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CONSTRUCTION AND VALIDITY OF AN ITEM BANK ON RISK SELF-MEDICATION

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ABSTRACT

Objective: to construct an item bank to measure risk self-medication and assess its content validity.
Method: this is a methodological study carried out from May to October 2022, with two phases: 1) item bank elaboration in the light of medication literacy and Theory of Planned Behavior based on a scoping review; and 2) content validity by twenty-two health experts. The Content Validity Index, Content Validity Ratio, binomial exact test for small samples and intraclass correlation coefficient were calculated.
Results: Risk Self-Medication construct item elaboration was based on a broad review of solidified national and international publications in the health area. The definitions were approved by judges, with their respective domains. In the first version, the bank contained 136 items. Two rounds of analysis were carried out with judges, which resulted in the removal of 87 items. The final version presented 49 items, distributed across three domains: Medication literacy; Behavioral intention; and Behavior. The total Content Validity Index was 0.89, with excellent reliability (0.964). There was significant disagreement in the attribution of scores among judges ($p>0.05$) in some items.
Conclusion: the item bank has satisfactory content. It is recommended to undergo semantic analysis and subsequent structure validity.

DESCRIPTORS: Self-medication. Validation study. Psychometrics. Health literacy. Patient safety.

CONSTRUÇÃO E VALIDAÇÃO DE UM BANCO DE ITENS SOBRE AUTOMEDICAÇÃO DE RISCO

RESUMO

Objetivo: construir um banco de itens para mensuração da automedicação de risco e realizar sua validação de conteúdo.

Método: estudo metodológico realizado no período de maio a outubro 2022, com duas fases: 1) elaboração do banco de itens, à luz do letramento em medicamentos e Teoria do Comportamento Planejado, a partir de revisão de escopo e 2) validação de conteúdo, por vinte e dois especialistas da saúde. Calculou-se o Índice de Validade de Conteúdo, *Content Validity Ratio*, teste exato binomial para amostras pequenas e coeficiente de correlação intraclasse.

Resultados: a elaboração dos itens do constructo Automedicação de Risco foi fundamentada na ampla revisão de publicações nacionais e internacionais solidificadas na área da saúde. As definições foram aprovadas pelos juízes, com seus respectivos domínios. Na primeira versão, o banco continha 136 itens; foram realizadas duas rodadas de análises com juízes, que resultaram na remoção de 87 itens. A versão final apresentou 49 itens, distribuídos em três domínios: Letramento em medicamentos, Intenção do comportamento e Comportamento. O Índice de Validade de Conteúdo total foi de 0,89, com confiabilidade excelente (0,964). Houve discordância significativa na atribuição da pontuação entre os juízes (p>0,05) em alguns itens.

Conclusão: o banco de itens apresenta conteúdo satisfatório. Recomenda-se passar por análise semântica e posterior validação da estrutura interna.

DESCRITORES: Automedicação. Estudos de validação. Psicometria. Letramento em saúde. Segurança do paciente.

CONSTRUCCIÓN Y VALIDEZ DE UN BANCO DE ÍTEMS SOBRE RIESGO DE AUTOMEDICACIÓN

RESUMEN

Objetivo: construir un banco de ítems para medir el riesgo de automedicación y evaluar su validez de contenido.

Método: estudio metodológico realizado de mayo a octubre de 2022, con dos fases: 1) elaboración del banco de ítems a la luz de la alfabetización en medicamentos y la Teoría del Comportamiento Planificado a partir de una revisión del alcance; y 2) validez de contenido por veintidós expertos en salud. Se calcularon el Índice de Validez de Contenido, el Content Validity Ratio, la prueba exacta binomial para muestras pequeñas y el coeficiente de correlación intraclase.

Resultados: la elaboración de los ítems del constructo Automedicación de Riesgo se basó en una amplia revisión de publicaciones nacionales e internacionales solidificadas en el área de la salud. Las definiciones fueron aprobadas por los jueces, con sus respectivos dominios. En la primera versión, el banco contenía 136 artículos. Se realizaron dos rondas de análisis con jueces, que resultaron en la eliminación de 87 ítems. La versión final presentó 49 ítems, distribuidos en tres dominios: alfabetización en medicina; Intención del comportamiento; y Comportamiento. El Índice de Validez de Contenido total fue de 0,89, con excelente confiabilidad (0,964). Hubo desacuerdo significativo en la atribución de puntuaciones entre los jueces (p>0,05) en algunos ítems.

Conclusión: el banco de artículos tiene un contenido satisfactorio. Se recomienda someterse a un análisis semántico y posterior validez de la estructura interna.

DESCRITORES: Automedicación. Estudio de Validación. Psicometría. Alfabetización en Salud. Seguridad del Paciente.

INTRODUCTION

Risky self-medication (RSM) is an inadequate form of self-medication, in which several potential elements of risk to individuals' health may occur[1], being composed of three non-linear and intercommunicating dimensions: Medication literacy (ML)[2–3]; Behavioral intention; and Behavior[4]. Thinking about RSM means considering the potential elements that could trigger negative health outcomes for those who practice it.

