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INSTRUMENTS VALIDATED IN BRAZIL FOR SPINAL CORD INJURY: SCOPING REVIEW

INSTRUMENTOS VALIDADOS NO BRASIL PARA LESÃO MEDULAR: REVISÃO DE ESCOPO

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ABSTRACT

Background: *The the spinal cord injury (SCI) impacts functioning, thus, it is necessary to use proper assessments to allow professionals to monitor the patients' progress.* ***Objectives:*** *Identify the validated instruments for persons with SCI in Brazil and correlate their items with the ICF components.* ***Methods:*** *This is a scoping review where searches were performed in the principals databases. The search strategies included the keywords: 'SCI, 'Brazil', 'validation study', and 'questionnaires'.* ***Results:*** *Eleven studies were included, totaling ten instruments that assess functional independence, quality of life, and urinary tract disorders in SCI. The frequencies in which the ICF components appear in the instruments were: body functions (42%), body structures (0%), activities and participation (50%), and environmental factors (7.8%).* ***Conclusion:*** *The findings of this study assisting the selection of the most appropriate tool for the assessment related to the biopsychosocial model of health in people with SCI.*

Key words: *Spinal cord injury; Validation Study; International Classification of Functioning, Disability and Health.*

RESUMO

Introdução: *A lesão medular (LM) impacta a funcionalidade, sendo necessário o uso de avaliações adequadas que permitam aos profissionais acompanhar a evolução dos pacientes.* ***Objetivos:*** *Identificar os instrumentos validados para pessoas com LM no Brasil e correlacionar seus itens com os componentes da CIF.* ***Métodos:*** *Esta é uma revisão de escopo na qual as buscas foram realizadas nas principais bases de dados. As estratégias de pesquisa incluíram as palavras-chave: 'LM', 'Brasil', 'estudo de validação' e 'questionários'.* ***Resultados:*** *Onze estudos foram incluídos, totalizando dez instrumentos, que avaliavam independência funcional, qualidade de vida e distúrbios do trato urinário na LM. As frequências em que os componentes da CIF aparecem nos instrumentos foram: funções corporais (42%), estruturas corporais (0%), atividades e participação (50%) e fatores ambientais (7,8%).* ***Conclusão:*** *Os achados deste estudo auxiliam na seleção da ferramenta mais adequada para a avaliação relacionada ao modelo biopsicossocial de saúde de pessoas com LM.*

Palavras-chave: *Lesão medular; Estudo de Validação; Classificação Internacional de Funcionalidade, Incapacidade e Saúde.*

INTRODUCTION

Spinal cord injury (SCI) is a health condition that leads to loss of motor and sensory functions, intestinal dysfunction, spasticity, neuropathic pain, autonomic dysreflexia, and urinary tract dysfunction, as well as emotional, psychosocial, and community participation impairments.[1] In Brazil, SCI is considered a public health concern, and its estimated incidence varies between 9 and 50 cases per million.[2]

This trauma impacts directly on the quality of life and functional capacity of the individual, leading to loss of independence in some daily life activities. Thus, it is necessary to use standardized and proper functional assessments to allow health professionals to individually monitor the patients' progress and identify the main challenges and deficiencies.[3]

The identification of these difficulties and deficiencies has become more comprehensive and assertive after the International Classification of Functioning, Disability and Health (ICF), proposed by the World Health Organization (WHO) in 2001. The ICF covers a biopsychosocial model of health that provides a conceptual framework and classification system that identifies body structures and functions, activities, participation, environmental, and personal factors components. It also comprises the interactions between different components, reflecting both the influence and the continuous bidirectional interaction between factors.[4]

In this context, individuals with SCI present impairments in body functions and structures, activity limitation, and participation restriction, while functioning is influenced by environmental factors that may act as barriers or facilitators.[5] Therefore, the focus of patient management has shifted to interventions aiming to improve functioning, quality of life, and involvement in life situations.[6]

Although generic instruments may be adequate to assess different health conditions, their sensitivity in individuals with specific neurological conditions, such as SCI, is questioned due to the disease complexity. Thus, to be reasonable for large-scale use, specific assessment tools for persons with SCI must be validated and based on the concept of health and functioning proposed by the ICF to provide the

development of goals for both the patient and family, as well as clinical comparisons for economic, social, and research purposes.[7, 8]

Therefore, this review aimed to identify and map the translated, adapted, and validated instruments for persons with SCI in Brazil, and correlate their items with the ICF components related to functioning.

