

Galician Network of Research Ethics Committees

Research Protocol

- **Project Title:** CLINICAL, FUNCTIONAL AND THERAPEUTIC CHARACTERIZATION OF WOMEN WITH URINARY INCONTINENCE AND ANALYSIS OF FACTORS ASSOCIATED WITH RESPONSE TO TREATMENT: RETROSPECTIVE OBSERVATIONAL STUDY IN A SPECIALIZED PELVIC FLOOR CLINIC
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Summary

Project Title	CLINICAL, FUNCTIONAL AND THERAPEUTIC CHARACTERIZATION OF WOMEN WITH URINARY INCONTINENCE AND ANALYSIS OF FACTORS ASSOCIATED WITH RESPONSE TO TREATMENT: RETROSPECTIVE OBSERVATIONAL STUDY IN A SPECIALIZED PELVIC FLOOR CLINIC. XINE-IU Project
Promoters and principal investigators	Javier Pereira Loureiro. University of A Coruña Fernando Cobián Sánchez. Cobián Clinic
Facility where the study is to be carried out	Cobián Clinic. A Coruña and Universidade da Coruña
Study design	Mixed observational study (retrospective for normalization of historical data and observational single cohort for follow-up of new participants)
Condition under study	Urinary Incontinence
Primary and secondary objectives	OP: To exploratorily analyze the baseline clinical, functional, and contextual factors associated with the response to UI treatment, as measured by variation in the ICIQ-UI SF. OS1: Describe the baseline sociodemographic, clinical and functional profile of the participants.

	OS2: Characterize the treatments received and analyze the evolution of symptoms, quality of life and satisfaction. OS3: Collect contextual variables (physical activity and sleep) using wearables and explore their association with clinical evolution. OS4: Identify patient profiles through exploratory multivariate analysis OS5. Retrospectively evaluate the relevance or not of using statistical models, including artificial intelligence models to segment the different patient profiles. OS6. Retrospectively evaluate the relevance or not of using statistical models, including artificial intelligence models to propose optimized treatments to improve both health outcomes and patient perception.
Primary endpoint	Severity of urinary incontinence, as measured by the ICIQ-UI SF (International Consultation on Incontinence Questionnaire – Urinary Incontinence Short Form)
Study population and total number of subjects	Women diagnosed with urinary incontinence 80 observational cases

This observational study aims to analyze which baseline clinical, functional, and contextual characteristics are associated with response to treatment in women with urinary incontinence treated at the Cobián Clinic, as measured by variation in the score of the ICIQ-UI SF questionnaire.

This study includes two phases. The **First phase** It is based on an improvement in the quality of the medical record through the inclusion of components of the monitoring of the patient's physical activity and the response to follow-up surveys. The above in compliance with the Decree of the Xunta de Galicia that authorizes the improvement of the information of the patient's EHR for care purposes. It will also have a [1]**Second phase** which is based on the analysis of the information collected and validating the technical feasibility of using or not using statistical models or artificial intelligence models. All this in accordance with and according to European and Galician legislation to carry out patient segmentation and suggest the treatments, or procedures, or combination of therapies, most appropriate for each patient according to their characteristics. It should be clarified that this phase [2][3]**will always be carried out retrospectively** and based on the data collected in the first phase. After the treatment of the participants is completed, a comparison will be made between the medical decision and the trained models. In no case will medical care be oriented or carried out for patients following the model or models developed from this study.

First Phase

The study combines a retrospective component, aimed at the normalization and structuring of the clinical history's historical data, with an active collection component for the follow-up of new participants for 12 months, with visits at 3, 6 and 12 months. The data collection integrates information from the medical history, validated clinical scales, functional evaluation of the pelvic floor, records of the medical devices used in the treatments, a standardized voiding diary, and contextual variables of physical activity and sleep obtained through wearable devices.

However, the analysis of these patients will be carried out **retrospectively** during the **Second Phase** once their medical care has been completed, as indicated in subsequent sections.

The results will allow us to characterize the profile of the patients, describe the treatments applied in routine clinical practice and their evolution, and identify response profiles in order to think about actions to improve treatments.

To do this, it will be necessary to carry out the following actions

- Complement the current medical record system by using pseudo-anonymous data (without names, addresses, dates of birth and other data that can characterize a person) for the preparation of the extraction via secure data extraction channels.
- Implement a local network connection within the clinic's infrastructure. The same clinic's information system will be used to access the consultations. The consultations will never include personal data, the patient's date of birth will be characterized by age groups. All communications will be encrypted.
- Creation of a platform based on a FHIR HL7 HAPI server with implementation of all the security measures required by current legislation in the field of digital health (GDPR, etc.) that receives the selected data of interest from the current information system.
- Standardization and structuring of patient records of physiotherapy-specific pelvic floor strengthening programs.
- Application of standardized assessment scales: ICIQ-UI SF; ICIQ-OAB; ICIQ-LUTSqol; PGI-S; PGI-I and Sandvik
- Three-day voiding diary (ICIQ Bladder Diary) with intakes (time, type of drink, quantity); urination (time, volume, urgency) leakage record (intensity, activity and use of absorbents (type, state when changing) and Pad Test.
- Access to data from the medical devices used in the different treatments:
 - Laser equipment: CO₂ (surgical/regenerative) and diode (dermatological/vascular).
 - HIFEM technology: EMSELLA® armchair (pelvic floor) and EMSculpt NEO® (radiofrequency + HIFEM for abdominal muscles and fat).
 - Monopolar Radiofrequency: INDIBA® Deep Care (448 kHz Proionic system).
 - Radiofrequency + Ultrasound: BTL Exilis Ultra 360™ for tissue remodeling and tightening.
 - Advanced Ultrasound (5D/E-Pelvis): High-end equipment for dynamic assessment of the pelvic floor and prenatal diagnosis.
- Record of each patient's personal satisfaction with an active consultation tool for future and recent past patients (less than 6 months since the last consultation).
- Habit recording monitored with wearable devices (bracelets and smartwatches) with local data storage.

To this end, a data collection platform will be developed that integrates the different data sources where data are currently generated or recorded in the treatment of patients' UI.

The study will last 36 months and an estimated sample of 80 patients will be used.

Second phase

Once the data has been collected, a characterization of patient profiles and description of the study population will be carried out. With this, it will be possible to know the profile of the patients, what treatment they have received or are receiving, the success of the treatment and the perceived personal satisfaction.

In the second phase, which is strictly planned as a technological Research and Development (R+D) stage and is outside the clinical production environment, this data will be used to train statistical models and artificial intelligence models. The purpose of this development will be to evaluate systems capable of determining the type of patient and proposing optimized treatments to improve both health and patient perception outcomes. **This study is limited exclusively to the field of scientific research and methodological exploration, so in no case is the development, exploitation or commercialization of a medical product, clinical diagnostic software or similar commercial solutions sought.**

Methodological clarification regarding Phase 2:

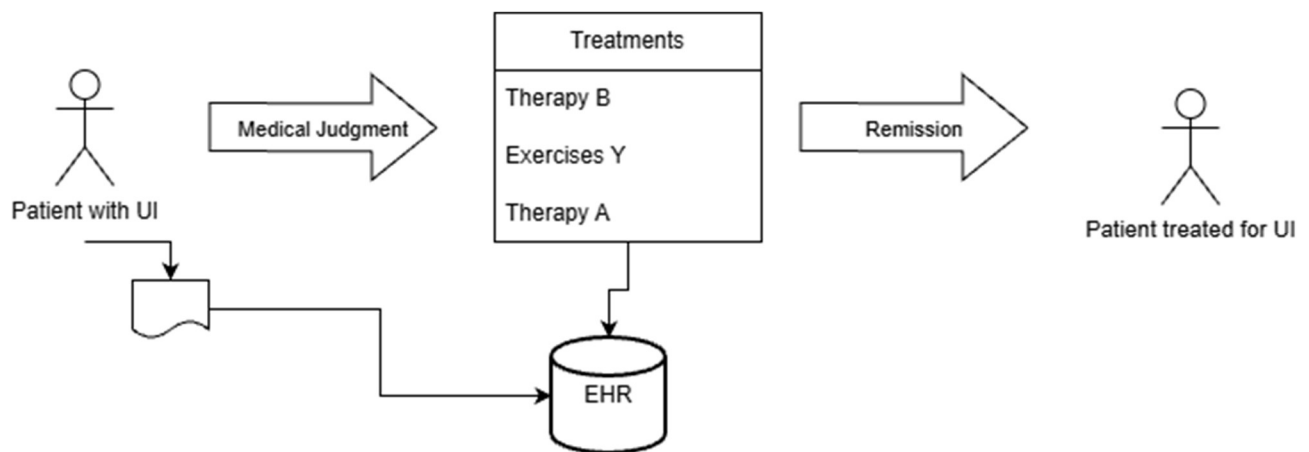
This second phase of R+D will be carried out in an isolated development environment (*sandbox*) and not in production, which means that it will not have a direct clinical impact or decision-making capacity on active patients, constituting a system developed and used with the sole objective of carrying out scientific research and development activities.

