Effectiveness of proprioceptive neuromuscular facilitation for improving for shoulder biomechanical parameters, function, and pain after axillary lymph node dissection: a randomized controlled study

Informed Consent Form (ICF)

NCT NO: 10840098-604.01.01-E.184

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Below is detailed information about this research, please read it all carefully.

WHAT IS OUR WORK?

This study examines the effect of Proprioceptive Neuromuscular Facilitation exercises for shoulder-arm problems in women between the ages of 18-65 who were diagnosed with breast cancer and received surgery and radiotherapy.

WHAT IS THE PURPOSE OF THE WORK?

Breast cancer treatment; It includes surgery, radiotherapy, chemotherapy and hormone therapy. In the studies performed, in the postoperative period in individuals undergoing breast cancer surgery; It is stated that limitation in shoulder joint range of motion, loss of strength, muscle shortness, scapular kinematic changes during arm movements, pain and decrease in arm function as a result of all these, problems occur in daily living activities. The aim of the study is to investigate the effectiveness of the Proprioceptive Neuromuscular Facilitation technique in order to reduce or eliminate the negative effects that may occur.

HOW TO MAKE AN APPLICATION?

Individuals will be evaluated and treated by a physical therapist. The cases will be randomly divided into 3 groups. Randomization will be carried out with the "randomization" website interval. An exercise program for the shoulder joint and arm will be applied to each patient twice a week for 8 weeks. Each session is programmed to be approximately 40-45 minutes. Before and after treatment; Demographic information questionnaire questioning information such as age, gender, body mass index, dominant hand, working status, DASH (Arm, Shoulder and Hand Problems Questionnaire), EORTC QLQ-C30 Quality of Life Scale, Tampa Kinesiophobia and Body Awareness Scale will be applied to the cases. Hand grip strength will be performed with Jamar Hand Dynamometer, muscle strength, power, endurance and proprioceptive sense measurement, Cybex Humac Norm Isokinet Test and Exercise System, joint range of motion measurement will be performed with Baseline Digital Goniometer. Operative side shoulder-arm pain will be measured with the Visual Analogue Scale (VAS). The tests to be applied do not have any negative side effects and will be done without tiring you.

WHAT ARE MY RESPONSIBILITIES?

Patients included in our study are expected to comply with the assessments. In cases where these conditions are not complied with, the investigator has the authority to exclude you from the program.

EXPERIMENTAL SECTIONS OF THE RESEARCH

Our research is not an experimental study.

WHAT ARE THE EXPECTED POSSIBLE RISKS OR DISORDERS WITH PARTICIPATION IN THE STUDY?

The assessment approaches to be applied in this study do not carry any risk and there is no effect that will disturb you. In addition, in cases where the expected benefit is not obtained, you will be given the necessary explanation about the reasons for this.

PARTICIPANTS' INVOLVEMENT

You will participate in the study voluntarily, or you may refuse to participate in the study and leave the study voluntarily without any sanction.

CONTACT

The contact and phone number of the patient or legal representatives in case of any problems with the research or the research are given below:

exp. Ft. Selen Güloğlu 05058886652

DURATION OF THE STUDY: Our study will continue until your treatment in the hospital is over.

CAN THE CONFIDENTIALITY BE PROVIDED ABOUT MY INFORMATION?

All your medical and identity information will be kept confidential and your identity information will not be given even if the research is published, however, the ethical committees and official authorities in charge of the research can access your medical information when necessary. You can also access your own medical information whenever you want.

Consent to Participate in the Study

I have read all the explanations in the “Informed Consent Form”. Written and verbal explanation about the research whose subject and purpose is stated above was given to me by the physician/physiotherapist whose name is mentioned below. I asked all the questions that came to my mind to the researcher, I have understood in detail all the written and verbal explanations made to me. I know that I have voluntarily participated in the research and that I can leave the research at any time with or without justification. I agree to participate in this research voluntarily, without any pressure or coercion.

A signed and dated copy of this form was given to me.

19.02.2022