Methods

Protocol and registration

This is a scoping review guided by the recommendations of the Joanna Briggs Institute (JBI) Reviewer's Manual,[9] and based on the following theoretical framework proposed by Arksey and O'Malley.[10]

1. Identification of the research question, based upon the PCC strategy:[9] P (Population) - Persons with SCI; C (Concept) – Instruments; and C (Context) - Brazil. Thus, the guiding question was: What validated instruments are used in Brazil to assess persons with SCI?
2. Identification of relevant evidence sources
3. Study selection
4. Charting the data
5. Collating, summarizing, and reporting the results.

The review was registered on the Open Science Framework platform (https://osf.io/tu6ze/) and followed the checklist of the Preferred Reporting Items for Systematic Review and Meta-Analyzes (PRISMA) for Scoping Reviews.[11]

Eligibility criteria

The inclusion criteria were: articles published from 2001 to 2020 in English, Portuguese, or Spanish, who conducted the validation of assessment instruments in Brazil, and with a sample composed of persons with traumatic and/or non-traumatic SCI. This period was considered due to the date of publication of the ICF, made in 2001. Exclusion criteria were: editorials, experience reports, reflective studies, reviews, duplicate articles, and studies performing only translation or cross-cultural adaptation.

Sources of information, search strategy, and study selection

The literature search was conducted between May and July 2020 within the following databases: Web of Science, Latin American and Caribbean

Literature in Health Sciences (LILACS), Public Medicine Library (PubMed), Scopus, Scientific Electronic Library Online (SciELO), and the grey literature (not peer-reviewed literature). The reference lists of the identified studies were manually searched for potentially relevant studies. The complete search strategy is shown in the Table 1.

The keywords and synonyms used were established in English, Spanish, and Portuguese, and based on the Health Sciences (DeCS) and Medical Subject Headings (MeSH) descriptors, as follows: (a) 'spinal cord injuries', 'spinal cord trauma', 'spinal cord transection', 'spinal cord laceration', 'spinal cord contusion'; (b) 'Brazil'; and (c) 'validation study', 'survey', 'questionnaires'. The Boolean operators 'AND' and 'OR' were used to combine all synonyms of the concepts. The terms were adapted to each database and kept consistent across all searchers. For data selection, the articles were analyzed by title and abstract and read in full afterwards.

Data collection and items

Data extraction was performed by two independent researchers considering author, year of publication, validated instrument, instrument purpose, original language, country of origin, instrument administration form (i.e., questionnaire, interview, tasks, or tests), application time, number of individuals included in the study, and the main characteristics of the sample.

The assessment instrument items were linked to the ICF categories by these two independent researchers, and results were expressed in absolute and relative frequencies. The correlation of the instruments to the ICF categories was performed by identifying significant concepts to the items of the validated questionnaires. The search for the best category associated with the ICF followed the recommendations described by Cieza et al.[12] This methodology is widely used in the literature and has already been updated twice.[13,14] This survey uses the most recent version of rules for linking items to ICF.

The correlation between the items and the following components was verified: body function, body structure, activity and participation, and environmental factors. For this coding, studies performing manual correlations were consulted, with the possibility of correlating an item with more than one ICF component.[12-14]

Summary of results

Data extracted from each study were organized and analyzed using the Microsoft Excel® 2016 program.

Results

Figure 1 shows the flowchart of search and article selection, number of selected sources of evidence, eligibility, and inclusion based on the PRISMA recommendations.[15]

The search resulted in 75 articles. After completing all the steps, 11 studies were considered for the theoretical basis of this review (Table 2), which contemplates the distribution of the selected articles according to the instruments validated in Brazil, purpose, characteristics, and studied sample.

The results show that the scientific literature on instruments validated for SCI in Brazil is relatively scarce, considering that 11 studies and ten instruments were found (four tests[19-22] and six questionnaires and/or interviews[8,16-18,23-25]). One of these instruments (Spinal Cord Independence Measure Version III [SCIM III]) was applied, validated, and reproducible in two studies,[8,16] one specifically for persons with non-traumatic SCI.[8]

The samples varied between 22 and 93 persons with SCI, and only four studies followed the Beaton et al.[26] guidelines, an international recommended method that considers an optimal sample size of 20 to 30 participants. Regarding the validation protocol, seven studies[8, 16-18,21-23] performed correlations with instruments considered the gold standard for concurrent validation. In this sense, it is possible to assess whether the investigated instrument agrees with previously validated external standards[27].

