ARTICLE

Cross-cultural adaptation and validation of the "Spinal Cord Injury-Falls Concern Scale" in the Italian population

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Abstract

Study design Psychometrics study.

Objective The objective of this study was to develop an Italian version of the Spinal Cord Injury-Falls Concern Scale (SCI-FCS) and examine its reliability and validity.

Setting Multicenter study in spinal units in Northern and Southern Italy. The scale also was administered to non-hospitalized outpatient clinic patients.

Methods The original scale was translated from English to Italian using the "Translation and Cultural Adaptation of Patient-Reported Outcomes Measures" guidelines. The reliability and validity of the culturally adapted scale were assessed following the "Consensus-Based Standards for the Selection of Health Status Measurement Instruments" checklist. The SCI-FCS-I internal consistency, inter-rater, and intra-rater reliability were examined using Cronbach's alpha coefficient and the intraclass correlation coefficient, respectively. Concurrent validity was evaluated using Pearson's correlation coefficient with the Italian version of the short form of the Wheelchair Use Confidence Scale for Manual Wheelchair Users (WheelCon-M-I-short form).

Results The Italian version of the SCI-FCS-I was administered to 124 participants from 1 June to 30 September 2017. The mean ± SD of the SCI-FCS-I score was 16.73 ± 5.88. All SCI-FCS items were either identical or similar in meaning to the original version's items. Cronbach's α was 0.827 ($p < 0.01$), the inter-rater reliability was 0.972 ($p < 0.01$), and the intra-rater reliability was 0.973 ($p < 0.01$). Pearson's correlation coefficient of the SCI-FCS-I scores with the WheelCon-M-I-short form was 0.56 ($p < 0.01$).

Conclusions The SCI-FCS-I was found to be reliable and a valid outcome measure for assessing manual wheelchair concerns about falling in the Italian population.

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Introduction

Although spinal cord lesions are less frequent than other rehabilitation pathologies, their social impact is very high [1]. Falls are common in people with spinal cord injuries (SCIs) who are wheelchair dependent. About 40–60% of people using manual wheelchairs report falls [2–8].

Falls represent 60–80% of the non-fatal accidents in wheelchair users, which often result from the wheelchair tipping or the person slipping while transferring [3, 5]. This is a serious public health problem that has a substantial impact on health and healthcare costs. Falls research on people with SCIs using wheelchairs is a relatively new field, but indications are that falls among people with neurological diseases are closely related to fear of falling [9–11]. Recent studies have shown that recurrent falls in the

previous year and a fear of falling were predictors of recurrent falls [8, 12].

Boswell-Ruys et al. [13] hypothesized that concerns about falling negatively affect independence by restricting a person's level of functioning and activity, interfering with the ability to participate in activities of daily living. On the basis of the Falls Efficacy Scale-International (FES-I) [14], a self-report outcome measure that assesses the level of concerns about falling during daily activities, Boswell-Ruys et al. [13] developed the Spinal Cord Injury-Falls Concern Scale (SCI-FCS), the first outcome measure for individuals with SCI to measure fall-related psychological issues [13] and to address the wheelchair users' concerns about falling. Developed in 2010 in Australia as a self-report scale, the SCI-FCS [13] describes 16 daily living activities associated with falling when using a wheelchair. According to the authors [13], the SCI-FCS can be used in both research and clinical practice.

The SCI-FCS is currently available in Sweden (2015) [15] and Norway (2016) [16]; however, to date, no such tool has been available in Italy to quantify these perceptions. It is imperative to have a universal, validated outcome measure to allow comparisons across practice. Validated and culturally adapted tools give researchers a standard mean in outcome assessment enabling and encouraging comparative research and meta-analysis.

According to the Gruppo Italiano Studio Epidemiologico Mielolesioni (GISEM), there are approximately 90,000 people with SCI in Italy in 2017, with an incidence of 3000 new cases per year [17–19]. The age at which a SCI occurs is, on average, between 40 and 60 years. The services dedicated to the treatment of this "disease" are inadequate and almost non-existent in the south of the country [20]. Only 38% of people with a SCI were hospitalized at a specialized center for SCIs with 24-h after-trauma care. Comparing the place of origin, 43% of people who were quickly assessed in a Spinal Unit were from Northern Italy, 34% from Central Italy, and 23% from Southern Italy [20].

