can be explained by education, since the majority of the population (70 %) have not completed secondary education and according to Guedes and collaborators (2018)[31] elderly people who do not have secondary education may not understand surveys or questionnaires very well.

Although forgetting is part of the aging process, biases related to understanding cannot be accepted. Therefore, to minimize the effects, the IVCF-20[23] cognition questionnaire was

applied to include participants in the study. By doing so, only those who responded positively to these questions were considered eligible to participate in the study. In contrast, as the interviews were not carried out with a cohabitant of the elderly person, as recommended in the questionnaire, only the participant responds about their cognitive capacity, without confirmation from their cohabitant, which is a limitation of the present study.

Another relevant limitation consists of the subjectivity regarding the interviewer's comprehension of what, according to the available alternatives, the phrase "completely understands" means. To minimize this occurrence, the researchers underwent calibration to avoid dissonance.

It is important to highlight that some terms explain and clarify others, and in the researchers' perception, the elderly understood that some terms that appeared later in the form were explanatory of a previous term. During the validation process with the reviewers, care was taken to use similar terms to facilitate understanding by the elderly[35].

Therefore, the importance of carrying out the evaluation of the questionnaire is highlighted to finalize the validation process of the instrument to be applied to the elderly during the benzodiazepine deprescription process[22]. Furthermore, a percentage of agreement was obtained, considered a very high degree of consensus[21]. It is also important to highlight that the study involved the participation of 30 elderly people, as recommended, for pre-tests[22].

To the best of our knowledge, this is the first study to develop and validate an instrument that identifies the signs and symptoms of benzodiazepine withdrawal in Brazilian elderly people, and it can be used in clinical practice by health teams to optimize the results of deprescription.

CONCLUSION

The developed instrument contains the signs and symptoms of withdrawal common to the process of deprescribing benzodiazepines in the elderly and was validated by reviewers to be applicable in the context of primary health care. In addition to being validated by professionals, the questionnaire presented adequate understanding for the population of interest. In this sense,

the validated and understandable instrument becomes a support instrument for clinicians in the process of deprescribing benzodiazepines in the elderly, by adequately identifying the signs and symptoms that can become barriers for the process to be effective and safe.

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