PURI-PRO Intervention

Urinary Incontinence Improvement/Treatment

Informed Consent

March 19th, 2024

Study Details

PURI-PRO (Portuguese URinary Incontinence PROject – Symptoms impact and eHealth Intervention for Menopausal Women with Urinary Incontinence) is a PhD study within the specialty of Health Psychology, under the responsability of the doctoral sudent Marta Porto (William James Center for Research, ISPA – University Institute), the guidance of Prof. Doctor Filipa Pimenta (ISPA – University Institute), the co-supervision of Prof. Doctor Teresa Mascarenhas (Faculty of Medicine – University of Porto) and Prof. Doctor João Marôco (Ispa – University Institute), and funded nationally by the Foundation for Science and Technology (2020.05710.BD). This investigation was approved by the Ethics Committee of Ispa – University Institute (ref. D/022/11/2019). This study aims at contributing to a greater well-being in portuguese women with Urinary Incontinence symptoms, during pre-, peri-, and postmenopause.

Intervention goals and nature

The PURI-PRO "Portuguese URinary Incontinence PROject" intervention is an experimental study, based on two behavioral change models (Common Sense Model and Health Action Process Approach) and behavioral change techniques (BCT´s). This intervention aims at reducing and treating Urinary Incontinence symptoms, and at promoting knowledge, skills and behaviors associated with the functional and effective management of Urinary Incontinence symptoms.

This will be an exclusively online intervention (supported through digital channels). The entire design of the intervention, as well as the materials shared in each session, are supported by scientific literature.

Who can participate in this intervention?

Anyone who meets the following criteria can participate in this intervention:
(1) Women of portuguese nationality or dual nationality;
(2) Women aged between 40 and 65;
(3) Women with urine leakage (not associated with pregnancy and/or up to 6 months postpartum);
(4) Women who have access to the internet and to the 'Zoom' platform (if necessary, the researcher in charge of the study can help installing the 'Zoom' program).
Anyone interested in participating in this intervention will be asked to complete an initial screening questionnaire to check their eligibility to take part in the study, in accordance with the inclusion criteria mentioned above. All women who do not meet one or more of the inclusion criteria will be excluded from the study, as will women who (1) have had surgery for urinary incontinence, (2) have a neurological disease, (3) have an oncological disease, (4) have a substance abuse disorder. All participants, whether or not they meet the inclusion criteria, will be contacted by email (with information on their inclusion or exclusion in the intervention) and will be referred if necessary.

What happens if you meet the inclusion criteria and decide to take part in the study?

You will receive an email after completing the screening questionnaire. If you are eligible to take part in the intervention and wish to do so, the procedure involves randomly assigning the participants to one of two groups - the experimental group and the control group.

Experimental Group and Control Group

Participants in the experimental group will have access to all the information materials that will be shared (free of charge), based on theoretical models and behavioral change techniques, as well as to 8 group sessions (online, at an agreed time), lasting 2 months.

Participants in the control group will have access to an information leaflet on health literacy. Once the evaluation period is over for both groups, all the participants in the control group will be able to take part in the intervention to which the experimental group had access and benefit from all the information materials and group sessions, if they wish, free of charge.

Evaluation Moments

Since the aim is to evaluate the effectiveness of this psychological intervention, PURI-PRO has several evaluation moments over time (longitudinal study):

(1) First evaluation moment – Completion of an online questionnaire lasting around 20 minutes.

Intervention:

Experimental group – Delivery of the intervention (8 group sessions, online, for 8 weeks – one 90-minute session per week at an agreed time).

Control group – Delivery of information leaflet.

(2) Second evaluation moment – Completion of an online questionnaire lasting around 20 minutes, four weeks after the start of the intervention/delivery of the leaflet.

(3) Third evaluation point – Completion of a 20-minute online questionnaire, nine weeks after the first evaluation point.

(4) Fourth evaluation moment – Completion of a 20-minute online questionnaire, three months after the first evaluation moment.

It is expected that all the participants in both groups, the experimental group and the control group, take part in all the evaluation moments.

