STUDY PROTOCOL – DO NOT COPY OR DISTRIBUTE

Title: Female Urinary Incontinence in middle-aged women in four hospitals in Northern Italy: a multicenter prevalence study

Protocol Acronym: WUIPS (Women Urinary Incontinence Prevalence Study)

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Centers:	Ospedale San Raffaele Turro, Milan Policlinico San Pietro, Ponte San Pietro (BG) Policlinico San Marco, Zingonia (BG)	
Expected duration of the study:	6 months	

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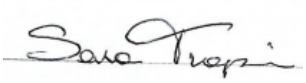
SIGNATURE PAGE

Title: Female Urinary Incontinence in middle-aged women in four hospitals in Northern Italy: a multicenter prevalence study

The undersigned has read and understands all aspects of the protocol detailed in this document and agrees to supervise and conduct the study in accordance with the protocol, the ICH E6 (R2) Good Clinical Practice Guidelines, the Declaration of Helsinki and all the applicable regulatory requirements.

Massimo Candiani		IRCCS Ospedale San Raffaele	25/11/2023
Authorized Sponsor Representative Name	**Signature**	**Affiliation**	**Date**

Sara Trapani		IRCCS Ospedale San Raffaele	23/08/2023
PRINCIPAL INVESTIGATOR	**Signature**	**Affiliation**	**Date**

Conflicts of interest
The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Confidentiality Statement
This document contains confidential information that must not be disclosed to anyone other than the Sponsor, the Investigator Team, host organisation, and members of the Research Ethics Committee, unless authorised to do so.

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1. RATIONALE OF THE STUDY

Bladder problems and urinary diseases, also known as Lower Urinary Tract Symptoms (LUTS), are common worldwide (Todhunter-Brown et al., 2022). One of these problems is Urinary Incontinence (UI), defined as "the complaint of any involuntary leakage of urine" (Abrams et al., 2003; Hylen et al., 2010). UI can be classified into three main subtypes. Stress UI (SUI) is the urine loss provoked by exertion, physical effort, sneezing or coughing; Urge UI (UUI) refers to urine leakage accompanied by a sense of urgency that is defined as a sudden and compelling desire to void urine (Haylen et al., 2010; Bo et al., 2017); Mixed UI consists of the combination of SUI and UUI (Abrams et al., 2003).

UI has been identified as a World Health Organization health priority (Parpio, Minaz & Haider, 2022), also because individuals with UI are projected to increase with time, with the greatest increase in burden anticipated in developing regions (Irwin et al., 2011). A worldwide prevalence study conducted in the last decade reported that an estimated 21.5% of the 2008 worldwide population ≥ 20 years (approximately 348 million subjects out of 4.3 billion) was affected by UI (Irwin et al., 2011). Particularly, SUI is the most common UI type (5.9% in women vs 0.49% in men in 2008). Numbers of patients affected by UUI in 2008 were 49 million, while 54 million individuals were affected by MUI (Irwin et al., 2011).

Currently, the Italian epidemiology for UI is approximately 5 million people (the 8,7% of the population), of which 3 million are women (Fincopp, 2022). According to the Italian Institute for Statistics (ISTAT), the Italian population is aging, and the average age of the population ranges between 40 and 65 years old (Sistema Statistico Italiano and Istituto Nazionale di Statistica (ISTAT), 2021). Statistics suggest focusing on this specific range of age, in which population's high quality of life and healthy lifestyle is expected, also because they are socially active subjects. In addition, the range 40-65 represents the starting point of significant occurrence of UI in the female population (Irwin et al., 2006; Wieland et al., 2019; Fincopp, 2022). In fact, a study conducted in an Italian urban area (Siracusano et al., 2003), investigating the UI prevalence by age subgroups in a sample of 2900 women, showed that more than one in four women suffered from incontinence episodes from 40 years of age onwards. Another Italian prevalence study (Bortolotti et al., 2000) interviewed 2767 women ≥ 40 years old and 2721 men ≥ 50 years old to assess the frequency of UI, finding that 3% of male sample and 11% of female participants reported at least one episode of UI during the previous year. Female data were substantially confirmed by an Italian cross-sectional study carried out in 2002 (Parazzini, Lavezzari & Arbitani, 2002). A total of 13365 women (mean age, 60.3 years) were identified by 774 general practitioners: the frequencies of UI were 10.2%. Instead, for men older than 40 years (mean 64.8 years) a fairly higher percentage than in previous data (8.3% vs 3%) experienced UI (Parazzini, Lavezzari & Arbitani, 2002). This discrepancy is probably linked to the fact that, in the study by Bortolotti and colleagues, men between the ages of 40 and 50 were not enrolled (Miano et al., 2012).

Regarding gender difference, UI affects both women (Sussman et al, 2020) and men (Gacci et al., 2022), but it is more common in female than in male population (Markland et al., 2011; Milsom & Gyhagen, 2019; Monticone et al., 2020) and women are more severely affected than men (Aslan et al., 2008), due to obstetric, gynecological and hormonal causes (Sensoy et al., 2013): these data highlight the importance of the phenomenon and the need to study in depth the female UI condition.