This topic is relevant, as RSM behaviors can have serious health consequences[5] and there are several reports of drug poisonings in Brazil and deaths[6].

Despite its relevance, this topic still has relevant scientific gaps. Currently, in Brazil, studies have used instruments with evidence of validity to measure self-medication[7–8], but there is no specification on RSM[7]. Among the studies found, only one measures RSM, but restricted to temporomandibular dysfunction[8].

It is necessary to measure self-medication at risk to human health in a comprehensive way, in order to cover this construct in the general adult population and in older adults as well as in people with high or low literacy levels. In relation to older adults, a study carried out in Brazil showed that 92.4% of this group practiced self-medication, and, to make the problem worse, 97.6% used medication daily. This practice can be considered very risky for this public[9].

To fill this gap and aim to determine and predict these behaviors, we based this study on the Theory of Planned Behavior (TPB), with its three dimensions: attitudes; subjective norms; and perceived power (behavioral intention). This choice was made due to its congruence with the topic, as a study carried out with women in Iran demonstrated that the TPB dimensions are relevant predictors for self-medication[10].

Furthermore, knowledge and appropriate use of health information are other relevant factors in RSM and can be referred to as ML. This involves the application of different skills in contexts of medication use, including assessing the information received/accessed and using it to change circumstances and ensure the effective and safe use of medications[11]. Inadequate ML is associated with RSM[3].

It is important to highlight that RSM is part of the policy concerns to promote the rational use of medications, being a priority in health research and becoming a focus of the Research Program for the SUS (PPSUS - *Programa de Pesquisa para o SUS*)[12]. Therefore, this work aimed to construct an item bank to measure risk self-medication and validate its content. Thus, healthcare professionals will be able to use this item bank to track people with RSM in clinical practice, identifying scenarios of subjects prone to adverse health situations and allowing healthcare services to develop targeted strategies based on the level of literacy, behavioral intention and behavior in order to minimize the harm caused by RSM.

METHOD

This is a methodological study designed based on theoretical content about RSM from the perspective of ML and TPB, in addition to recommendations for creating items contained in the theoretical pole of psychometrics[13]. This study was conducted in two phases, carried out from May to October 2022: 1. Theoretical: a scoping review was carried out to map the predictive items of risk self-medication in light of ML and TPB; and 2. Construction: instrument development and content validity verification by experts.

In the first phase, a scoping review was initially carried out with the aim of clarifying the definition of risk self-medication and mapping the dimensions and definitions that constitute the attributes. The review was developed based on the Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) checklist[14] and the method proposed by JBI[15]. The Latin American and Caribbean Literature in Health Sciences (LILACS), National Library of Medication (PubMed), Scopus, Web of Science (WoS), EMBASE and Science Direct databases were consulted.

All studies that addressed self-medication, health/ML and risk behavior related to self-medication were included. Moreover, gray literature studies were considered, such as Google Scholar, Brazilian Digital Library of Theses and Dissertations, Catalog of Theses and Dissertations (CTD) of the Coordination for the Improvement of Higher Education Personnel (CAPES - *Coordenação de Aperfeiçoamento de Pessoal de Nível Superior*), OpenGrey, Open Access Theses and Dissertations (OATD) and ProQuest Dissertations and Theses (PQDT), in addition to the New York Academy of Medicine (NYAM) Library. Duplicate studies and those that were not central in the aforementioned attributes were excluded. There was no temporal delimitation.

To formulate the research questions, we used the mnemonic PCC (Population, Concept and Context). Therefore, the following elements were defined: P: adult and older adults; C: self-medication, health literacy and ML; and C: RSM behavior. From this, the following questions emerged: which self-medication behaviors are related to health/ML in adults and older adults? Which behavioral, normative and control beliefs predict risk behaviors in self-medication in adults and older adults?

To answer the two guiding questions, we developed two search equations. We used the three controlled health vocabularies: Health Sciences Descriptors (DeCS), Medical Subject Headings (MeSH) and EMTREE, together with the Boolean operators AND and OR.

In the first paired search for articles, the objective was to clarify the construct dimensions and map the constitutive definitions of self-medication, grouping them according to health/ML skills. We used the three controlled health vocabularies: 1) adult OR aged; 2) self medication; and 3) health literacy OR medication literacy. This resulted in the following combination: adult OR aged AND self medication AND health literacy OR medication literacy. In the end, 16 studies were analyzed, which clarified the definition of self-medication focused on ML, resulting in 60 constitutive definitions in the medication literacy domain.

The second paired search for articles aimed to clarify the construct dimensions and map the constitutive definitions of behaviors and beliefs related to RSM. We used the following health vocabularies: 1) adult OR aged; 2) health risk behaviors OR high risk behavior OR risky behavior OR risk-taking; and 3) self medication. After the necessary adaptations, the search equation was established as follows: adult OR aged AND health risk behaviors OR high risk behavior OR risky behavior OR risk-taking AND self medication. In the end, 64 articles were analyzed, which clarified the risk self-medication domains, such as behavioral intention and behavior.

To map the constitutive definitions, the TPB was used, which explains several health-related behaviors. This theory encompasses the behavioral intention (attitudes, subjective norms and perceived behavioral control) and behavior (practice of RSM) attributes. This resulted in 76 constitutive definitions, of which 46 belonged to behavior and 30 to behavioral intention.

