23-08-21

Informed Consent Form

Dear Participant:

The Universidad Católica del Maule is carrying out an investigation entitled: "Effects of hypopressive exercise associated with strength and resistance training in the management of fatigue, symptoms of urinary incontinence, sexual function and quality of life in women treated for gynecological cancer: a randomized clinical trial", developed by undergraduate Kinesiology students Francisca Valdivia, Valeria Roteli and Camila Rojas (collaborating researchers) in conjunction with medical oncologists (Nicolás Yáñez and Francisco Ortega), a Kinesiologist Master in Kinesiology with training in kinesthetic rehabilitation in the treatment of cancer (Lily Berríos Contreras) and the doctor in physiotherapy Ivana Leao Ribeiro, tutor professor and Researcher Responsible for the Project, within the framework of the internal contest "SUPPORT FOR UNDERGRADUATE STUDENTS SAPERE AUDE-DARE TO LEARN 2021" of the Catholic University of Maule. The purpose of this document is to inform you of the details of the study and to request your informed consent to participate in it.

1. Research objective

To assess whether a 4-week remotely supervised intervention improves fatigue, urinary incontinence symptoms, sexual function and quality of life in women treated for gynecological cancer.

2. Brief description of the project

The treatment of gynecological cancer is very important to increase the life expectancy of affected women. However, it can present secondary effects regarding fatigue and changes in pelvic floor strength related to symptoms of urinary incontinence, decreased sexual function and poor quality of life. However, little has been studied on remote kinesthetic management in women treated for gynecological cancer. The importance of the study is to generate information on the applicability of remote exercises in reducing or controlling the side effects of gynecological cancer treatment.

3. Metodology

The present study consists of 3 evaluations and an intervention with training: the first two will be carried out before starting the intervention, with an interval of one week each; the third evaluation will be carried out after 4 weeks of intervention. The evaluations will be carried out by two collaborating researchers, a Kinesiologist Master in Kinesiology (Lily Berríos Contreras) and an undergraduate student in Kinesiology (Francisca Valdivia) and will last approximately 40 minutes. An online platform will be used according to your preference to carry out all the measurements that will be the following:

a) Personal data related to age and history of gynecological cancer, such as date of diagnosis and previous treatments performed.
b) Evaluation of fatigue, symptoms of urinary incontinence, sexual function and quality of life, through specific questionnaires for patients treated for cancer (you will be asked to answer the questionnaires).
c) Recording of your perception of effort to exercise, using a scale, evaluation of the rhythm of your breathing, by counting your chest movements during breathing and heartbeat, with your help by counting the pulsation of your carotid artery, located in the neck.

The training will be carried out remotely, being supervised twice a week and once unsupervised, following a pattern of exercises at home, for 4 weeks. The intervention will be carried out by the main researcher (Ivana Leao Ribeiro), the students Valeria Roteli and Camila Rojas. You will be randomly assigned to the conventional or unconventional intervention group. The conventional intervention consists of aerobic and muscle strength exercises (3 sets of 8-12 repetitions of 8 exercises), using only body weight. The intervention will last 50 minutes each session. The unconventional intervention, in addition to the exercises included in the other conventional intervention group, is associated with an additional low-pressure abdominal exercise that will be performed in 10 minutes, therefore, the intervention in this group will have a total duration of 60 minutes. You are required to wear comfortable clothing and shoes during supervised and unsupervised training sessions for your safety.

4. Your participation in the study

Your participation in this study is free and voluntary, and you may request to be excluded from this research and that your interventions not be considered in this research without prior justification or prejudice to you.

If you participate in this research, you do so with your express informed consent, which you sign and authorize. In addition, you have the right to withdraw from the activity at any time, without explanation. Once the activity is finished and the data has been collected, you have the right to access the results obtained in the activity.

5. Confidentiality

The confidentiality of your identity will be protected by the following measures:
1. Only the principal investigator and her team will have access to the data collected during the evaluations.
2. The interview and answers to the questionnaires will receive a code for each participant, which will only be known by the researcher responsible for this study and will be carried out in a favorable environment that stimulates communication and the anonymity chosen by the participant.
3. All members of the research team agree to protect the confidentiality of the data, by signing a confidentiality letter.
4. The Google Meet, Teams and WhatsApp platforms have adequate security and privacy when it is the host who creates the meetings and/or makes the video calls.