In addition, UI negatively influences the physical, psychological, social and financial life of the affected people (Batmani et al., 2021; Parpio, Minaz & Haider, 2022). The health-related quality of life impact

of incontinence is similar to that observed with other chronic medical conditions like osteoarthritis, chronic obstructive pulmonary disease, and stroke (Subak et al., 2006). Specifically, it was seen that UUI is the UI subtype with the higher impact on the quality of life (Aslan et al., 2009), due to the frequency of incontinence episodes and the urge to urinate, which interrupts the daily routine. Reducing these symptoms is a priority for women and it is demonstrated by their willingness to pay for continence improvement (Subak et al., 2006). In fact, women with UI consume significantly higher medical resources and incur higher costs to payers, compared to women without this problem (Datar et al., 2022).

Although it is a widely discussed literature topic, UI is an underestimated condition (Tran & Puckett, 2022). In fact, sometimes people do not report this problem, because it is still considered a taboo and a source of shame and embarrassment (Elenskaia et al., 2011). In addition, the last published Italian prevalence studies date back to the first decade of the new millennium (Bortolotti et al., 2000; Parazzini, Lavezzari & Arbitani, 2002; Siracusano et al., 2003). For this reason, a prevalence study focused on UI in Italy could provide significant information.

The current study will indagate the prevalence, predictors and effects (quality of life and costs) of UI in middle-aged women (40-65 years old) identified in four hospitals in Northern Italy, which are the reference centers for Vita-Salute San Raffaele University (UniSR).

2. STUDY DESIGN

A multicenter prospective and prevalence observational study will be conducted. A prevalence study is essential for establishing the distribution of the condition in the population and projecting the need for health and medical services supporting health care professionals to make preventive and treatment decisions. The study will follow the STrengthening the Reporting of OBservational studies in Epidemiology (STROBE) Checklist (Vandenbroucke et al., 2007).

3. OBJECTIVE

The study will aim to punctually investigate and describe prevalence, predictors, quality of life and costs of Urinary Incontinence among female patients, female caregivers and female personnel in four hospitals in Northern Italy.

4. OUTCOMES

Primary outcome

- Prevalence of middle-aged women with urinary incontinence.

Secondary outcomes

- Description of UI and related predictors, quality of life, social impact and costs.
- Association between UI and related predictors, quality of life, social impact and costs.

5. EXPECTED RESULTS

The collection of data and information through this study will aim to:

a) Understand the percentage of middle-aged women with UI.

b) Describe the socio-demographic and clinical characteristics of women with UI.
c) Identify UI predictors.
d) Describe the quality of life, social impact and costs of women with UI.

6. STUDY POPULATION

All female patients, female caregivers, female healthcare professionals and female administrative workers who meet the inclusion criteria will be included. Participants will be enrolled in four centers in Northern Italy which are the reference centers for UniSR: San Raffaele hospital in Milan, San Raffaele Turro hospital in Milan, Zingonia Policlinico San Marco (BG) and Policlinico San Pietro in Ponte San Pietro (BG).

7. INCLUSION/EXCLUSION CRITERIA

7.1 Inclusion criteria

- Female sex
- Middle age (40-65 years old)
- Informed consent signed
- Comprehension of written and spoken Italian language
- Female outpatients intended for any hospital unit (outpatient clinic, day surgery and day hospital patients included) and every female caregiver respecting the previous inclusion criteria, recruited at the central admission and at the private admission of the four hospitals involved
- Female workers (healthcare professionals and administrative personnel) of the four hospitals

7.2 Exclusion criteria

- Male sex
- Young age (< 40 years) and older age (> 65 years)
- Pregnant women
- Puerperium women (up to 40 days post-partum)
- Women who had undergone urinary and gynecology surgery

8. PARTICIPANT REGISTRATION

Data collection will be carried out through the use of two questionnaires validated in Italian language and a survey built by the researchers on the basis of the scientific literature.

Two different paths have been designed to recruit participants, depending on whether they are female personnel or female patients and female caregivers:

- for healthcare professionals and administrative workers of the four hospitals, one week before the administration of the data collection tools (a survey and two validated questionnaires), an email will be sent to the work account to present the topic and the aim of the study. A second email will then be sent with a link to access the online survey/questionnaires (RedCap) and with a deadline by which to fill it out. The email will be sent to all workers, asking for the compilation only to women of 40-65 age range group and who meet the inclusion criteria. Participants will agree to a brief privacy policy and electronic release of informed consent before completing the survey and the questionnaires.
- for female patients and female caregivers' registration, participants will be recruited at the central admission and at the private admission of four hospitals in Northern Italy. At recruitment, inclusion and exclusion criteria will be evaluated through a brief preliminary interview, lasting about a couple of minutes. It will take place immediately before the administration of the questionnaires at the central and private reception of the hospitals involved. On this occasion, a researcher in charge of data collection will ask the participant for information on: age, pregnancy/puerperium status and past history of gynecological surgery. Each participant who joins the study will be provided with a paper module, containing the survey and the questionnaires, marked with a progressive identification number: after signing the informed consent, all participants will be asked to answer questions voluntary and anonymously at the moment and return the completed module to researchers.

