Assessment on the measurement properties of the Brazilian Portuguese language version of the International Consultation on Incontinence Questionnaire Female Sexual Matters Associated with Lower Urinary Tract Symptoms Module (ICIQ-FLUTSsex)

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Abstract

Objectives: to assess internal consistency and reliability in providing a Portuguese version of the International Consultation on Incontinence Questionnaire Female Sexual Matters Associated with Lower Urinary Tract Symptoms Module (ICIQ-FLUTSsex).

Methods: a validation study was conducted by applying questionnaires for 56 women over 18 years old with active sexual life and presenting urinary incontinence, excluding those who had urinary infection in the past 6 months. Three questionnaires were used, one for personal identification; the International Consultation on Incontinence Questionnaire - Short Form (ICIQ-SF) and the ICIQ-FLUTSsex. SPSS software was used for data analysis. Cronbach's alpha was used to verify reliability of the items on the questionnaires and Kappa coefficient was used to assess the agreement between the questionnaires applied in the test-retest.

Results: the median age was 49.1 years old, mostly were mixed colored skin and married, with a high prevalence of mixed urinary incontinence. Cronbach's alpha score was 0.80, which was considered good. Kappa value was moderate, ranging from 0.36 to 0.76.

Conclusion: internal consistency was considered good and reliability moderate. The Portuguese version of ICIQ-FLUTSsex was proven to be valid to use on women with urinary incontinence, contributing for clinical practice, as it provides as a quick tool for research on sexual dysfunction.

Key words *Validation, Urinary incontinence, Questionnaire*

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Introduction

According to the International Continence Society (ICS), Urinary Incontinence (UI) is defined as any involuntary urine loss.[1] It has a multifactorial etiology and is more frequent in women. Among the main predisposing factors, there are: number of pregnancies, vaginal childbirth, climacteric, hypoestrogenism, diabetes, obesity and trauma on the pelvic floor muscles.[2,3]

UI is classified in three main types: (1) Stress Urinary Incontinence (SUI), when there is urine loss during some effort that increases intra-abdominal pressure, such as coughing, sneezing or physical exercise; (2) Urge Incontinence or Urgency Urinary Incontinence (UUI), is characterized by urine loss accompanied by a strong sensation of urgency to urinate; (3) Mixed Urinary Incontinence (MUI), is when there is a complaint of loss associated with urgency and also physical efforts.[4]

One of the hardest concerns of women with UI is their sexuality, affecting more specifically their sexual satisfaction, in which this can reduce their quality of life (QOL). Shame and acceptance are the main emotional problems faced by women with urinary incontinence, directly interfering in the couple's sexual activity.[5]

Female sexual dysfunction (FSD) is characterized by a significant clinical disturbance in a person's ability to respond sexually or to experience sexual pleasure.[6] It is considered as a frequent health problem, that includes: dysfunction in sexual desire/arousal, orgasm dysfunction and genito/pelvic pain.[7]

Women with incontinence have reported complaints of urinary loss during sexual intercourse, during penetration and orgasm, in addition to having difficulties in reaching orgasm, decreased desire, lubrication and satisfaction.[8] Findings from a cross-sectional study was carried out with 356 women on the impact of UI on female sexual dysfunction, concluded that women with UI were more likely to be sexually abstinent than continent women. In addition, these women with UI showed less desire, comfort and sexual satisfaction.[9]

A Brazilian study showed that 58% of women had sexual complaints, the most frequent were: lack of sexual desire (34.6%), orgastic dysfunction (29.3%) and pain during intercourse (21%).[6] Despite being considered as a major health problem, FSD continues to be underdiagnosed and undertreated, because as it is a disease that depends of self-reporting, either for diagnosis and treatment, valid and reliable measures by identifying it can help treat this issue, such as, the use of validated questionnaires.[7]

The International Consultation on Incontinence Questionnaire Female Sexual Matters Associated with Lower Urinary Tract Symptoms Module (ICIQ-FLUTSsex) is a brief questionnaire that performs a detailed assessment on female sexual behavior associated with lower urinary tract symptoms and their impact on QOL. Composed of eight questions, it has the advantage of its easy and quick application contributing to its use in clinical practice worldwide.[8]

Other questionnaires addressing urinary incontinence and sexual dysfunction have previously been validated for the Brazilian Portuguese language version, such as the Female Sexual Function Index (FSFI) and the International Consultation on Incontinence Questionnaire- Short Form (ICIQ-SF).