Likewise, all the data used in this second phase will be subjected to a pseudonymization process before analysis. Since the development team will work exclusively with data dissociated from any care flow, this activity does not constitute a new clinical intervention, but an **observational study for which the corresponding specific informed consent will be requested.**

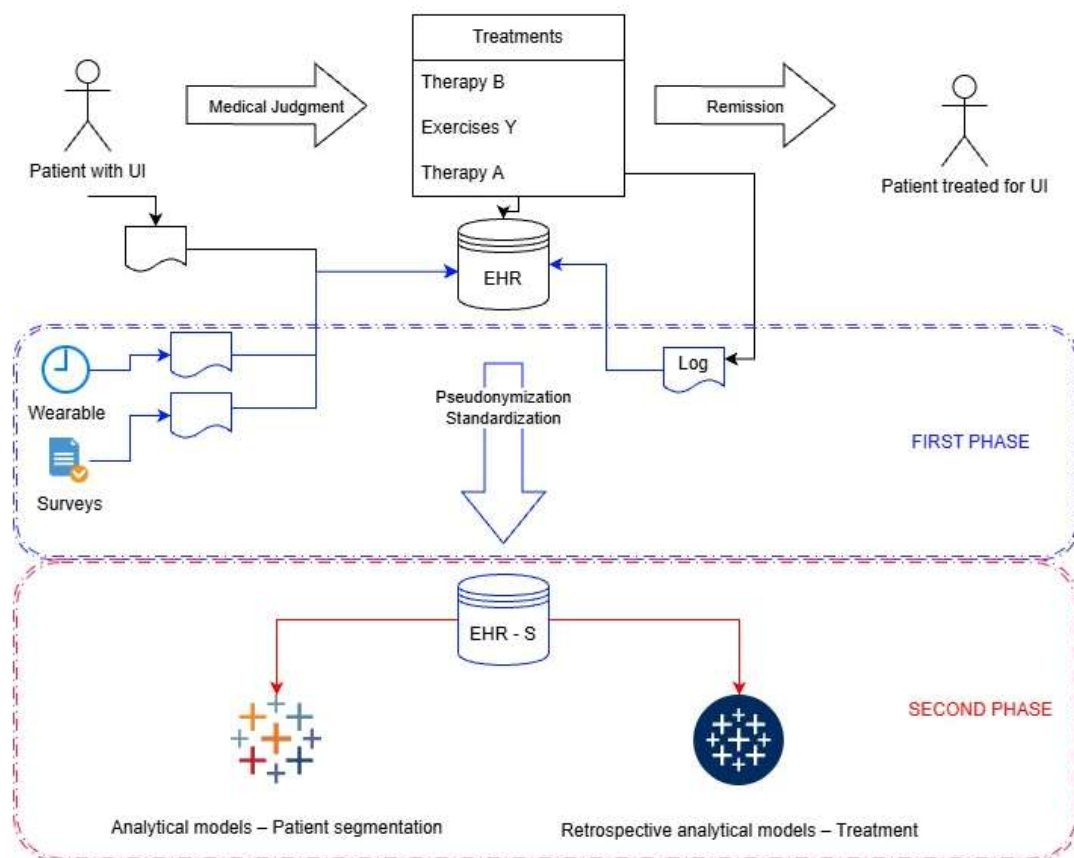
Current care scheme and the proposed study

The clinical care protocol is not altered by any of the study phases, the first phase complements the EHR Electronic Medical Record and the second phase retrospectively analyzes the information from the Electronic Medical Record in an EHR-S pseudonymized manner, with analytical models including artificial intelligence.

Current care scheme



Study Outline



Background and justification

Urinary incontinence (UI) is a health problem that is as prevalent as it is underdiagnosed, with public health, social and economic repercussions.

Definition

The *International Continence Society (ICS)*, 2002,[4] defines urinary incontinence as: "Involuntary leakage of urine through the urethra that is objectively demonstrable that causes a social or medical problem"

Causes of urinary incontinence

On many occasions, urinary incontinence is multifactorial, the most frequent reasons being:

1. Vaginal deliveries (due to damage to the structures responsible for urinary continence)
2. Pelvic surgery
3. Obesity: increases pressure on the bladder
4. Sedentary lifestyle
5. Smoking
6. Weakness of the muscles that support the bladder
7. Chronic diseases: hypertension, diabetes, lung disease
8. Impact Sports
9. Menopause, due to the **decrease** in ESTROGEN that causes:
 - vaginal and urethral atrophy that weakens its walls
 - reduced pelvic floor muscle tone
 - Alterations in the bladder mucosa
 - changes in vaginal pH
 - pelvic organ prolapse

Repercussions of urinary incontinence

Urinary incontinence has important repercussions for patients who have it in:

PHYSICAL SPHERE: it is more common for people with urinary incontinence to have pressure ulcers, perianal erythema, recurrent urinary tract infections, falls (especially with nocturnal incontinence) and an increased incidence of fractures.

PSYCHIC SPHERE : they tend to depression, isolation and dependence.

SOCIAL SPHERE generates stress in family, friends and caregivers and the predisposition to institutionalization is greater.

ECONOMIC SPHERE Urinary incontinence generates an increase in economic costs (laundry, management of complications, work of nurses and caregivers).

Types of urinary incontinence

There are several types of urinary incontinence [5]

1. **Stress incontinence:** It occurs when activities that increase intra-abdominal pressure, such as coughing, laughing, sneezing or lifting heavy objects, exceed the retention capacity of the bladder. It is very common in women, especially after pregnancies or vaginal births, since these processes can weaken the pelvic floor muscles.

2. **Urge incontinence:** It is characterized by the sudden onset of an urgent need to urinate, which can lead to involuntary loss of urine before reaching the bathroom. This type is related to the overactivity of the detrusor muscle (the bladder wall) and can be associated with neurological conditions or urinary tract infections.
3. **Mixed incontinence:** This is the combination of the symptoms of stress and urge incontinence. People who have this type have both problems controlling the release of urine during physical exertion and a sudden need to urinate.
4. **Overflow incontinence:** This occurs when the bladder does not empty completely, causing a constant drip. This type is common in people who have obstructions in the urinary tract (for example, due to prostatic hyperplasia in men) or alterations in neurological function that prevent complete emptying.
5. **Functional incontinence:** Here the leakage of urine is not due to a problem in the function of the bladder or perineal muscles, but to physical or cognitive limitations that prevent the individual from reaching the bathroom in time. This type is common in elderly patients with reduced mobility or cognitive impairment.

Each of these types requires a **detailed clinical evaluation** to determine the most appropriate treatment and improve the patient's quality of life. The correct classification allows for a more specific therapeutic intervention, which can include everything from pelvic floor strengthening exercises and behavioral therapies to pharmacological or surgical interventions, decisions that depend largely on the characteristics of each patient.

Epidemiology

Urinary incontinence (UI) is a prevalent condition that affects millions of people worldwide, with significant variations depending on region, gender, and age. Below are detailed epidemiological data at the global, European, in Spain, and specifically in Galicia, supported by reliable sources.

Worldwide prevalence

The prevalence of urinary incontinence in adult women ranges from 25% to 45%, depending on the definition and methodology used in each research. This figure exceeds other common pathologies such as diabetes, osteoarthritis or osteoporosis. [6]

Prevalence in Europe

In Europe, the prevalence of urinary incontinence varies between 14% and 29% in men and between 28% and 51% in women over 65 years of age, depending on the country and the methodology of the studies. But all studies indicate a high prevalence and impact on their quality of life. [7]

Prevalence in Spain

In Spain, the prevalence of urinary incontinence is similar to that observed in other European countries. According to data from the National Incontinence Observatory (ONI), the prevalence

is similar to the rest of Europe, with a significant increase in people over 65 years of age. In addition, it is estimated that more than six million people in Spain suffer from urinary incontinence. [8] [9]

Prevalence in Galicia

In Galicia, a study carried out in 2002 found that the prevalence of urinary incontinence in people over 64 years of age was 35.1%, with a higher incidence in women (38-51%) compared to men (15-28%). These data highlight the relevance of urinary incontinence in the elderly Galician population. [10]

As can be seen from studies, urinary incontinence is more common in women than in men and its prevalence increases with age. In addition, many cases are not diagnosed due to social stigma and lack of medical consultation, which underlines the need to increase awareness, improve access to appropriate treatments and develop prevention policies, both from health administrations and from the clinical centers themselves

Current treatments

Urinary **incontinence** in women can be addressed through a variety of therapeutic options, which are selected based on the type and severity of incontinence, as well as the individual characteristics of each patient.