Regarding the administration time, variability between 5 and 45 minutes was found enhancing practicality and improving viability in both research and clinical environments. All instruments quantitatively evaluated persons with SCI; eight used the obtained score, and two used the Likert scale[17, 25].

Table 3 shows the statistics used for the psychometric properties analyses, the numbers of items of each instrument, and the distributions related to the ICF components.

A total of 158 items and 256 significant concepts were identified and linked to different ICF categories. The total frequencies in which the ICF

components appeared in the included instruments are shown in Figure 2.

Discussion

The instruments mentioned in this review were developed and recommended for the assessment of several neurological conditions except for the one-repetition maximum (1RM) test, the Functional Independence Measure (FIM), and the Body Appreciation Scale (BAS), which present generic characteristics and can be applied in different populations. Only the battery of motor tests, the Spinal Cord Independence Measure Version III (SCIM-III), the Thoracic-Lumbar Control Scale (TLCS), the Adapted Manual Wheelchair Circuit (AMWC-Brazil), and the Exercise Self-Efficacy Scale (ESES-Brazil) were developed specifically for the evaluation of persons with SCI.

In eight instruments,[8,16,19,20-25] functioning was measured using one or few ICF components and addressed in a reduced and simplified manner. It was also observed that none of the instruments addressed the body structures component or integrated all components of the biopsychosocial model. The instruments that included more ICF components and categories were the FIM, SCIM III, ESES-Brazil, and Neurogenic Bladder Symptom Score (NBSS) since presented items related to body functions, activities and participation, and environmental factors. Therefore, knowledge regarding the ICF components and categories incorporated in each instrument is essential for the proper use according to each patient's needs.

The results demonstrate that the activities and participation component was the most contemplated in the included instruments. However, it is worth noting that aspects related to activities are more evaluated than participation within this component. The body functions component was also considered in the instruments. Conversely, the environmental factors were evaluated in a small number of factors included in the instruments. None of the instruments evaluated changes in body structure.

The Qualiveen was developed to assess the specific impact of urinary problems on the quality of life of persons with SCI. It focuses mainly on the psychosocial and functional impacts, assessing inconvenience, restrictions, fears, and impact on daily life.[17] Until recently, the Qualiveen was the only

questionnaire available in the Portuguese language for persons with neurogenic lower urinary tract dysfunction (NLUTD); however, Cintra et al.[18] validated another assessment measure for persons with congenital or acquired NLUTD (i.e., the NBSS). This scale assesses components that represent the spectrum of neurogenic bladder dysfunction, such as incontinence, storage, urination, and the consequences regarding both the bladder emptying method and the impact on the quality of life.[18]

Currently, the most used instrument to assess functioning is the FIM.[30] Despite being a non-specific measure for SCI, it integrates motor and cognitive tasks focused on self-care, transfers, locomotion, sphincter control, communication, social cognition, memory, social interaction, and problem-solving.[24] Nevertheless, trunk function is assessed indirectly and qualitatively by this instrument. A complete assessment can be performed using the TLCS, one of the specific and sensitive instruments for detecting impairments in persons with SCI, which quantitatively and qualitatively evaluates the function and the motor capacity of the thoracic and lumbar regions in supine, prone, sitting, and standing positions.[22]

An alternative to the FIM is the SCIM III, an instrument that measures the burden of care to perform daily living activities, locomotion, and functional changes in persons with SCI. This instrument covers three areas of functioning: self-care, breathing, sphincter control, and mobility (in the bedroom, bathroom, indoor, and outdoor).[8]

Also, another critical issue for the proper assessment of both functional and independence capacities in persons with SCI is the wheelchair use. In this context, the AMWC-Brazil consists of performing specific circuits that assess independent mobility skills in the wheelchair by scoring 14 skill and performance items.[21] With similar objectives, there is also the battery of motor tests related to activities of daily living for persons with SCI and paraplegia. The battery of tests was proposed based on the Brazilian cultural reality, with executable tests reflecting ordinary activities of these populations.[19]