Thus, the construct was delineated from a complex phenomenon with three dimensions: Medication literacy (Knowledge); Behavioral intention (Beliefs); and Behavior. At the end of this phase, 136 operational definitions were obtained.

In the knowledge dimension, we considered ML, which is the degree to which people can acquire, understand, communicate, calculate and process specific information about their medications, in order to make healthcare decisions safely and effectively, regardless of the way in which content is delivered. The constitutive definition of the behavioral intention dimension encompasses a person's decision to act and the perception of the effort they are willing to make to perform a certain behavior, including constructs such as attitudes, subjective norms and perceived power. The behavior dimension definition concerns the practical function that originates from information or beliefs[4].

After identifying the constitutive definitions of the elements that make up RSM, we moved on to the elaboration of operational definitions. Operational definition construction consists of transforming the abstract into concrete, characterizing it as the phase in which instrument validity is based. From this process, pilot instrument items were developed to assess the latent trait of RSM[13].

Thus, 136 operational definitions were created, of which 60 belong to the ML (knowledge) dimension, 30 to the behavioral intention dimension and 46 to the behavior dimension. After constructing the item bank, it was submitted to a committee of health experts to verify its content validity.

In the second phase, the classification system proposed by Jasper[16] was used as a criterion for choosing experts, in which experts must meet at least two of the following criteria: having skills/knowledge acquired through experience; having specialized skills/knowledge; having special ability in a certain study design; passing a specific test to identify experts; having a high rating assigned by an authority. Experts who met at least two of the criteria described were selected.

Experts were chosen through access and research on the Brazilian National *Lattes* Platform. In the "*Lattes* resume" window, the "Search" option was chosen and filters were applied to the results by "Professional activity", selecting the "Health sciences" major area and the "Pharmacy, medication and nursing" area. An electronic search was then carried out using the "self-medication", "validation study", "health literacy" and "medication literacy" descriptors. PhD holders and other researchers of Brazilian nationality were selected. The snowball technique was also adopted to appoint new experts.

It is noteworthy that content validity was assessed in two rounds with experts. In the first round, 22 experts assessed the RSM item bank constitutive and operational definitions, meeting the number of experts recommended for this assessment[17]. From the first round, the second version of the instrument emerged, resulting from adjustments and suggestions of items by experts. Text changes were readjusted and included in the second round of content validity. This round proved necessary, with emails being sent to the 22 experts who participated in the first, with feedback from 11 respondents to the instrument's assessment.

Experts' assessment of item relevance as a research phenomenon was carried out using a five-point ordinal categorical scale: 1) Not indicative; 2) Very little indicative; 3) Neither agree nor disagree; 4) Considerably indicative; and 5) Very indicative. Ten days were available to return the completed material.

For the content validity step of Risk Self-Medication Questionnaire (QAR - *Questionário de Automedicação de Risco*) items, the data collected in the first and second round were organized and stored in an electronic database in Microsoft® Excel 2016 and exported to the Statistical Package for the Social Sciences (IBM SPSS) version 23.0 for statistical analysis. After checking the normality of the data with the Kolmogorov-Smirnov test, qualitative variables were expressed as means and standard deviation (age and time since graduation) and median and quartiles (p25-p75) (length of care experience). Qualitative variables were expressed as absolute and relative frequencies.

Content validity was verified by the Content Validity Index (CVI), through the calculation of the Item-level Content Validity Index (I-CVI) referring to each item of the instrument and the overall CVI. The assessment standard considered was the following: I-CVI ≥ 0.78, excellent; I-CVI between 0.60 and 0.71, good; and I-CVI < 0.59, poor, the latter being eliminated[18] and overall CVI ≥ 0.90[19]. Furthermore, the Content Validity Ratio (CVR) was calculated based on a classification of items as 0=disagree, 1=partially agree and 2=completely agree, subsequently converted into dichotomous values for the correct calculation of the CVR, with the combination of options 1 and 2=essential and 0=non-essential[20].

The CVR was calculated using the formula $CVR = [(E - (N/2)) / (N/2)]$, where N represents the total number of experts and E the number that classified the object as essential. A significance level of $p<0.05$ and a final number of participating experts were considered, being 0.455 and the minimum number of 16 judges necessary to agree with the essential item[20].

To verify whether the proportion of evaluators is statistically equal to or greater than the pre-determined value, the exact binomial distribution test was performed, considering a significance of $p>0.05$ and an agreement proportion of 0.80[21]. Reliability was estimated by the Intraclass Correlation Coefficient (ICC) and its 95% intervals, based on a two-way mixed effects model, mean classification and definition of consistency relationship, classified as poor (<0.50), moderate (between 0.50 and 0.75), good (0.75 to 0.90) and excellent (>0.90)[22]. The research was approved by the Research Ethics Committee of the *Universidade Estadual do Ceará*, under Opinion 5,198,364, in 2022, and is in line with the Brazilian National Health Council Resolution 466/12.