There are several classifications to define the different treatments, but in this report we will use the most interesting one for the approach to the project

Treatment with change of habits and pelvic floor physiotherapy

Examples of actions are bladder training, using more time when urinating, scheduling times to go to the bathroom, setting temporary guidelines (e.g., urinating every two to four hours instead), fluid control, and diet [11][12]

Treatment with electrical stimulation

Low-intensity electrical currents are applied to strengthen the pelvic floor muscles and improve bladder control. It is a technique that can be effective for both stress incontinence and urge incontinence types.

Pharmacological treatment

- Anticholinergic drugs, such as oxybutynin, trospium, tolterodine, solifenacin, fesoterodine, propiverin
- Mirabegrón
- Topical estrogens

Medical Device Treatment

- Urethral occluder: it is like a tampon, which is inserted into the urethra before performing the activity that triggers incontinence, to prevent leakage.

- **Pessary:** This is a rigid ring that is placed in the vagina and worn throughout the day. The pessary holds the bladder and prevents urine from leaking.

Treatment with interventional therapies

Interventional therapies that may be helpful for incontinence include:

- Injections of filler material into the urethral area (close the urethra and reduce urine leakage in stress incontinence)
- Botulinum toxin type A (decrease in involuntary bladder contractions in urge or mixed incontinence)

Treatment with surgery

When other treatments do not work, then several surgical procedures could be considered , such as:

- **Mesh or headbands (TOT or TVT)**, for the treatment of stress urinary incontinence.
- **Burch colposuspension (bladder neck suspension)**, for the treatment of stress or mixed urinary incontinence.
- **Artificial urinary sphincter**
- **Prolapse surgery:** anterior colporrhaphy

There is therefore a wide variety of therapeutic options available. Personalized medicine seeks to adapt these treatments to individual characteristics, both physiological and habits, and the impact of their environment. But the complexity of clinical decision-making often makes it difficult to identify the optimal intervention plan for each patient profile and is based on the knowledge and experience of the medical team. There is a lack of studies that systematically integrate environmental factors, such as physical activity habits and sleep quality, with clinical outcomes and patient-perceived satisfaction to improve clinical decision-making.

The advancement of Information and Communication Technologies (ICT) currently makes it possible to process and analyse large volumes of data, integrating different data sources that make it possible to define patient profiles based on their characteristics and discover new clinical correlations and health patterns that may go unnoticed in conventional reviews.

To achieve the objectives of the project, it is proposed to carry out a study based on a new platform capable of supporting the personalization of treatments, integrating not only data from advanced medical devices, but also the subjective perception of the patient through PROMs (*Patient-Reported Outcome Measures*) methodologies. This integration guarantees a more participatory medicine based on clinical evidence, optimizing resources and improving the final satisfaction of users.

Study hypothesis

In women with urinary incontinence seen in a specialized pelvic floor clinic, the systematic integration of baseline clinical, functional, and contextual variables, including medical history

data, standardized physiotherapy records, validated scales, medical device parameters, wearable habits, and patient-reported outcome measures (PROMs) will allow us to identify which baseline characteristics are associated with a favorable response to treatment, as measured by variation in the ICIQ-UI SF questionnaire score.

Objectives

Main objective

To exploratorily analyze which baseline clinical, functional, and contextual characteristics are associated with response to treatment in women with urinary incontinence seen at the Cobián Clinic, as measured by variation in the ICIQ-UI SF questionnaire score throughout follow-up.

Secondary objectives

- OS1. To describe the baseline sociodemographic, clinical, and functional profile of the women with urinary incontinence participating in the study, including the type and severity of UI, quality of life, and pelvic floor function.
- OS2. To characterize the treatments applied in routine clinical practice and to analyze the evolution of UI symptoms, quality of life, and satisfaction perceived by patients throughout the follow-up period using standardized assessment tools and PROMs.
- OS3. To collect and describe contextual variables related to physical activity habits and sleep quality using wearable devices, and to explore their relationship with the clinical evolution of the participants.
- OS4. Identify profiles or groups of women with UI through exploratory techniques of multivariate analysis, integrating clinical, functional, therapeutic and contextual variables.
- OS5. Retrospectively evaluate the relevance or not of using statistical models, including artificial intelligence models to segment the different patient profiles.
- OS6. Retrospectively evaluate the relevance or not of using statistical models, including artificial intelligence models to propose optimized treatments to improve both health outcomes and patient perception.

Type of study

This project is an observational, retrospective and analytical study. This means that clinical, therapeutic, contextual variables reported by the participants in routine clinical practice will be observed and recorded. In addition, this study is observational, since the participants will be monitored throughout their participation, with information recorded at different times through their medical history, assessment tools, questionnaires, wearable devices and data from the clinical devices used in the treatments.

Access to pseudo-animated retrospective data is required to define which data from the current electronic medical record are to be used and how they were being collected in the clinic's information system. In the same way, access to data from pelvic floor physiotherapy treatments is needed to standardize the information that is collected and apply it in future treatments.

Therefore, it can be considered as a mixed, retrospective observational study for the normalization of historical data and an observational single cohort study for the follow-up of new participants. Each approach has different objectives within the same protocol: to normalize previous data and integrate new data for patient profiling.

Material and methods

Scope of study

This study will be carried out at the facilities of the Cobián Clinic, a health centre specialising in the treatment of pelvic floor dysfunctions and, in particular, in the treatment of urinary incontinence in women.

In this centre, clinical and functional assessments are carried out on a regular basis, as well as treatments based on pelvic floor muscle training, biofeedback and other specialised physiotherapy techniques. The clinic also has medical devices capable of monitoring the evolution of patients.

Definition of study subjects

The study will be carried out at the Cobián Clinic in the city of A Coruña.

Although the study is observational, access to retrospective data and new patients is required:

Historical patients of the Cobian Clinic: To know the type and quality of the relevant data stored in the current information system with textual medical reports and in the follow-up records of the pelvic floor physiotherapy programs where it is necessary to standardize and structure the information for processing.

The processing of this data will be carried out in a pseudonymized way: The data will be separated from any direct identifier (name, ID). Researchers will not have the "key" to re-identify the patient.

It is considered that contacting all these patients to obtain informed consent is a disproportionate effort, since it is not technically or logistically possible to contact hundreds of old patients (out of 600) to explain and ask for authorisation. The use of these health data for research purposes without the consent of the patients is covered by Additional Provision 17 of LO 3/2018 of 5 December, and will be subject to the favourable assessment of this report by the Galician Drug Research Ethics Committee.

Current and new patients of the Cobian Clinic: For the participation of new patients, a presentation of the study will be made on an individual basis and they will be asked to sign the informed consent.

Inclusion criteria:

- Women over 18 years of age.
- Diagnosis of urinary incontinence (stress, urgency, or mixed)
- Patients who come to the Cobián Clinic for consultation.
- Individuals who are willing to participate in follow-up and complete required questionnaires (PROMs)

Exclusion criteria:

- Inability to give informed consent.
- Serious pathologies or clinical conditions that, in the opinion of the investigator, may interfere with participation in the study or with the interpretation of the results.
 - Neurological Pathologies: (Causes of Neurogenic Bladder) Disorders of the central or peripheral nervous system drastically alter the control of urination, so UI is not due to common mechanical or functional causes (such as exertion or standard urgency).
 - Multiple Sclerosis (MS).
 - Advanced Parkinson's disease or parkinsonian syndromes.
 - Traumatic or medical spinal cord injuries (paraplegia, quadriplegia).
 - Recent Cerebrovascular Accident (CVA) or with severe cognitive/motor sequelae.
 - Severe diabetic autonomic neuropathy (occurring with detrusorian hypotonia or retention).
 - Oncological Conditions and Therapeutic History: Cancer in the pelvic area or its treatments permanently modify the anatomy and viability of the bladder tissue.
 - Active urinary or gynaecological tract cancer (bladder, prostate, urethra, uterus, cervix).
 - History of pelvic radiation therapy: Causes chronic actinic cystitis, fibrosis, and irreversible loss of bladder compliance.
 - Current chemotherapy (due to systemic impact and possible bladder toxicities, such as cyclophosphamide).
 - Urological and Urogynecological Pathologies: Local conditions that confuse the diagnosis of common UTI or that require immediate surgical treatment.
 - Severe Pelvic Organ Prolapse (POP) (POP-Q Stage III or IV), as it usually causes overflow obstruction or incontinence.
 - Urogenital fistulas (vesicovaginal, urethrovaginal), where urine leakage is anatomical and continuous.
 - Urethral diverticula or severe urethral stricture.