Data will be collected anonymously by a paper module for patients and caregivers and by RedCap for healthcare professionals and administrative workers. Then, the data on the platform will be extracted to the eCRF; the paper data will be uploaded to the eCRF by the researchers.

9. DATA COLLECTION

All the data will be collected based on a series of variables which derive from an accurate narrative review of the UI predictors, costs and quality of life of the women affected by the problem (Danforth et al., 2006; Datar et al., 2022; Goren et al., 2014; Harding et al., 2023; Sensoy et al., 2013). These variables are described in Table 1. The obtained information will be gathered in the eCRF, which the investigators will only access during the analyses and synthesis of data.

Table 1 - Outcome and description of the investigated variables

OUTCOME	VARIABLE	DESCRIPTION
UI predictors	Age	The prevalence of UI seems strongly related to the age of the woman and specifically prevalence figures increase with increasing age (Milsom & Gyhagen, 2019)

	Ethnicity	The risk of SUI appears to be lower in black and Asian-American women compared to white women (Danforth et al., 2006; Thom et al., 2006)
	Scholarship	According to some studies (Batmani et al., 2021; Marques et al., 2015), increasing the level of education is an important factor in reducing the incidence of urinary incontinence
	Body Mass Index (BMI)	There is evidence that the prevalence of both UUI and SUI increases proportionately with BMI (Harding et al., 2023)
	Comorbidities	Lower urinary tract symptoms are associated with multiple comorbid conditions including: • cardiac failure • chronic renal failure • chronic obstructive pulmonary disease • diabetes • hypertension • metabolic syndrome • pelvic organs prolapse • urinary tract infections • bowel disorders (constipation, irritable bowel syndrome) • sleep disturbances • depression • neurological disease • general cognitive impairment (Batmani et al., 2021; Harding et al., 2023; Sensoy et al., 2013; Wang et al., 2010)
	Pelvic or uro-gynecological surgery	Other factors positively associated with SUI include previous pelvic or uro-gynecological surgery (Ellström Engh et al., 2006; Harding et al., 2023)

	Menopause	Menopausal status seems to influence the onset and characteristics of urine leakage (Sensoy et al., 2013; Thangarajah et al., 2020)
	Parity	Pregnancy and childbirth are triggers for SUI (Li et al., 2023; Bortolotti et al., 2000)
	Lifestyle factors	• Unhealthy voiding behavior (Hu and Pierre, 2019) and low physical activity may contribute to UUI onset (Li et al., 2023) • Smoking cessation is a general public health measure and has been shown to be weakly associated with improving urgency, frequency and UI (Danforth et al., 2006; Harding et al., 2023) • Decrease in fluid intake may improve some symptoms in patients with SUI and idiopathic detrusor overactivity (Swithinbank et al., 2005) • Reduction of caffeine intake may reduce symptoms of frequency and urgency (Harding et al., 2023) • An association was seen between alcohol consumption and urinary incontinence in middle-aged and older women (Lee & Hirayama, 2012)
UI prevalence and symptomatology	Frequency of urine leakage	To assess the severity of UI among female, we need measuring the “frequency” and “usual amount” of leakage ranged from “moderate” to “strong” (Avery et al., 2004)
	Perceived quantity of urine leakage	
	Type of urine leakage	It is focused on subtypes of urinary incontinence (SUI, UUI and MUI) (Abrams et al., 2003)
	Time of onset of urine leakage	The mean age in which urine leakage begins seems to be lower for SUI compared to MUI and UUI (Thangarajah et al., 2020)

UI quality of life, social impact	General interference with daily life	The measurement of UI should incorporate the impact that the condition may have on quality of life (Avery et al., 2004)
	Interference with specifical activities	Specifically: • Physical Activity • Social Relationships • Travel • Emotional Health (Monticone et al., 2021; Shumaker et al., 1994)
	Interference with sexual life	Some articles report that UI affects sexual aspects of the individual (Felsted & Supiano, 2019; Marques et al., 2015). According to other studies, sexual activity does not seem to be damaged by UI (Siracusano et al., 2003)
Costs	Work productivity	UI imposes a high economic burden because of work productivity loss (Goren et al., 2014)
	Weekly costs of hygiene care products	UI is associated with substantial routine care "costs" (Subak et al., 2006)
	Healthcare resource utilization: 1. Specialist visits 2. Treatments	Women with SUI/MUI consume significantly higher medical resources and incur higher costs to payers, compared to women without SUI/MUI (Datar et al., 2022)

9.1 Instruments

Three instruments will be employed to collect data, as reported in Table 2.

Table 2 - Instruments employed in the study

Instrument	**Data of interests**
UI Survey	Women's socio-demographic and clinical characteristics based on the variables reported in Table 1
Italian version of the International Consultation of Incontinence Modular Questionnaire Urinary Incontinence Short Form (ICIQ UI-SF) (Tubaro et al., 2006)	Prevalence and symptomatology of UI (Bedretdinova et al., 2015)
Italian version of the Incontinence Impact Questionnaire-7 (IIQ-7) (Monticone et al., 2020)	Impact on life of urinary incontinence among women (Shumaker et al., 1994)

A survey, written in Italian by the authors and tested on a sample of 13 women between 40 and 65 years old, will collect socio-demographic, economic and clinical characteristics of all the female participants included in the study. The requested data will be based on the variables reported in Table 1.

