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Adherence and uncertainty during rehabilitation for urinary incontinence: Validation of a scale

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Abstract

We sought to create an Italian version of Mishel's Uncertainty in Illness Scale, dedicated to people undergoing conservative rehabilitation for urinary incontinence, for studying uncertainty as a determinant of therapeutic adherence. Urinary incontinence has a high prevalence worldwide, ranging from 25% to 45%. Incontinence is often treatable with conservative interventions but demands a long and intensive commitment from the patient. Results are not immediate, and relapses are possible. These patients can experience uncertainty and difficulty complying with rehabilitation programs, hence the importance of the therapeutic relationship with a healthcare professional. Mishel's theory of uncertainty can be used to measure uncertainty and the effects of such a relationship, but no instrument currently exists for this purpose. Prospective observational study enrolling all male and female adult patients admitted to a nurse-led outpatient pelvic clinic for non-neurogenic urinary incontinence, excluding puerpera. A scale named MUIS-PF (pelvic floor) was created, based on previous versions of Mishel's scale, and administered during the first consultation and at the end of the rehabilitation program. Internal consistency was assessed, and exploratory factor analysis was conducted. A total of 109 patients enrolled (54 M, 55 F) aged 64 ± 5 years, medial initial leakage 245 grams/day, IQR [90; 370]. Seventy-nine percent obtained continence; there were no dropouts during the study. Internal consistency of the MUIS-PF was high (93%), and structure analysis yielded a clear separation of the factors. Patient uncertainty decreased significantly at the end of the

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program compared to the first consultation ($p < 0.001$). The MUIS-PF is valid and reliable. Utilizing the correct approach, the nurse could significantly reduce the uncertainty of persons with incontinence by listening, giving clear information and searching for the best solution for their continence issues.

KEYWORDS
advanced nursing practice, clinical decision making, communication, continence, health psychology, lower urinary tract symptoms

What is known about this topic

- Rehabilitation for urinary incontinence can be long and frustrating for the patients, generating uncertainty that can undermine adherence to the therapeutic program
- The nurse–patient therapeutic relationship is paramount in these cases, and it would be useful to have data on the components of patient uncertainty.
- Mishel's uncertainty theory has been applied to other clinical settings, but no validated tool exists for incontinence rehabilitation.

What this paper adds

- We developed and validated a scale based on Mishel's theory
- The scale proved valid, reliable, and easy to use also for aged persons
- Our scale also has positive organizational repercussions, as it can highlight the value of a nurse–patient therapeutic relationship with scientific data.

1 | BACKGROUND

Urinary incontinence is a common problem worldwide; the overall prevalence[1] among women ranges from 25% to 45%, while in men, it reaches 49% after radical prostatectomy, one of the most common causes.[2] Incontinence is still seen as taboo and can cause great embarrassment and shame for those affected.[3,4] The quality of life of people with incontinence is often compromised in both women[5] and men.[6] Incontinence is usually treatable with conservative interventions, that is, neither pharmacological nor surgical.[7] These treatments demand a lot of commitment from the patient, as the muscles that ensure continence require an average of 3 to 6 months to be adequately trained through progressive exercise programmes.[8] During this period, people sometimes experience difficulties in learning the rehabilitation exercises to perform daily. They may go through periods of loss improvement, stagnation and even worsening of incontinence, depending on one's initial condition and ability to follow the programme.[9] Because results are not immediate and relapses are possible,[8] persons with incontinence need support from the professional supervising the rehabilitation, with unambiguous information about treatments and what they can expect from the programme.[4] The person is faced with an intimate and often disabling problem and needs to undertake a complex programme to deal with the events related to their condition. During this programme, they may experience discouragement related to the fluctuations of urine leakages and the impact on quality of life.

This difficult situation was defined as 'uncertainty' by the American nurse Mishel as a general concept without a precise reference to incontinence, generating the homonymous theory formulated at the beginning of the 1980s and revised in the following years.[10,11] The theory of uncertainty investigates four domains: *unpredictability* (lack of certain outcomes concerning treatment received and disease prognosis), *ambiguity* (vague information about disease status), *complexity* (multiple and intricate features of the disease and health pathway) and *inconsistency* between previous and current information received. The content of these domains is congruent with the experiences reported by people with incontinence.[4] For this reason, uncertainty is a possible component of the rehabilitation process, at least in some phases.