The FSFI assesses the female sexual response from six domains: sexual desire, sexual arousal, vaginal lubrication, orgasm, sexual satisfaction and pain. The ICIQ-SF is used to assess the impact of UI on QOL and to qualify urinary loss in patients of both sexes. However, there is no questionnaire validated in Brazil to assess sexual complaints related to the lower urinary tract.[9,10]

Although the cross-cultural adaptation of ICIQ-FLUTSsex in Brazil has already been published, by the authors themselves, and Congress proceedings, but the publication of the Portuguese version was not available to the public.[11] Furthermore, the analysis of measurement properties (Cronbach 's alpha and *Kappa*) had not been performed yet. Thus, this could not be used to support the assessment on sexual dysfunction associated with lower urinary tract in Brazil or in any other Portuguese speaking countries (Figure 1).

The objective of this study was to evaluate the following measurement properties: internal consistency and reliability and to provide a Brazilian Portuguese language version of the ICIQ-FLUTSsex questionnaire.

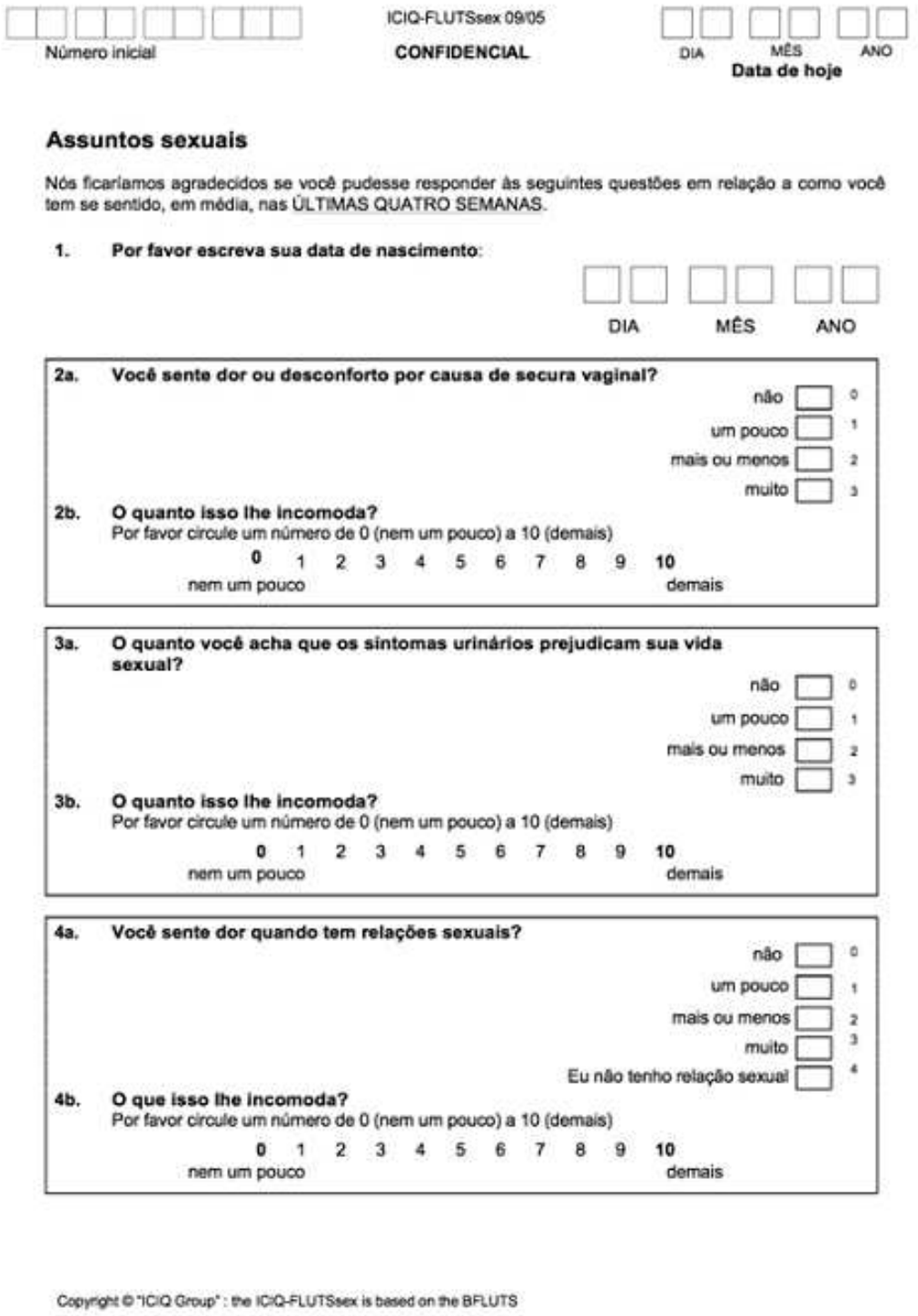
Methods

The present study is part of a validation study, carried out at the Women's Physiotherapy Outpatient Clinic of the *Instituto de Medicina Integral Prof. Fernando Figueira* (IMIP) in Recife, Pernambuco, from April 2017 to June 2018. This study was approved by the Ethics Committee at the *Faculdade Pernambuca de Saúde* (CAAE: 49429915.4. 0000.5569).