RESULTS

Initially, 22 experts were characterized, all healthcare professionals with clinical, research and publication experience on the topic. Of them, 18 (81.8%) came from the Northeast region, followed by the Southeast (3; 13.6%) and Center-West (1; 4.5%) regions. Most experts were female (16; 72.7%), with a mean age of 40.5 (+8.1) years. Regarding academic training, 13 (59.1%) were nurses, 8 (36.4%) were pharmacists and 1 (4.5%) was a doctor. Regarding academic degrees, 15 (68.2%) were PhD holders, 6 (27.3%) were master's degree holders and 1 (4.5%) was post-doctoral degree holder. The length of care experience ranged from up to 30 years, with a median of 10 years.

Regarding the risk self-medication construct theoretical dimensionality, the definitions were approved with their respective domains and subdomains. It is worth highlighting that expert 4 suggested in the self-medication practice subdomain, referring to the RSM behavior domain, that examples be added that constitute the inappropriate use of medications, such as suspending medication without medical advice, increasing medication dose, changing medication intake times and combining medications where there is an exacerbation or reduction in the effects of a medication. These points find theoretical support in reports from the World Health Organization[4].

Expert 6 suggested that the 'medicine literacy' domain be replaced by the term "medication literacy". This foundation is found in previous studies[3,10]. In this same domain, expert 14, referring to the constitutive definition of ML, requested a theoretical update. Thus, a conceptual model of ML in Brazil[10] was used, with this theoretical framework being used to define ML. More details are in Chart 1.

Chart 1 – Theoretical pole with constitutive definitions of the latent trait risk self-medication and its respective domains. Fortaleza, CE, Brazil, 2022.

Latent trait definition: Risky self-medication	
It is an inappropriate form of self-medication, in which several potential elements of risk to individuals' health may occur, consisting of three non-linear and intercommunicating dimensions: medication literacy, behavioral intention and behavior[1–4].	
Domains/constitutive definition	**Domains/constitutive definition**
Medications literacy: it is the degree to which individuals can obtain, understand, communicate, calculate and process specific information about their medications to make health decisions safely and effectively regardless of the way in which the content is delivered (written, oral and visual)[2–3].	**Access information**: ability to search, find and obtain information related to medications from different sources[11].
	Understanding: the ability to understand medication-related information obtained or received from different sources[11].
	Assessment and processing: assessment of information on the safe and effective use of medication[2].
	Application/usage: use of the information obtained about their medications to make health decisions safely and effectively[2].
Behavioral intention: sum of a person's decision to act and the perception of the effort they are willing to make to perform a certain behavior, involving factors such as attitudes, subjective norms and perceived behavioral control[4].	**Attitudes**: set of behavioral beliefs for assessing favorable or unfavorable outcomes[4].
	Subjective norms: normative beliefs about the subjective influences of references (parents, friends, family, spouse, co-workers) on medication selection and use[4].
	Perceived behavioral control: individual belief related to the perceived power factors (difficulty or ease) in performing behavior[4].
Behavior: it is the practical function that comes from information or beliefs[4].	**Risky self-medication practice**: inappropriate use of medication, involving suspension of medication without medical advice, increasing medication dose, changing medication intake times and combining medications where there is an exacerbation or reduction of the effects of the medication[1].

In the first round of content analysis, in relation to item scoring, it was found that (n=98) items received low scores (I-CVI<0.78 and CVR below the cut-off point). Of these, 27 items did not achieve a satisfactory CVR and 97 items achieved a low CVR. Furthermore, there was significant disagreement (p>0.05) in relation to 78 items, justified by experts due to similarity of content, the need to group items or the fact that an item did not measure the construct. Of these, 70 items were excluded, and adjustments to the text were suggested in 36 items, resulting in 66 items (30 in the medication literacy domain, 15 in the behavioral intention domain and 25 in the behavior domain) for the second round of content validity. Regarding reliability, it was considered excellent (0.964), as confirmed by confidence interval (95%CI=0.940-0.983) (Supplementary Material 1).

During the content analysis process, some experts requested changes in spelling, joining of items, exclusion of items with same meaning as well as replacement of words that were difficult to understand for subjects with low literacy and the rewriting of some confusing items. Most of experts' suggestions were accepted, with the aim of improving understanding of items. At the end of the first assessment, of the 136 items in the QAR, 66 items remained, subdivided into 26 in the medication literacy domain, 15 in the behavioral intention and 25 in the behavior dimension.

In the second content analysis assessment, the reorganized QAR was sent again to the 22 experts from the first round, and 11 (50%) of them participated in this step. Regarding validity, it was observed that item 9 of the medication literacy domain did not reach a satisfactory CVI value. Validity by CVR indicated the removal of 15 items: 13 (items 3,6,7,8,9,10,11,12,13,14,16, 23 and 24) in the first domain, two items (items 29 and 39) in the second domain and one (item 45) in the third domain. Two experts identified items in the behavioral intention domain that best fit the medication literacy domain, and these items were transferred to the first domain.

There was significant disagreement (p>0.05) in item scoring (6,7,9,12, 14 and 24). Regarding reliability, it was considered excellent (0.931), as confirmed by confidence interval (95%CI=0.858-0.978). In relation to experts' suggestions regarding the QAR items, adjustments were made to the text of items 17,33, 41 and 42 (Table 1).