The Italian version of the International Consultation of Incontinence Modular Questionnaire Urinary Incontinence Short Form (ICIQ UI-SF) will be used to investigate UI symptoms in women (Avery et al., 2004; Tubaro et al., 2006).

The Italian version of the Incontinence Impact Questionnaire-7 will be used to assess the impact of UI on women's quality of life (Monticone et al., 2021; Shumaker et al., 1994).

The materials necessary for data collection will be included in a paper module for patients and caregivers and online for staff (see attachment). Each subject included will fill in the module which will be transmitted to the Promoter with the appropriately anonymized data. Given the growing need for digital data management in clinical trials and in compliance with current regulatory requirements, researchers will independently set up the eCRF (electronic Case Report Form), via the RedCap platform.

In each hospital center involved in the study, a nurse will be identified, as the contact person of the Center, who will be responsible for supervising the appropriate recording of data and compliance with this research protocol.

9.1.1 UI Survey

A survey, written in Italian by the authors, will collect women's socio-demographic, economic and clinical characteristics, based on the variables reported in Table 1. The entire survey is attached in Appendix.

A total of 29 questions will attempt to acquire information about some of the previously defined variables: specifically, 23 questions will be related to socio-demographic and clinical predictors of UI (n. 1-23), one question will be about the onset of the UI symptomatology (n. 35), one question about sexuality (n. 36) and four questions will investigate the direct and indirect costs of UI (n. 37-40). The survey was tested as a pilot on a sample of 13 women aged between 40 and 65 years old and was assessed as suitable for the following aspects: understanding and clarity of the questions, absence of questions that put the participant in difficulty, completion time (which resulted maximum of 5 minutes).

9.1.2 International Consultation of Incontinence Modular Questionnaire Urinary Incontinence Short Form (ICIQ UI-SF)

The International Consultation of Incontinence Modular Questionnaire Urinary Incontinence Short Form (ICIQ UI-SF) is a questionnaire that allows the assessment of the prevalence, frequency, and perceived cause of UI and its impact on everyday life. It is an appropriate scale for estimating national prevalence in representative samples (Bedretdinova et al., 2015).

ICIQ UI-SF was developed and validated in English for the first time by Avery and colleagues in 2004, and then Tubaro and colleagues made an Italian Validation in 2006. This last version will be used in the study.

The questionnaire comprises four question items and the reference period for symptom assessment is the four weeks preceding the day that the questionnaire is administered. The total score for the ICIQ-SF is calculated as the sum of scores obtained from the frequency of urinary incontinence episodes (from 0 or 'never', increasing by 1 unit up to 5 or 'always'), perceived quantity of urine losses (0 or 'no loss', increasing by 2 units up to 6 or 'a large amount') and quality of life (from 0 or 'no interference' of urinary incontinence with life, increasing by 1 unit up to 10 or 'maximum interference'). The theoretical range of total score values is therefore 0-21. A higher score indicates greater impairment from incontinence. The fourth question is an unscored self-diagnostic item about the type of urine leakage (Tubaro et al., 2006).

The instrument has a GRADE A on the level of validation according to the International Consultation of Incontinence (ICI) grades of recommendation; this means that the questionnaire has good validity, reliability and responsiveness established with rigor in several data sets. Specifically, the internal consistency of the ICIQ-SF is satisfactory overall, with a Cronbach's α of 0.896. Also the test-retest reliability is good; the Pearson r coefficient is almost equal to 1 for the total score and varies steadily at ≈ 0.9 for all items. Intraclass correlation coefficients for the total score and the quality of life item are, respectively, 0.93 and 0.96 (Tubaro et al., 2006). The entire questionnaire is attached in the Appendix (questions n. 24-27).

9.1.3 Incontinence Impact Questionnaire-7 (IIQ-7)

The Incontinence Impact Questionnaire-7 (IIQ-7) was developed in 1994 to assess the impact on life of urinary incontinence among women (Shumaker et al., 1994).

IIQ-7 is a self-administered, seven-item questionnaire referring to the individual's perceived impact of urinary incontinence on daily activities, relationships, and feelings. Each item has a four-point response scale, where individuals rate the extent to which urine leakage affects their daily functioning (0 = not at all;

1 = slightly; 2 = moderately; 3 = greatly). According to the original authors, this tool examines four domains: physical activity (items 1 and 2), travel (items 3 and 4), social activities (item 5) and emotional health (items 6 and 7). The sum is averaged and the mean (from 0 to 3) is multiplied by 33 1/3 to obtain a score on a 0–100 scale (Uebersax et al., 1995). A higher score indicates more severe symptoms and lower quality of life (Monticone et al., 2020).

Overall, the Italian version of the Incontinence Impact Questionnaire-7 shows acceptable basic psychometric properties: time to complete the questionnaire is almost four minutes, Cronbach's α is 0.88, item-scale correlations are all > 0.66, and item-rest correlation values (rs) range from 0.53 (item 1 "Household chores") to 0.70 (item 4 "Travel > 30 min away from home"). Test–retest reliability is excellent (ICC 2.1 = 0.92 with 95% confidence interval 0.88–0.94). The Standard Error of Measurement and Minimum Detectable $Change_{95}$ are, respectively, 6.5 and 18.1 points (Monticone et al., 2021). The entire questionnaire is presented in the Appendix (questions n. 28-34).