The literature emphasizes the importance of the therapeutic nurse–patient relationship for the person with incontinence.[12] A reference professional allows therapeutic education and training in self-care, improving the person's ability to understand the meaning of their situation, form a cognitive-behavioural scheme and adhere to the therapeutic program. These skills are fundamental in Mishel's theory to reduce uncertainty.[11] Currently, there are no studies on the characteristics and effects of the therapeutic nurse–patient relationship during the rehabilitation programme for incontinence. Data availability would allow the rehabilitation nurse to better support the patients during the rehabilitation process, thus improving compliance and outcomes, two aspects linked together.[13]

Several authors have studied the concept of uncertainty in urology, for example, in patients undergoing prostatectomy[14] and in men with prostate cancer in general.[15] These authors have used Mishel's scale to collect data. Still, no study was conducted to adapt the instrument to the specific characteristics of the rehabilitation pathway for urinary incontinence, which differs from that of the prostate cancer

patient. The scale was also modified and validated in Italian on people with chronic diseases.[16] Although incontinence has some characteristics common to long-term health problems, it is not a disease.[17] Therefore, this scale is only partially suitable for studying the situation of persons undergoing pelvic floor rehabilitation. It is necessary to develop instruments suitable for the study of uncertainty in the rehabilitation of people with incontinence. These instruments should be suitable for people of both genders and investigate aspects of the therapeutic patient–nurse relationship.

2 | AIMS

To develop and validate an Italian version of the MUIS (Mishel's Uncertainty in Illness Scale) dedicated to people undergoing conservative rehabilitation for urinary incontinence. We also want to study the components of uncertainty in this population and the characteristics of the therapeutic nurse–patient relationship that can reduce uncertainty during conservative rehabilitation for urinary incontinence.

3 | MATERIALS AND METHODS

A single-centre, prospective, observational study was conducted at a university hospital in Milan, Northern Italy. All male and female patients admitted to the outpatient pelvic floor rehabilitation clinic for urinary incontinence over 2 years were enrolled.

3.1 | Study setting and participants

The outpatient clinic treats non-neurological adult patients of both genders but not puerpera, who midwives treat in a separate setting according to hospital protocols. The case mix of the clinic includes mainly menopausal women and men undergoing prostate and bladder surgery, both open and robot-assisted,[18] with about 25% of both genders between 30 and 45 years of age.

The treatments offered are conservative and include therapeutic pelvic floor exercises (PFMT, Pelvic Floor Muscle Training) for all patients because European guidelines and recommendations[17,19] support PFMT. Based on the literature and patient situation, the exercises can be combined with biofeedback,[20] transcutaneous posterior tibial nerve stimulation,[21] functional electrical stimulation[22] and transcutaneous sacral root stimulation.[23] Treatments are administered by a nurse specialist dedicated to the outpatient clinic; rehabilitation progress, quality of life and therapeutic education interventions are documented according to the indications in the literature[24,25] and through validated questionnaires and forms.[26] Urine leakage is measured using the 24-h pad test.[17] Admission to treatment, patient assessment, multidisciplinary collaboration (e.g., with urologists) and the decision to terminate the programme (due to achievement of outcome or lack of clinically relevant improvement) are based on criteria defined by the International Continence Society.[17] Patients who do not achieve results are referred to the Level II consultation, following the same indications as in the literature,[17] after an interview explaining the reason for stopping the programme.

3.2 | Scale development

A scale was prepared based on the Italian version of the Mishel scale for chronic patients,[16] as it was the closest to the long-term situation experienced by people with urinary incontinence. The scale for people with prostate cancer[15] was also considered, but the items were not used, as they were dedicated exclusively to men in an acute condition. The original scale consists of 33 items based on a 5-point Likert scale (1 = strongly disagree, 5 = strongly agree). We deleted the median value *Undecided*, thus reducing the Likert points to 4 (1 = strongly disagree, 2 = partially disagree, 3 = partially agree, 4 = completely agree) to simplify the scale and obtain more precise answers to the items. Compared to the original scale, some modifications were made to better adapt the instrument to the rehabilitation context, reported in Table 1 and related to the type of incontinence and the rehabilitation program.

