

Construction and validation of an instrument for assessing the functionality of individuals with schistosomiasis

Construção e validação de instrumento de avaliação da funcionalidade de indivíduos com esquistossomose
Construcción y validación de instrumento de evaluación del funcionamiento de individuos con esquistosomiasis

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ABSTRACT

Objectives: to construct and validate an instrument for assessing the functionality of individuals with schistosomiasis. **Methods:** methodological study, developed in three stages: 1) construction of the instrument and its association with categories of the International Classification of Functionality, which the study used to elaborate the questions; 2) validation of content, performed by judges experts in the subject; 3) application of the instrument by the test-retest technique in the population with schistosomiasis in 14 days. The study used the correlation coefficient kappa to calculate the degree of agreement between the judges kappa. **Results:** in its final version, the instrument consists of 27 items, 9 of which are from the Body functions component, 6 from Body structures, 4 from Activity and participation, and 8 from Environmental factors. **Conclusions:** the constructed instrument has a biopsychosocial approach, considering four components of the ICF, besides presenting good validity and interobserver reliability.

Descriptors: Schistosomiasis; International Classification of Functioning, Disability and Health; Disability Evaluation; Validation Study; Epidemiology.

RESUMO

Objetivos: construir e validar um instrumento de avaliação da funcionalidade de indivíduos com esquistossomose. **Métodos:** estudo metodológico, desenvolvido em três etapas: 1) Construção do instrumento e associação deste com categorias da Classificação Internacional de Funcionalidade, que foram usadas para elaborar as perguntas; 2) Validação de conteúdo, realizada por juízes especialistas na temática; 3) Aplicação do instrumento pela técnica de teste-reteste na população com esquistossomose no intervalo de 14 dias. Para o cálculo do grau de concordância entre os juízes, utilizou-se o coeficiente de correlação kappa. **Resultados:** em sua versão final, o instrumento constitui-se por 27 itens, sendo 9 do componente de Funções do corpo, 6 de Estruturas do corpo, 4 de Atividade e participação e 8 de Fatores ambientais. Foi considerado válido e confiável. **Conclusões:** o instrumento construído tem abordagem biopsicossocial, considerando quatro componentes da CIF, além de apresentar boa validade e confiabilidade interobservador.

Descritores: Esquistossomose Mansonii; Classificação Internacional de Funcionalidade, Incapacidade e Saúde; Avaliação da Deficiência; Estudos de Validação; Epidemiologia.

RESUMEN

Objetivos: construir y validar instrumento de evaluación del funcionamiento de individuos con esquistosomiasis. **Métodos:** estudio metodológico, desarrollado en tres etapas: 1) Construcción del instrumento y su asociación con categorías de la Clasificación Internacional del Funcionamiento, que fueron usadas para elaborar las preguntas; 2) Validez de contenido, realizada por jueces especialistas en la temática; 3) Aplicación del instrumento por la técnica de test-retest en la población con esquistosomiasis en el intervalo de 14 días. Para cálculo del grado de concordancia entre los jueces, se utilizó el coeficiente de correlación kappa. **Resultados:** en su versión final, el instrumento se constituyó por 27 ítems, siendo 9 del componente de Funciones del cuerpo, 6 de Estructuras del cuerpo, 4 de Actividad y participación y 8 de Factores ambientales. Fue considerado válido y confiable. **Conclusiones:** el instrumento construido tiene abordaje biopsicosocial, considerando cuatro componentes de la CIF, además de presentar buena validez y confiabilidad interobservador.

Descriptorios: Esquistosomiasis; Clasificación Internacional del Funcionamiento, de la Discapacidad y de la Salud; Evaluación de la Discapacidad; Estudio de Validación; Epidemiología.

INTRODUCTION

Schistosomiasis is a dangerous parasitic disease, water-borne and caused by *Schistosoma mansoni*. After infection, parasitized individuals may present the acute clinical form or evolve into the chronic phase of the disease⁽¹⁻²⁾. The evolution of the disease can bring functional limitations and restrictions of participation in society⁽³⁻⁴⁾. Schistosomiasis presents a burden of 13 to 15 million DALYs (sum of years of productive life lost due to disability), with significant consequences in the socio-economic context of family members and the health system⁽⁵⁻⁶⁾ and behavioral and environmental factors that may contribute to disease transmission^(5,7-9).

It is evident the need for a more rigorous biopsychosocial approach given the complexity of transmission and control of schistosomiasis⁽¹⁰⁾. In addition, there are significant gaps in the functionality of these individuals. It makes it challenging to plan interventions, services, monitoring, evaluation, and funding to minimize their consequences⁽¹¹⁾.

Degrees of disability in individuals with a specific health condition are fundamental to determining the impact on the functionality and are widely used for setting priorities in research and public policy⁽⁴⁾. In order to deepen knowledge about different approaches in health and classify functionalities, the World Health Organization (WHO) published the International Classification of Functionality, Disability, and Health (ICF) in 2001⁽¹²⁾.

In the context of ICF, environmental, social, and personal factors are no less important than the presence of the disease in determining function, activity, and participation. Because of this, the ICF and its model have great epidemiological importance since the social factor is a determinant for the health level of the population⁽¹²⁾. This classification can help health professionals identify the dysfunctions and disabilities of the patient through a standard-language, described by its components⁽¹³⁾.