Table 1 – Agreement statistics of the second content analysis of the Risk Self-Medication Questionnaire (QAR - *Questionário de Automedicação de Risco*) items. Fortaleza,CE, Brazil, 2022.

Items		n(%)	CVI*	p-value†	CVR ‡
Domain – Medication literacy			0.78		
01	Before using medication on my own, I read the information in the leaflet.	09 (81.8)	0.82	0.102[a]	0.636
02	Before using medication on my own, I read the information on the label.	09 (81.8)	0.82	0.102[a]	0.636
03	Before using medication on my own, I look for information on the internet.	08 (72.7)	0.73	0.070[a]	0.454
04	Before using medication on my own, I seek information from friends/family.	10 (90.9)	0.91	0.431[a]	0.818
05	Before using medication on my own, I seek information from pharmacy clerks.	09 (81.8)	0.82	0.102[a]	0.636
06	Before using medication on your own, I understand the information contained in its leaflet.	07 (63.6)	0.64	0.001[a]	0.272
07	Before using medication on your own, I understand the information on its label.	07 (63.6)	0.64	0.001[a]	0.272
08	Before using medication on my own, I know to check whether the information on the internet is reliable.	08 (72.7)	0.73	0.070[a]	0.454
09	Before using medication on my own, I know when information from friends/family is trustworthy.	06 (54.5)	0.55	0.001[a]	0.091
10	Before using medication on my own, I understand that the information from the pharmacy clerk is reliable.	08 (72.7)	0.73	0.070[a]	0.454
11	Before using medication on my own, I know how to assess the possibility of an unwanted reaction.	08 (72.7)	0.73	0.070[a]	0.454
12	Before using medication on my own, I know how to correctly assess the information about food interfering with the effect of a medication.	07 (63.6)	0.64	0.001[a]	0.272
13	Before using medication on my own, I know that I should not take the medication with alcohol.	08 (72.7)	0.73	0.070[a]	0.454
14	Before using medication on my own, I know how to assess the possibility of this medication interfering with the effect of another medication I am already using.	07 (63.6)	0.64	0.001[a]	0.272
15	Before using medication on my own, I assess the appropriate amount to take.	09 (81.8)	0.82	0.102[a]	0.636
16	Before using medication on my own, I check the expiration date on the label.	08 (72.7)	0.73	0.070[a]	0.454

Table 1 – Cont.

Items	n(%)	CVI*	p-value†	CVR ‡
17 I take medication on my own even though I have doubts regarding the information contained in the leaflet.	10 (90.9)	0.91	0.431ᵃ	0.818
18 When taking a medication on my own, I follow the instructions contained in the leaflet regarding the number of days to be medicated.	09 (81.8)	0.82	0.102ᵃ	0.636
19 When taking a medication on my own, I follow my previous experience with the same medication.	10 (90.9)	0.91	0.431ᵃ	0.818
20 When taking medication on my own, I follow previous medical appointments.	09 (81.8)	0.82	0.102ᵃ	0.636
21 When taking medication on my own, I follow previous medical prescriptions.	10 (90.9)	0.91	0.431ᵃ	0.818
22 When taking medication on my own, I follow information from the internet.	10 (90.9)	0.91	0.431ᵃ	0.818
23 I take medication on my own when I use antibiotics without a prescription.	11 (100.0)	1.00	0.569	1.000
24 When I use medication on my own, I tell my healthcare professional when the problem gets worse.	07 (63.6)	0.64	0.001ᵃ	0.272
25 When using medication on my own, in the presence of a drug reaction, I look for information on the internet.	10 (90.9)	0.91	0.431ᵃ	0.818
26 When using medication on my own, in the presence of a drug reaction, I seek information from family/friends.	09 (81.8)	0.82	0.102ᵃ	0.636
Behavioral intention domain		0.93		
27 I believe that using medication(s) on my own relieves symptoms quickly	11 (100.0)	1.00	0.569	1.000
28 I believe that using medication(s) on my own has the desired effect.	10 (90.9)	0.91	0.431ᵃ	0.818
29 I believe that I would stop using the medication prescribed by the doctor if I felt an unwanted reaction.	08 (72.7)	0.73	0.070ᵃ	0.454
30 I believe that I would stop using the medication prescribed by the doctor when it does not have the expected effect.	10 (90.9)	0.91	0.431ᵃ	0.818
31 I believe I would discontinue use of the medication prescribed by the doctor if symptoms improved.	11 (100.0)	1.00	0.569	1.000
32 I believe that I would suspend the use of the medication prescribed by the doctor and use it at another time.	10 (90.9)	0.91	0.431ᵃ	0.818
33 I would take medication on my own because I trusted the opinion of friends/neighbors.	10 (90.9)	0.91	0.431ᵃ	0.818
34 I would take medication on my own because I value the opinion of family members.	09 (81.8)	0.82	0.102ᵃ	0.636
35 I am able to take medication on my own because I do not need a medical appointment.	11 (100.0)	1.00	0.569	1.000
36 I am able to take medication on my own because I have it at home.	11 (100.0)	1.00	0.569	1.000
37 I am able to take medication on my own because I know how to calculate the dose.	10 (90.9)	0.91	0.431ᵃ	0.818
38 I am able to take medication on my own because I understand the leaflet.	10 (90.9)	0.91	0.431ᵃ	0.818
39 I am able to take medication on my own because I read the label.	10 (90.9)	0.91	0.431ᵃ	0.818
40 I am able to take medication on my own even without knowing how to identify adverse reactions.	11 (100.0)	1.00	0.569	1.000
41 I am able to take medication on my own even without medical or nursing advice.	11 (100.0)	1.00	0.569	1.000

Table 1 – Cont.