- Active bladder lithiasis or a history of untreated low-compliance bladder.
- Severe or Unstable Systemic Diseases: Conditions that put the patient's life or adherence to the study at risk, or that generate symptoms that are confused with UI.
 - Decompensated Congestive Heart Failure (CHF): Causes massive nocturnal polyuria and edema, interfering with voiding diaries and nocturia.
 - Advanced Chronic Renal Failure ($\text{GFR} < 30 \text{ mL/min/1.73m}^2$ or on dialysis).
 - Uncontrolled diabetes mellitus ($\text{HbA1c} > 8.5\%$ or 9%), due to osmotic polyuria that masks the actual frequency and urgency.
 - Severe psychiatric illnesses or moderate-severe cognitive impairment (e.g. Alzheimer's disease): They prevent giving valid informed consent or correctly filling out assessment tools (voiding diaries, quality of life questionnaires).
- Recent Pelvic Surgeries
- Recent urogynecologic or prostate surgery: (usually < 6 to 12 months before screening), such as radical prostatectomy, total hysterectomy, or slinging, as the tissue is still in the healing and remodeling phase.
- Situations that make it difficult for researchers to follow up properly.
- Patients of the clinic who have given birth less than a year ago when the study begins in order to avoid the influence of the recent puerperium on the pelvic floor musculature and the symptoms of UI.
- Patients of the clinic who have undergone antepartum treatment one year prior to the start of the study.
- Concurrent participation in other clinical studies that may interfere with the objectives of the present study.

Withdrawal criteria:

- Voluntary withdrawal of consent at any time, without the need for justification.
- Failure to comply with the study procedures that prevents the correct collection of data.
- Appearance of clinical or personal circumstances that, in the opinion of the research staff, advise withdrawal for reasons of safety or feasibility.
- Decision of the principal investigator for justified reasons related to the development of the study.

Recruitment and recruitment of participants

This project will be carried out at Clínica Cobián, where women will be recruited to come to the center for assessment or treatment related to urinary incontinence.

Potential participants will be attended by the clinic's care team. During the consultation, a person responsible for the research or care team will inform those women who meet the

selection criteria about the possibility of participating in the study, explaining their main characteristics and the implications of their participation. This participation will consist of the collection of clinical data, information from assessment tools, questionnaires, wearable devices and data derived from the clinical equipment used in routine treatments. Likewise, the mechanisms established to guarantee the confidentiality of information and the protection of their personal data will be explained.

After the initial explanation, each interested person will be given the information sheet to participants, so that they can review it and decide on their participation. Subsequently, the person responsible for the project will resolve any possible doubts or queries and, if the participant maintains her interest in participating, the informed consent document will be signed.

In addition to the patients who come to the clinic, recruitment will be carried out through dissemination and dissemination actions of the project (informative material, website and social networks, citizen science fairs), aimed at the potentially interested general population, who will be able to contact the research team to receive information and assess their participation in the study.

In all cases, it is the staff of the Cobián Clinic who are in charge of presenting the study in detail and obtaining consent

Justification of the sample size

The study has an exploratory-analytical observational design, whose main objective is to identify baseline clinical, functional and contextual factors associated with treatment response, defined as obtaining an improvement equal to or greater than the MCID (Minimal Clinically Important Difference) of 2.52 points in the ICIQ-UI SF questionnaire. Consequently, the sample size is justified from three complementary perspectives.

Exploratory analysis of factors associated with response. For the analysis of baseline predictors of response to treatment by binary logistic regression, the methodological literature recommends a minimum of 10 events per predictor variable included in the model (EPV criterion, events per predictor variable). Assuming a treatment response rate of 50%, conservative estimation consistent with the published effectiveness data for non-invasive pelvic floor interventions, and a sample of $n = 80$ participants, approximately 40 (responder) events are expected, which allows up to 4 predictor variables to be included in the model with sufficient methodological guarantees for an exploratory analysis. The results of this analysis will not be confirmatory and must be validated in subsequent studies with a larger sample size.

Longitudinal analysis of the primary endpoint (ICIQ-UI SF). To detect a clinically relevant variation in the ICIQ-UI SF score between baseline and 6-month follow-up (MCID = 2.52 points; reference standard deviation = 4.0 points, according to Espuña Pons et al. , the minimum sample size for a bilateral contrast with significance level $\alpha = 0.05$ and power $1-\beta = 0.80$ in a repeated-measures design is $n = 20$ participants. With a sample of $n = 80$ participants and

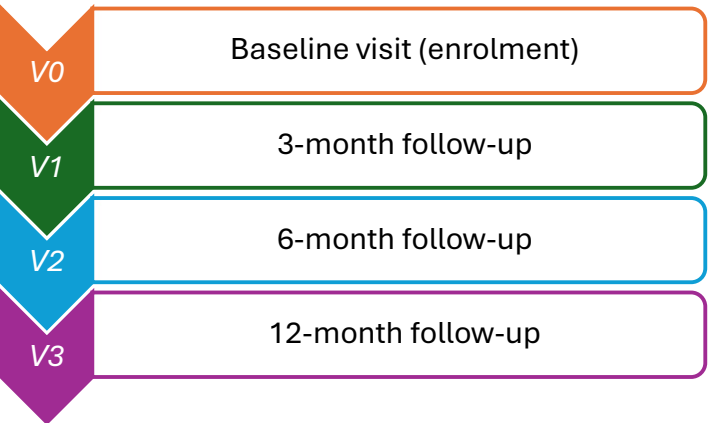
conservative adjustment for losses of 15% (effective $n \approx 68$), the statistical power for this contrast is greater than 99%, with the sample size being more than sufficient for this objective.[13]

Retrospective component. The extraction and normalization of approximately 600 previous medical records from the Cobián Clinic is not subject to sample size calculation in the strict sense, since its use is limited to the standardization of the information system and exploratory analyses of clinical patterns. However, this database provides a sufficient historical reference for the characterization of the population served, the identification of reference distributions of the clinical variables, and the definition of the range of variability expected in the outcome measures.

Consequently, it is considered that the planned sample size ($n = 80$ participants with full follow-up) is adequate for the objectives of the study, given its exploratory nature, and that its combination with the available retrospective data ($n \approx 600$ records) provides a sufficient basis for the planned patient profile analysis.

Primary and secondary variables

Schedule of the registration of variables



Main variable

The main endpoint of the study is the **severity of urinary incontinence**, measured by the total score of the *ICIQ-UI SF (International Consultation on Incontinence Questionnaire – Urinary Incontinence Short Form) questionnaire*.

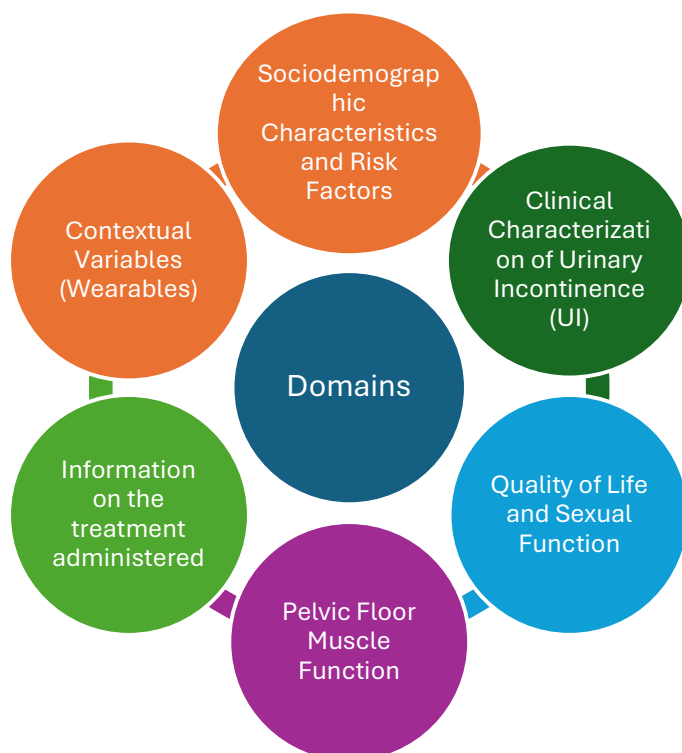
This instrument is recommended as a reference standard by the International Continence Society (ICS) and has complete psychometric validation in Spanish.