However, the ICF proposes what to evaluate and not how to evaluate. In this context, there is no instrument for assessing the functionality of individuals with schistosomiasis to identify and measure changes. Thus, the construction of such an instrument considering the ICF is fundamental since it provides a conceptual basis that provides a common language, describing the health states and the states related to it, in addition to generating health indicators.

Family Health Team professionals, especially nurses, doctors, and physiotherapists in the Extended Family Health and Primary Care Center can use the instrument for assessing the functionality of individuals with schistosomiasis, according to the specificity of each question. Thus, it will serve as a guiding tool for strategic actions to improve the productivity and efficiency of interventions.

OBJECTIVES

To construct and validate an instrument for assessing the functionality of individuals with schistosomiasis.

METHODS

Ethical aspects

The study was approved by the Ethics and Research Committee (ERC) for human beings of the Federal University of Sergipe as established in Resolution No. 466/12.

Design, period and place of study

It is a methodological study carried out online to validate content with the target audience in the town of Ribeira, in the municipality of Itabaiana, State of Sergipe, Brazil. The research took place in the years 2016 and 2017. The study used the SQUIRE 2.0 instrument of the EQUATOR network to guide the methodology.

Sample; criteria of inclusion and exclusion

For content validation, the study invited four judges according to the following inclusion criteria: being a health professional and working for at least three years with schistosomiasis, knowing the signs, symptoms, clinical forms, and functionality of these patients, being a teacher or researcher in schistosomiasis, and having knowledge about the ICF.

The sample of the target audience for the application of the proposed instrument was composed of individuals with and without schistosomiasis. The group with schistosomiasis included individuals diagnosed with schistosomiasis, living in the town of Ribeira, of both genders, age group from 18 years, and who were not in the treatment phase of acute comorbidities. The group without schistosomiasis had the same inclusion criteria, except the positive diagnosis for the *S. mansoni*.

Study protocol

The study adopted three psychometric procedures, which included theoretical, empirical (experimental), and analytical (statistical), as recommended by Pasquali⁽¹⁴⁻¹⁷⁾. The study had three stages consisting of the construction of the instrument, validation of content, and application of the instrument by the test-retest technique.

The theoretical procedure corresponds to the construction of the instrument, which was based on scientific productions relevant to the pathogenesis and clinical picture⁽¹⁸⁾, changes in the structure of organs and systems⁽¹⁸⁻¹⁹⁾, disability and life qualities^(3-5,18,20), behavioral, social factors and physical environment^(5-6,8,21-22) of individuals with schistosomiasis, and association of the main indicators with ICF categories.

After selecting the categories, researchers drawn up questions from the descriptions of such divisions. The answers were based on the ICF qualifiers, which considered "no disability" (0), "mild disability" (1), "moderate disability" (2), "Severe Disability" (3), "complete disability" (4). Meetings were held with three researchers with knowledge about schistosomiasis and ICF to analyze the questions and answers previously elaborated. After the discussion, researchers rewrote items or kept them according to the recommendations of each one, reaching a consensus on the minimum number of categories selected. The language used was an easy understanding, clear, simple, and objective communication, without allowing doubt in the interpretation, as recommended by Pasquali⁽¹⁴⁾.

Then, researchers performed the empirical (experimental) procedure through the validation of content and the application of the instrument by the test-retest technique.

After the creation of the questions and qualification criteria stage, the instrument was submitted to judges considered experts

in the subject to validate the content (Delphi study). However, for the analysis of the agreement, they were divided into two groups, called Group 1, composed of researchers who work with schistosomiasis and ICF; and Group 2, formed by researchers who work only with schistosomiasis.

Thus, the judges evaluated each item according to the criteria of clarity, understanding, language, and relevance to verify the dimension and representativeness of the domains of the instrument⁽¹⁷⁾. Each criterion was classified as follows: 1 – not relevant; 2 – relevant but needs revision; and 3 – very relevant. Also, they could suggest the withdrawal, addition, or modification of the items.

After the content validation stage, researchers changed the items following the judges' suggestions and applied the new version of the instrument by the test-retest technique. Four trained researchers participated, whose inclusion criteria were: being a health professional or being in the process of training; participating in studies on schistosomiasis; and knowing the clinical picture, functionality, and environmental factors related to schistosomiasis. According to the practice field of each judge, the study established that two from the physiotherapy area would be responsible for the application of the parts of the instrument related to Body functions, Activity and participation, and Environmental factors; and the other two, from medical, would assume the area related to body structures.

The sample for the application of the instrument mentioned above was composed as follows: the group with schistosomiasis had 14 individuals, six women, and eight men, and the mean age was 49.9 years. The group without schistosomiasis involved 33 individuals: 26 women and seven men, and the mean age was 50 years. The instrument was applied again (with the same groups) as part of the retest method with an interval of 14 days, time considered adequate to verify the temporal stability of the instrument⁽²³⁾.

Data analysis and statistics

For the analytical (statistical) procedure, the study calculated the degree of agreement and interobserver reliability. When validating the content, the expert judges verified the content validity index (CVI) of each item of the instrument⁽²⁴⁻²⁵⁾. They considered valid the items in which the CVI was higher than 0.75⁽²⁶⁾. The degree of agreement between the members of the group of expert judges, according to the relevance of the items, was calculated using the correlation coefficient kappa.