In the general analysis of the data, a code structure will be used to identify the information that arises, its belonging to the instrument and the moment in which it was carried out.

Given the characteristics of the study, the data will only be used in academic research instances and those specific to research dissemination.

In the presentation of results, any possible indication that allows a possible identification such as places, institutions, etc. will be reserved.

Likewise, the Responsible Investigator assumes a confidentiality commitment to protect the identity of all those involved in this study. It is important to consider that the evaluations and intervention will not be recorded.

6. Benefits

This study presents a direct benefit to you. In this sense, after completing the interview and answering the questionnaires, you will receive 4 weeks of standardized kinesthetic intervention, with specific exercises for managing the side effects of gynecological cancer treatment. As a result of your participation, no economic incentives of any kind will be generated. It should be noted that your participation in this study only has eventual data network costs associated with you to participate in the remote evaluation and intervention, via an online platform.

7. Risks or inconveniences associated with participation

If any discomfort is generated as a result of any question or reflection during your participation in the interview and answers to the questionnaires, the responsible Kinesiologist collaborator will try to emotionally contain and provide the required assistance.
During the first training sessions, you may feel discomfort in the muscles as a result of the exercises performed, but it is transitory and does not usually last more than 48 hours. The intensity of the exercises is maintained according to your tolerance and without generating pain. If the discomfort persists, the exercise will be performed at a lower intensity or interrupted.

8. Storage and protection of information

All the information collected from this investigation will always be protected and in the care of the Responsible Investigator, who will allocate a locked locker in her office where all documents of this investigation will be kept. It is important to consider that only in the event that the interview is conducted directly to your telephone number will your authorization to participate in the study be recorded, the interview and data collection will not be recorded.

The interview and application of the questionnaires will only be carried out by the Researcher responsible for recruiting the participants, who will send the data to the Researcher Responsible for the study. All electronic material will be duly stored and backed up in personal computer equipment with the researcher's password. In addition, the research team

undertakes to maintain the protection of the information collected during and after the end of the study.
Both this consent and the printed documents that are generated and necessary to use will be stored for five years from the end of the study, once the term has ended, they will be removed in a reserved manner.

9. Access to research results

The participants will be able to consult the information that they have generated at any time during the execution of the project, with prior request to the researcher responsible for the study, who agrees to provide cooperation and propose ways for such access.

Likewise, the Responsible Investigator undertakes with each participant to send the research report that is generated at the end of the study to the respective emails, as well as a copy of the scientific articles that may result from the study.

10. Commitment

By accepting the participants agree to:
1. Provide real information in each instance that is requested and respond according to their conceptions, knowledge and experiences, as well as to use a habitual language when responding.

11. Contact

If you have questions about your rights as a participant in this study, complaints or doubts about this research, please contact the Responsible Investigator, Ivana Leao Ribeiro, phone 965990637, email ivanaleao@gmail.com or the president of the Committee of Scientific Ethics of the Catholic University of Maule, Dr. Marcelo Correa Schnake, to the email Comité-etica@ucm.cl.

I declare to know the terms of this informed consent, the objectives of the research, the forms of participation, the costs and risks involved, and the access and protection of information that is produced in the study. I acknowledge that the information I provide in the course of this investigation is strictly confidential and anonymous. In addition, this will be used only for scientific dissemination purposes.

I have been informed that I can ask questions about the project at any time and that I can withdraw from it when I so decide, without having to give explanations or suffer any consequence for such a decision.

I agree to participate in the study ( ) Yes ( ) No

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Responsible researcher
Ivana Leao Ribeiro
PhD in Physiotherapy, academic of Kinesiology
Faculty of Health Sciences
Universidad Católica del Maule

"Effects of hypopressive exercise associated with resistance and resistance training in the management of fatigue, urinary incontinence symptoms, sexual function and quality of life in women treated for gynecological cancer: a randomized clinical trial."
Catholic University of Maule

Collaborators:
Francisca Valdivia
Valeria Roteli
Camila Rojas
Nicolás Yáñez
Francisco Ortega
Lily Berríos Contreras

It is hereby recorded that upon receipt of this document (informed consent) the participant must reply to the email or text/audio message stating "I accept" or "I do not accept" to participate in the study. This response will be recorded by the Responsible Investigator.