The "Società Italiana Midollo Spinale" (SIMS) and the "Coordinamento Nazionale Operatori Professionali Unità Spinali" (CNOPUS) have expressed the need to have a tool in Italy to address wheelchair users' concerns about falling. Thus, the aim of our study was to translate and culturally adapt the SCI-FCS into Italian and evaluate its psychometric properties to enable the assessment of concerns about falling in the Italian SCI population.

Methods

After receiving consent from the developers of the original instrument, the SCI-FCS was translated from English to Italian using the "Translation and Cultural Adaptation of Patient Reported Outcomes Measures—Principles of Good Practice" guidelines [21].

Translation and cultural adaptation

The first stage in the adaptation was forward translation. The original Australian version of the SCI-FCS was translated into Italian by two native English speakers and one Italian pneumologist familiar with English. These individuals produced three independent literal translations. An independent native speaker of the target language who had not been involved in any of the forward translations synthesized the results of the translations. Working from the temporary version of the questionnaire, three Italian translators then translated the questionnaire back into the original language without having seen the original version. The back-translated version of the instrument was compared with the original. To adapt the translated version to the Italian culture, two Italian rehabilitation professionals (an occupational therapist and a physiotherapist) and one pneumologist, who were familiar with both English and Italian, reviewed the first translated version, and then reworded and reformulated some items to minimize any differences from the original version. The expert committee's role was to consolidate all versions of the questionnaire and to develop what would be considered the pre-final version of the questionnaire for field testing.

Pre-test (cross-cultural validity)

The pre-final translated version of the SCI-FCS, according to Perneger et al. [22], was administered to a small representative group of individuals to evaluate its cross-cultural validity. The same professional tested each participant twice in order to avoid bias. The time interval between administrations was 4–6 days to ensure that no clinical change had occurred. This resulted in the final Italian version of the SCI-FCS (SCI-FCS-I).

Participants

According to preceding validations of the tool [13–16], a minimum sample size of 54 participants with acute and chronic SCIs was required [23].

To be included in the study, participants had to:

- Be at least 18 years old
- Have a SCI level from C5 to L5
- Have level A,B, C, or D on the "American Spinal Cord Injury Association" Impairment Scale [24]
- Use a manual wheelchair as their primary means of mobility (>50% of hours per day)
- Communicate in Italian as their primary language.

Individuals with emotional or psychiatric problems (as determined by clinical screening) were excluded from the study. Eligible participants who met the inclusion criteria were informed about the study; interested individuals gave their consent before inclusion in two scheduled testing sessions [25, 26]. The reliability and validity of the culturally adapted scale were assessed following the "Consensus-Based Standards for the Selection of Health Status Measurement Instruments" (COSMIN) checklist [27].

Reliability

The internal consistency of the SCI-FCS-I was examined by Cronbach's alpha (α) to assess the homogeneity of the scale measuring the interrelatedness of the items. Nunnally [28] has suggested that the α coefficient for a new questionnaire should be at least 0.7 as an indicator of satisfactory homogeneity of the items within the total scale. In accordance with other reliability studies of the scale using examiners rather than self-reports, we decided to evaluate inter-rater and intra-rater reliability instead of the test–retest reliability. The SCI-FCS-I was administered to a sample of participants living in Rome by three trained rater occupational therapists. Two physiotherapists and three more occupational therapists across Italy were informed by e-mail of the purpose and method of administration. In order to evaluate the inter-rater and intra-rater reliability, the SCI-FCS-I was administered twice to a representative, randomized subgroup of the sample by three different professionals, and after 48 h, by one of these professionals. In order to measure inter-rater and intra-rater reliability, the intraclass correlation coefficient (ICC) was calculated. The scale was considered stable at the test–retest for an ICC of > 0.70.

Validity

Concurrent validity was assessed using Pearson's correlation analyses to determine the association between the SCI-FCS-I and the Italian version of the short form of the Wheelchair Use Confidence Scale for Manual Wheelchair Users (WheelCon-M-I-short form) [29–31]. The WheelCon-M-I-short form is a self-report questionnaire composed of 21 items and designed to measure wheelchair confidence in relation to two areas: managing the physical environment (13 items) and managing the social environment (8 items). This tool was developed and validated in 2015 in Canada for use in people with SCI. It is the only valid and reliable tool available in Italy, from 2017, to assess the use of a wheelchair. It analyzes through self-efficacy (the belief in one's capabilities to organize and execute the sources of action required to manage prospective situations) the confidence that a person has with using his or her own wheelchair. We hypothesized that a high degree of confidence with one's own means of mobility is associated with less concern about falling from it. The SCI-FCS-I and WheelCon-M-I-short form were administered together to a representative, randomized subgroup of Roman individuals with SCI. Scales measuring similar concepts should show correlations of $r > 0.50$.