Some original scale items were removed because they referred to side effects irrelevant to the proposed treatments (no. 9, 15, 18, 21, 22, 26). Others were modified because they referred to 'disease' since incontinence is not a disease.[27] Overall, the scale was shortened, given the presence of elderly patients with low education in the sample. Table 2 shows the scale in its final version (the Italian version is available on request to the authors of this article). It was decided to maintain the domains originally envisaged by the author of the MUIS. The new instrument was named MUIS-PF (Pelvic Floor).

The rehabilitation specialist and a research nurse made modifications. The instrument was submitted to 8 nurses with at least 5 years of experience in urology and research to calculate the Content Validity Index.[28] The scale showed satisfactory content validity (CVI-I = 0.96 and CVI-S = 0.97). It was administered to patients at the outpatient clinic at the first consultation with the nurse and at the end of the rehabilitation programme. It was defined according to the outpatient clinic protocols.

Approval of the study was granted by the Bachelor School of Nursing of the University of Milan as part of a dissertation project (approval AD/ST No. 4–20) and by the Department of Urology of the hospital. The written informed consent obtained from all participants complied with the recommendations of the Regional Ethical Committees Association 28 regulations; all data were collected anonymously. The patients could withdraw from the study at anytime without consequences on their treatments. No further approval was necessary, as the questions contained in the MUIS-PF were compliant with the standard interview documented in the nursing records and did not affect the rehabilitation program in any way; in this regard, our study was similar to another prospective observational research following standard clinical practice.[29] The study did not imply any additional procedure, treatment, or cost for the participants. It was conducted

TABLE 1 Changes to the original MUIS scale.

Original item	Modified item	Motivation
'I don't know when to expect them to do something to me (tests, therapies…)'.	'I don't know when to expect them to do anything to me (therapies, treatments…)'.	No diagnostic tests are performed as per the original scale
'Doctors tell me unclear things'	'The health workers tell me unclear things'.	The rehabilitation program is run by nurses
'The course of the disease keeps changing. I have my ups and downs'.	'Due to the course of my treatment what I can or cannot do keeps changing'.	Incontinence is not a disease, according to the classification of the International Continence Society.
'I don't know when I will be able to take care of myself'.	'I don't know if I will be able to follow my therapy effectively'.	The rehabilitation program requires active daily exercise and involvement of the person
'The therapies I am following have helped other people before'.	'The treatments I am following have helped other people before'.	No drug therapy is administered as per the original instrument
'They did not give me specific explanations about my illness'.	'They did not give me specific explanations about my health problem'.	Incontinence is not a disease
'I can count on the medical team when I need them'.	'I can count on the outpatient staff when I need them'.	The rehabilitation program is managed by nurses and involves a multidisciplinary team
'The doctors and nurses use terms I can understand'.	'Health personnel use terms that I can understand'.	The rehabilitation program is managed by nurses and involves a multidisciplinary team

TABLE 2 The MUIS-Pelvic Floor scale items.

Item
(1) I have many unanswered questions
(2) I don't know if I'm getting better or worse.
(3) It is not clear how severe my symptoms will be.
(4) I don't understand what they told me about my health problem.
(5) The purpose of each treatment is clear to me
(6) When I have symptoms, I know what they mean in the context of my condition.
(7) I don't know when to expect them to do something to me (e.g., treatment)
(8) I understand everything that has been explained to me
(9) Healthcare workers tell me unclear things
(10) I know how long my health problem will last and I know the course of my health problem.
(11) My treatment is too complicated to understand
(12) It is difficult to know if the treatments I am following are helping me.
(13) As my condition keeps changing, I cannot plan for the future.
(14) Due to the course of my treatment what I can or cannot do keeps changing
(15) It is not clear what will happen to me
(16) I don't know if my treatments will work.
(17) I don't know if I will be able to effectively follow my treatment pathway
(18) I'm sure I won't have any more problems
(19) The treatments I am following have helped other people before.
(20) They did not give me specific explanations about my health problem.
(21) My symptoms are predictable: I know when I will feel better or worse.
(22) I can count on the staff of the rehabilitation service when I need them.
(23) Health personnel use terms that I can understand

Note: 1 = Strongly disagree, 2 = Partly disagree, 3 = Partly agree, 4 = Totally agree.

by the principles of the Declaration of Helsinki[30] and the Italian law on data protection.