After expert judges' suggestions, the pre-final version of the instrument was obtained, used in the test-retest, in which the kappa was unweighted, with linear weighting and with quadratic weighting to verify agreement and reliability. In the evaluation of the correlation coefficient kappa, the following values were adopted: > 0.8 (almost perfect correlation); 0.61-0.8 (substantial correlation); 0.41-0.6 (moderate correlation); and < 0.4 (weak correlation). The correlations were considered almost perfect and substantial for the validation of the items⁽²⁷⁾.

RESULTS

At the stage of the theoretical procedure (construction of the instrument), based on the information obtained in scientific

productions, 41 relevant information on schistosomiasis was extracted, which were linked to categories of the ICF. Therefore, the first version of the instrument consisted of 41 items: thirteen of body functions, six of body structures, thirteen of activity and participation, and nine on environmental factors.

In the empirical (experimental) procedure, the process of judging the validation of content, the data concerning the components Functions of the body and Body structures are represented in Table 1. In the Body functions component, of the total of 13 items, the study excluded one ("B28014 Do you feel pain in your arms or hands"?) for not being considered representative of the content under study since it presented a CVI of 0.70 and kappa of 0 in Group 1. The CVI of the item "b530 Can you keep in your ideal weight" was 0.73, indicating the need to reformulate the question according to the judges' suggestions. The other items presented a CVI > 0.75, within the range that considers a validated item. For the kappa, two items had a value of 0.667 in Group 1, which indicates a substantial agreement, and the others had a value of 1, representing a perfect agreement.

In the Body structures component, all items presented CVI above 0.75, and two had CVI = 1. For the correlation coefficient kappa, two items presented values of 0.667; and the others, of 1.

All items in the Activity and participation component presented CVI > 0.89 and kappa = 1. In the Environmental factors component, all items presented CVI > 0.81 and kappa = 1. And the items "e450 Do health professionals assist in measures to prevent and combat schistosomiasis?" and "e5800 Are there health services in the community or region? Are services provided when needed?" had CVI of 1 (Table 2).

At this stage, judges also suggested modifications regarding clarity, understanding, and language, including the replacement of terms to improve the wording and representativeness of the items. In the items related to pain (b2800, b28012, b28013, b28014, b28015), the judges reported difficult distinction between severe and complete disability, so they chose to use the numerical scale of pain; the item description b530 was replaced by "you lost weight in the last year due to some health problem"; in b5251, the answer option "liquid stool" was added; s4203 s810, more qualifiers regarding the location; item 5300 was divided into two: one referring to the water supply; and another, energy.

For the calculation of the degree of agreement and reliability by the test-retest, in the items related to the Body functions component (Table 3), only two questions presented a kappa not weighted with a substantial correlation, represented by categories b5150 and b530, with values of 0.632 and 0.777, respectively. Judges considered these items valid. The other items presented values of kappa unweighted classified as moderate and weak correlation; questions b28012, b5352, b5350, b5351, b5252, b5251, and b840 were reformulated according to the needs perceived by the judges during the application of the instrument, and they excluded three.

For the body structure component (Table 3), the items s120, s4101, and s560 presented kappa unweighted, with linear and quadratic weighting equal to 1, corresponding to a perfect concordance, and item s120 was reformulated; in the others, it was not possible to calculate the kappa.

Table 1 – Content analysis performed by the judges (n = 4) considering the degree of agreement and reliability of items referring to the components Body functions and Body structures

	CVI Item	Kappa	
		G1	G2
Items relating to the Body functions component			
(b2800) Do you feel pain all over your body?	0.87	0.667	1
(b28012) Do you feel pain in your stomach or abdomen?	0.95	1	1
(b28013) Do you feel back pain?	0.95	1	1
(b28014) Do you feel pain in your arms or hands?*	0.70	0	1
(b28015) Do you feel pain in your legs and feet?	0.95	1	1
(b5352) Do you experience any abdominal discomfort, such as colic? Does it bother you?	0.96	1	1
(b530) Can you keep at your ideal weight?	0.73	0.667	1
(b5350) Do you feel nauseous? Does it bother you?	0.95	1	1
(b5351) Do you feel your abdomen distended, swollen? Does it bother you?	0.95	1	1
(b5252) Do you have diarrhea? What is the frequency of defecation?	0.95	1	1
(b5252) Do you have intestinal constipation? What is the frequency of defecation?	1	1	1
(b5251) What is the consistency of your stool?	0.95	1	1
(b840) After entering or using the water of the river, stream, water puddle, well, did you feel any itching?	1	1	1
Items relating to the Body structure component			
(s120) Are you diagnosed with schistosomal myeloradiculopathy (SMR)? If yes, analyze on imaging tests medullary granuloma characteristic of SMR	0.85	0.667	1
(s4102) Presence of varicose veins in the abdomen?	0.95	1	1
(s4203) Physical examination of spleen	0.91	0.667	1
(s540) Physical examination of the intestine	1	1	1
(s560) Physical examination of the liver	1	1	1
(s810) Did you experience cercarian dermatitis after coming into contact with the water of the river, stream, lake, puddle, well?	0.85	1	1

CVI – Content validity index; G1 – Schistosomiasis Group and ICF; G2 – Schistosomiasis Group; * non-validated items.