10. DATA MANAGEMENT AND QUALITY CONTROL

The data collection process will be carried out by nurses and midwives of the four involved hospitals and Vita-Salute San Raffaele University, who will be specifically trained by the research group. The data of the survey and the questionnaires will be collected in the eCRF. Only researchers and authorized users will be able to view the dataset. It will present suitable privacy and anonymity protection requirements according to the provisions of European law (General Data Protection Regulation (GDPR), 2016; available at: https://gdpr-info.eu/). Jamovi 2.3.21 software will be used to conduct the data statistical analyses.

11. NUMBER OF CASES

The population sample cannot be decided accurately in advance. Population studies from numerous countries have reported that the prevalence of UI among all adult women ranged from approximately 5% to 70% worldwide, with most studies reporting a prevalence of UI in the range of 25–45% (Miano et al., 2012; Milsom & Gyhagen, 2019). To date, limited epidemiologic research has been conducted in Italy on this matter. One of the most recent Italian studies was conducted in 2002 and prevalence of UI was found to be 10.2% in a sample of 13365 women older than 40 years (Miano et al., 2012; Parazzini, Lavezzari & Arbitani, 2002).

To define an indicative sample size for our search, reference will be made to the sample considered by two prevalence studies conducted in some specifical Italian districts. The first one proposed telephonic interviews to the population of a big area composed by six cities, including a total of 2.767 women aged ≥ 40 years old (Bortolotti et al., 2000). The second study investigated by questionnaire the prevalence and characteristics of UI in a female sample composed by 2.900 subjects aged between 18 and 49 years living in the urban area of Trieste (Siracusano et al., 2003).

Our study will investigate UI prevalence in middle-aged women (40-65 years old) identified in four hospitals in Northern Italy. The competent Departments were asked for data on the average daily accesses of patients to the hospitals involved and the number of female personnel hired with an age range of 40-65

years. As regards the female personnel between 40 and 65 years old hired at San Raffaele Hospital and San Raffaele Turro Hospital, there are 1.842 employees. The sample will be determined based on the data we will receive from other hospitals.

After this study, we could expand the protocol to include other centers to better evaluate the phenomenon and investigate the prevalence in a larger population.

12. SUBJECT'S POTENTIAL RISKS AND BENEFITS

No subject's potential risks are associated with the study and study procedures.

12.1 Bias risk

The included population could present Recall Bias (Delgado-Rodríguez, 2004) during the survey filling, particularly with the ICIQ-UI SF, because it refers to the last four weeks before the filling. This study could present the Underreporting Bias (Delgado-Rodríguez, 2004) because the survey asks for behaviors that negatively affect the personal and social life. The researchers decided to use a bias risk assessment tool during the drafting of the protocol to ensure the study quality. This tool will also accompany the writing of the paper in the future. It consists of a modification and an upgrade of the existing tool developed initially by Leboeuf-Yde and Lauritsen (Leboeuf-Yde & Lauritsen, 1995; Hoy et al., 2012). The tool is based on the Grades of Recommendation, Assessment, Development and Evaluation (GRADE) and Cochrane approaches (Higgins & Green, 2008; Terracciano et al, 2010).

The tool consists of 10 items addressing four domains of bias plus a summary risk of bias assessment: items 1 to 4 assess the external validity of the study (domains are selection and nonresponse bias), and items 5 to 10 assess the internal validity (items 5 to 9 assess the domain of measurement bias, and item 10 assesses bias related to the analysis) (Hoy et al., 2012). Table 3 illustrates the items of the risk of bias tool.

After completing the reporting of the manuscript (except for the risk of bias assessment), two blinded raters will give their opinion on the quality of the study. Response options for individual items (from 1 to 10) will be "low" or "high" risk of bias (if there will be insufficient information in the report to permit a judgment for a particular item, then the item will be deemed to be at high risk of bias). Response options for the summary assessment (item 11) will be "low", "moderate", or "high" risk of bias (Hoy et al., 2012). Overall interrater agreement will be calculated by considering each of the 10 items plus the summary assessment.

Table 3 - The items of the risk of bias tool

#	Item
1	Was the study's target population a close representation of the national population in relation to relevant variables?
2	Was the sampling frame a true or close representation of the target population?

3	Was some form of random selection used to select the sample, or was a census undertaken?
4	Was the likelihood of nonresponse bias minimal?
5	Were data collected directly from the subjects (as opposed to a proxy)?
6	Was an acceptable case definition used in the study?
7	Was the study instrument that measured the parameter of interest shown to have validity and reliability?
8	Was the same mode of data collection used for all subjects?
9	Was the length of the shortest prevalence period for the parameter of interest appropriate?
10	Were the numerator(s) and denominator(s) for the parameter of interest appropriate?
11	Summary item on the overall risk of study bias

13. STATISTICAL ANALYSES

Descriptive and position analyses (mean, median, standard deviation, and interquartile range) will be conducted for the description of the quantitative variables. Categorical variables will be described with linear models. Any classification or stratification techniques (multivariate statistics) will be applied to identify participants' profiles. All the statistical analyses will be conducted using the statistical package for the social sciences, Jamovi 2.3.21 software.