Continuous variables were described with mean and standard deviation if normally distributed (Kolmogorov–Smirnov, Anderson-Darling, Kramer-von Mises test) or with median and interquartile range (Me, IQR) otherwise. Nominal variables were described by frequencies. Internal consistency was assessed with Cronbach's alpha coefficient[31] after reversing the items 5, 6, 8, 10, 18, 19, 21, 22 and 23. These items concern the positive aspects of the rehabilitation programme. Therefore, the uncertainty in these items decreases as the score increases. In the remaining items of the scale, on the other hand, uncertainty rises in parallel with the score because they investigate the negative aspects of the rehabilitation programme. Construct validity was assessed with exploratory factor analysis; the factors were extracted with the factorisation of the main axis and rotated with the Oblimin method based on scientific literature.[32] The number of factors was determined with parallel analysis[33] and the loadings were evaluated with the Stevens criterion.[34] Bartlett's sphericity test and the Kaiser-Meyer-Olkin (KMO) measurement were used to assess the suitability of the sample for analysis.[35]

Regarding sample size, we followed the literature criteria recommending a minimum of 100 persons for exploratory factor analysis[36,37] with responders: items ratio[38] of 3 to 6. Communality ≥0.40 was deemed acceptable.[32] The significance threshold for all analyses was set at 5%. All analyses were performed with R® software version 4 (The R Foundation, 2021).

4 | RESULTS

One hundred nine patients were enrolled (54 males, 55 females) of mean age 64 ± 5 years, with no significant differences

between the two genders ($p = 0.35$). Forty-eight of the 54 men had accessed the outpatient clinic for stress urinary incontinence after radical prostatectomy and 6 for incontinence after TURP (Trans-Urethral Resection of the Prostate). Forty-nine of the 55 women were postmenopausal; 31 of 55 had stress incontinence, and 24 mixed (stress and urgency together). The median number of comorbidities was 2 (range 0–4), with the prevalence of hypertension ($n = 42$), dyslipidemia ($n = 18$) and heart disease ($n = 13$).

All patients in the sample followed a course of PFMT, to which 28 (15 men and 13 women) associated functional electrostimulation, 24 transcutaneous pudendal nerve stimulation, and 23 posterior tibial nerve stimulation for wet overactive bladder. Initial daily urine losses had a median of 245 g, IQR [90; 370]. Patients who did not achieve continence at the end of the programme started from significantly higher values (Me = 320, IQR [290; 385], $p = 0.03$). The median duration of rehabilitation programs was 12 weeks, IQR [11; 19], with no significant differences between men and women ($p = 0.18$). The overall treatment success rate was 79% ($n = 86$), with no significant differences between the different types of rehabilitation programmes ($p = 0.11$). No patient dropped out of the programme; all agreed to complete the scale once the outpatient programme was declared finished, whatever the outcome.

4.1 | Scale validation

The internal consistency of the instrument was excellent (alpha = 0.93, minimum value = 0.92 with subtraction of each item after inversion of the items concerning the positive aspects of the rehabilitation pathway). The sample was suitable for the analysis (KMO = 0.937, Bartlett $p < 0.001$). The factorial model explained 57.3% of the variance, similar to other scales investigating the patients' experience during their healthcare pathway or constructs concerning learning (the comparison is useful since the rehabilitation programme involves aspects of therapeutic education[39]). The factor loadings (Table 3) were higher than Stevens' cutoff and distributed in 4 domains, congruent with the logical structure of Mishel's theory and yielded clear separation between the factors. The mean communality was 0.57 ± 0.18, considered satisfactory according to the reference manuals.