Table 2 - Content analysis performed by the judges (n = 4) considering the degree of agreement and reliability of items related to the Activity and participation component

	CVI Item	Kappa	
		G1	G2
Items related to the Activity and participation component			
(d4102) Do you need help getting out of the position from sitting on your feet to kneeling?	0.95	1	1
(d4103) Do you need help getting out of the lying or standing position to sitting?	0.95	1	1
(d4104) Do you need help getting out of the lying or sitting position to stand?	0.95	1	1
(d4105) Do you have difficulty tilting the trunk forward to catch an object on the ground?	0.95	1	1
(d4500) Do you have difficulty walking indoors or near your home?	0.95	1	1
(d4552) Do you have difficulty walking along your community or city?	0.89	1	1
(d4551) Do you have difficulty going up and down stairs, ramps, sloping surfaces?	0.95	1	1
(d510) Do you have trouble showering and drying yourself?	0.95	1	1
(d540) Do you have difficulty putting on clothes and putting on shoes?	0.95	1	1
(d5702) Do you often seek help and follow guidance from health professionals often?	1.00	1	1
(d810-d839) What is your level of education?	1.00	1	1
(d8451) Can you work independently?	1.00	1	1
(d870) How many minimum wages is the family's monthly income?	0.98	1	1
Items related to the Environmental factors component			
(e1101) Do you use any medications?	0.98	1	1
(e2101) Do you usually perform the following activities in the river, streams, puddles, well, streams?	0.98	1	1
(e2201) Do the rivers, streams, puddles, well, streams that you frequent contain snails?	0.98	1	1
(e310) Does your family help you with your activities and other things you need?	0.81	1	1
(e355) Do you have access to all the healthcare professionals you need?	0.87	1	1
(e450) Do health professionals assist in measures to prevent and combat schistosomiasis?	1	1	1
(e5300) Are there basic sanitation services in your region? If so, do they help or harm your life?	0.95	1	1
(e5300) Are there water and power supply services in the region? If so, do they help or harm your life?	0.85	1	1
(e5800) Are there health services in the community or region? Are services provided when needed?	1	1	1

CVI – Content Validity Index; G1 – Schistosomiasis Group and ICF; G2 – Schistosomiasis Group.

Table 3 – Content analysis performed by the judges (n = 4) in the test-retest considering the degree of agreement and reliability of the items referring to the components Body functions and Body structure

	Not weighted	Linear weighting	Quadratic weighting
Items relating to the Body functions component			
(b2800) Do you feel pain all over your body?	0.473	0.691	0.828**
(b28012) Do you feel pain in your stomach or abdomen?	0.347	0.535	0.692*
(b28013) Do you feel back pain?	0.266	0.408	0.514**
(b28015) Do you feel pain in your legs and feet?	0.449	0.635	0.758**
(b5150) Do you have your gut stuck?	0.632	0.729	0.813
(b5352) Do you experience any abdominal discomfort, such as colic? Does it bother you?	0.286	0.285	0.352*
(b530) Have you lost weight in the last year due to health problem?	0.777	0.777	0.777
(b5350) Do you feel nauseous? Does it bother you?	0.357	0.478	0.621*
(b5351) Do you feel your abdomen distended, swollen? Does it bother you?	Could not calculate the kappa		
(b5252) Do you have diarrhea?	0.127	0.099	0.050*
(b5251) What is the consistency of your stool?	0.293	0.293	0.293*
(b840) After entering or using the water of the river, stream, water puddle, well, did you feel any itching?	0.474	0.372	0.331*
Items relating to the Body structure component			
(s120) Are you diagnosed with schistosomal myeloradiculopathy (SMR)? If yes, analyze on imaging tests medullary granuloma characteristic of SMR	1	1	1
(s4102) Presence of varicose veins in the abdomen?	Could not calculate the kappa		
(s4203) Physical examination of spleen	1	1	1
(s540) Physical examination of the intestine	Could not calculate the kappa		
(s560) Physical examination of the liver	1	1	1
(s810) Did you experience cercarian dermatitis after coming into contact with the water of the river, stream, lake, puddle, well?	Could not calculate the kappa		

kappa (unweighted, linear weighting, quadratic weighting); * reworked items; ** excluded items

Table 4 - Analysis performed by the judges (n = 4) in the test-retest considering the degree of agreement and reliability of the items referring to the components Activity and participation and Environmental factors

	Not weighted	Linear weighting	Quadratic weighting
Items related to the Activity and participation component			
(d4102) Do you need help getting out of the position from sitting on your feet to kneeling?	0.579	0.751	0.873**
(d4103) Do you need help getting out of the lying or standing position to sitting?	0.438	0.524	0.576**
(d4104) Do you need help getting out of the lying or sitting position to stand?	0.378	0.519	0.627**
(d4105) Do you have difficulty tilting the trunk forward to catch an object on the ground?	0.342	0.509	0.639**
(d4500) Do you have difficulty walking indoors or near your home?	0.238	0.357	0.464**
(d4552) Do you have difficulty walking along your community or city?	0.379	0.540	0.669*
(d4551) Do you have difficulty going up and down stairs, ramps, sloping surfaces?	0.409	0.567	0.657**
(d510) Do you have trouble showering and drying yourself?	0.357	0.478	0.621**
(d540) Do you have difficulty putting on clothes and shoes?	0.466	0.572	0.657**
(d5702) Do you often seek help and follow guidance from health professionals often?	0.330	0.393	0.483**
(d810-d839) What is your level of education?	0.962	0.969	0.978
(d8451) Can you work independently?	0.480	0.631	0.778*
(d870) How many minimum wages is the family's monthly income?	0.858	0.866	0.879
Items related to the Environmental factors component			
(e1101) Have you used any schistosomiasis medication?	0.758	0.804	0.843
(e2101) Do you usually perform the following activities in the river, streams, puddles, well, streams?	0.875	0.879	0.886
(e2201) Do the rivers, streams, puddles, well, streams that you frequent contain snails?	0.915	0.915	0.915
(e310) Does your family help you with your activities and other things you need?	0.094	0.068	0.047*
(e355) Do you have access to all the healthcare professionals you need?	0.030	0.153	0.258**
(e450) Do health professionals assist in measures to prevent and combat schistosomiasis?	0.282	0.456	0.602**
(e5300) Are there basic sanitation services in your region? If so, do they help or harm your life?	0.035	0.035	0.035*
(e5300) Are there water supply services in the region? If so, do they help or harm your life?	1	1	1
(e5300) Are there power supply services in the region? If so, do they help or harm your life?	1	1	1
(e5800) Are there health services in the community or region? Where necessary, are services provided?	0.259	0.232	0.184*

