TITLE: EFFECTIVENESS OF PREHABILITATION ON PELVIC FLOOR WEAKNESS, FUNCTIONAL PERFORMANCE AND RECOVERY EFFICIENCY AMONG POST SURGICAL CERVICAL CANCER WOMEN

NCT: Not yet assigned

Unique Protocol Id: 063/05/2025/ISRB/PGSR/SCPT

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Subjects: Patients with cervical cancer undergoing radical hysterectomy.

Sampling technique: Simple random sampling technique.

Sample size: 34

Selection criteria

The selection criteria for the present study were carefully formulated to ensure the inclusion of participants who could safely undergo the intervention and provide reliable outcome data, while excluding individuals with conditions that could confound the results or pose medical risks. The criteria were applied uniformly during participant screening prior to enrollment.

Inclusion Criteria

Women aged between 40 and 60 years

Confirmed diagnosis of cervical cancer

Preoperative diagnosis of early-stage cervical cancer

Planned to undergo radical hysterectomy

Karnofsky Performance Scale score between 50 and 70

Ability to actively engage in pelvic floor and resistance training protocols

Willingness to participate in the study

Provision of written informed consent prior to inclusion

Exclusion Criteria

Diagnosis of locally advanced or metastatic cervical cancer

Presence of cardiopulmonary comorbidities limiting exercise tolerance

Active urinary tract infection at the time of assessment

Cognitive impairments interfering with understanding or compliance with intervention

Any medical condition contraindicating participation in structured exercise programs

Study procedure

After obtaining approval from the Institutional Ethics Committee, the study was conducted as a randomized controlled trial among patients diagnosed with cervical cancer and scheduled to undergo radical hysterectomy. The study setting included the inpatient and outpatient departments. Potential participants were screened by the investigator based on the predefined inclusion and exclusion criteria. Eligible participants were approached individually and a detailed explanation of the study objectives, procedures, potential benefits and possible risks was provided in a language understandable to them. Adequate time was given for clarification of doubts following which written informed consent was obtained prior to enrolment in the study.

A total of 34 participants who satisfied the selection criteria were included. Simple random sampling was adopted for participant selection and random allocation into two groups was carried out using the lottery method to ensure unbiased group assignment. The participants were equally divided into two groups, the intervention group and the control group, with 17 participants in each group. Allocation concealment was maintained throughout the recruitment process to minimize selection bias.

Baseline assessments were conducted four weeks prior to the scheduled surgical procedure. Pre-test measurements included assessment of pelvic floor muscle strength using the Brink score, evaluation of overall functional status using the Karnofsky Performance Scale and assessment of recovery efficiency through the anticipated duration of hospital stay. All baseline assessments were performed before the commencement of the exercise intervention to ensure uniformity in data collection.

Participants allocated to the intervention group underwent a structured prehabilitation exercise program for a duration of four weeks prior to surgery. The prehabilitation protocol consisted of three supervised sessions per day, each lasting 20 minutes, amounting to a total of 60 minutes of exercise daily. The first session focused on aerobic training, which included activities such as walking, cycling and treadmill exercises based on the individual's choice, tolerance and fitness level. The second session emphasized pelvic floor muscle strengthening exercises, which were individualized and performed as two sets of ten repetitions to improve pelvic floor muscle activation and endurance. The third session consisted of resistance training exercises targeting both upper and lower limb muscle groups using appropriate equipment also performed as two sets of ten repetitions. Exercise intensity and progression were individualized based on the participant's functional capacity and clinical status.

Participants in the control group received a generalized standard exercise protocol for four weeks prior to surgery. This protocol included free exercises, breathing exercises

and walking, delivered in three daily sessions similar in duration to the intervention group. However, no structured or targeted prehabilitation components such as resistance training or specific pelvic floor muscle strengthening were included in the control protocol.

Following surgery, participants in both groups underwent standardized postoperative rehabilitation for a period of two weeks. Postoperative rehabilitation included breathing exercises, pelvic floor strengthening exercises such as Kegel exercises and pelvic bridging and core strengthening exercises aimed at promoting early mobilization, improving functional recovery and preventing postoperative complications. The postoperative rehabilitation protocol was uniform for both groups to ensure comparability. Post-intervention assessments were conducted as per the study timeline after two weeks to evaluate the effectiveness of the intervention.