14. ETHICAL ASPECTS

This study will be conducted in accordance with the present protocol, with the principles of good clinical practice, according to the ICH Good Clinical Practice standards and the requirements of the Guidelines, with the principles of the Declaration of Helsinki. The study protocol and all other necessary documents will be submitted to the Competent Authorities. Amendments and new versions of the protocol will be promptly shared with the competent Ethics Committee. The present study will be conducted in accordance with the protocol defined by the investigators involved.

Before starting any study procedure, the study protocol and documents will be notified to the Clinical Trial Center and the Ethics Committee of the San Raffaele Hospital in Milan.

15. PARTICIPANT INFORMATION AND CONSENT

All the participants will be invited to voluntarily contribute to the study. The purpose of the study and related procedures will be explained to them. The participants will also be allowed to clarify doubts or uncertainties by asking questions and receiving clear and satisfactory answers. Having read the study information, the participants will have the time to decide whether to proceed with signing the informed consent. Healthcare professionals and administrative workers will agree to a brief privacy policy and electronic release of informed consent (by email) before completing the survey and the questionnaires. For female patients and female caregivers', a paper informed consent will be required to be signed. The decision not to participate in the survey will not affect future nursing care. All participants receive the same care and support from healthcare personnel. Prior to participation in the study, the subjects will receive a copy of the signed and dated written informed consent form.

16. DATA QUALITY, DATABASE MANAGEMENT

The research group will be responsible for data management, data control and quality assurance. The anonymous data will be collected in the eCRF: the data deriving from healthcare professionals and administrative workers will be directly registered in RedCap, while the paper data of patients and caregivers will be manually uploaded.

The data collected will be recorded, processed, managed and archived in paper form and in an automated and computerised form for the sole purposes connected with research, in compliance with Legislative Decree 30/06/2003 n°196 and subsequent authorizations and in compliance with the European regulation n. 679 of 2016. The Principal Investigator will be responsible for data management.

In each hospital center involved in the study, a nurse will be identified as the contact person of the Center, who will be responsible for supervising the appropriate recording of data and compliance with this research protocol.

All data contained in the database specifically set up for the study cannot be attributable to the individual patient: the data are collected anonymously. The patient's personal data are not of interest to the Experimentation in question.

16.1 Data confidentiality and privacy

The privacy of the recruited subjects will be completely guaranteed, and the data will be treated confidentially in the terms prescribed by Italian law in the Legislative Decree 30 June 2003, n. 196, "Code regarding the protection of personal data" (Official Gazette n. 174 of 29 July 2003 – Ordinary Supplement n. 123) and in compliance with the European General Data Protection Regulation n.679 of 2016. The data collected during the study will be kept anonymous and processed for scientific purposes only. They will never be published as individual data but will serve exclusively, in an aggregated way with those of all the other

participants in the study, to produce descriptive analysis results. The investigators ensure that the confidentiality of the participants will be maintained and only an identification number in the register will identify them. All documents will be kept securely and accessible only by the investigators or other authorised personnel. The study will comply with the Italian laws on protecting personal data and the guidelines stipulated on July 24, 2008.

16.2 Data ownership

The ownership of the data relating to the study, its execution and its results belong to the Promoter (DL 17/12/2004). The Coordinating Center will be responsible for data management and storage in compliance with the current regulations (DL 196/2003: “Data Protection Code personal data, June 30, 2003"). The study is promoted by the IRCCS San Raffaele Hospital (Milan), which will also take care of the scientific and operational coordination and which will be responsible for the ownership of the data deriving from the research.

17. DATA PUBLICATION

The research will be made known to the population and to all interested people through communications at conferences, congresses, symposiums, dissemination articles and articles in national and international scientific journals. The research group must authorise and coordinate any studies derived from subgroup analyses. The research group will prepare the study's final report, which will be presented in a meeting. The research group will define the authorship of the works that will be produced in relation to the involvement and work done by the individual. In all the works that will be produced, the promoter of the study must be reported and mentioned in the acknowledgements section.

All publications and/or communications related to the study will be approved in advance by the research group. The transmission or dissemination of global data, through scientific publications and / or presentation in congresses, conferences and seminars, will take place exclusively following the consent of the Promoter Center and the Hospital Centers included in the study after statistical processing of the same and in any case in aggregate and anonymous form.

18. CONSERVATION OF STUDY DOCUMENTS

All information relating to the study participants, the documentation relating to the submission and approval by the EC and the regulatory documentation will be kept by the Principal Investigator in the archive of the IRCCS San Raffaele Hospital (Milan).

19. FINANCIAL ARRANGEMENTS

The study is non-profit. Given the observational nature of the study, insurance coverage is not provided as it is unnecessary.

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APPENDIX

UI SURVEY – SCHEDA di RACCOLTA DATI

Gentilissima, nel ringraziarla per aver accettato di contribuire a questa ricerca, la invitiamo a rispondere alle domande di seguito, di natura clinica e socio-demografica, con le quali indaghiamo alcuni fattori che potrebbero essere predisponenti all'insorgenza di una condizione nota come incontinenza urinaria.