All statistical analyses were done using IBM-SPSS version 23.00.

Results

Participants were recruited from April 2017 through the following spinal units: US Centro Paraplegici Gennaro di Rosa Ostia (RM); US Centro Traumatologico Ortopedico Andrea Alessini (CTO) Rome; IRCCS Santa Lucia Rome; US Città della Salute e della Scienza Turin; US Niguarda Milan; IRCCS Montecatone Rehabilitation Institute, Imola (Bologna); US Santa Maria della Misericordia Perugia; and US Azienda Ospedaliera Cannizzaro, Catania; and from the Social Cooperative Centro Per l'Autonomia (CpA) Rome. The Italian version of the SCI-FCS (SCI-FCS-I) was also administered to non-hospitalized outpatient clinic attendees formerly hospitalized in one of the spinal units listed above from 1 June 2017 to 30 September 2017.

Pre-test (cross-cultural validity)

Cross-cultural validity was evaluated with 20 participants in May 2017. The characteristics of the participants are summarized in Table 1. The results were strikingly similar to those found using the Australian version [13], and no items were modified. However, the participants agreed that some items needed more explanation to improve comprehensibility and applicability. Therefore, we added the following

Table 1 Pre-test analysis: demographic characteristics and total score of the pre-test population

	Sample, $n=20$
Age (mean±SD)	52.3±15.3
Gender men, number (%)	13 (65)
Level of injury, number (%)	
Tetraplegia[a]	4 (20)
Paraplegia[a]	16 (80)
SCI-FCS-I score (mean±SD) test	20.06±5.8
SCI-FCS-I score (mean±SD) retest	20.5±6.1

[a] Neurological level defined by the International Standards for Neurological Classification of SCI

Table 2 Demographic characteristics for the 124 participants in the reliability study SCI-FCS-I

Characteristics	Sample, $n=124$
Age (mean±SD)	46.2±15.0
Gender men, number (%)	100 (81)
Paraplegia[a], number (%)	93 (75)
Complete[b] paraplegia, number	61
Tetraplegia[a], number (%)	31 (25)
Complete[b] tetraplegia, number	21
Acute spinal cord injury, ≤12 months, number (%)	35 (28)
ASIA[a], number (%)	
A	82 (66)
B	25 (20)
C	15 (12)
D	2 (2)
Falls last month, number (%)	
0	104 (84)
1	1 (11)
2	5 (4)
3	1 (1)
Falls last 6 months, number (%)	
0	80 (64)
1	17 (14)
2	15 (12)
3	3 (2)
4	5 (4)
5	2 (2)
6	2 (2)

[a] Neurological level defined by the International Standards for Neurological Classification of SCI

[b] Completeness of SCI classified according to American Spinal Injury Association (ASIA) Impairment Scale (AIS)

examples: reset the bed; move bedside table (item 2); the possibility of using TAI-transanal irrigation (item 3); slope of 6% (item 14); bring an object up on the knees (item 16) (see Appendix 1).

Participants

From 1 June 2017 to 30 September 2017, of 125 participants with acute and chronic SCIs met the inclusion criteria

One hundred twenty-four agreed to participate (mean age = 46.2 ± 15) and were enrolled in the present study. A larger number of participants than required was recruited [23] to match the original study [13] and to have a representative sample in each spinal unit. The larger sample increased the precision of estimates. The demographic characteristics of the participants are summarized in Table 2. The mean ± SD of the SCI-FCS-I score for the reliability data were 16.73 ± 5.88; the mean, median, and inter-quartile ranges (Q3–Q1) of the total sample were 18.69 ± 6.24, 17, and 21–16, respectively.

Reliability

The SCI-FCS-I was found to have good internal consistency. Cronbach's α for the SCI-FCS-I was 0.82 ($p < 0.01$). Internal consistency was calculated for the entire scale; the item-total correlation showed positive results as reported in Supplementary Table 3 (S1: Item-total analysis: Cronbach's alpha for each item of the Italian version of the SCI-FCS). A randomized subgroup of the Roman sample ($n = 40$) not submitted to the analysis was submitted to inter-rater and intra-rater reliability procedures. The SCI-FCS-I was reliable with respect to inter-rater reliability with an ICC of 0.972 ($p < 0.01$) and > 0.7 for each item (range of ICC values, 0.768–0.977) as reported in Supplementary Table 4 (S2: Inter-rater analysis: range of ICC parameters of each item for the SCI-FCS-I). The test–retest reliability, ICC of 0.973 ($p < 0.01$), were > 0.7 (range of ICC values, 0.765–1.0) in each item as reported in Supplementary Table 5 (S3: Intra-rater analysis: range of ICC parameters of each item for the SCI-FCS-I).