kappa (Unweighted, linear weighting, quadratic weighting); * reworked items; ** excluded items.

In the items related to the Activity and participation component (Table 4), only d810-d839 and d870 presented the kappa not weighted with a perfect correlation; the others had moderate or weak correlation. In the linear weighting analysis, the study classified items d4102 and d8451 as substantial correlation, and d810-d839 and d870 had perfect correlation. In the quadratic weighting, the items d4104, d4105, d4552, d4551, d540, and d8451 presented substantial correlation; and d4102, d810-d839, and d870, perfect correlation, and nine were excluded.

In the analysis of kappa not weighted for the Environmental factors component, item e1101 presented substantial correlation, and e2101, e2201, e5300, and e5300 had perfect correlation. Items e1101, e2101, e2201, e5300, and e5300 showed linear and quadratic weighting with perfect correlation; and two items were excluded (Table 4).

The judges made changes to the items not validated through the information obtained during the application of the instrument to make it clearer and objective. They reformulated 11 items: 6 items of the Body functions component; 2 of Activity and participation; and 3 of Environmental factors.

The items b28012, b5352, b5350, b5252 began to present two answer options (yes or no); in b5251, the term “most of the time” was added; b840 kept only three answer options; in d4552, judges recommended to leave the answers more objective, then they were with the same description of the qualifiers; d8451 changed to “Do you have difficulty to work?”; the wording of e450 has been replaced by “Do health professionals carry out activities of education, prevention and fight against schistosomiasis?”; in e5300, the term “basic sanitation” was replaced by “sewer network”; in e5800, the study specified that the services would be from the Basic Health System (SUS).

In its final version, the instrument consisted of 27 items, nine of the Body functions component, six of Body structures, four of Activity and participation, and eight of Environmental factors. Figure 1 represents the process of construction and validation of the instrument.

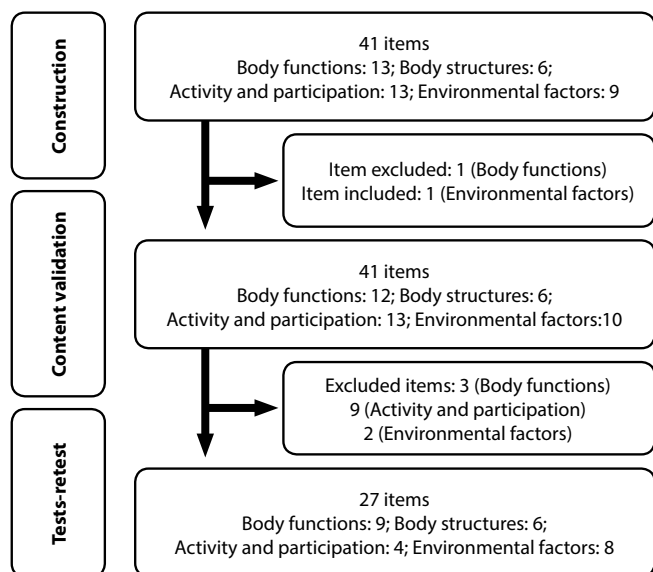


Figure 1 - Flowchart of the instrument construction and validation process

DISCUSSION

Environmental factors influence schistosomiasis^(5-6,8,22). It is an endemic and disabling disease, which, with the evolution of the symptomatological picture, can trigger changes in the functionality and restriction of living in society^(3,11). However, the Schistosomiasis Control Program (SCP) does not record data regarding functionality since there is no consensus on the assessment instruments to map and monitor such aspects in individuals with schistosomiasis. ICF can be used to support the creation of such tools, which can provide a conceptual basis for standardization and contribute with information on health and disability worldwide.

The development of an assessment instrument usually starts with a higher number of items to obtain the ideal number in the final validation version⁽²⁸⁾, and there should be questions in sufficient number and quality to meet the objectives of the evaluation⁽²⁹⁾. The study adopted categories of the four components of the ICF, as there is a need for them to be correlated with each other by their different components, corroborating the biopsychosocial model of health⁽³⁰⁾. In addition, the ICF has significant potential to serve as a basis for the development of clinical instruments to measure functionality, being used for several health condition⁽³¹⁻³⁵⁾.

Van't Noordende et al. (2016) evaluated the functionality of individuals with infectoparasitic diseases through a Delphi study and the use of questionnaires for individuals with Chagas disease, leprosy, leishmaniasis, and schistosomiasis, in northeastern Brazil. The authors highlighted the need for a holistic approach in the assessment of physical, social, and behavioral implications to substantiate interventions analyzing the situation of the population in its different aspects and to prevent and manage the occurrence of disability⁽¹¹⁾.