The population was composed of women

Figure 1

ICIQ-FLUTSsex questionnaire used to assess sexual dysfunction.



Número inicial

ICIQ-FLUTSsex 09/05

CONFIDENCIAL

DIA MÊS ANO

Data de hoje

Assuntos sexuais

Nós ficaríamos agradecidos se você pudesse responder às seguintes questões em relação a como você tem se sentido, em média, nas ÚLTIMAS QUATRO SEMANAS.

1. Por favor escreva sua data de nascimento:

DIA MÊS ANO

2a. Você sente dor ou desconforto por causa de secura vaginal?

não 0
um pouco 1
mais ou menos 2
muito 3

2b. O quanto isso lhe incomoda?
Por favor circule um número de 0 (nem um pouco) a 10 (demais)

0 1 2 3 4 5 6 7 8 9 **10**
nem um pouco demais

3a. O quanto você acha que os sintomas urinários prejudicam sua vida sexual?

não 0
um pouco 1
mais ou menos 2
muito 3

3b. O quanto isso lhe incomoda?
Por favor circule um número de 0 (nem um pouco) a 10 (demais)

0 1 2 3 4 5 6 7 8 9 **10**
nem um pouco demais

4a. Você sente dor quando tem relações sexuais?

não 0
um pouco 1
mais ou menos 2
muito 3
Eu não tenho relação sexual 4

4b. O que isso lhe incomoda?
Por favor circule um número de 0 (nem um pouco) a 10 (demais)

0 1 2 3 4 5 6 7 8 9 **10**
nem um pouco demais

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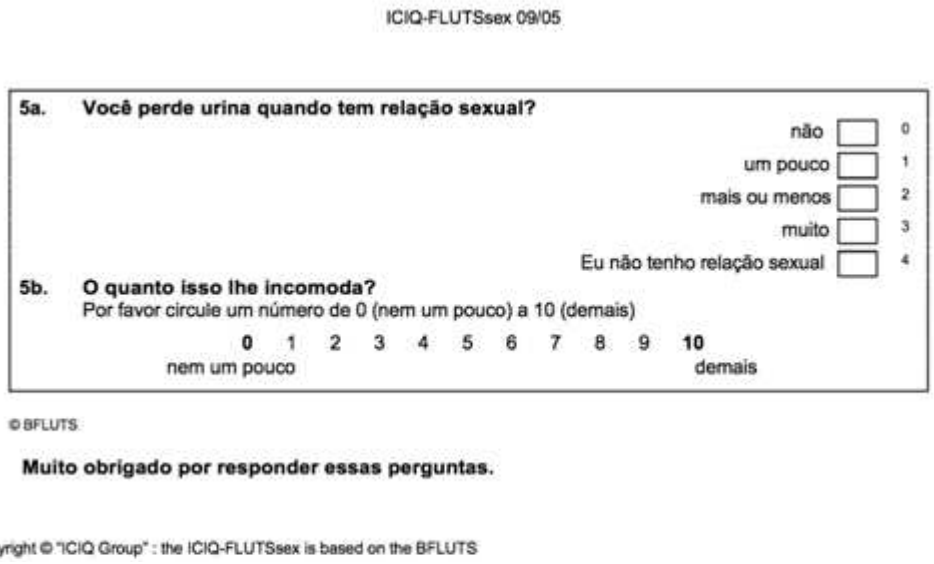
continue

Figure 1 **concluded**

ICIQ-FLUTSsex questionnaire used to assess sexual dysfunction.