Materials Required

The materials required for the study included basic exercise and assessment equipment. For the intervention group, resistance bands, weight cuffs, dumbbells and a Swiss ball were used to perform aerobic, resistance and pelvic floor strengthening exercises. For outcome assessment, a couch and a stopwatch were used to facilitate standardized functional and pelvic floor muscle evaluations.

Outcome measures

To evaluate the effectiveness of the prehabilitation program on functional status, pelvic floor muscle performance, and recovery efficiency, standardized and clinically validated outcome measures were utilized. These measures were selected to comprehensively capture both functional and physiological changes associated with the intervention and to allow objective comparison between the intervention and control groups across the study period.

Brink Score: The Brink Score was used to evaluate pelvic floor muscle strength. The Brink score is a digital vaginal palpation scale used to assess pelvic floor muscle function by evaluating pressure (strength), duration (endurance), and vertical displacement (lift). With the patient in supine or crook-lying position, a gloved finger is inserted vaginally and the patient is instructed to contract the pelvic floor muscles. Each component is scored from 0 to 4, giving a total score of 0–12. Scores of 0–3 indicate severe weakness, 4–6 moderate weakness, 7–9 fair strength and 10–12 strong pelvic floor muscles.

Karnofsky Performance Scale: The Karnofsky Performance Scale (KPS) is a standardized tool used to assess a patient's functional status and ability to perform daily activities, particularly in oncology and chronic illness care. KPS is widely used to evaluate disease severity, prognosis, treatment tolerance, and eligibility for therapies, and to monitor changes in functional capacity over time.

Duration of hospital: The duration of hospital stay was used as a measure of recovery efficiency. It was calculated as the number of days from the date of surgery to the date of hospital discharge, as documented in medical records. Shorter hospital stay was interpreted as improved recovery and functional readiness for discharge.

Data Analysis

The collected data were analyzed using SPSS with a significance level set at $p < 0.05$. Normality of continuous variables was assessed using the Shapiro–Wilk test, which indicated a non-normal distribution of the primary outcome measures, including Brink score and Karnofsky Performance Status (KPS). Due to the non-parametric nature of the data, within-group comparisons of pre and post-intervention scores were performed using the Wilcoxon signed-rank test, which is appropriate for evaluating paired differences in related samples when the assumption of normality is not met. Between-group comparisons at baseline and post-intervention were conducted using the Mann–Whitney U test, a non-parametric alternative to the independent samples t-test, suitable for comparing two independent groups with skewed data. Effect sizes were calculated to determine the clinical significance of observed changes in outcome measures.Recovery efficiency measured as hospital stay duration was summarized using descriptive statistics specifically mean and standard deviation to reflect the overall trend in postoperative recovery between groups. This combination of non-parametric tests and descriptive statistics ensured accurate and robust evaluation of the intervention's impact on pelvic floor strength, functional performance and recovery outcomes among post-surgical cervical cancer women.

INFORMED CONSENT FORM

SAVEETHA COLLEGE OF PHYSIOTHERAPY

SIMATS, CHENNAI-602105

Informed Consent Form

I----------Agree to take part in the study conducted by **Akshya S** post graduate student of Saveetha College of Physiotherapy, SIMATS.

TITLE: **:** Effectiveness of Prehabilitation on Pelvic Floor Weakness and Quality of Life Among Cervical Cancer Population Undergoing Hysterectomy.

I acknowledge that the study has been explained to me and I agree to participate and I am willing to provide information about my health status to the investigator. I allow the investigator to have access to my medical records, pertaining to the purpose of the study. Participate in the analysis program. Make myself available for further analysis required. I have been informed about the purpose producers and measurements involved in the study and my queries towards the study have been clarified. I have been informed that this study consists of a grouping and I also agree to come regularly for the study period of **6 weeks.**

I Provide consent to the investigator to use the still photographs with masked face for educational purposes only. No funds / fees / remuneration is taken from the subjects on the course of the study.

I understand that my participation is voluntary and can with draw at any stage of the study.

Place:

Date:

Signature