Overall, these results show that the tool is valid and reliable.

4.2 | Uncertainty

A global uncertainty score was obtained from the sum of all items after reversing those with positive connotations for the reasons explained above. The score could range from 23 to 92, corresponding

TABLE 3 Factor loadings of the MUIS-PF scale.

Item	Ambiguity	Incongruence	Complexity	Unpredictability
d15	0.851			
d3	0.821			
d2	0.768			
d16	0.643			
d19	0.571			
d1	0.769			
d10	0.644			
d7	0.628			
d12	0.505			
d18	0.678			
d6	0.693			
d23		0.961		
d20		0.618		
d22		0.534		
d8		0.621		
d9		0.694		
d4		0.628		
d5			0.700	
d11			0.652	
d17			0.637	
d14				0.854
d13				0.838
d21				0.601

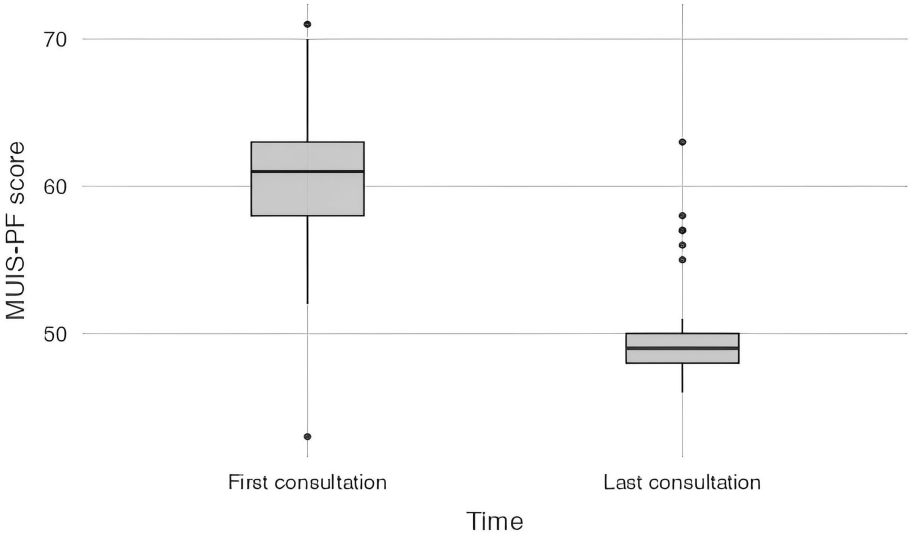

FIGURE 1 MUIS-PF total scores at the beginning and end of the programme.

to response scenarios of lowest and highest uncertainty. At the beginning of the rehabilitation programme, the median uncertainty score was 51, IQR [46; 53] with a maximum of 71 (one patient only). Considering the theoretical range of the scale, these values could be defined as 'medium uncertainty'. At the end of the outpatient pathway, the uncertainty had a median of 27, IQR [25; 30] with a maximum of 57 points (only one patient), as shown in Figure 1. Since the theoretical minimum is 23, the score at the end of the program substantially corresponds to minimum uncertainty; the difference between the scores at the beginning and the end of the rehabilitation program is statistically significant ($p < 0.001$).

To analyse the individual items in detail and thus the elements contributing to uncertainty, the patients' answers were dichotomised ('strongly/partially disagree' vs. 'partially/agree'). In all but three items, there was a statistically significant improvement in the responses indicating uncertainty, as shown in Table 4.

Ever since the first consultation, all patients reported to be 'completely in agreement' with the statement 'I can count on the staff of the rehabilitation service when I need them'. This positive judgement remained unchanged at the end of the rehabilitation programme for all patients, including those who did not achieve the result. At the final interview, these persons reported that they could always get honest information and attention to their needs from the staff, developing a relationship of trust.

The item 'Health care staff use terms I can understand' did not show any significant differences as from the first consultation, no patient 'totally disagreed' with it; 101 patients (92.7%) at the beginning of the course and 106 at the end (97.2%) completely agreed with the item. The last item that did not show significant differences at the end of the programme ('I am sure that I will not have any more problems') was related to comorbidities: people with more concomitant health problems than the median had worse scores in this item ($p = 0.03$).