ICIQ-FLUTSsex 09/05

5a. Você perde urina quando tem relação sexual?

não	0
um pouco	1
mais ou menos	2
muito	3
Eu não tenho relação sexual	4

5b. O quanto isso lhe incomoda?

Por favor circule um número de 0 (nem um pouco) a 10 (demais)

0 1 2 3 4 5 6 7 8 9 **10**

nem um pouco — demais

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Muito obrigado por responder essas perguntas.

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followed up from the Women's Physiotherapy Outpatient Clinic at IMIP and the inclusion criteria were: women equal or older than 18 years old, sexually active, had at least one sexual intercourse in the last four weeks and presented urinary incontinence. The only exclusion criterion was those with the presence of urinary tract infection in the past six months. The calculated sample was considered from the seven subject items on the questionnaire.[12] As the ICIQ-FLUTSsex has eight items, the final sample was composed of 56 women. In addition, according to Sapnas and Zeller,[13] a minimum of 50 subjects and a maximum of 100 are sufficient when the intention is to assess the properties of the health measurement instruments. The sampling was consecutively based on the spontaneous demand of the outpatient clinic.[13]

The inclusion and validity of the information obtained by the volunteers were only included in the study after the validation of the eligibility criteria and the women's consent to participate in the research by signing of the Consent Forms.

Three instruments were used for data collection: the first was a personal identification questionnaire for sociodemographic data (age, ethnicity, marital status, education, occupation and family income), clinical (hypertension, asthma, diabetes, heart disease, primary dysmenorrhea, traumato-orthopedic pain and surgery, physical activity), obstetric (number of pregnancies, number of childbirths, types of delivery, number of abortions, children and complications during pregnancy) and gynecological (age of menarche, age of the last menstruation, previous surgeries such as tubal ligation or hysterectomy and type of incontinence).

The second was the ICIQ-SF questionnaire, used to rectify the volunteers' UI complaint, assess the impact of UI on QOF and to qualify urinary loss of the analyzed patients. The ICIQ-SF consists of four questions that assess the frequency, severity and impact of urinary incontinence, in addition to a set of eight self-diagnosis items, related to the causes or situations of UI experienced by the patients.[10] For the analysis on their answers, numerical values were assigned, in which the total score varied from 0 to 21 points, and the greater the sum of points, the greater the severity and impact of UI on QOL. The impact on QOL is classified as follows: zero (0), no impact; from 1 to 3 points, mild impact; 4 to 6 points, moderate; 7 to 9 points, severe; and 10 or more points, very severe.[14]

The third instrument was the ICIQ-FLUTSsex in the Brazilian Portuguese language version, a questionnaire that evaluates the sexual issues associated with lower urinary tract, composed of eight questions, of which four assess the presence of pain or discomfort due to vaginal dryness, impact of urinary incontinence in their sexual life, presence of pain

and urine loss during sexual intercourse. The remaining questions assess how much each question disturbs them, with numerical answers ranging from 0 (not at all) to 10 (too much). The final score of the questionnaire can vary between 0 and 16. Higher values indicate greater severity of symptoms.[11]

The process of cross-cultural adaptation of the instrument took place in five stages (translation, synthesis of translations, back-translation, reviewed by a committee of experts and pre-test). The results were carried out before this study and was published.[11] After these stages, the questionnaire was available to be applied in order to verify its measurement properties.

The data were typed, tabulated, and analyzed by using the Statistical Package for Social Sciences (SPSS) software, version 21. To assess the internal consistency, Cronbach's alpha coefficient was calculated in order to verify the homogeneity of the items, that is, its accuracy. As a general rule, the accuracy should not be less than 0.80 if the scale is widely used, but values above 0.60 already indicate consistency between the items.[15]

The reliability of applying the questionnaire was performed using test-retest, performed by the same examiner with an interval of 8 to 15 days to be repeated, starting from the first application of the qustionaire in the attempt to verify the precision of the responses. The reliability was assessed for each item separately. During the study period, the participants were undergoing physiotherapy with a weekly frequency, which facilitated the performance to do the retest.

