**Official Title:** Comparison Between a Telerehabilitation Program for Urinary Incontinence Versus a Conventional Face-to-face Program: a Longitudinal Study in Pandemic Times

Date: 8th March 2021

# FREE AND INFORMED CONSENT

## FOR INVESTIGATION PURPOSES

Considering the "Declaration of Helsinki" of the World Medical Association (Helsínquia1964; Tóquio1975; Veneza1983; Hong Kong1989; Somerset West 1996, Edimburgo 2000, Seoul 2008, Fortaleza 2013)

SÃO JOÃO

**Study Designation**

Comparison Between a Telerehabilitation Program for Urinary Incontinence Versus a Conventional Face-to-face Program: a Longitudinal Study in Pandemic Times

*I confirm that I have explained to the participant/legal representative, in an adequate and understandable way, the referred investigation, the benefits, risks and possible complications associated with its realization.*

Attached written information ☐ No ☐ Yes (Number of _____)

**The principal investigator**

Name: _____ _____

legible signature

**Participants' Information**

Name: _____

Citizen Card number: _____

**Participant / Legal Representative**

· I understood the explanation given to me about the study to be carried out: the objectives, methods, benefits, risks and possible discomfort.

· I requested all the information I needed, knowing that clarification is essential for a good decision.

· I was allowed the possibility of freely refuse or abandon my participation in the study at all times, without this having any detrimental effect on the care that is provided to me.

· I declare that I have not been included in any other research project in the last three months.

*I agree with the participation in this study, in accordance with the clarifications given to me, as stated in this document, of which I was given a copy.*

Date: ____/____/____ _____

signature

Name *(Parents/ Legal Representative)* _____

Citizen Card Number _____ Degree of kinship _____

Date: ____/____/____ _____

signature

# Participant Information Sheet

The present investigation aims to compare an urinary incontinence telerehabilitation program with a conventional face-to-face program.

It is part of an Integrated Master of Medicine' dissertation, of the fifth-year student Pedro Teixeira, co-authored by Doctor Mariana Santiago and supervised by Doctor Susana Moreira.

The study aims to evaluate the effectiveness of an urinary incontinence treatment using remote methods compared to face-to-face treatment, in pandemic times.

The study included two groups submitted to therapeutic intervention with a goal of treating your urinary incontinence problem, with potential improvement, without any foreseeable side effects or inconveniences.

The patients in the telerehabilitation group will have to dislocate themselves to the Centro Hospitalar Universitário de São João for two initial face-to-face therapeutic sessions and one at 8 weeks and two face-to-face medical consultations, an initial and a final one, as well as intermediate teleconsultations, in which the privacy and confidentiality is assured, without any recording of content (image and sound).

Patients in the control group will have two face-to-face therapeutic sessions per week during the 12 weeks intervention and two face-to-face medical consultations, an initial and a final one.

The decision to participate in this investigation is completely voluntary, and you can withdraw at any time, without any penalty on your medical care and your legal rights, or obligation to justify.

You will also be presented with the Informed Consent, a document in which you agree to participate in the investigation, which must be signed by both parts, and which will be kept by the investigator.

Patients are asked to complete the following questionnaires: Portuguese version of the King's Health Questionnaire, Portuguese version of the Female Sexual Functioning Index, Portuguese version of the Hospital Anxiety & Depression Scale, Portuguese version of the International Consultation on Incontinence Questionnaire - Short Form and Global Perception of Improvement of the Patient through the Portuguese version of the Patient Global Impression of Improvement.

Filling the questionnaires should not exceed fifteen minutes and will be applied in the first and last consultation. All data collected are anonymous and confidential and will be worked statistically in a collectively way and never individually.

For any question or if you want to know about the overall results of the study, you should contact the researcher through the email address *up201605226@med.up.pt*.

The investigation was approved by the Ethics Committee of the Centro Hospitalar Universitário de São João.

If you have any questions about how your personal data is handled, to find out more about your rights in the field of data protection, you can contact the Centro Hospitalar Universitário de São João Data Protection Officer at the email address: *epd@chsj.min-health.pt.*

If you believe that your data is not being legitimately processed you can, at any time, file a complaint with the competent authority, the National Data Protection Commission (www.cnpd.pt).