1. Indichi il suo anno di nascita:

2. Indichi la sua nazionalità:
   - ☐ 1. Italiana
   - ☐ 2. Straniera (specificare _____)

3. Indichi la regione di domicilio:
   - ☐ 1. Lombardia
   - ☐ 2. Altra regione (specificare _____)

4. Se è domiciliata in Lombardia, indichi la provincia del suo domicilio:
   - ☐ 1. Bergamo
   - ☐ 2. Brescia
   - ☐ 3. Como
   - ☐ 4. Cremona
   - ☐ 5. Lecco
   - ☐ 6. Lodi
   - ☐ 7. Mantova
   - ☐ 8. Milano
   - ☐ 9. Monza
   - ☐ 10. Pavia
   - ☐ 11. Sondrio
   - ☐ 12. Varese

5. Indichi il suo peso in chili:

Kg

6. Indichi la sua altezza in centimetri:

cm

7. Indichi il grado massimo di studi raggiunto (scolarità):
   - ☐ 1. Educazione primaria (elementari, medie)
   - ☐ 2. Educazione secondaria o avanzata (diploma di istituto professionale, tecnico o liceo, laurea)

8. Soffre o ha mai sofferto di una delle seguenti patologie? (Può indicare anche più di una risposta):
   - ☐ 1. Insufficienza cardiaca
   - ☐ 2. Insufficienza renale cronica
   - ☐ 3. Broncopneumopatia cronico-ostruttiva (BPCO)

- ☐ 4. Diabete
- ☐ 5. Ipertensione
- ☐ 6. Sindrome metabolica
- ☐ 7. Prolasso vescicale / vaginale / rettale
- ☐ 8. Infezione ricorrente delle vie urinarie
- ☐ 9. Sindrome da intestino irritabile
- ☐ 10. Stipsi
- ☐ 11. Disturbi del sonno
- ☐ 12. Depressione
- ☐ 13. Patologia neurologica
- ☐ 14. Disabilità cognitiva generale
- ☐ 14. Altro (specificare: _____)

9. Ha mai subito interventi di chirurgia ginecologica e/o urologica?
   - ☐ 1. Sì
   - ☐ 2. No

10. Se alla domanda precedente ha risposto Sì, specifichi quale/i intervento/i ha subito:

_____
_____
_____

11. In quale stato menopausale si definirebbe?
    - ☐ 1. In pre-menopausa
    - ☐ 2. A inizio menopausa
    - ☐ 3. In post-menopausa

12. Ha figli?
    - ☐ 1. Sì
    - ☐ 2. No

13. Se alla domanda precedente ha risposto Sì, indichi il numero di figli:
    - ☐ 1
    - ☐ 2
    - ☐ ≥ 3

14. Indichi l'anno di nascita dell'ultimo figlio

15. Quanti parti per via vaginale ha avuto?
    - ☐ 0
    - ☐ 1
    - ☐ 2
    - ☐ ≥ 3

16. Quanti parti cesarei ha avuto?
    - ☐ 0
    - ☐ 1
    - ☐ 2

☐ ≥ 3

17. Pratica attività fisica in maniera frequente?
    - ☐ 1. Per niente
    - ☐ 2. Poco
    - ☐ 3. Abbastanza
    - ☐ 4. Molto
18. Fuma o ha mai fumato?
    - ☐ 1. Attuale fumatore
    - ☐ 2. Ex fumatore
    - ☐ 3. Mai fumatore
19. Se fuma o fumava, quante sigarette al giorno consuma/consumava?
    - ☐ 1-5
    - ☐ > 5-10
    - ☐ > 10-20
    - ☐ > 20
20. Quanti caffè assume in media al giorno?
    - ☐ 0
    - ☐ 1
    - ☐ 2
    - ☐ ≥ 3
21. Quanti drinks alcolici assume in media a settimana?
    - ☐ 0
    - ☐ 1-7
    - ☐ 8-14
    - ☐ 15-21
    - ☐ ≥ 22
22. Quanta acqua beve in media al giorno?
    - ☐ 1. Meno di ½ litro
    - ☐ 2. Tra ½ litro e un litro
    - ☐ 3. Più di un litro, fino a un litro e ½
    - ☐ 4. Più di un litro e ½
23. Quante volte al giorno svuota la vescica mediamente?
    - ☐ 1. Ogni ora o più frequentemente
    - ☐ 2. Ogni due-tre ore circa
    - ☐ 3. Ogni quattro ore o meno frequentemente

ICIQ-UI Short Form (Italian)

A molte persone capita, a volte, di avere delle perdite di urina. Stiamo tentando di determinare quante persone abbiano delle perdite di urina e quanto ciò costituisca, per loro, un problema. Le saremmo grati se rispondesse alle seguenti domande facendo riferimento a come si è sentita, in media, nelle ULTIME QUATTRO SETTIMANE.