Variable	Instrument	Type	Range	Pick-up time
UI severity (ICIQ-UI SF score)	ICIQ-UI SF (4 items)	Discrete quantitative	0–21	V0, V1 (3m), V2 (6m), V3 (12m)

For this questionnaire, the MCID (Minimal Clinically Important Difference) = 2.52 points. validated in Spanish by Espuña Pons et al. [13]

Secondary Variables

The secondary variables are grouped into six domains, corresponding to the secondary objectives of the study:



Domain A. Sociodemographic Characteristics and Risk Factors

Variable	Source / Instrument	Type	Values	Timing
Age	Medical history	Continuous quantitative	Age	V0
Body mass index (BMI)	Medical history/anthropometry	Continuous quantitative	kg/m ²	V0
Parity (number of pregnancies and births)	Medical history	Discrete quantitative	No.	V0
Mode of delivery (vaginal/cesarean/instrumental)	Medical history	Nominal qualitative	Categories	V0
Menopausal status	Medical history	Qualitative dichotomous	Yes/No	V0
Work activity and type of work (physical exertion)	Questionnaire	Ordinal qualitative	Categories	V0
Regular sports activity	Questionnaire	Ordinal qualitative	Categories	V0
Intake of fluids and stimulants (coffee, tea, alcohol)	Questionnaire / diary	Continuous quantitative	ml/day	V0
Relevant concomitant drug treatments	Medical history	Nominal qualitative	List	V0, V2
Relevant chronic diseases (HTN, DM, COPD...)	Medical history	Nominal qualitative	List	V0

Domain B. Clinical Characterization of UI

Variable	Instrument	Type	Values	Timing
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UI Type (Effort/Urgency/Mixed)	Medical history + questionnaire	Nominal qualitative	Categories	V0
UI Severity — Sandvik Index (ISI)	ISI (2 items)	Ordinal quantitative	0–12 (mild/mod/severe/very severe)	V0, V2
Symptoms of Overactive Bladder — ICIQ-OAB	ICIQ-OAB (8 items)	Discrete quantitative	0–16	V0, V1, V2, V3
UI Evolution Time	Questionnaire	Continuous quantitative	Months	V0
Use of absorbents/protectors	Questionnaire	Discrete Quantitative/Nominal	No./day; type	V0, V1, V2
Daytime and nighttime urination frequency (nocturia)	3-day voiding diary	Discrete quantitative	Nº/24h	V0, V2
Number of UI episodes / 24 hours	3-day voiding diary	Discrete quantitative	No.	V0, V2
Amount of loss (standardized test pad 1h)	Pad test 1 hour (ICS)	Continuous quantitative	gr	V0, V2

Domain C. Quality of Life and Sexual Function

Variable	Instrument	Type	Values	Timing
Lower urinary tract-specific quality of life	ICIQ-LUTSqol (19 items)	Continuous quantitative	19–76	V0, V1, V2, V3
Overall impression of severity perceived by the patient	PGI-S (1 item, FDA/EMA)	Ordinal quantitative	1–4	V0
Overall impression of improvement perceived by the patient	PGI-I (1 item, FDA/EMA)	Ordinal quantitative	1–7	V1, V2, V3
Sexual function	FSFI (if applicable)	Continuous quantitative	View Scale	V0, V1, V2, V3

Domain D. Pelvic Floor Muscle Function

Variable	Instrument	Type	Values	Timing
Pelvic floor muscle strength	Oxford scale (vaginal examination)	Ordinal quantitative	0–5	V0, V2
PERFECT Functional Assessment	PERFECT protocol (P, E, R, F, E, C, T)	Discrete quantitative	Multi-parameter	V0, V2
Perineal pressure (if available)	Perinometry	Continuous quantitative	cmH ₂ O	V0, V2

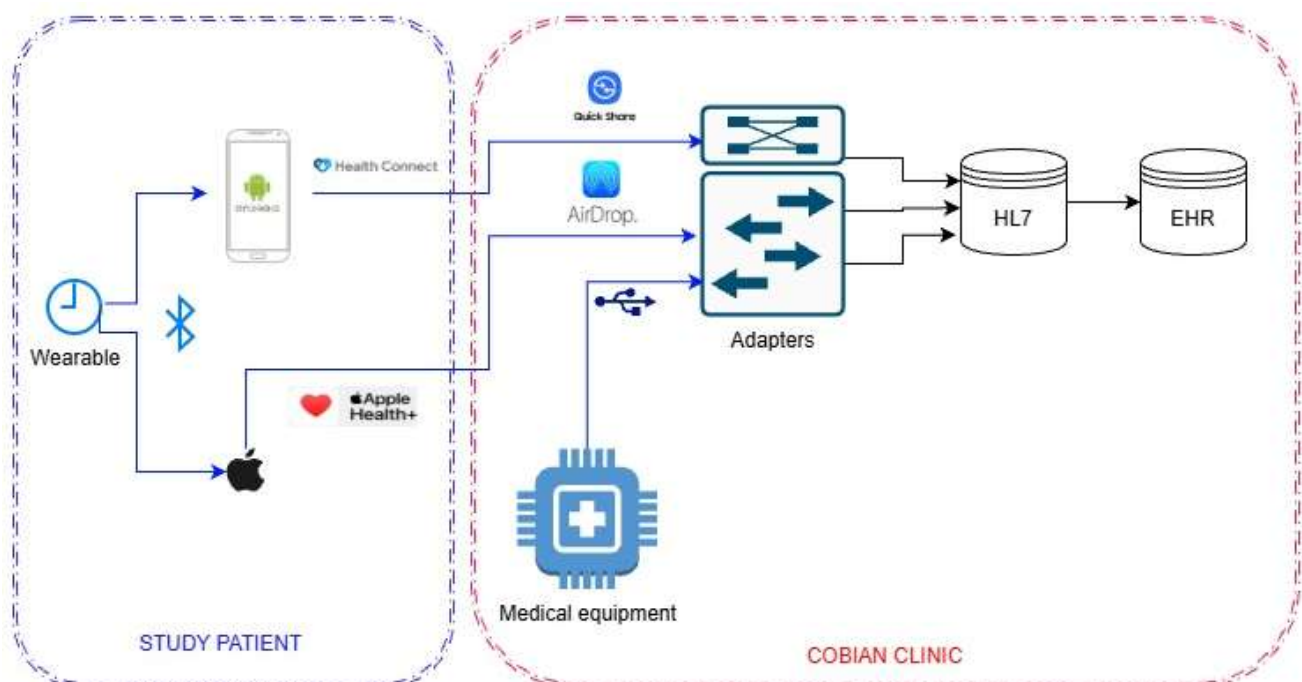
Domain E. Information on the Treatment Applied

Variable	Source	Type	Values	Timing
Assigned treatment modality	Medical history / physiotherapy record	Nominal qualitative	Categories	V0, continuous
Technical parameters of medical devices (CO ₂ laser, diode, EMSELLA, radio frequency, shock waves)	Medical Device Data	Continuous / mixed quantitative	Multi-parameter	Per session
Number of sessions completed	Physiotherapy Registration	Discrete quantitative	No.	V1, V2, V3
Adherence to treatment	Physiotherapy Registration	Continuous quantitative	%	V1, V2
Concomitant pharmacological treatment for UTI	Medical history	Nominal qualitative	Yes/No; type	V0, V2

Domain F. Contextual Variables (Wearables)

Variable	Instrument	Type	Values	Timing
Daily physical activity (steps, active time)	Wearable wristband (local storage)	Continuous quantitative	Steps/day; active min/day	Continuous
Hours and quality of sleep	Wearable wristband (local storage)	Continuous quantitative	h/night; score	Continuous
Average daily heart rate	Wearable wristband (local storage)	Continuous quantitative	Damn it	Continuous

Data from wearable devices is stored locally, without sending to the manufacturer's external servers, in compliance with the GDPR.



The base architecture will have three well-differentiated modules implemented in such a way that they are scalable in the face of the appearance of new peripherals from which to obtain data.

Raw data:

In this first section you will find the data obtained from the different work tools that have been detailed in this ethics committee. In the original plan, the data would be obtained from the following sources:

- Mobile devices: Technologies such as health connect for Android devices and AppleHealth for Apple devices would be used to access data from the study participants' wearable devices on both iOS and Android devices. This data will be uploaded to the intranet application that connects to the adapter system.

- Medical measurement equipment of the clinic: Locally, medical specialists will access the logs of the machines of the equipment they use in their consultations. To export them, they will use a USB device. With these logs, and using the clinic's computers, the data will be uploaded to the intranet application that connects to the adapter system. Patient identification data is not stored in these equipment.

Adapter System:

The adapter system is the integration layer responsible for receiving and normalizing data from multiple heterogeneous sources, including mobile devices (iOS through Apple Health and Android through Health Connect) and medical measurement equipment used in the clinic.

This component will be developed in Python using the FastAPI framework and will apply the Adapter design pattern to transform the different source formats into a common data structure. During this process, only the clinical information necessary for the objectives of the study will be extracted, discarding those elements that are not relevant to the research.

Once the transformation process is completed, the standardised data will be transferred to the clinical interoperability system based on international standards, where it can be encoded, stored and used by the project's authorised services.

The fact of using an adapter pattern allows us to keep the project scalable in the face of the possible appearance of new medical equipment in the clinic.

