TITLE: EFFECTIVENESS OF PREHABILITATION ON PELVIC FUNCTION AND QUALITY OF LIFE AMONG POST-SURGICAL CERVICAL CANCER WOMEN

DOCUMENT DATE: May 14th 2026

NCT: Not yet assigned

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

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

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

This parallel-group, randomized controlled trial evaluated the effectiveness of a four-week multimodal prehabilitation programme on postoperative pelvic function and quality of life among women with cervical cancer undergoing radical hysterectomy at a tertiary care teaching hospital. A total of 46 women were assessed for eligibility. Seven participants were excluded prior to enrolment, of whom four did not meet the inclusion criteria and three declined to participate. The remaining 39 eligible participants were randomized in a 1:1 ratio to either the prehabilitation group (n = 19) or the control group (n = 20). During the course of the study, five participants were excluded from the final analysis due to postponement of surgery (n = 1), withdrawal of consent (n = 1), incomplete outcome assessment (n = 2), and loss to follow-up (n = 1). Consequently, data from 34 participants (17 per group) were included in the final analysis.

Eligible participants were consecutively recruited from the Department of Gynecologic Oncology after screening according to predefined inclusion and exclusion criteria. Written informed consent was obtained from all participants before enrolment. Randomization was performed using a computer-generated randomization sequence prepared by an independent investigator. Allocation concealment was maintained using sequentially numbered, opaque, sealed envelopes that were opened only after participant enrolment. Owing to the nature of the intervention, blinding of participants and treating physiotherapists was not feasible. However, all outcome assessments were performed by an independent physiotherapist who was blinded to group allocation.

Baseline assessments (T0) were conducted four weeks before the scheduled surgery, prior to the commencement of the intervention. The primary outcome was pelvic

function, objectively assessed using transabdominal ultrasound (TAUS) by measuring bladder base displacement during maximal voluntary pelvic floor muscle contraction. Participants were instructed to attend the assessment with a comfortably filled bladder. The ultrasound examination was performed in the supine crook-lying position using a standardized suprapubic scanning technique. Three maximal voluntary pelvic floor muscle contractions were recorded with adequate rest between trials, and the greatest bladder base displacement (measured in millimetres) was considered for analysis.

Secondary outcomes included pelvic floor distress assessed using the Pelvic Floor Distress Inventory-20 (PFDI-20) and quality of life assessed using the European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire Cervical Cancer Module (EORTC QLQ-CX24). The PFDI-20 is a validated 20-item patient-reported questionnaire that evaluates symptoms related to urinary distress, colorectal-anal dysfunction, and pelvic organ prolapse. Scores range from 0 to 300, with higher scores indicating greater pelvic floor symptom severity and distress. The EORTC QLQ-CX24 is a validated cervical cancer-specific quality-of-life questionnaire that evaluates symptom experience, body image, sexual activity, sexual and vaginal functioning, sexual worry, peripheral neuropathy, menopausal symptoms, lymphoedema, and treatment-related concerns. Questionnaire scoring was performed according to the EORTC scoring manual. Demographic and clinical characteristics, including age, body mass index, menopausal status, FIGO stage, and relevant comorbidities, were also documented at baseline.

Participants allocated to the intervention group underwent a supervised four-week multimodal prehabilitation programme before surgery. The programme was conducted five days per week, with each supervised session lasting approximately 60 minutes. It comprised moderate-intensity aerobic exercise, pelvic floor muscle training, progressive resistance exercises for the upper and lower limbs using resistance bands, dumbbells, and weight cuffs, flexibility exercises, breathing exercises, and cool-down activities. Exercise intensity and progression were individualized according to each participant's baseline functional capacity and tolerance under the supervision of an experienced physiotherapist. Participant attendance and adherence were monitored and recorded throughout the intervention period.

Participants allocated to the control group received the institution's standard preoperative physiotherapy programme consisting of breathing exercises, active range-of-motion exercises, postural education, and walking advice of comparable duration. No structured multimodal prehabilitation programme, pelvic floor muscle training, or progressive resistance exercises were provided during the preoperative period.