Predictably, patients who were unsuccessful with the outpatient programme showed worse scores in the items 'I don't know if my therapies will work' and 'My symptoms are predictable' ($p = 0.02$ and $p = 0.03$, respectively) but not in 'I don't know if I am getting worse' which showed no significant difference ($p = 0.07$). This result relates to the fact that these patients still received clear information about their situation during the rehabilitation programme. The failure of the rehabilitation programme did not generate statistically significant differences in the scores of the remaining items ($p > 0.05$ for all analyses).

5 | CONCLUSIONS

A nursing approach based on listening, clear information and the constant search for the best solution for the problem of the person with incontinence significantly reduces uncertainty during rehabilitation for urinary incontinence. This results in high levels of awareness of the patients, who, from the beginning, have a clear picture of their situation and what will happen next. For example, the initial extent of urinary leakage is one of the negative prognostic factors. Apart from the clinical results, however, relying on rehabilitation staff certainly helps.

The nurse's role was investigated in this study, but other researchers have considered physiotherapists. Depending on the type of patient and the professional competencies, other figures such as midwives or medical specialists are involved in rehabilitation[17]; the scale developed for the present study is suitable for nurses and can be applied to other rehabilitation team members. Future studies may focus on possible specific features of programmes run by professionals other than nurses on patient populations with different characteristics.

Completing the MUIS-PF took an average of 10 minutes for patients, without creating difficulties for older people; therefore, it seems possible to administer it in contexts such as the waiting room to use the results during the consultation without prolonging the time too much. Our sample's uncertainty levels were low already at the

TABLE 4 Differences between the items at the beginning and after the rehabilitation programme.

Item	T0 versus T1
(1) I have many unanswered questions	<0.001
(2) I don't know if I'm getting better or worse.	<0.001
(3) It is not clear how severe my symptoms will be.	<0.001
(4) I don't understand what they told me about my health problem.	<0.001
(5) The purpose of each treatment is clear to me	<0.001
(6) When I have symptoms, I know what they mean in the context of my condition.	<0.001
(7) I don't know when to expect them to do something to me (e.g., treatment)	<0.001
(8) I understand everything that has been explained to me	<0.001
(9) Healthcare workers tell me unclear things	0.005
(10) I know how long my health problem will last and I know the course of my health problem.	<0.001
(11) My treatment is too complicated to understand	<0.001
(12) It is difficult to know if the treatments I am following are helping me.	<0.001
(13) As my condition keeps changing, I cannot plan for the future.	<0.001
(14) Due to the course of my treatment what I can or cannot do keeps changing	<0.001
(15) It is not clear what will happen to me	<0.001
(16) I don't know if my treatments will work.	<0.001
(17) I don't know if I will be able to effectively follow my treatment pathway	<0.001
(18) I'm sure I won't have any more problems	0.618
(19) The treatments I am following have helped other people before.	<0.001
(20) They did not give me specific explanations about my health problem.	<0.001
(21) My symptoms are predictable: I know when I will feel better or worse.	<0.001
(22) I can count on the staff of the rehabilitation service when I need them.	NA*
(23) Health personnel use terms that I can understand	0.301

*All the responses were the same ('completely agree') and the *p*-value could not be calculated.

beginning of the rehabilitation programme; a possible bias may be given by the decision to welcome the person with a complete consultation before giving them a form to fill in. This criterion has always been valid at the survey centre for all questionnaires and scales, even the clinical ones. However, considering the results at the end of the programme, this choice does not represent a relevant bias regarding the goodness of the instrument obtained and the results of the study.

In conclusion, the MUIS-PF scale is a valid and reliable tool for measuring uncertainty in a person with non-neurological urinary incontinence undergoing a conservative rehabilitation programme. Furthermore, the MUIS-PF can point out the usefulness of the nurse–patient therapeutic relationship inside the healthcare organization and highlight the strengths and weaknesses of nursing care, thus allowing service improvement.

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CONFLICT OF INTEREST STATEMENT

The authors declare no conflict of interest.

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