HL7 Local Database

The data processed by the adapter system will be stored on a local server located at the Cobián Clinic. This module aims to guarantee the interoperability of clinical information by adopting international standards widely used in the healthcare field.

To this end, the normalized data will be transformed into the HL7 FHIR (Fast Healthcare Interoperability Resources) standard, thus allowing clinical observations, biometric measurements and other health information to be represented through structured and standardized resources following the current standard. Likewise, the clinical variables and metrics recorded will be coded using the LOINC (Logical Observation Identifiers Names and Codes) terminology, favoring semantic interoperability with other health information systems.

The standardised information will be exposed through a secure REST API, accessible only by authorised systems and users and only from the clinic itself. The authentication, access control and encryption mechanisms for communications will be implemented in accordance with the clinic's current security policies and the applicable regulations on the protection of personal and health data.

Description of the intervention

The present study is observational in nature and does not involve the performance of any invasive procedure or the application of therapeutic interventions in addition to those indicated by routine clinical practice. Data collection procedures will be carried out as described below, together with the schedule of visits and planned actions. It is important to mention that patients who participate in the study will not assume any additional cost to that already assumed for their treatment, for participating in the study.

In addition to diagnostic tests, medication and results of medical tests, participation in the study will involve the participant recording levels of physical activity through the use of activity bracelets, as well as the evaluation of the follow-up data recorded during and after their medical and physiotherapeutic treatment.

The care processes and the care procedures or therapies indicated that make up the patient's treatment will not be modified or altered by participating in the study. The only additional activity that the patient must perform will be the completion of follow-up surveys which are carried out according to the development of the treatment. In summary, medical care will be the same whether the patient participates or not in the study.

Observational Nature of the Study

The participants in the observational study will receive the treatment that corresponds to them according to the clinical criteria of the professionals of the Cobián Clinic, without the study interfering in any way with the therapeutic decision. The treatments available in the clinic include:

- Pelvic floor physiotherapy: Kegel exercises, PERFECT technique, hypopressives, biofeedback.
- Laser equipment: CO₂ (surgical/regenerative) and diode (dermatological/vascular).
- HIFEM technology: EMSELLA® armchair (pelvic floor) and EMSCULPT NEO® (radiofrequency + HIFEM for abdominal muscles and fat).
- Monopolar Radiofrequency: INDIBA® Deep Care (448 kHz Proionic system).
- Radiofrequency + Ultrasound: BTL Exilis Ultra 360™ for tissue remodeling and tightening.
- Advanced Ultrasound (5D/E-Pelvis): High-end equipment for dynamic assessment of the pelvic floor and prenatal diagnosis.

The study observes and records the treatments applied and their results, without assigning or modifying treatments.

Study-specific procedures

In addition to what has been included in routine clinical practice, the study includes the following specific research procedures:

- Completion of validated scales (ICIQ-UI SF, ICIQ-OAB, ICIQ-LUTSqol, PGI-S/PGI-I, FSFI) at the established times.
- Completion of the 3-day voiding diary at baseline and at the 6-month visit.
- Standardized 1-hour pad test (SCI) at baseline and at 6 months.
- Functional evaluation of the pelvic floor with Oxford scale and PERFECT protocol at baseline and at 6 months.
- Use of a wearable device (own or project-specific activity bracelet) to record physical and sleep habits during the monitoring period or for as long as they agree to wear it with a minimum of 7 days to establish the activity or sedentary life profile and sleep quality

Schedule of visits and procedures

The schedule of visits (V1-V3) and the procedures foreseen in each of them are presented below:

Procedure	V0. Basal (Month 0)	V1. 3 months	V2. 6 months	V3. 12 months
Information and signing of informed consent	✓	—	—	—
Inclusion/exclusion criteria	✓	—	—	—
Complete medical history (history, risk factors)	✓	—	—	—
Type and severity of UI (diagnostic classification)	✓	—	—	—
ICIQ-UI SF (primary variable)	✓	✓	✓	✓
ICIQ-OAB	✓	✓	✓	✓
ISI. Sandvik Severity Index	✓	—	✓	—
ICIQ-LUTSqol (quality of life)	✓	✓	✓	✓
PGI-S (Global Severity Impression)	✓	—	—	—
PGI-I (Global Impression of Improvement)	—	✓	✓	✓
FSFI (sexual function, if applicable)	✓	✓	✓	✓
3-day voiding diary	✓	—	✓	—
Pad test 1 hour (ICS)	✓	—	✓	—
Muscle function evaluation (Oxford + PERFECT)	✓	—	✓	—

Procedure	V0. Basal (Month 0)	V1. 3 months	V2. 6 months	V3. 12 months
Wearable device delivery and configuration	✓	—	—	—
Wearable data collection	—	Continuous		
Record of treatment received and technical parameters	—	Continuous		
Treatment satisfaction survey	—	✓	✓	✓
Adverse Event Log/Recalls	—	✓	✓	✓

Visits V1, V2 and V3 should preferably coincide with follow-up visits already planned in routine clinical practice. When this is not possible, an independent study visit should be arranged.

Historical Data Collection

Prior to the start of recruitment, the retrospective data stored in the electronic medical record system of the Cobián Clinic will be extracted, pseudonymised and normalised. This process will be carried out in a pseudonymised way, without access by the research team to the direct identifiers, and under the supervision of the data protection officer of the Cobián Clinic. The retrospective data will be used for exploratory analyses and data normalisation.

Timeline and expected completion date

The study will be carried out over 36 months, 12 months for each patient. It will begin with obtaining the favourable opinion of the CEIC (Month 1) until the publication of the final results. Data collection will not begin until all the mandatory authorisations are obtained. The schedule of tasks with the planned time distribution is detailed below.

Stages of the study

- Stage 1 (Months 1–3): Preparation. Obtaining the IRB opinion, setting up the FHIR platform, training the team and preparing the data collection notebooks.
- Stage 2 (Months 3–10): Extraction and normalization of retrospective data. Exploratory analysis of the historical base and definition of variables.
- Stage 3 (Months 3–30): Recruitment. Recruitment, informed consent and follow-up of participants throughout their scheduled visits.
- Stage 4 (Months 5–32): Data collection and analysis. Descriptive, inferential and profile analysis.
- Stage 5 (Months 3–5 and 24–36): Dissemination. Scientific publications, participation in congresses and citizen science activities. Sporadic actions at the beginning of the study to attract participants.

Research Team

CITIC. University of A Coruña	
Javier Pereira Loureiro	Dr. Computer Science IP Technological Main
Patricia Concheiro Moscoso	PhD in Health Sciences. Collaborating researcher
Betania Groba González	PhD in Health Sciences. Collaborating researcher
Jorge Rivadulla Brey	Computer Engineer. Collaborating Researcher
Freddy Pérez Zorro	Master of Bioinformatics. Collaborating researcher

Cobián Clinic	
Fernando Cobián Sánchez	PI Clinical Principal Gynecologist
Belén García Riol	Physiotherapist. Collaborating researcher
Brenda Colares Coimbra	Physiotherapist. Collaborating researcher
Raquel Ramos Veiguela	Nurse Midwife. Collaborating Researcher

Gantt Chart

Project Months (1–36)

Task	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	
Preparation. Obtaining the opinion of the CEIC, configuration of the FHIR platform, training of the team and preparation of the data collection notebooks.	✓	✓	✓																																		
Extraction and normalization of retrospective data. Exploratory analysis of the historical base and definition of variables.			✓	✓	✓	✓	✓	✓	✓	✓																											
Recruitment. Recruitment, informed consent and follow-up of participants throughout their scheduled visits			✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓							
Data collection and analysis. Descriptive, inferential and profile analysis					✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓				
Dissemination. Scientific publications, participation in congresses and citizen science activities. Actions at the beginning to attract participants			✓	✓	✓																			✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

Expected completion date

The expected date of commencement of recruitment is **Month 3** after obtaining the favourable opinion of the IRB. The **expected date of completion of the study** (closure of the database and delivery of the final report) is **Month 36**. Derived scientific publications may be extended up to 12 months after the formal closure of the study.