Validity

The Italian version of the WheelCon-M-I-short version was also distributed to a randomized subgroup ($n = 40$) of the Roman sample. Pearson's correlation coefficient of the SCI-FCS-I with the total score of the WheelCon-M-I-short form [31] was 0.56 ($p < 0.01$), indicating that the SCI-FCS-I has good concurrent validity. Pearson's correlation coefficient of each item is reported in Supplementary Table 6 (S4: Gold standard analysis: Pearson's correlation between SCI-FCS-I and WheelCon-M-I-short form).

Discussion

In this study, we developed an Italian version of the SCI-FCS (SCI-FCS-I), and in this article, we reported on the translation and cultural adaptation of the SCI-FCS-I for use among Italian individuals with SCI, and the subsequent evaluation of its validity. Translation and linguistic

adaptation were performed using the "Translation and Cultural Adaptation of Patient-Reported Outcomes Measures—Principles of Good Practice" guidelines [21]. This proved to be straightforward under the supervision of the developers of the instrument and a panel of experts who ensured that the original meaning of the items was retained. The reliability and validity of the culturally adapted scale were assessed following the COSMIN checklist [27]. The participants in this study were either hospitalized in spinal units or patients in outpatient clinics throughout the national territory, and all were generally confident with manual wheelchair use. The mean±SD SCI-FCS-I for the reliability data (16.73 ± 5.88) in this study was comparable to those in other reliability studies but significantly lower compared with the original English version [13] (23.0) and the Norwegian version (22.6). The same can be said for comparing the mean of the total sample (18.69 ± 6.24) of our study and the one obtained from the Swedish version (21.0), which may indicate relatively lower fall concerns in the Italian population.

However, our lower result may be due to the interpretation that we have considered in the administration of the scale. According to the original Australian–English version of the tool, received by the original author, if an individual did not do one of the activities proposed by the test, it was necessary to proceed by asking: "if you currently don't do the activity (e.g. if someone does your shopping for you), please answer to show whether you think you would be concerned about falling IF you did the activity on your own". Some participants preferred not to answer this question. Considering that in clinical practice, a participant may not want to answer a question, and considering that the SCI-FCS was developed as a self-administration scale, we decided to evaluate the reliability and validity of the test by assigning a score of "zero" to this type of answer. In contrast, this type of answer was reported by the original author as "unable to complete on own". However, to make standardized and comparable results in clinical and research practice, the scale has to be considered in its Italian version, as well as in the previous versions, with a total score ranging from 16 = not at all concerned to 64 = very concerned. In clinical practice, the total score may be <16 (minimum reference score). In this case, for values ranging from 0 to 16 a specific assessment of which activities the individual does not perform is required.

It was determined that the SCI-FCS-I has good internal consistency and strong retest reliability. The SCI-FCS-I produced similar results to the Norwegian version [16], demonstrating good internal consistency with a Cronbach's α of 0.82 and 0.88, respectively, but lower than the original English version (0.92) and the Swedish version (0.95) [15]. As Norwegian authors have pointed out, the slightly lower Italian and Norwegian values might not be a weakness because Cronbach's α describes the extent to which all items measure the same construct, therefore a very high Cronbach's α may indicate overlap between items [16]. The first explanation for our slightly lower result may be related to the way we chose to administer the tool; another reason could be that the previous studies used telephone and self-administered interviews, whereas we used rater-administered interviews. It is also important to note that our result comes from a multicenter study with different raters across Italy. The difference in access to spinal units and rehabilitation programs between the North and South is evident, and moreover, northern cities are known to be more wheelchair friendly. The SCI-FCS-I's ICCs of 0.972 for inter-rater reliability and 0.973 for intra-rater reliability were very good. The high level of interrelatedness among the items shows the cross-cultural validity of the adapted scale, which reflects the performance of the original SCI-FCS [13].

Furthermore, all versions produced excellent test–retest reliability, with ICCs of 0.93 and 0.83 for the original [13] and the Norwegian versions [16], respectively. The high SCI-FCS-I reliability indicates that the scores remained stable after repeated measurements and after different raters' measurements.