It is necessary to understand the essential role of maintaining regular physical activity, especially in people with functional impairments. A

contribution to this assessment can be performed using the ESES-Brazil, which is an instrument that measures the perceived exercise self-efficacy in persons with SCI.[23] Also, one can use the 1RM to determine the workload and prescribe the exercise intensity since it is generically used in different populations. This test is performed by lifting the maximum amount of weight in a controlled manner and is considered the best isolated assessment to predict total dynamic strength. Also, the 1RM results have practical value for allied health professionals in assessing and prescribing strength training programs for persons with SCI.[20] Another useful tool to monitor the rehabilitation process and its impact on body image characteristics of persons with SCI is the BAS.[25]

Strengths and limitations of the scoping review

The strengths of this review include the protocol registration in the Open Science Framework and elaboration of the steps according to the PRISMA guidelines for scoping reviews, which contributed to minimizing possible biases. Although other assessment instruments have already been translated and cross-culturally adapted for use in Brazil, these have not been included since no validation studies were identified for persons with SCI. Thus, the importance of validating an instrument for this population is emphasized since the effectiveness of an intervention depends, among other things, on the use of a standard set of valid and reliable instruments that respond to changes and reflect clinically essential results.[31] Therefore, assessment instruments suitable for clinical practice and presenting the analysis of measurement properties are essential to assist health professionals and researchers in choosing the most relevant for persons with SCI. The limitations of this study refer to the possible article loss and the lack of methodological quality assessment of the included studies. Nevertheless, scoping reviews are characterized by presenting descriptive analyzes, and a formal methodological quality assessment is not mandatory.[10]

Furthermore, the study presents critical contributions regarding the scarcity of instruments validated for the Brazilian population with SCI and shows that body functions and activity limitations are more included in these tools than body structure, participation,

and environmental factors components. Thus, an assessment instrument that globally contemplates functioning and covers the ICF core sets is indispensable for persons with SCI.[32]

Conclusion

The ten assessment instruments evaluated in the present study aimed to measure functional independence, quality of life, and urinary tract disorders in Brazilian persons with SCI. The most covered components were body functions and activities and participation. Within the activities and participation component, the participation component was little included in the categories evaluated. None of the instruments fully addressed all ICF components, and the body structures component was the most neglected. Also, to date, no specific validated instrument is available for measuring participation in persons with SCI in Brazil.

The number of assessment instruments found in the last two decades demonstrates that the scientific literature on instrument validation for persons with SCI is relatively scarce. Even though the included studies integrated instruments validated for this population in Brazil, only five were specific to SCI. The information reported here is valuable for assisting clinicians and researchers in understanding the strengths and limitations of the instruments and selecting the most appropriate assessment tool related to the biopsychosocial model of health. Finally, further studies are necessary to validate instruments for Brazilian persons with SCI to assist professionals in conducting adequate health care and improving the assessment of this population.

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FIGURE 1. FLOWCHART OF THE SEARCH AND STUDY SELECTION PROCESS.