Distribution of tasks

Researcher	Tasks assigned in the study
Javier Pereira Loureiro	☒ Scientific direction and global coordination of the study. ☒ Coordination of the technological development of the data integration platform. ☒ Supervision of the FHIR platform and data integration processes. ☒ Responsible for statistical analysis ☒ Supervision of data anonymization and pseudonymization. ☒ Communication with the CEIC and regulatory authorities.
Fernando Cobián Sánchez	☒ Clinical direction of the study at the Cobián Clinic and global coordination of the study. ☒ Design of the protocol and data collection notebook. ☒ Supervision of recruitment and inclusion/exclusion criteria. ☒ Presentation of the study to potential participants and obtaining IQ ☒ Initial clinical evaluation (history, diagnosis of UI type). ☒ Review of clinical protocol and follow-up procedures ☒ Representation of the study at medical congresses. ☒ Coordination with the CITIC team for the integration of data sources.
Raquel Ramos Veiguela	☒ Administration of the scales validated to the participants in each visit. ☒ Delivery of wearable devices. ☒ Administration of scales and questionnaires in follow-up visits. ☒ Recording of clinical data in the collection notebook (CRD). ☒ Supervision of adherence to treatment. ☒ Support in recruitment and dissemination activities of the project. ☒ Verification of exclusion criteria (postpartum <1 year). ☒ Delivery of the information sheet and accompaniment during the informed consent process.
Belén García Riol Brenda Colares Coimbra	☒ Performing the functional assessment of the pelvic floor (Oxford, PERFECT). ☒ Supervision and recording of physiotherapy and medical device sessions. ☒ Data recording of physiotherapy sessions at the CRD. ☒ Management of the collection of data from wearables. ☒ Support in recruitment and dissemination activities of the project.
Betania Groba González Patricia Concheiro Moscoso	☒ Data Quality Monitoring and Tracking ☒ Support in statistical data analysis ☒ Coordination of scientific publications ☒ Preparation of dissemination material and presentation in society and scientific environments ☒ Configuring wearable devices. ☒ Support in attracting participants in informative activities (fairs, associations).
Jorge Rivadulla Brey Freddy Pérez Zorro	☒ Definition of the protocols for the secure extraction of data from the medical record system. ☒ Monitoring compliance with security standards (GDPR, ENS). ☒ Development of the integration layer between the clinic's EHR system and the FHIR platform. ☒ Development of medical device data capture interfaces.

PI: Principal Investigator. CI: Informed Consent. CRD: Data Collection Notebook. EHR: Electronic Medical Record. FHIR: Fast Healthcare Interoperability Resources (HL7 standard).

Data Management Plan and Pseudonymization Procedure

Secure Data Capture and Storage

Clinical and patient perception data will originally be collected in the clinic's healthcare setting by authorized personnel, using the usual electronic health record system. This data will be stored in a secure repository with restricted access using individual credentials and data encryption both in transit and at rest.

Pseudonymization (Dissociation) Procedure

To carry out the phases of advanced statistical analysis and the training of the statistical and artificial intelligence models (Second Phase), a strict pseudonymization procedure will be applied before the data leaves the purely healthcare environment:

- **Separation of Identifiers:** A member of the clinical team (who will not participate in the technological development of AI) will extract the data necessary for the study and will immediately proceed to remove any direct identifier of the patient (such as name, surname, DNI/NIE or telephone number).
- **Assignment of Unique Code:** Instead of identifying data, each patient will be assigned a random, unambiguous alphanumeric code (e.g., *IU-001*).
- **Custody of the Relationship Table (Dissociation Key):** The table that links the alphanumeric code to the patient's real identity (the "key" of the process) will be stored in a separate, encrypted file. This file will remain under the strict custody of the Principal Investigator of the healthcare facility and will be completely isolated from the data development and engineering team.

Access and Transfer to the Development Environment (Sandbox)

The dataset resulting from the above process will be composed exclusively of clinical variables, treatments and satisfaction levels linked only to the dissociated alphanumeric code.

This "pseudonymised" dataset will be transferred to the sandbox for the training of statistical and AI models. The technical team in charge of computing will work at all times with dissociated data, ensuring that it is impossible to re-identify participants during the research process. The data will be destroyed or kept blocked after the legally established period for the retention of research data has ended.

Statistical analysis plan

The statistical analysis plan has been designed to adjust to the objectives of the study and the variables collected, guaranteeing the traceability, reproducibility and methodological rigor of the results. All analyses will be carried out on previously pseudonymized data, in compliance

with current data protection regulations. Open-source statistical software (Python 3.12+, with the corresponding statistical packages) will be used.

Pseudonymization of information

The pseudonymization of the information will be carried out by: Principal Health Investigator following the protocol already described in the *Data Management Plan and Pseudonymization Procedure* section, for compliance with the seventeenth additional provision of Organic Law 3/2018, guaranteeing a technical and functional separation between the research team and those who carry out the pseudonymization.

Descriptive analysis of the sample

A complete descriptive analysis of the baseline characteristics of the participants will be performed. Quantitative variables will be described by mean and standard deviation (SD) if they follow a normal distribution, or by median and interquartile range (IQR) otherwise. Qualitative variables will be presented with absolute (n) and relative (%) frequencies. The normality of the quantitative variables will be assessed using the Shapiro-Wilk test ($n < 50$) or Kolmogorov-Smirnov test ($n \geq 50$), complemented by graphical inspection (Q-Q plots, histograms).

Primary Endpoint Analysis (ICIQ-UI SF)

The evolution of the ICIQ-UI SF score throughout the four measurement moments (V0, V1, V2, V3) will be analysed by:

- Repeated measures ANOVA (if normality and sphericity are verified) or the Friedman test as a non-parametric alternative (more than two temporal measurements).
- Wilcoxon test for related samples or Student's t test for paired samples, in comparisons of two specific time points (e.g., baseline vs. 6 months).
- The proportion of patients achieving MCID (≥ 2.52 points improvement in the ICIQ-UI SF) at each follow-up visit will be calculated.
- Multiple comparisons will be corrected using the Bonferroni or Benjamini-Hochberg method.

Analysis of secondary variables

- ISI, ICIQ-OAB, ICIQ-LUTSqol: baseline scores by domain will be described and their temporal evolution will be analyzed with the same methods as the main variable.
- PGI-I (Perceived Overall Improvement): The proportion of patients reporting improvement (scores 1–2 on a scale of 1–7, "much better" or "much better") at each visit will be calculated.
- Pad test and voiding diary: baseline and 6-month values will be compared using Student's t or Wilcoxon's test according to distribution.

- Wearable variables (physical activity and sleep): their distribution will be described and the correlation with clinical scales will be explored using the Pearson or Spearman correlation coefficient.
- Satisfaction with treatment: the proportion of satisfied or very satisfied patients per treatment group will be calculated.

Patient profiling analysis (secondary objective)

To identify subgroups of patients with similar characteristics (phenotyping), unsupervised multivariate analysis techniques will be applied:

- Principal Component Analysis (PCA) for dimensionality reduction and pattern visualization.
- Cluster analysis (k-means, hierarchical clustering) on baseline clinical, functional and quality of life variables, with determination of the optimal number of clusters using the silhouette coefficient or the Calinski-Harabasz criterion.
- The identified profiles will be described and compared with each other in terms of baseline characteristics, treatments received and clinical evolution.

Analysis of factors associated with response to treatment

In an exploratory stage, it will be analyzed which baseline variables are associated with a greater or lesser response to treatment (defined as reaching the ICIQ-UI SF MCID). To do this:

- A bivariate analysis of the baseline variables will be performed as a function of response (answer vs. non-response), using chi-square or Fisher's exact test for qualitative variables, and Student's t test or Mann-Whitney test for quantitative variables.
- The variables that are statistically significant ($p < 0.10$) in the bivariate analysis will be introduced into a multivariate logistic regression model to identify independent predictors of response, adjusting for possible confounding factors.
- The OR (odds ratio) and its 95% confidence intervals will be calculated.

Additional considerations

- Level of statistical significance: $\alpha = 0.05$ (bilateral) for all analyses unless otherwise indicated.
- Missing data will be handled by sensitivity analysis; if the proportion of missing data exceeds 10% on any key variable, the use of multiple imputation will be considered.
- A complete case analysis will be performed including all participants with data available at each follow-up point. A sensitivity analysis will be performed to explore the impact of missing data.
- For data from wearables, weekly averages will be calculated and time series analysis techniques will be used if the length of the records allows it.
- All analysis scripts will be documented and deposited in a repository with version control (CITIC's private GitHub), guaranteeing the reproducibility of the results.

Ethical-legal aspects

The study will establish measures to guarantee the rights of the participants. The research team undertakes to comply, throughout the development of the research, with the ethical principles for research with human beings established in the Declaration of Helsinki of the World Medical Association (October 2024 revision), the Oviedo Convention of the Council of Europe, and the Standards of Good Clinical Practice (BPC/ICH-GCP, CPMP/ICH/135/95).

Informed consent models.

The informed consent procedure will be carried out with all candidates who decide to participate. To this end, they will be informed of the characteristics of the study and their participation in it, both orally and in writing.

The participants will be given the Information Sheet, and the main ideas will be explained and any doubts that may arise about the study will be answered. Once participation in the study has been accepted, the IC will be signed.

The participant information sheet is available in Annex I, while the IC document is available in Annex II.

Confidentiality of Information.