The Pearson's correlation coefficient of the SCI-FCS-I with the WheelCon-M-I-short form [31] indicates good concurrent validity, showing small significant positive correlations with the total score of the WheelCon-M-I-short form. Our results confirm most of the hypotheses regarding the relationships between the variable used to assess concurrent validity and the SCI-FCS-I. The small magnitudes of the relationship between the instruments was as expected, given that the WheelCon-M-I-short form [31] does not evaluate the same construct of the SCI-FCS (concerns about falling) but it describes a number of situations that can challenge confidence when using a manual wheelchair, where confidence refers to the belief in one's ability to perform each activity independently and safely. The WheelCon-M-I-short form assesses the confidence of manual wheelchair users to manage their physical environment, as well as their social environment, taking into account moving in situations that may induce anxiety or nervousness, which is the focus of the SCI-FCS-I. Other WheelCon-M-I-short form items involve assessing confidence related to problem solving, advocacy, managing social situations, and managing emotions, which are areas not covered in the SCI-FCS-I. Indeed, the Pearson's correlation coefficient shows correlation with the total score and not with the other domains, showing that greater confidence in wheelchair use is related to a lower concern about falling. This condition does not directly depend on the management of either the physical or the social environment, but rather a combination of the two.

Despite the fact that we have not captured data regarding mean scores in low versus high functioning individuals, we agree with the Norwegian authors that the low mean scores in all versions of the tool may indicate that the SCI-FCS fails to accurately capture fall-related concerns of more active individuals, and that it is better suited for evaluating lower-functioning individuals with SCI. These authors found most of the items to be relatively nonhazardous activities [16]. Furthermore, according to the same authors, the tool could include items regarding recreational activities, such as physical activity, and the social effects of falling that independently contribute to avoiding an activity [16].

On the basis of these studies [13, 15, 16], the SCI-FCS-I could be used in both research and clinical settings as a screening tool for individuals with high levels of concern, individuals who have an acute injury, or individuals who obtained their SCI as a result of a fall. It may guide professionals working to rehabilitate people with SCIs in the implementation of tailored intervention strategies aimed at addressing excessive levels of concern about falling, setting activity goals for individuals to prevent falls, encouraging the mastery of activities necessary for an individual with SCI to live independently, thereby enhancing individuals' mobility and independence, and enabling greater community participation [13]. It is important to remember that wheelchair training and the personalized setting of the wheelchair (user-center of gravity-wheelchair) are crucial to increase self-esteem and self-confidence and reduce concerns of falling.

Limitations of the study

This study has certain limitations. We do not have enough data from Northern and Southern Italy to perform a subgroup analysis between the two regions to see if participants in those regions have different scores. Further validation of the SCI-FCS-I is needed to examine the impact of the differences between the wheelchair friendliness across these regions. It may also be interesting to examine the relationships of the SCI-FCS-I with measurements of quality of life, depression, anxiety, positive effects, physical ability, and participation, as in the Swedish version [15]. Indeed, in clinical settings, it should be considered that people with SCI who have experienced more anxiety and/or depressive symptoms, as well as a reduced quality of life have shown greater concerns about falling [15].

In using the SCI-FCS-I, it is important to recognize that the reliability and validity described above are limited to a sample of adults with SCI. Further testing with people with other health conditions who are also wheelchair users could determine if concern about falling is unique to SCI or it is also present in people with different diagnoses. Although

further work is needed, this Italian version of the SCI-FCS holds promise as a clinical and research tool.

Conclusion

The culturally adapted Italian version of the SCI-FCS (SCI-FCS-I) has been shown to be a valid, reliable, and rapidly administrable scale to assess concerns about falling in an acute and chronic sample of people with SCI who depend on manual wheelchairs. This scale was previously unavailable in the Italian language; thus, a tool has been provided for professionals across Italy to measure and capture data on concerns about falling.

Despite the study's limitations and the need for further study, the SCI-FCS-I is the first tool to be rigorously developed and psychometrically tested in the Italian context to measure concerns about falling in individuals with SCI. Clinicians now have a method to measure concerns about falling in people with SCI, and they will be able to make informed decisions when prescribing the use of manual wheelchairs and when training clients in their use. The SCI-FCS-I also provides researchers with a tool in an important and relevant area of study for future research.

Statement of human and animal rights

All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2008. Informed consent was obtained from all participants for being included in the study.

Data archiving

There were no data to deposit.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

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