BIRUNI UNIVERSITY

SCIENTIFIC RESEARCH ETHICS COMMITTEE
INFORMED VOLUNTARY CONSENT FORM

Effects of Aerobic Exercise and Guided Imagery on Low Anterior Resection Syndrome After Rectal Cancer Surgery: A Randomized Controlled Trial

30.12.2025

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You are being invited to participate in the research study described below. Whether or not you decide to participate is entirely your own choice. Before deciding whether you wish to participate, it is important that you understand why the research is being conducted, how your information will be used, what the study involves, its potential benefits and risks, and any possible discomforts it may cause. Please take the time to read the following information carefully. If you decide to participate in the study, please sign the **Informed Consent Form for Participation in the Study**. You are free to withdraw from the study at any time without giving any reason. You will not receive any payment for participating in this study, nor will you be asked to make any financial or material contribution. All materials to be used in the study and any expenses that may arise during the research will be covered by the researcher.

STUDY PURPOSE AND OBJECTIVE

Following the surgical removal of a tumor located in the rectum (the final part of the large intestine), the affected segment of the bowel is excised and the remaining bowel ends are reconnected using a circular stapling device. To protect the safety of this bowel connection (anastomosis), the end of the small intestine is sometimes temporarily brought out through an appropriate opening in the abdominal wall, allowing stool to pass through this opening for a limited period of time (protective ileostomy). Approximately two months after the initial operation, the bowel is returned to the abdominal cavity during a second surgical procedure (ileostomy closure).

This informed consent form has been prepared to assist you in deciding whether or not to participate in our study investigating the effects of relaxation training and aerobic exercise on pelvic floor symptoms in patients who have undergone surgery for rectal cancer, received and subsequently undergone closure of a protective ileostomy, and have been diagnosed with **Low Anterior Resection Syndrome (LARS).**

STUDY PROCEDURES

Following rectal cancer surgery, patients may develop symptoms such as frequent bowel movements, sudden urgency to defecate, and fecal incontinence. To treat these symptoms, pelvic floor muscle training with biofeedback, as described above, is routinely provided to patients at the **Pelvic Floor and Bowel Health Unit of Memorial Bahçelievler Hospital** after ileostomy closure following rectal cancer surgery.

Biofeedback is a procedure in which adhesive electrodes are placed on the skin around the anus, allowing muscle contractions and relaxation to be monitored on a computer screen. This enables the strength of the pelvic floor and anal sphincter muscles to be

improved and their function to be enhanced. This procedure will be performed in the clinic under the supervision of a specialist physiotherapist. In addition, participants in our study will receive relaxation training and a walking program as an aerobic exercise intervention to promote relaxation.

A total of **50 patients** will be enrolled in the study. Participants will be randomly assigned by lottery to one of two groups, each consisting of **25 patients**. Participants in **Group 1 (the control group)** will receive routine treatment, including basic patient education, medical treatment, and pelvic floor muscle training with biofeedback. Participants in **Group 2 (the intervention group)** will receive, in addition to the routine treatment, relaxation training and aerobic exercise.

The training sessions will be conducted **one day per week in the clinic and on at least three days per week outside the clinic.**

As part of the relaxation training, you will be asked to listen to the instructions provided in an audio recording while in your most comfortable and relaxed position, with the aim of achieving mental relaxation. A copy of this audio recording will be provided to you. As part of the aerobic exercise program, you will be asked to perform **moderate-intensity walking** for **8 weeks**, with the duration of the exercise increasing by **10 minutes every two weeks**. You will be asked to walk for **40 minutes during the first four weeks, 50 minutes during Weeks 5–6, and 60 minutes during Weeks 7–8.**

WHAT ARE THE BENEFITS OF PARTICIPATING IN THIS STUDY?

This study aims to determine whether the addition of relaxation training and aerobic exercise to pelvic floor rehabilitation, which is routinely provided in the clinic and whose effectiveness has been demonstrated in scientific studies, provides additional benefits. By participating in this study, you will contribute to determining whether these additional interventions improve the various pelvic floor symptoms associated with **Low Anterior Resection Syndrome (LARS)** following surgery.

WILL THERE BE ANY COST TO ME FOR PARTICIPATING IN THIS STUDY?

Your participation in this study will not impose any financial burden on you, and you will not receive any payment for participating.

DO I HAVE TO TAKE PART IN THIS STUDY?

Your participation in this study is entirely voluntary. Even if you sign this consent form now, you are free to withdraw from the study at any time without providing any reason. If you choose not to participate or decide to withdraw from the study, the treatment plan considered most appropriate for you will be provided by your **investigator/physician (PLEASE SELECT ONE)**. Likewise, the **investigator/physician (PLEASE SELECT ONE)** conducting the study may determine that it is no longer in your best interest to continue participating and may withdraw you from the study. In such a case, the treatment considered most appropriate for you will be provided.

HOW WILL MY PERSONAL INFORMATION BE USED?

Your investigator/physician (PLEASE SELECT ONE) will use your personal information for the purposes of conducting the research and performing statistical analyses. However, your identity and personal information will be kept strictly confidential. Only when necessary may your information be reviewed by ethics committees or authorized regulatory authorities. At the conclusion of the study, you have the right to request information regarding your individual study results. The results of the study may be published in the medical literature after the study has been completed; however, your identity will not be disclosed.

CONSENT TO PARTICIPATE IN THE STUDY

I have discussed the above information in detail with the investigator, and all of my questions have been answered. I have read and understood this informed consent form. I voluntarily agree to participate in this research study and sign this consent form of my own free will. This consent does not waive any of my legal rights or invalidate any applicable laws or regulations. The investigator has provided me with a copy of this consent form for my records.

Volunteer's Full Name: **Date:**

Telephone: **Signature:**

Legally Authorized Representative's Full Name (if applicable): **Date:**

Telephone: **Signature:**

Witness's Full Name: **Date:**

Telephone: **Signature:**

Investigator's Full Name: **Date:**

Telephone: **Signature:**