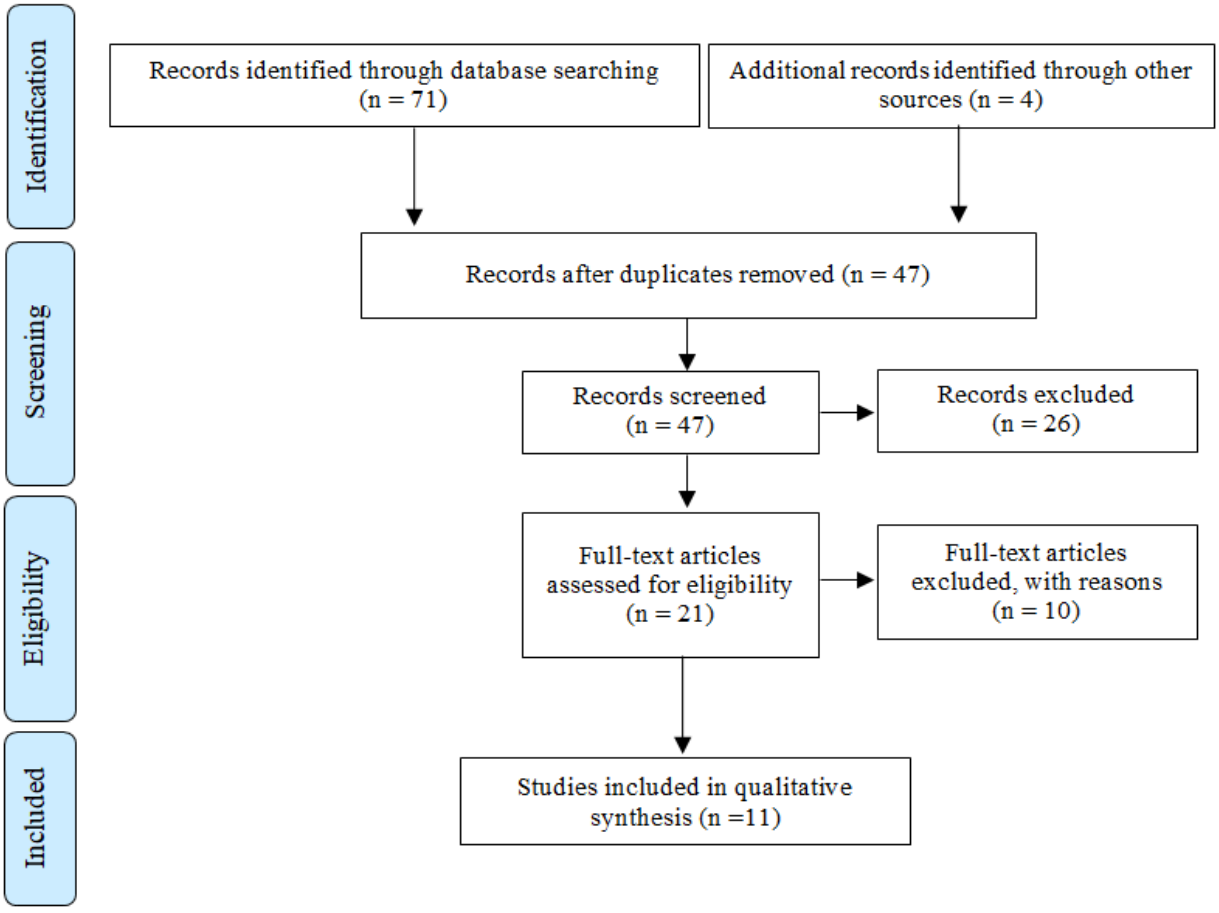

FIGURE 2. DISTRIBUTION OF QUESTIONNAIRE ITEMS CONCERNING THE ICF COMPONENTS.