When assessing the items' content, judges should prioritize clarity, understanding, language, and relevance to verify the dimension and representativeness of the domains according to the theme of the study and the ease of comprehension by the target audience⁽¹⁷⁾. In this study, the judges reported problems related to clarity, comprehension, and language. With it, our findings have undergone modifications for better adaptation and public understanding-target: patients with schistosomiasis.

In the Body functions component, the study reformulated six items: four related to pain assessment (b2800, b28012, b28013, b28015), in which respondents reported difficulty to understand and distinguish between the responses. This reformulation was scientifically based according to the national and international literature, choosing to correlate the numerical scale of pain, a validated test, with the ICF qualifiers. The correlation of validated assessment instruments with ICF categories and qualifiers is widely accepted by the scientific community and provides a universal language based on different assessment protocols, facilitating communication between professionals over time^(30,36-38).

The present study sought to meet the suggestions of the judges as a way to improve the instrument, according to the methodological criteria described by Pasquali⁽¹⁴⁻¹⁷⁾: the items presented short sentences, with simple and unequivocal expressions, so that the difficulty of understanding the items was not a limiting factor in the response of the individuals.

After content validation, the instrument was submitted to the target population by the test-retest technique. Range kappa it was 0.030 - 1 (unweighted), 0.035-1 (with linear weighting) and 0.035-1 (with quadratic weighting). The values of kappa with quadratic weighting were higher compared to linear. It shows that the discrepancy between the responses was greater in neighboring values than between extreme values, which was better investigated by the unweighted.

The low kappa values in the test-retest may be explained by the fact that all individuals in the schistosomiasis group presented mild infection intensity, without significant impairment of body functions and structures, without limiting the execution of the questioned activities. Studies show that individuals with chronic schistosomiasis may remain asymptomatic and complain of light abdominal symptoms⁽³⁹⁾. In the most severe forms of the disease, individuals present some degree of disability, with consequent impairment in development and physical fitness, reduction in the performance of usual activities, mobility, and self-care^(3,39).

At the end, the instrument consisted of 27 items, with twelve validated. Eleven questions were reworded, although they did not have kappa values indicating that the item was validated since it is information considered representative of the clinical picture. The study used the criterion based on the information most often seen in articles on the health condition of individuals with schistosomiasis to maintain non-validated items. The study considered the suggestions regarding the understanding of the instrument to adapt these items because, in these cases, it needed more detailed explanations to obtain the answer. It was not possible to calculate the kappa in 4 items, which were kept in the instrument, also reformulating one of them. The items that were not validated in the test-retest reinforce the specific character of the instrument, indicating the need for reformulation to make them more evident for the evaluation.

Limitations of the study

A limitation of the study consists in some items of the Body Functions and Activity and Participation components being associated with the individual's health condition on the day of the assessment, which may have influenced the validation. As the questions and answers of the instrument were designed based on the selected categories and ICF qualifiers, respectively, which are described in scientific and medical terms, the study required adaptation to a more understandable language. Therefore, the items that have not been validated and are considered essential to understanding the health condition of individuals with schistosomiasis must be reformulated, relying on information

obtained during the application of the instrument to make them more evident and more understandable.

Another point noted is that the study could not detect whether the problems are caused by schistosomiasis or another condition. The application sample of the instrument was characterized by mild clinical conditions, which compromised the analysis of some items. In addition, the new items reformulated after the test-retest phase were not subjected to new validation protocols.

Contributions to the field of Public Health

The biopsychosocial approach allows verifying the relationship of schistosomiasis with the functions and structures of the body, activity, and participation of the individual, in addition to the influence of environmental factors on functionality. Thus, the study suggests that the information obtained in the evaluation be used to deepen the knowledge of the health situation of individuals with schistosomiasis and, therefore, monitor and develop better and more effective strategies for the control of schistosomiasis in Brazil.

CONCLUSIONS

The instrument for the assessment of the functionality of individuals with schistosomiasis based on ICF has good validity and interobserver reliability. The final version consists of items that address all components of the ICF: Body functions and structures, Activity and participation, and Environmental factors. It is necessary to apply the instrument by different categories of health professionals and in different samples of individuals with schistosomiasis.

SUPPLEMENTARY MATERIAL

Insert supplement 1: an instrument for assessing the functionality of individuals with schistosomiasis. <https://doi.org/10.48331/scielodata.SANDJ8>

Insert supplement 2: guidelines for completing and interpreting the functionality assessment instrument for individuals with schistosomiasis. <https://doi.org/10.48331/scielodata.TJUEQN>

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REFERENCES

1. Bizimana P, Polman K, Geertruyden J-PV, Nsabiyeumva F, Ngenzebuhoro C, Muhimpundu E, Ortu G. Capacity gaps in health facilities for case management of intestinal schistosomiasis and soil-transmitted helminthiasis in Burundi. *Infect Dis Poverty*. 2018;7(1):66. <https://doi.org/10.1186/s40249-018-0447-y>
2. Turner HC, French MD, Montresor A, King CH, Rollinson D, Toor J. Economic evaluations of human schistosomiasis interventions: a systematic review and identification of associated research needs. *Wellcome Open Res*. 2020;5:45. <https://doi.org/10.12688/wellcomeopenres.15754.2>