Following completion of the four-week intervention period, all participants underwent radical hysterectomy according to the institution's standard surgical protocol. After surgery, both groups received an identical standardized postoperative rehabilitation programme for four weeks comprising breathing exercises, early mobilization, progressive ambulation, pelvic floor muscle exercises, core stabilization exercises, lower-limb strengthening, and functional mobility training. Standardizing postoperative rehabilitation ensured that postoperative care was comparable between groups, allowing any observed between-group differences in postoperative outcomes to be attributed to the preoperative multimodal prehabilitation programme.

Post-intervention assessments (T1) were performed four weeks after surgery by the same blinded assessor using identical assessment procedures. Pelvic function was reassessed using transabdominal ultrasound, pelvic floor distress was reassessed using the Pelvic Floor Distress Inventory-20 (PFDI-20), and quality of life was reassessed using the EORTC QLQ-CX24. The postoperative assessment was conducted to determine the effect of the four-week preoperative multimodal prehabilitation programme on postoperative pelvic function, pelvic floor-related symptoms, and quality of life following radical hysterectomy. Participant adherence, postoperative complications, adverse events, and withdrawals were documented throughout the study.

Statistical analyses were performed using IBM SPSS Statistics. Descriptive statistics were used to summarize participant demographics, clinical characteristics, and outcome measures. Continuous variables were expressed as mean ± standard deviation, depending on data distribution, whereas categorical variables were presented as frequencies and percentages. The normality of continuous variables was assessed using the Shapiro–Wilk test. Baseline characteristics between groups were compared using appropriate statistical tests. Changes in pelvic function, pelvic floor

distress, and quality-of-life outcomes within and between groups were analyzed using appropriate statistical methods based on the distribution and characteristics of the data. Effect sizes and 95% confidence intervals were reported where appropriate. All statistical tests were two-tailed, and a p-value of less than 0.05 was considered statistically significant.

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.

The primary outcome was pelvic function, assessed using transabdominal ultrasound (TAUS) by measuring bladder base displacement (BBD) during maximal voluntary pelvic floor muscle contraction. Participants were assessed in the supine crook-lying position with a comfortably filled bladder using a standardized suprapubic ultrasound protocol. Three maximal voluntary pelvic floor muscle contractions were performed with adequate rest between trials, and the greatest bladder base displacement (measured in millimetres) was recorded for analysis. Greater cranial displacement of the bladder base indicated better pelvic floor muscle function.

The secondary outcomes included pelvic floor distress and quality of life. Pelvic floor distress was evaluated using the Pelvic Floor Distress Inventory-20 (PFDI-20), a validated 20-item patient-reported questionnaire assessing urinary, colorectal-anal, and pelvic organ prolapse symptoms. Total scores range from 0 to 300, with higher scores representing greater symptom severity and pelvic floor-related distress.

Quality of life was assessed using the European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire Cervical Cancer Module (EORTC QLQ-CX24). This validated questionnaire evaluates cervical cancer-specific quality of life across multiple domains, including symptom experience, body image, sexual activity, sexual and vaginal functioning, sexual worry, peripheral neuropathy, menopausal symptoms, lymphoedema, and treatment-related concerns. Scores were calculated according to the EORTC scoring manual, where higher functional scores represent better functioning and higher symptom scores represent greater symptom burden.

Data Analysis

The collected data will be analyzed using IBM SPSS Statistics.Descriptive statistics will be used to summarize the demographic and clinical characteristics of the participants. Continuous variables will be expressed as mean ± standard deviation, while categorical variables will be presented as frequencies and percentages. Data normality will be assessed using the Shapiro–Wilk test. Baseline characteristics between the two groups will be compared using appropriate statistical tests. Changes in pelvic function, pelvic floor distress, and quality-of-life outcomes within and between groups were analyzed using appropriate statistical methods based on the distribution and characteristics of the data. Effect sizes and 95% confidence intervals were reported where appropriate. All statistical tests were two-tailed, and a p-value of less than 0.05 was considered statistically significant.

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 Function and Quality of Life Among Post-Surgical Cervical Cancer Women

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 **8 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