The *Kappa* coefficient was used to distinguish the disagreement or agreement between the assessments performed.[16] Values can be interpreted as: small (0.00 to 0.20); regular (021 to 0.40); moderate (0.41 to 0.60); substantial (0.61 to 0.80) and almost perfect (0.81 to 1.00).[17]

Results

For this study, 80 women were evaluated for elegibility, of which two did not accept to participate because of issues that involved sexuality and 22 were excluded because they did not have an active sexual life, totaling the final sample of 56 women. The average age of the participants was 49.1 years old (SD= 11.6). Sociodemographic characteristics showed that 40 (71.4%) were married, 26 (46.4%) were mixed color skin; 19 (33.9%) graduated from high school; 31 (55.4%) had an income up to a minimum wage and 32 (57.1%) were employed (Table 1).

Regarding the obstetric history, 52 (92.9%) said that they had already been pregnant, with a median of 2.71 (SD= 1.8) childbirths, per participant, either vaginal or cesarean section, with means of 2.13 (SD= 1.9) and 0.67 (SD= 0.7), respectively.

Regarding to the type of incontinence, most women, 34 (60.7%) had MUI, while 13 (23.2%) had USI and nine (16.1%) had UUI (Table 2). Furthermore, 39 (69.6%) women had undergone hysterectomy.

The analysis on the UI impact on QOF, using the ICIQ-SF questionnaire, showed that 46 (82.1%) participants had a very serious impact; seven (12.5%) were severe; one (1.8%) was moderate and two (3.6%) had no impact. Investigating the frequency of urine loss, 33 (58.9%) reported urine loss several times a day, 25 (44.6%) responded that the amount of loss was low and the interference in their daily life, on a scale of 0 to 10, 22 (39.3%) scored 10 (Table 3).

The result of the internal consistency analysis on the ICIQ-FLUTSsex questionnaire measured by Cronbach's Alpha was 0.80. Concerning the agreement between the answers given in the first and second ICIQ-FLUTSsex assessments (test-retest), were performed with 41 (73.2%) participants, the *Kappa* coefficient had a mean of 0.59 (SD= 0.12) ranging from 0.36 to 0.76. (Table 4).

Discussion

The present study assessed the internal consistency and reliability of the Brazilian Portuguese language version of ICIQ-FLUTSsex in women with urinary incontinence. To our knowledge, this is the first study that assessed the measurement properties of a specific questionnaire to assess sexual dysfunction in women with lower urinary tract dysfunction. The results showed that the ICIQ-FLUTSsex used in this population was quickly applied and showed good internal consistency and moderate test-retest reliability.

Most participants were not nulliparous, the most frequent type of childbirth was vaginal. A cohort study carried out in Sweden with 5,236 women found that having vaginal childbirth, compared to cesarean section, increased the risk of UI by 275% for the period of 10 years and 67% 20 years after childbirth.[18] Not only the type of childbirth, but pregnancy itself can influence the onset of urinary

Table 1

Sample on the demographic characteristics.

Variables	N	%
Marital status		
Single	9	16.1
Married	40	71.4
Divorced	5	8.9
Widow	2	3.6
Race		
White	22	39.3
Black	8	14.3
Mixed	26	46.4
Education		
Incomplete primary school	17	30.4
Complete primary school	5	8.9
Incomplete high school	6	10.7
Complete high school	19	33.9
Incomplete higher education	4	7.2
Complete higher education or more	5	8.9
Income (minimum wage)		
Upto 1	31	55.4
1 to 4	25	44.6
Occupation		
Employed	32	57.1
Unemployed	24	42.9

Table 2

Sample on the gynecological history description.

	N	%
Hysterectomy		
Yes	17	30.4
No	39	69.6
Type of urinary incontinence		
Urgency incontinence	9	16.1
Stress incontinence	13	23.2
Mixed incontinence	34	60.7

Table 3

Sample on the description of number and percentage of the ICIQ-SF result.