Items		n(%)	CVI*	p-value†	CVR ‡
Behavior domain			0.96		
42	How often I took medication on my own in the last three months.	11 (100.0)	1.00	0.569	1.000
43	I use medication on my own when I do not need a prescription from the pharmacy.	10 (90.9)	0.91	0.431ª	0.818
44	I use medication on my own even when prescription retention is required at the pharmacy.	11 (100.0)	1.00	0.569	1.000
45	I use medication on my own during meals.	08 (72.7)	0.73	0.070ª	0.454
46	I use medication on my own along with teas.	09 (81.8)	0.82	0.102ª	0.636
47	I use medication on my own along with alcoholic beverages.	10 (90.9)	0.91	0.431ª	0.818
48	I use medication on my own because I have previous treatment experience.	11 (100.0)	1.00	0.569	1.000
49	I use medication on my own because I have old prescriptions.	11 (100.0)	1.00	0.569	1.000
50	I use medication on my own because I have medication stored at home.	10 (90.9)	0.91	0.431ª	0.818
51	I use medication on my own even without knowing the right amount.	11 (100.0)	1.00	0.569	1.000
52	I use medication on my own even without knowing how long it will be used.	11 (100.0)	1.00	0.569	1.000
53	I use medication on my own because it is faster to solve my health problem.	11 (100.0)	1.00	0.569	1.000
54	I use medication on my own because it is recommended by friends/neighbors/family.	11 (100.0)	1.00	0.569	1.000
55	I use medication on my own because I do not need guidance from healthcare professionals.	11 (100.0)	1.00	0.569	1.000
56	I use more than one medication on my own at the same time.	11 (100.0)	1.00	0.569	1.000
57	I use medication on my own to treat symptoms of illnesses I already have (hypertension, diabetes, others).	11 (100.0)	1.00	0.569	1.000
58	I reduce the dose of the medication the doctor or nurse prescribed when symptoms improve.	11 (100.0)	1.00	0.569	1.000
59	I increase the dose of the medication the doctor or nurse prescribed when I realize that I am not improving.	11 (100.0)	1.00	0.569	1.000
60	I stop using medication on my own when I feel better.	11 (100.0)	1.00	0.569	1.000
61	I have already increased the number of days of treatment.	11 (100.0)	1.00	0.569	1.000
62	I have already reduced the number of days of treatment.	11 (100.0)	1.00	0.569	1.000
63	When I take medication on my own, I continue even if my health condition worsens.	09 (81.8)	0.82	0.102ª	0.636
64	When I take medication on my own, I continue even in the presence of unwanted reactions.	09 (81.8)	0.82	0.102ª	0.636
65	I use antibiotics on my own.	11 (100.0)	1.00	0.569	1.000
66	I use prescription medications (for anxiety, depression, pain) on my own.	11 (100.0)	1.00	0.569	1.000
Total		–	0.89	–	–
CCI (95%CI)§			0.931 (0.858-0.978)		

*CVI = Content Validity Index; †p-value = binomial exact test (ª: alternative hypotheses states that the proportion of cases in the first group <0.80); ‡CVR = Content Validity Ratio; §CCI (95%CI) = Intraclass Correlation Coefficient with 95% Confidence Interval; T.N. – this questionnaire was freely translated.

After analysis of experts' agreement and suggestions, the final version of the instrument resulted in 49 items, with 14 in the first domain, 10 in the second domain and 25 in the third domain (Chart 2).

Chart 2 – Final version of the Risk Self-Medication Questionnaire in the light of medication literacy and Theory of Planned Behavior. Fortaleza, CE, Brazil, 2022.