The research team undertakes to guarantee the confidentiality of the data obtained from the different participants in the study, in accordance with the provisions of Regulation 2016/679 of the European Parliament and of the Council on the protection of data of natural persons (GDPR) with regard to the processing of personal data and on the free movement of such data, in force since 25 May 2018 and in accordance with current national regulations on data protection (Organic Law 3/2018, of 5 December, on the Protection of Personal Data and guarantee of digital rights).

The institutions in which this research is carried out are responsible for the processing of the data. The Data Protection Officers (DPO), together with the work team, will establish the appropriate security principles for the data collected and transmitted. In the event that participants want to consult information, they can consult it with the staff of the Cobian Clinic and the DPO of the University of A Coruña or with the principal investigators.

A Data Protection Impact Assessment (DPIA) will be carried out before the start of data processing, as required by Article 35 of the GDPR, informing the DPOs of the University of A Coruña and the Cobián Clinic.

The impact that the use of the procedures defined in the project may cause on the protection of participants' personal data will be evaluated, highlighting that such data will never leave the information system of the Cobian Clinic with identification data. The confidentiality of the data and their anonymity will be maintained through pseudonymization techniques. Once the study

is completed, the data will be stored in a pseudonymized manner with the prior authorization of the participants.

The data collected from the wearable devices are never sent outside the context of the project and at no time are they sent to any accommodation outside the scope of the project. Specific software developed by the research team will be used for its acquisition (never through the manufacturer's cloud) that captures the data from the patient's phone with her explicit authorization and stores it on the study's data collection platform.

Handling of biological samples in accordance with Law 14/2007 and RD 1716/2011

No biological sample is used in this study.

Justification for the absence of an insurance policy

In this study, no invasive intervention or procedure is performed on the participants, so a civil liability policy is not necessary.

Commitment to publish results

The researchers intend to publish the results:

- In impact journals indexed in the JCR, prioritizing open Access.
- In scientific congresses mainly in the medical field.
- In dissemination days between associations and other entities interested in the study.
- In citizen science actions with the aim of raising awareness of the problem of urinary incontinence and giving visibility to the effects it has on the environment of people who suffer from it.
- The data will be evaluated for publication as OpenData in repositories such as Zenodo or Mendeley Data and in journals such as Scientific Data (Springer Nature), Data (MDPI) or Data in Brief (Elsevier).

Financial report and financing

This study is part of a research project led by the Cobián Clinic and in which the technology companies Aldaba Servicios Profesionales and Try New Roads (TNR) and CITIC (Center for Research in Information and Communication Technologies) of the University of A Coruña also participate. The project is called "APPLICATION OF ARTIFICIAL INTELLIGENCE IN THE PERSONALIZATION OF THE PREVENTION AND OUTPATIENT TREATMENT OF URINARY INCONTINENCE (UI) IN WOMEN: XINE-IA PROJECT" and its objective is to design an AI-based platform capable of recommending the best personalized treatment for each patient with urinary incontinence, integrating clinical data, subjective perceptions and previous results.

The project is co-financed by the GAIN (Galician Innovation Agency) of the Xunta de Galicia through the NEXOS 2025 program.

The current study is the first phase of the project where it is necessary to study the characteristics of the patients. For this study, as indicated in this protocol, recruitment will only be carried out by the Cobián Clinic with patients who normally come to the clinic, without active recruitment or beyond the clinic's consultation, as well as data with patient identification. The design, development of the study that includes the data collection mechanisms, and all the communication of results are the responsibility of the CITIC of the University of A Coruña.

For this reason, the costs of the study are within the aid received in the Science Business Program received by the CITIC of the University of A Coruña and are estimated according to the following table

Description	Amount
OpenAccess publications. 2 publications	2.800 €
Physical activity bracelets for participants who do not have their own wearables. 80 bracelets x 40 €/unit	3.200 €
Outreach and recruitment days	1.200 €
Participation in scientific congresses. 2 international congresses (2 x 2.500 €) and 1 national congress (1.800 €)	6.800 €
Software licenses AI platforms to support development	4.200 €
TOTAL	18.200 €

The costs of hosting and web publishing are free within the University

The costs of the personnel are not quantified since it is a participation for which no type of economic compensation will be received from the CITIC team.

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Annex 1 - Table of Scales and Assessment Instruments

Scale/ Instrument	Full Name	Items	Domains / Subscales	Scoring Range	Interpretation	Validation in Spanish	Pick-up time
ICIQ-UI SF	International Consultation on Incontinence Questionnaire – Urinary Incontinence Short Form	4	Frequency of loss (0-5) Loss Amount (0-6) Impact on quality of life (0-10) Diagnostic item (not scored)	0–21	Higher score = greater severity. MCID = 2.52 points (Espuña Pons et al., 2004)	Yes. Espuña Pons et al., Med Clin 2004	V0, V1, V2, V3
ICIQ-OAB	International Consultation on Incontinence Questionnaire – Overactive Bladder	8	Urinary urgency Daytime frequency Nocturia Urge incontinence	0–16	Higher score = greater affectation. There is no MCID established in Spanish	Spanish validation available	V0, V1, V2, V3
ISI (Sandvik)	Incontinence Severity Index	2	Frequency of loss Amount of loss	0–12	Mild: 1–2 Moderate: 3–6 Severe: 8–9 Very Severe: 10–12	Yes. Spanish validation available	V0, V2
ICIQ-LUTSqol	International Consultation on Incontinence Questionnaire – Lower Urinary Tract Symptoms Quality of Life	19	Impact on daily activities Social and personal relationships Feelings and emotions Global quality of life	19–76	Higher score = greater deterioration. Complementary to KHQ	Yes. Validated Spanish version	V0, V1, V2, V3

Scale/ Instrument	Full Name	Items	Domains / Subscales	Scoring Range	Interpretation	Validation in Spanish	Pick-up time
PGI-S	Patient Global Impression of Severity	1	Global perception of severity by the patient	1–4	1 = Normal 2 = Mild 3 = Moderate 4 = Serious	FDA/EMA instrument; international use	V0
PGI-I	Patient Global Impression of Improvement	1	Overall perception of improvement by the patient	1–7	1 = Much better 2 = Much better 3 = A little better 4 = No Change 5 = A little worse 6 = Much worse 7 = Much worse	FDA/EMA instrument; international use	V1, V2, V3
FSFI	Female Sexual Function Index	19	Desire Arousal Lubrication Orgasm Satisfaction Pain/dyspareunia	2–36	Cut-off point ≤ 26.55 indicates female sexual dysfunction. Higher score = better function	Yes. Validated Spanish version (Sánchez- Sánchez et al.)	V0, V1, V2, V3
Modified Oxford Scale	Modified Oxford Scale (evaluation of pelvic floor muscle function by vaginal examination)	1 (clinical evaluation)	Pelvic floor muscle contraction force	0–5	0 = No contraction 1 = Barely noticeable contraction 2 = Weak 3 = Moderate 4 = Good (with elevation) 5 = Strong	International Standard Clinical Use (ICS/IUGA)	V0, V2

Scale/ Instrument	Full Name	Items	Domains / Subscales	Scoring Range	Interpretation	Validation in Spanish	Pick-up time
PERFECT Protocol	Power, Endurance, Repetitions, Fast, ECo-contraction, Co-contraction, Timing	7 parameters	P: Power (Oxford 0-5) E: Resistance (seconds of sustained contraction) A: Repetitions (with resistance) F: Fast Contractions ECo: Lifting Anus Shrinkage C: Co-contraction T: Timing/Automation	Multi-parameter (no global score)	Multidimensional assessment of pelvic floor muscle function. Each parameter is recorded individually	International clinical protocol (Laycock & Jerwood, 2001)	V0, V2
Pad Test 1h (ICS)	1-hour standardized pad test (International Continence Society)	Objective measurement	Objective quantification of urine loss in grams during 1 hour of standardized physical activity	≥ 0 g	< 2 g: continent 2–10 g: mild UI 10–50 g: Moderate UI > 50 g: Severe UI	ICS standard. International use	V0, V2
3-day Voiding Journal (ICIQ)	ICIQ-BD (ICIQ Bladder Diary) 72-hour standardized voiding diary	Registration	Daytime urination frequency Nocturia UI/24h episodes Urinary urgency Volume by urination Type/amount of fluid intake Use of absorbents	Multiple quantitative variables	Descriptive analysis of voiding pattern. ICS reference for normality: ≤ 8 urinations/day, ≤ 1 nocturnal episode	ICS Standard. International Clinical Instrument	V0, V2

Abbreviations: V0 = Baseline visit; V1 = 3 months; V2 = 6 months; V3 = 12 months. UI = Urinary incontinence. MCID = Minimal Clinically Important Difference. ICS = International Continence Society. FDA/EMA = instruments recognized by regulatory agencies