ICIQ questionnaire	N	%
Frequency of urine loss		
Never	3	5.4
About once a week or less	2	3.6
Two or three times a week	7	12.5
Once a day	5	8.9
Several times a day	33	58.9
Allthe time	6	10.7
Amountof urine loss		
None	2	3.6
A small amount	25	44.6
A moderate amount	19	33.9
A large amount	10	17.9
Interference of urine loss in everyday life		
0	3	5.4
2	5	8.9
3	1	1.8
4	3	5.4
5	7	12.5
6	3	5.4
7	5	8.9
8	3	5.4
9	4	7.1
10	22	39.3
ICIQ-SF SCORE		
No impact	2	3.6
Moderate impact	1	1.8
Severe impact	7	12.5
Very severe impact	46	82.1

Table 4

Kappa results for the ICIQ-FLUTSsex questionnaire.

ICIQ-FLUTSsex questionnaire	K (*Kappa*)
2a. Do you have pain or discomfort because of a dry vagina?	0.711
2b. How much does this bother you?	0.542
3a. To what extent do you feel that your sex life has been spoilt by your urinary symptoms?	0.558
3b. How much does this bother you?	0.502
4a. Do you have pain when you have sexual intercourse?	0.696
4b. How much does this bother you?	0.365
5a. Do you leak urine when you have sexual intercourse?	0.760
5b. How much does this bother you?	0.596

incontinence. Another cross-sectional study carried out in Brazil with 220 women, two years after having a cesarean section, reported that this type of childbirth does not prevent urinary incontinence.[19]

The result on the ICIQ-SF shows that many women have a very serious impact of UI in their QOL. A qualitative study adds that UI has a negative impact on the lives of affected women, changing their daily behavior, imposing restrictions and even compromising their social life.[20] One of the domains affected women with incontinence was their sexuality.[21] Many may feel embarrassed, because of the risk of urine loss during intercourse. In addition to the fear of urine loss, some women may experience discomfort, such as vaginal pain or dryness.

Analyzing the results, we can infer that the internal consistency on the ICIQ-FLUTSsex questionnaire, assessed by Cronbach's alpha (0.80) was good. According to COSMIN criteria, Cronbach 's alpha must be between 0.70 and 0.95.[22] Comparatively, the Greek version of the same questionnaire obtained an alpha of 0.69 (moderate internal consistency).[23] However, due to the variation of the sample and the intervention during the retest interval, it is not possible to conclude that the Brazilian Portuguese language version is superior to the Greek version.

Analyzing the test-retest reliability values, through *Kappa*, the results varied from a weak agreement to a substantial agreement. The values of this research ranged from 0.36 to 0.76, with a mean of 0.59, which is considered moderate. The item with less agreement was related to pain during intercourse.

According to Terwee *et al*.[24] criteria on the interval between repeated questionnaire applied among the participants must be long enough to avoid remembrance of the qustionnaire, although short enough interval is to ensure that clinical change has not occurred, often, a week or two would be appropriate.[24]

A limitation in this study was that all the participants were being treated by pelvic physiotherapy, which could possibly interfere with the retest result, having a possible improvement of the symptoms.

The validation of this questionnaire in the Greek version, the retest was answered after 14 to 21 days after the first assessment and its results obtained a *Kappa* range of 0.61 to 0.86, which means a substantial value to almost perfect.

As perspectives for future research, it would be relevant to assess responsiveness, a property to detect differences between two points in time (changes in over time) within groups, that is, a clinically relevant change in the scores of a measure ofhealth-related functional status, so that the questionnaire could also be used to monitor the treatment on sexual dysfunction.

The objective of this study was to assess the internal consistency and reliability of the ICIQ-FLUTSsex and publish it in the Brazilian Portuguese language version, and so, provide another assessment tool for women who have sexual complaints associated with the lower urinary tract. ICIQ-FLUTSsex has the advantage of being simple, easy to apply and understand, thus it contributes to a better assessment on sexual dysfunctions.

The Brazilian Portuguese language version of ICIQ-FLUTSsex is available, demonstrating as a valid tool, easy to apply, and to assess sexual dysfunction in women with complaints on urinary incontinence.

Authors' contribution

Andrade BF was responsible for collecting and analyzing the data, writing and discussing the article. Rangel EOR performed data collection and analysis. Guendler JA contributed with data analysis and critical review of the article. Katz L performed a critical review of the article. All authors approved the final version of the manuscript and are publicly responsible for the content of the article.

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