Benefits Associated with Participation

The PURI-PRO intervention aims to improve the management of your urinary incontinence symptoms.

TENA Voucher

TENA (intimate hygiene products company) will offer a Voucher (minimum 25 EUROS) to all participants who complete all phases of this intervention, the last phase being the evaluation carried out 3 months after the end of the intervention.

All participants in the Experimental Group and the Control Group who take part in all stages of the evaluation will be eligible to receive the Voucher.

Voluntary participation

Participation is completely voluntary and you can withdraw at any time without any consequences for you.

If you agree to take part, you will be asked to sign this Informed Consent for participation in the study and data processing, before starting the first evaluation moment. Signing this Consent is intended to ensure that you have received all the information and that you freely express your willingness to participate. This signature does not imply any commitment on your part to continue with the study, it does not constitute a contractual obligation, nor does it represent a waiver of your rights. Participation in this study is completely free of charge.

Risks associated with taking part in the intervention

Some of the topics covered may cause you some emotional discomfort. However, the researcher in charge is a health psychologist and will be available to listen to you, talk to you and guide you if necessary.

Processing of Personal Data

In order to start the intervention, which will be completely online for all participants, the following data will be required:

Telephone contact: the telephone contact will be necessary in order to send written messages (SMS) to notify each participant of the evaluation moments. It will also be used to include the participant in a WhatsApp group (a group that will be created by the researcher in charge, with other participants, as a space for sharing and exchanging experiences). You will only be included in the group if you wish to. If you don't want to, you won't be added to the group, and this won't jeopardize your participation in the intervention in any way. If you want to join the WhatsApp group, but for some reason want to leave at any time (self-exclusion), you can do so without any consequences for you.

Email address: the email address will be used to send the link to access the 'Zoom' platform (for the weekly meetings), as well as to share the materials presented in each session of the intervention. It will also be used to send the link to access the evaluation moments and to send any necessary information about the intervention.

In addition, at the first evaluation moment, you will be asked some sociodemographic data (e.g. number of children, education level). This information is important for the success of the study.

All personal data acquired during this study will be processed in full compliance with the legislation provided by Regulation (EU) 679/2016 entitled "General Data Protection Regulation (GDPR)" which came into force on May 25, 2018.

Data Storage: Personal and research data (participation forms, consent forms and questionnaires) will be stored by the researcher in charge only for as long as necessary to achieve the purposes associated with the study (a maximum period of up to 5 years after the completion of the study). Personal data that is no longer needed will be anonymized or destroyed.

Confidentiality

The data is confidential and will be processed in accordance with the above-mentioned legislation in force. The data provided during the evaluation will be made non-identifiable, i.e., the material collected will be anonymous and will not be linked to the identity of any participant in the intervention (an alphanumeric code will be created for each participant). This material will only be analyzed and disseminated in a scientific context (in congresses and/or publications in scientific journals), without ever disclosing their identity.

The information shared between the participants in the experimental group and the researcher in charge will be confidential, and only the research team and the participants in the group in question will have access to the information shared within the group. Likewise, we ask that you commit to guaranteeing the confidentiality of the identity of the other participants, as well as the information shared by them in the group/during the intervention.

If you wish to leave the study, no further data will be collected about you.

Participation is not anonymous, as personal data such as name, email and telephone contact will be collected for the purposes explained in the previous point. However, the research data collected will subsequently be anonymized.

Other important information

This study will be conducted in accordance with the internationally defined "Standards of Good Clinical Practice" and in compliance with the ethical principles established in the "Declaration of Helsinki" (1964) and subsequent revisions.

Your participation is extremely important, allowing us to contribute to the advancement and development of scientific knowledge, and to intervene more effectively and successfully in the management of Urinary Incontinence symptoms and the promotion of well-being in middle-aged women with urine leakage.

For any questions and/or further clarification, please contact the Psychologist and Lead Researcher, Dr. Marta Porto.

Thank you so much!

The PURI-PRO's Team,

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PURI-PRO: Portuguese URinary Incontinence PROject

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