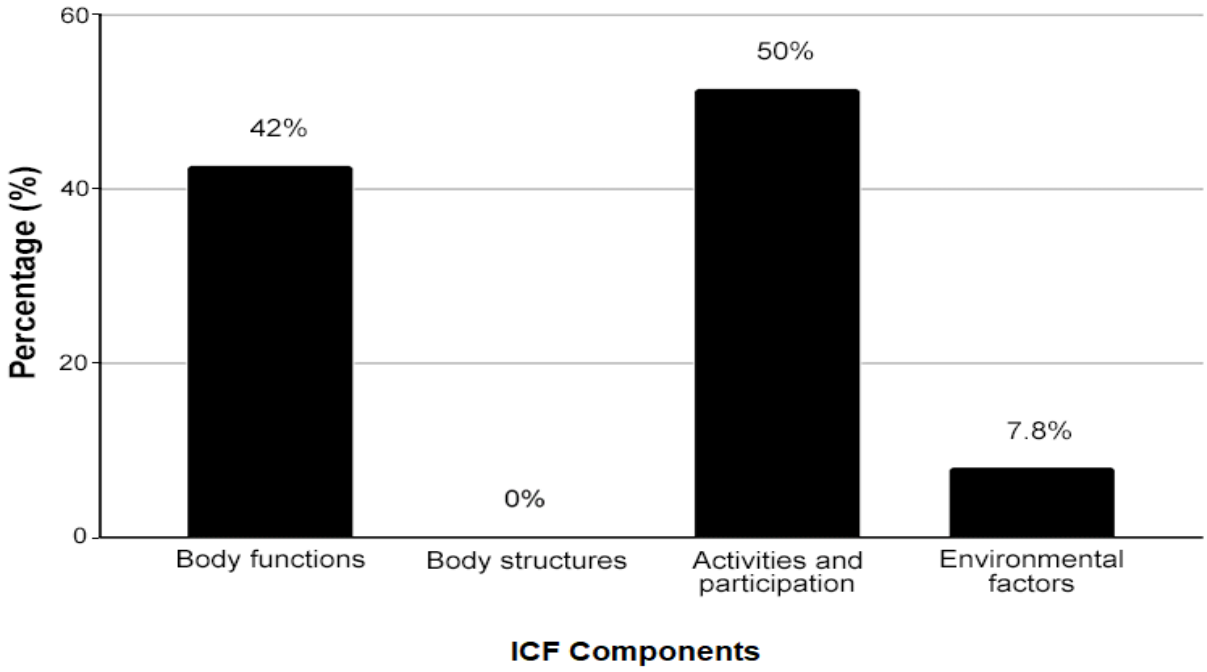

TABLE 1. SEARCH STRATEGY USED TO TRACK ARTICLES IN THE DATABASES

Database	Language	Set of words 1	Set of words 2	Set of words 3
PubMed, Web of Science, LILACS, Scopus, Scielo	English	(Spinal Cord Injuries OR Spinal Cord Trauma OR Spinal Cord Injury OR Spinal Cord Transection OR Spinal Cord Laceration OR Spinal Cord Contusion) AND	Brazil AND	(Validation Study OR Surveys and Questionnaires OR Questionnaires OR Questionnaire)
LILACS, Scielo	Portuguese	(Lesões da Medula Espinal OR Lesões da Medula Espinhal OR Traumas Medulares OR Traumas da Medula Espinal OR Traumas da Medula Espinhal OR Traumatismos Medulares OR Traumatismos da Medula Espinhal) AND	Brasil AND	(Estudo de Validação OR Inquéritos e Questionário OR Questionário OR Questionários)
LILACS, Scielo	Spanish	(Traumatismos de la Médula Espinal OR Lesiones de la Médula Espinal) AND	Brasil AND	(Estudio de Validación Encuestas y Cuestionarios OR Cuestionario Cuestionarios)

TABLE 2. CHARACTERIZATION OF THE INCLUDED STUDIES

Author/Year of Publication	Instrument	Instrument purpose	Original Language/ Country of Origin	Administration /time	n; Sample
Almeida et al. (2016) [8]	Spinal Cord Independence Measure Version III	Assess the independence and functioning of persons with SCI	English/ Israel	Interview administered by the clinician; 30-45 minutes	30; Persons with non-traumatic SCI
Riberto et al. (2014) [16]	Spinal Cord Independence Measure Version III	Assess the independence and functioning of persons with SCI	English/ Israel	Interview administered by the clinician; 30-45 minutes	83; Persons with SCI
D'Ancona et al. (2009) [17]	Qualiveen	Assess the quality of life in neurological patients with urinary dysfunction	English/France	Self-administered questionnaire; 40 minutes	33; Persons with SCI
Cintra et al. (2019) [18]	Neurogenic Bladder Symptom Score	Assess symptoms and consequences of lower urinary tract disorders in neurological patients	English/Canada	Self-administered questionnaire or interview; NS	66; Persons with SCI

Kawanishi, Greguol (2014) [19]	Battery of motor tests	Assess the functional independence of persons with SCI	Portuguese/ Brazil	Tests administered by the clinician; NS	22; Persons with SCI
Ribeiro Neto et al. (2017) [20]	One-repetition maximum	Dynamically assess the strength and determine the workload for prescribing exercise intensity	English/NS	Task/Test; ~ 5 minutes	45; Males with SCI
Ribeiro Neto et al. (2019) [21]	Adapted Manual Wheelchair Circuit	Assess mobility/independent ability in SCI wheelchair users	English/ Netherlands	Tasks/Tests; NS	66; Males with SCI
Pastre et al. (2011) [22]	Thoracic-Lumbar Control Scale	Assess function and motor capacity of the thoracic and lumbar regions after SCI	English/ United States	Tasks/Tests; 15 minutes	22; Persons with SCI
Pisconti et al. (2017) [23]	Exercise Self-Efficacy Scale	Measure perceived exercise self-efficacy in persons with SCI	English/ United States	Self-administered questionnaire; ~5 minutes	76; Persons with traumatic SCI
Riberto et al. (2004) [24]	Functional Independence Measure	Assess disability and burden of care required to perform motor and cognitive tasks	English/ United States	Interview administered by the clinician; ~45 minutes	93; Persons with SCI

Neves et al. (2015) [25]	Body Appreciation Scale	Assess body image in persons with SCI	English/ United States	Self-administered questionnaire; ~15 minutes	70; Males with SCI

NS: Not specified; n: Sample size.