Domain 1: Medication literacy	
1	Before using medication on my own, I read the information in the leaflet.
2	Before using medication on my own, I read the information on the label.
3	Before using medication on my own, I assess the appropriate dose to be taken.
4	Before using medication on my own, I ask my questions in the leaflet.
5	Before using medication on my own, I follow the instructions contained in the leaflet regarding the number of days to use the medication.
6	Before using medication on my own, I seek information from friends/family.
7	Before using medication on my own, I seek information from pharmacy clerks.
8	Before using medication on my own, I follow my previous experience with the same medication.
9	Before using medication on my own, I follow previous medical prescriptions.
10	Before using medication on my own, I follow information from the internet.
11	When using medication on my own, in the presence of a drug reaction, I look for information on the internet.
12	When using medication on my own, in the presence of a drug reaction, I seek information from family/friends.
13	When taking medication on my own, I know how to calculate the dose.
14	When taking medication on my own, I understand the leaflet.
Domain 2: Behavioral intention	
15	I intend to take medication on my own because it relieves the symptoms quickly.
16	I intend to take medication on my own because it has the desired effect.
17	I intend to take medication on my own because I trust the opinion of friends/neighbors/family.
18	I intend to take medication on my own because I do not need a medical appointment.
19	I intend to take medication on my own because I have it at home.
20	I intend to take medication on my own even without knowing how to identify adverse reactions.
21	I intend to take medication on my own even without medical, pharmacist or nurse advice.
22	I would intend to stop using the medication prescribed by the doctor if it did not have the expected effect.
23	I would intend to discontinue use of the medication prescribed by the doctor if symptoms improved.
24	I would intend to suspend the use of the medication prescribed by the doctor and use it at another time.
Domain 3: Behavior	
25	I have taken medication on my own for the last three months.
26	I use medication on my own when I do not need a prescription from the pharmacy.
27	I use medication on my own even when prescription retention is required at the pharmacy.
28	I use medication on my own during meals.
29	I use medication on its own along with teas.
30	I use medication on my own along with alcoholic beverages.
31	I use medication on my own because I have previous treatment experience.
32	I use medication on my own because I have old prescriptions.
33	I use medication on my own because I have medication stored at home.

Chart 2 – Cont.

34	I use medication on my own even without knowing the right amount to take.
35	I use medication on my own even without knowing how long it will be used.
36	I use medication on my own because it is quicker to solve my health problems.
37	I use medication on my own because it is recommended by friends/neighbors/family.
38	I use medication on my own because I do not need guidance from healthcare professionals.
39	I use more than one medication on my own at the same time.
40	I use medication on my own to treat symptoms of illnesses I already have (hypertension, diabetes, others).
41	I reduce the dose of the medication the doctor or nurse prescribed when symptoms improve.
42	I increase the dose of the medication the doctor or nurse prescribed when I realize that I am not improving.
43	I stop and use medication on my own when I feel better.
44	I have already increased the number of days of treatment.
45	I have already reduced the number of days of treatment.
46	When I take medication on my own, I continue even if my health condition worsens.
47	When I take medication on my own, I continue even in the presence of unwanted reactions.
48	I use antibiotics on my own.
49	I use prescription medications (for anxiety, depression, pain) on my own.

T.N. – this questionnaire was freely translated.

DISCUSSION

Using instruments validated with criteria and scientifically recognized allows healthcare professionals to access scientific technologies to carry out strategies and clinical practice[23]. The instrument development and validity process in this research was carried out in order to allow theoretical deepening, as it was supported by a literature review on RSM in the light of ML[2,10] and TPB[4].

When developing and validating the QAR, it was found that it represents an innovative tool. Therefore, using the QAR can help healthcare professionals identify the main behaviors that pose a risk to the health of adults who use medications without a prescription. Construct measure materializes in three non-linear and intercommunicating dimensions, namely: knowledge, which is supported by ML[11], involving TPB[4], which supports the behavioral intention and behavior dimensions. Such dimensions are non-linear and intercommunicating, intrinsically linked to health and its problems, highlighting it as an important concept for health research, in addition to directing healthcare professionals to devise appropriate strategies to promote public health, reducing risks to health.

The ML dimension arises from subjects' need to obtain, understand, communicate, calculate and process specific information about medications to make health decisions for safe and efficient use[2,11]. Studies have shown that an inadequate level of ML is directly associated with RSM[3,24]. This dimension covered items related to search for information (with unqualified people, internet, medication labels and leaflets), understanding information (from the leaflet and medication labels), information assessment (medication dose) and information application and use (calculating the right dose, clarifying doubts in the leaflet, using the right dose, recognizing an adverse reaction while using medication, experience with previous treatments).

An individual's high level of health literacy is one of the factors associated with rational use of medications, which can guarantee an increase in the effectiveness and safety of drug treatment[25]. On the other hand, a study carried out in Jordan with adults found that people with low health literacy are prone to engaging in inappropriate self-medication behaviors. Moreover, it was identified that two thirds of participants used antibiotics without a prescription[26]. This reinforces the importance of the ML dimension for measuring RSM.

From this perspective, improving health/ML skills can reduce RSM[26]. Thus, the ML dimension will provide healthcare professionals with support to draw up a user diagnosis regarding their abilities in medication use and ability to make decisions. Thus, an educational intervention study developed by healthcare professionals with the adult population of Indonesia showed significant improvements in ML, being able to promote responsible self-medication[27].

Among the constituent elements of RSM is behavior. To do so, it was necessary to use the TPB, which is an important predictor of behavior. Thus, the theory accounts for two domains, behavioral intention and behavior. This theory has been shown to be a predictor of health behaviors, including self-medication[9].

Regarding the behavioral intention dimension, it involves predictive factors such as attitudes, subjective norms and perceived power. This dimension involved items that show individuals' intent/intention to carry out RSM, showing the motivation and decision-making in carrying out this practice. The items assess self-medication outcomes (relief from symptoms, being quicker to solve health problems and having the expected effect), subjective influences from references (friends, neighbors and family)[28] on medication selection and use and the ability to perform self-medication (even with health risks)[4].

