Effects of Hypopressive Exercise Associated With Strength and Resistance Training in the Management of Fatigue, Urinary Incontinence Symptoms, Sexual Function and Quality of Life in Women Treated for Gynecological Cancer

Study Protocol (23-08-2021)

Research design

Experimental, single-blind randomized clinical trial type.

Determination of sample size

The sample size was calculated using the GPower version 3.1 software, considering a size of effect, Cohen's d of 0.2, to achieve a power of 80%, with a significance level of 5%. was used the analysis of variance of repeated measures, considering interaction between and within groups using 2 measurements. Thirty-six participants (18 per group) were suggested.

Randomization and blinding

Participants will be assigned randomly assigned to one of the two groups studied (Hipopresive exercise group, HEG; conventional exercise group, CEG). Randomization will be performed by a member of the team, blinded to the study protocol. A computer program will be used to perform the randomization (https://www.graphpad.com/quickcalcs/randomize1.cfm). Both groups will receive 4 weeks of supervised training with a frequency of three times a week, with an approximate duration of 60 minutes each session. Figure 1 presents the flowchart with the experimental design of the study.

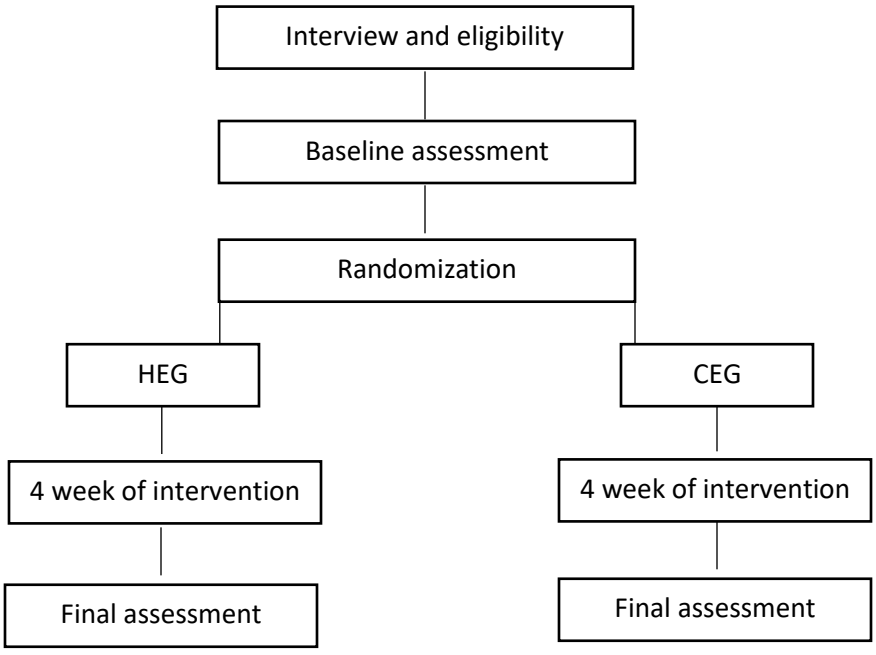

Figure 1.

Protocol of therapeutic exercise

Both groups of exercises will train three times a week, twice in a synchronous online way and once in an asynchronous way, considering a standardized exercise guide. In all of the intervention sessions, the conventional exercises will be guided by the standardized exercise guide previously developed by the team of the study for 4 weeks. Each session will last approximately 60 minutes. In all sessions, exercise perception (using the Borg scale), respiratory rate and heart rate will be monitored, considering instructions via remote. For aerobic training, a light to moderate intensity will be considered (Borg 9-13). Resistance exercises will be carried out using large muscle groups and the participants' body weight. All the exercise sessions will be the same for the groups and will begin with a five-minute warm-up with exercises that involve large muscle groups in a perceived exercise rating of 10 to 12 on the Borg scale and the sessions conclude with a 10 minutes that include dynamic and static muscle stretching activities of the main muscle groups worked in the session. In the first week of training, a familiarization with the perception of perceived effort will be carried out using the Borg scale.

The strength training will consist of 3 sets of 8-12 repetitions of 8 exercises, using leg extensions and lower limbs, biceps curls and extensions, lunges, chest curls, abdominal curls, shoulder curls and back extension. Participants will perform exercises without charge in all sessions. The training progress will be related to the increase in volume according to what corresponds to each week: a) weeks 1 and 2 (3 sets of 8 repetitions, adaptation weeks), b) week 3 (3 sets of 10 repetitions) and c) week 4 (3 sets of 12 repetitions).

Hypopressive Exercise Protocol

The hypopressive exercises will be carried out by the GEH group at the end of the strength and resistance training session. It will be considered the static hypopressive exercise in the supine position, with a variant of arms in flexion, abduction and extension, consisting of 3 exercises. The dosage will consist of 3 series of each exercise, using a protocol adapted from the previous study by Cabañas and Chapinal. Participants must perform 3 cycles of deep inspiration (nose) and forced breathing (mouth). After the last breath, the participants will be instructed to maintain the position performing 3 cycles of normal breathing, without performing the apnea, to guarantee the safety of the user and that the intervention is remote. During the breathing phase, participants will be instructed to perform pelvic floor contraction. The procedure must be repeated 3 times in each variant of arms.

Recruitment

Participants will be recruited through the referral of a medical oncologist from the Regional Hospital of Talca in Chile. Potential study participants will be called for an initial evaluation where eligibility will be determined and the objectives of the research will be explained. Participants who agree to participate must sign an informed consent.

Generation and hiding of sequences

After selecting the sample and performing the baseline evaluations, the participants will be randomly assigned to one of the two study groups. Randomization will be performed by a member of the team, blinded to the study protocol. A computer program will be used to perform the randomization (https://www.graphpad.com/quickcalcs/randomize1.cfm). Both groups will receive 4 weeks of supervised training with a frequency of three times a week, with an approximate duration of 60 minutes each session. Figure 1 presents the flowchart with the experimental design of the study.

Blinding (masking)

Outcome assessments before and after the intervention will be performed by a physical therapist blinded to the allocation of participants in each group.

Data collection

Standardized forms will be used to record pre- and post-intervention evaluations. The registry will consider demographic data, social and health habits, clinical variables: comorbidities, blood pressure, body mass index (weight, height), type of gynecological cancer, cancer staging and type of oncological treatment. In addition, the dosage of the kinesthetic intervention will be recorded according to the Borg scale for each session.

Data management

All study information will be securely stored in the Clinical Research Laboratory, Department of Kinesiology, Universidad Católica del Maule, Chile, in locked cabinets. The information of each patient will be classified by means of numerical codes and will be kept 5 years after the end of the investigation in closed filing cabinets. Access to the information will be limited to people outside the research team of this study.

Statistical Analysis

Statistical analysis will be performed using a statistical package SPSS (version 17.0). The data will be expressed as mean, standard deviation (SD), lower and upper limit of the confidence interval (CI, 95%) or median, minimum, maximum, first and third quartile, according to normality distribution using the Kolmogorov Smirnov test. To assess fatigue, symptoms of urinary incontinence, sexual function and quality of life, a two-way mixed analysis (two-way ANOVA) will be performed, considering time (pre-intervention and post-intervention) as an intra-subject and group factor as a between-subjects factor. The significance level will be set at .05 for all statistical analyses. The intragroup effect sizes for the aforementioned variables will also be calculated using the Cohen d index. An effect size of more than 0.8 will be considered large, approximately 0.5 moderate, and less than 0.2 small (Cohen,1988).

Reference:

Cohen J. Statistical Power Analysis for the Behavioral Sciences. 1988. 1–17 p.