TABLE 3. PSYCHOMETRIC PROPERTIES AND DISTRIBUTION OF ICF COMPONENTS IN EACH INSTRUMENT

Instrument	Psychometric properties and results	Assessed category	Number of items	ICF components: n (%)
Spinal Cord Independence Measure Version III [8, 16]	IRR: (ICC=0.918) TRR: (ICC=0.991) Correlation with total FIM (0.94) [17]	Self-care Breathing and Sphincter Control Mobility	19	Body functions: 2 (6.9%) Activities and Participation: 24 (83%) Environmental Factors: 3 (10%) [28]
Qualiveen [17]	IC: (Cronbach α =0.75-0.90); TRR (ICC: 0.62-0.86) Correlation with ICIQ-SF (NS)	Specific impact of urinary problems on quality of life Overall Quality of Life	39	Body functions: 23 (55%) Activities and participation: 16 (385%) Environmental factors: 3 (7.1%)
Neurogenic Bladder Symptom Score [18]	IC: (Cronbach α=0.81); CV with Qualiveen-SF:	Incontinence Storage and voiding Consequences	24	Body functions: 26 (86%)

	(PC: r= 0.66 [95% CI, 0.40-0.82]; p<0.0001) TRR: (ICC=0.86 [95% CI, 0.76 - 0.92] (p<0.0001)			Activities and participation: 2 (6.6%) Environmental factors: 2 (6.6%)
Battery of motor tests [19]	Reproducibility (ICC > 0.85)	Wheelchair suspension Transfer Muscle resistance Functional reach Degree crossing Wheelchair touch	10	Body functions: 3 (30%) Activities and participation: 7 (70%)
One-repetition maximum [20]	ICC: 0.96-0.99	Strength	1	Body functions: 1 (100%)
Adapted Manual Wheelchair Circuit [21]	CV: (SCC: 0.72-0.78 p<0.01) Correlation with SCIM-III (NS) ICC: (0.961 e 0.986)	Capacity Performance Wheelchair propulsion Trunk extension in prone	14	Activities and participation: 15 (100%)
Thoracic-Lumbar Control Scale [22]	IC: (Cronbach α=0.934) Correlation with FIM total score: r=0.64. p=0.001	Elevation of the pelvis Trunk flexion in supine Trunk rotation Sit to supine	10	Activities and participation: 10 (100%)

		Supine to sit Sitting posture Trunk extension in sitting Sitting balance Standing balance. Overcome barriers and challenges Finding ways and means		
Exercise Self-Efficacy Scale [23]	IC (α1 Cronbach= 0.856; α2 = 0.855; α3 = 0.822) TRR (ICC = 0.97) Correlation with FIM and SF-36 (SCC=0.708)	Accomplish goals Solutions When feeling depressed Without the support of family members Without the help of a therapist No access to establishments	10	Body functions: 11 (44%) Activities and participation: 11 (44%) Environmental factors: 3 (12%)
Functional Independence Measure [24]	NS	Self-care Sphincter control Transfers Locomotion Communication	18	Body functions: 31 (38%) Activities and participation: 41 (50%)

		Social cognition		Environmental factors: 9 (11 %) [29]
Body Appreciation Scale [25]	ICC: (α e CC> 0.70) VC: (AVE> 0.50) DV: (R2 < √AVE)	Favorable opinion about the own body Body acceptance Respect for the body Protection against unrealistic body ideals	13	Body functions: 10 (76.92%) Activities and participation: 3 (23.08%)

NS: Not specified. ICC: Intraclass correlation coeficient; IC: Internal consistency; VC: Construct Validity; PC: Pearson correlation; TRR: Test-Retest Reliability; SCC: Spearman correlation coefficient; IRR: Inter-rater reliability; CC: Composite reliability; CV: Convergent validity; DV: Discriminant validity; AVE: Average variance extracted; FIM: Functional Independence Measure; ICIQ-SF: International Consultation on Incontinence Questionnaire-Short Form; SCIM-III: Spinal Cord Independence Measure version III; SF-36: 36-item Short-Form Health Survey.