3. Jia TW, Utzinger J, Deng Y, Yang K, Li YY, Zhu JH, et al. Quantifying quality of life and disability of patients with advanced schistosomiasis japonica. *PLoS Negl Trop Dis*. 2011;5(2):e966. <https://doi.org/10.1371/journal.pntd.0000966>
4. Fürst T, Silué KD, Ouattara M, N'Goran DN, Adiossan LG, N'Guessan Y, et al. Schistosomiasis, soil-transmitted helminthiasis, and sociodemographic factors influence quality of life of adults in Côte d'Ivoire. *PLoS Negl Trop Dis*. 2012;6(10):e1855. <https://doi.org/10.1371/journal.pntd.0001855>
5. Nascimento GL, Pagado HM, Domingues ALC, Ximenes RAA, Itria A, Cruz LN, Oliveira MRF. The coast of a disease targeted for eliminations in Brazil: the case of schistosomiasis mansoni. *Mem Inst Oswaldo Cruz*. 2019;144:e180347. <https://doi.org/10.1590/0074-02760180347>
6. Adenowo AF, Oyinloye BE, Ogunyinka BI, Kappo AP. Impact of human schistosomiasis in sub-Saharan Africa. *Braz J Infect Dis*. 2015;19(2):196–205. <https://doi.org/10.1016/j.bjid.2014.11.004>
7. Guan Z, Dai SM, Zhou J, Ren XB, Qin ZQ, Li YL, et al. Assessment of knowledge, attitude and practices and analysis of risk factors regarding schistosomiasis among fishermen and boatmen in the Dongting Lake Basin, the people's Republic of China. *Parasit Vectors*. 2020;13(1):273. <https://doi.org/10.1186/s13071-020-04157-4>
8. Strunz EC, Addiss DG, Stocks ME, Ogden S, Utzinger J, Freeman MC. Water, sanitation, hygiene, and soil-transmitted helminth infection: a systematic review and meta-analysis. *PLoS Med*. 2014;11(3):e1001620. <https://doi.org/10.1371/journal.pmed.1001620>
9. Sevilimedu V, Pressley KD, Snook KR, Hogges JV, Polits MD, Sexton JK, et al. Gender-based differences in water, sanitation and hygiene-related diarrheal disease and helminthic infections: a systematic review and meta-analysis. *Trans R Soc Trop Med Hyg*. 2016 Nov;110(11):637–48. <https://doi.org/10.1093/trstmh/trw080>
10. Pearson G. Low prevalence of intestinal schistosomiasis among fisher folk north-western Uganda: a biosocial investigation. *J Biosoc Sci*. 2016;48(suppl 1):74–91. <https://doi.org/10.1017/S0021932016000237>
11. Van't Noordende AT, Kuiper H, Ramos AN, Mieras LF, Barbosa JC, Pessoa SMF, et al. Towards a toolkit for cross-neglected tropical disease morbidity and disability assessment. *Int Health*. 2016;8 (suppl 1):71–81. <https://doi.org/10.1093/inthealth/ihw006>
12. Organização Mundial de Saúde. Classificação Internacional de Funcionalidade, Incapacidade e Saúde. 2ª Ed. São Paulo: Edusp; 2015. 333p.
13. Monsen M, Stapelfeldt CM, Rosbjerg R, Escorpizo R, Labriola M, Bjerrum M. International classification of functioning, disability and health in vocational rehabilitation: a scoping review of the state of the field. *J Occupat Rehabil*. 2019;29(2):241–273. <https://doi.org/10.1007/s10926-018-9788-4>
14. Pasquali L. Princípios de elaboração de escalas psicológicas. *Rev Psiquiatr Clin [Internet]*. 1998 [cited 2018 Jun 5];25(5):206–13. Available from: <http://bases.bireme.br/cgi-bin/wxislind.exe/iah/online/?!sIsScript=iah/iah.xis&src=google&base=LILACS&lang=p&nextAction=Ink&prSearch=228044&indexSearch=ID>
15. Pasquali L. Validade dos Testes Psicológicos: Será Possível Reencontrar o Caminho. *Psic: Teor e Pesq*. 2007; 23(spe):99–107. <https://doi.org/10.1590/S0102-37722007000500019>
16. Pasquali L. Psychometrics. *Rer Esc Enferm USP*. 2009;43(spe): 992–9. <https://doi.org/10.1590/S0080-62342009000500002>
17. Pasquali L. Instrumentação psicológica: fundamentos e práticas. *Porto Alegre Artmed*; 2009. 560p.
18. World Health Organization (WHO). Key facts. Schistosomiasis [Internet]. 2016 [cited 2018 Jun 2]. Available from: <https://www.who.int/news-room/fact-sheets/detail/schistosomiasis>
19. Andrianah GEP, Rakotomena D, Rakotondrainibe A, Ony LHNR, Ranoharison HD, Ratsimba HR, et al. Contribution of ultrasonography in the diagnosis of periportal fibrosis caused by schistosomiasis. *J Med Ultrasound*. 2020;28(1):41–43. https://doi.org/10.4103/JMU.JMU_16_19
20. Molyneux DH, Savioli L, Engels D. Neglected tropical diseases: progress towards addressing the chronic pandemic. *Lancet*. 2017;389(100660):312–325. [https://doi.org/10.1016/S0140-6736\(16\)30171-4](https://doi.org/10.1016/S0140-6736(16)30171-4)
21. Sacolo H, Chimbari M, Kalinda C. Knowledge, attitudes and practices on Schistosomiasis in sub-Saharan Africa: a systematic review. *BMC Infect Dis*. 2018;18:46. <https://doi.org/10.1186/s12879-017-2923-6>
22. Paz WS, Gomes DS, Ramos RE, Cirilo TM, Santos JGA, Ribeiro CJ, et al. Spatiotemporal clusters of schistosomiasis mortality and association with social determinants of health in the Northeast region of Brazil (1980–2017). *Acta Trop*. 2020; 212:105668. <https://doi.org/10.1016/j.actatropica.2020.105668>
23. Streiner DL, Norman GR, Cairney J. Health measurement scales: a practical guide to their development and use. 5th ed. Oxford University Press; 2015. <https://doi.org/10.1093/med/9780199685219.001.0001>
24. Matos FR, Rossini JC, Lopes RFF, Amaral JDHF. Translation, adaptation, and evidence of content validity of the Schema Mode Inventory. *Psicol Teor Prat*. 2020;22(2):18–38. <https://doi.org/10.5935/1980-6906/psicologia.v22n2039-59>
25. Souza AC, Milani D, Alexandre NMC. Adaptação cultural de um instrumento para avaliar a satisfação no trabalho. *Rev Bras Saúde Ocup*. 2015;40(132):219–27. <https://doi.org/10.1590/0303-7657000113715>
26. Tibúcio MP, Melo GSM, Balduino LSC, Costa IKF, Dias TYAF, Torres GV. Validação de instrumento para avaliação da habilidade de mensuração da pressão arterial. *Rev Bras Enferm*. 2014;67(4):581–7. <https://doi.org/10.1590/0034-7167.2014670413>
27. Cicchetti DV, Sparrow SA. Developing criteria for establishing interrater reliability of specific items: applications to assessment adaptive behavior. *Am J Ment Defic [Internet]*. 1981 [cited 2018 Sep 8];81(2):127–37. Available from: <https://pubmed.ncbi.nlm.nih.gov/7315877/>
28. Raymundo VP. Construção e validação de instrumentos: um desafio para a psicolinguística. *Let Hoje [Internet]*. 2009 [cited 2018 Sep 8]; 44(3):86–93. Available from: <https://revistaseletronicas.pucrs.br/ojs/index.php/fale/article/view/5768>