A study demonstrated an association between TPB constructs and self-medication, such as research carried out in Malaysia on self-medication of over-the-counter medications[29]. Therefore, measuring the intention to self-medicate is an important aspect, as it is an event that precedes the behavior itself. Another point is that this measure could enable health interventions, since these are aspects that can be modified[4].

The third dimension is behavior. This involves RSM practice, which is related to potential risks to human health[1]. This dimension covers frequency of self-medication, practice of self-medication on the recommendation of non-qualified people (friends, family and neighbors), without guidance from a healthcare professional, interaction (with food and/or other medications), based on prescriptions or old consultations, without knowing the adverse reaction, dose and duration, interference with the treatment prescribed by the doctor or nurse, medications that require prescriptions (antibiotics and/or psychotropics).

The fact is that using medications incorrectly can lead to several risks. A study carried out in Brazil with older adults showed the highest number of falls found in participants who used analgesics, muscle relaxants and anti-inflammatories[30]. This group requires greater attention in RSM practice, considering possible drug interactions, since they already continually use medications to treat chronic non-communicable diseases, which may lead to a reduction or enhancement of a drug's action.

When analyzing RSM from the dimensions listed, a break with traditional measures (measuring self-medication in general) is perceived, approaching health risk conditions, in addition to anticipating behavior through behavioral intention, knowing what can drive subjects to carry out such practice as well as ML that favors decision-making to carry out risky self-medication or appropriate self-medication. Considering the complexity of this latent trait and its repercussions, healthcare professionals must be prepared to outline appropriate strategies to minimize health risks and enable users to achieve better health promotion.

The content assessment of dimensions and items was carried out by a group of experts in self-medication and instrument construction, from different professions in the health area that involve using medications and from three regions of Brazil. Most experts were female. This preponderance was identified in another study that aimed to construct and validate instruments in health[31].

Expert analysis is a technique materialized in a validity study, as it assesses the expansion that each instrument item can represent the latent variable studied[23]. To assess the instrument, the nursing, pharmacy and medicine categories with expertise in self-medication were used, the majority of whom had a PhD, contributing more carefully to the process of judging the instrument, thus cooperating towards the validity of a higher quality instrument[31].

In the aforementioned content analysis phase by experts, a qualitative approach is used through assessments of their expertise and, after that, a quantitative approach using CVI[23]. Therefore, based on experts' analysis/suggestions, within the technical and scientific capabilities for judging the questionnaire, it was possible to analyze the concept of the latent trait of RSM, its constitutive and operational dimensions and items.

Therefore, selecting experts from different regions allows the instrument to contain a more comprehensive language, overcoming the limits of regionalism[23]. The first round of assessment culminated in maintaining the concept of the RSM latent trait and its dimensions. However, some items were excluded because they were not appropriate, had similarities, were grouped together or were not in line with the respective dimension.

As in a previous study[32], in the present study, greater criteria and rigor were considered in the agreement analysis process using the analysis of two agreement parameters: the CVI and the CVR. Although the first round of content analysis presented many items with low CVI and CVR, it must be considered that the intraclass coefficient was excellent, showing a correlation between experts' responses. Intraclass correlation is a statistical measure used to assess the reliability between various responses between different observers[22]. Thus, the first content analysis showed that experts maintained response trends with the same relative classification.

The items that were considered by experts as appropriate and the other items that were suggested for adaptation in language and grouped together underwent the second content analysis. In this analysis, the vast majority of items were considered adequate and relevant to measure RSM in their respective dimensions. On the other hand, the second round of content analysis, after statistics, found that the three dimensions obtained excellent CVI, with the behavior dimension obtaining a higher level of agreement, according to the framework used[18].

As in a previous study[33], more than one round of content validity was necessary to have adequate agreement indexes (CVI and CVR), thus providing greater security in the proposal to measure risk self-medication in terms of ML, intention to carry out self-medication and self-medication practice.

Regarding the limitations of this study, there was a large number of items involved in the first round of content analysis, which made it difficult for experts to provide feedback. Furthermore, many items presented similar or repeated contexts, which required a second round of content analysis. Another limitation attributed to carrying out this study was the need for clinical validity. To this end, it should be noted that the instrument is in the process of clinical validity and that exploratory and confirmatory factor analyzes will be carried out to better size the instrument.

From this study, it is expected that RSM measurement can guarantee healthcare professionals a diagnosis of the risk that the population may have when using medications on their own, in addition to supporting that the actions performed by these professionals can be directed according to the level of ML, behavioral intention and self-medication practice, promoting actions that guarantee patient safety.

CONCLUSION

The item bank presents satisfactory content and is composed of three dimensions: medication literacy, behavioral intention and behavior. A thorough assessment of innovation was carried out in item bank on risk self-medication in its broadest sense. The final version of the bank had 49 items after extensive and diverse analyzes by experts. It is recommended to undergo semantic analysis and subsequent internal structure validity. Finally, using the item bank in healthcare services is recommended in strategies that can modify RSM predictors, promoting the rational use of medications in the population.

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