24. Con quale frequenza le capita di avere delle perdite di urina? (faccia una crocetta su una sola casella)
    - ☐ 1. Mai
    - ☐ 2. Una volta la settimana o meno
    - ☐ 3. Due tre volte la settimana

- ☐ 4. Circa una volta al giorno
- ☐ 5. Più volte al giorno
- ☐ 6. Continuamente

25. Ci piacerebbe sapere qual è, secondo lei, la quantità di urina che perde. Quanta urina le capita di perdere di solito (sia quando indossa una protezione che quando non la indossa)? (faccia una crocetta su una sola casella)
    - ☐ 1. Per niente
    - ☐ 2. Una piccola quantità
    - ☐ 3. Una discreta quantità
    - ☐ 4. Una notevole quantità
26. In generale, in che misura le perdite di urina hanno interferito con la sua vita quotidiana? La preghiamo di fare un cerchietto attorno ad un numero tra 0 (per niente) e 10 (moltissimo)

0 1 2 3 4 5 6 7 8 9 10

per niente moltissimo

27. In che occasione le capita di avere delle perdite di urina? (Indichi, tra le seguenti, tutte le situazioni che corrispondo al suo caso)
    - ☐ 1. Mai – non ho perdite di urina
    - ☐ 2. Ho perdite di urina prima di riuscire a raggiungere il bagno
    - ☐ 3. Ho perdite di urina in occasione di colpi di tosse o starnuti
    - ☐ 4. Ho perdite di urina quando sono addormentata
    - ☐ 5. Ho perdite di urina quando sono in movimento e durante l'attività fisica
    - ☐ 6. Ho perdite di urina quando ho finito di urinare e mi sono rivestita
    - ☐ 7. Ho perdite di urina senza ragioni particolari
    - ☐ 8. Ho perdite di urina continuamente

Incontinence Impact Questionnarie-7 (Italian)

Le saremmo grati se rispondesse a queste ultime domande, per comprendere l'influenza sulla qualità di vita delle perdite di urina che ha riscontrato.

NOTA BENE: Se non ha mai riscontrato perdite di urina, le chiediamo di apporre una crocetta sul seguente quadratino e di non rispondere alle domande nella tabella. Grazie per la collaborazione.

- ☐ Non ho perdite di urina

Se ha riscontrato perdite di urine, queste perdite hanno influenzato…

	Per nulla	Molto poco	Un po'	Molto
28. La sua capacità di fare le faccende domestiche (cucina, pulizie di casa, lavanderia, ecc.)?	0	1	2	3
29. Le sue attività fisiche ricreative, come camminare, nuotare, o fare	0	1	2	3

altro esercizio?				
30. Le sue attività del tempo libero (andare al cinema, concerti, ecc.)?	0	1	2	3
31. La sua capacità di viaggiare in auto o in autobus per più di 30 minuti da casa?	0	1	2	3
32. La sua partecipazione ad attività sociali fuori casa?	0	1	2	3
33. La sua salute emotiva (nervosismo, depressione, ecc.)?	0	1	2	3
34. I suoi sentimenti di frustrazione?	0	1	2	3

Di seguito le poniamo qualche domanda su insorgenza, evoluzione, impatto della patologia e costi da essa derivanti.

NOTA BENE: Se non ha mai riscontrato perdite di urina, le chiediamo di apporre una crocetta sul seguente quadratino e di non rispondere alle domande successive. Grazie per la collaborazione.

- ☐ Non ho perdite di urina

35. Da quanto tempo ha delle perdite di urina?
    - ☐ 1. Da 1 anno o meno
    - ☐ 2. Da 2-5 anni
    - ☐ 3. Da 6-10 anni
    - ☐ 4. Da più di 10 anni

36. Le sue perdite di urina hanno influenzato la sua vita sessuale?
    - ☐ 1. Per nulla
    - ☐ 2. Molto poco
    - ☐ 3. Un po'
    - ☐ 4. Molto

37. Le sue perdite di urina hanno comportato assenteismo o minore produttività sul posto di lavoro?
    - ☐ 1. No
    - ☐ 2. Sì, raramente
    - ☐ 3. Sì, a volte
    - ☐ 4. Sì, spesso

38. In media, potrebbe fornire una stima della spesa settimanale che sostiene per l'acquisto di prodotti igienici specifici per le perdite di urina (assorbenti o pannoloni, salviettine, detergenti intimi specifici, ecc)?
    - ☐ 1. Non acquisto alcun prodotto specifico per le perdite di urina
    - ☐ 2. Spendo meno di 3 euro a settimana
    - ☐ 3. Spendo fino a 5 euro a settimana

- ☐ 4. Spendo tra i 6 e i 10 euro a settimana
- ☐ 5. Spendo più di 10 euro a settimana

39. Ha svolto delle visite specialistiche per il problema delle perdite di urina?
    - ☐ 1. No (perché_____)
    - ☐ 2. Sì, con un ginecologo / un urologo
    - ☐ 3. Sì, con un'ostetrica / un infermiere / un fisioterapista
    - ☐ 4. Sì, con un altro professionista sanitario (specificare _____)

40. Sta seguendo qualche trattamento per risolvere il problema delle perdite di urina?
    - ☐ 1. Sì (specificare_____)
    - ☐ 2. No

LA RINGRAZIAMO MOLTO PER AVER RISPOSTO ALLE NOSTRE DOMANDE