29. Vieira, S. Como elaborar questionários. São Paulo: Atlas; 2009.175p.
 30. Park M, Choi EJ, Jeong M, Lee N, Kwak M, Lee M, et al. ICT- based comprehensive health and social-needs assessment system for supporting person-centered community care. *Healthc Inform Res.* 2019;25(4):338-343. <https://doi.org/10.4258/hir.2019.25.4.338>
 31. Raji P, Hassani Mehraban A, Aliabadi F, Ahmadi M, Schiariti V. Content validity of the comprehensive ICF Core Set for children with cerebral palsy aged 0-6 years: Iranian Occupational Therapists Perspective. *Iran J Child Neurol* [Internet]. 2018[cited 2018 Sep 8];12(3):40-58. Available from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6045943/>
 32. Huang J, Reinhardt JD, Dai R, Wang P, Zhou M. Validation of the brief international classification of functioning, disability, and health core set for obstructive pulmonary disease in the Chinese context. *Chron Respir Dis.* 2019;16:1-14. <https://doi.org/10.1177/1479973119843648>
 33. Carter K, Tannous C, Walmsley S, Rome K, Turner DE. Linking the patient experience of foot involvement related to psoriatic arthritis to the International Classification of Functioning, Disability and Health. *Rheumatol Adv Pract.* 2020; 4(2):1-11. <https://doi.org/10.1093/rap/rkaa028>
 34. Lucki M, Chlebus E, Warcenzak A, Lisinski P. The ICF Classification system to assess risk factors for CVD is secondary prevention after ischemic stroke and intracerebral hemorrhage. *Medicina.* 2021;57(3):190. <https://doi.org/10.3390/medicina57030190>
 35. Otorhinolaryngol EA, Kisser U, Michaela CA. The development of an ICF-based clinical guideline and screening tool for the standardized assessment and evaluation of functioning after head and neck cancer treatment. *Eur Arch Otorhinolaryngol.* 2017;274(2):1035-43. <https://doi.org/10.1007/s00405-016-4317-6>
 36. Moura L, Santos WR, Castro SS, Ito E, Silva DCL, Yokata RTC, et al. Applying the ICF linking rules to compare population-based data from different sources: an exemplary analysis of tools used to collect information on disability. *Disabil Rehabil.* 2019;41(5):601-612. <https://doi.org/10.1080/09638288.2017.1370734>
 37. Carter K, Tannous C, Walmsley S, Rome K, Turner DE. Linking the effect of psoriatic arthritis- related foot impact scale using the International Classification for Functioning, Disability and Health: a study to assess content validity. *J Foot Ankle Res.* 2020;13(1):52. <https://doi.org/10.1186/s13047-020-00420-0>
 38. Griffis DN, Lussier EF. Automated Coding of Under- Studied Medical concept domains: linking physical activity reports to the international classification of functioning, disability, and health. *Front Digit Health.* 2021;3. <https://doi.org/10.3389/fdgth.2021.620828>
 39. Colley DG, Bustinduy AL, Secor WE, King CH. Human schistosomiasis. *Lancet.* 2014;383(9936):2253–64. [https://doi.org/10.1016/S0140-6736\(13\)61949-2](https://doi.org/10.1016/S0140-6736(13)61949-2)
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