Effect of lymphedema prevention program based on theory of Knowledge-attitude-practice on postoperative breast cancer patients: a randomized clinical trial

Informed Consent

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Informed Consent Form · Notification page

Dear Patient：

Hello! We invite you to participate in a research project "Construction and empirical study of upper limb lymphedema prevention program for breast cancer patients after surgery". This study is sponsored by the Department of Breast Surgery, The First Affiliated Hospital of Xi 'an Jiaotong University. It is important for you to read and understand this informed consent form before agreeing to participate in this study. This document explains to you the research purpose, steps, benefits brought to you, risks you have to bear and other precautions.

1. Why was this study conducted?

Breast cancer has become the most common malignant tumor in women worldwide, and surgery is the primary treatment for breast cancer, but it brings a series of complications. Among them, upper limb lymphedema after breast cancer surgery is one of the most common complications, with an incidence of about 24-49%, which will lead to difficulties in daily activities, appearance impairment, anxiety and depression and other psychological problems, and further reduce the quality of life of breast cancer patients. At present, the treatment of upper extremity lymphedema is difficult, so the prevention of BCRL is emphasized in clinical practice.

The purpose of this study was to observe the effect of upper limb lymphedema prevention program on the incidence of upper limb lymphedema, grip strength, shoulder range of motion, upper limb function, and quality of life in patients after breast cancer surgery. To explore the effect of this prevention program on your postoperative rehabilitation, hoping to develop a standardized and effective lymphedema prevention program for breast cancer patients in the future.

2. What do you need to do if you participate in the study?

After you sign the informed consent form, we will randomly assign you to the control group or the intervention group, and we will provide you with the usual care or care using the lymphedema prevention program. This study will not affect your treatment. Your upper arm volume, grip strength, shoulder mobility, and quality of life will be assessed with a scale and a non-invasive measurement tool before your surgery and during your third and sixth chemotherapy sessions, respectively.

3. If you decide to participate in the study, you can participate in the study only if you meet the following conditions:

①Female patients aged ≥18 years,②Pathological biopsy confirmed breast cancer, ③Patients with clinical TNM stage Ⅰ-Ⅲ, who planned to undergo breast cancer surgery and received 6 or more chemotherapy in the later stage,④Clear consciousness, aware of the condition, no cognitive dysfunction and communication disorders.

4. If you have any of the following conditions, you should not participate in this study:

①Bilateral breast cancer, recurrence, metastasis or other malignant tumors,②A history of upper limb or neck trauma, infection, or surgery,③ Patients with serious diseases of cardiovascular, cerebrovascular, liver, kidney, etc.④ If the upper limb is disabled or the

affected limb has edema before operation,⑤Thrombosis of the blood vessels of the affected limb.

5. If participating in the study, when can I stop?

1) If you agree to participate in the study, you can terminate the study after completing the above research contents under the guidance of the research team.

2) You request automatic exit.

6. What are the treatment options?

During your hospitalization, we will communicate with you at the time set by the study and carry out the intervention for you. If you do not agree to participate in the study, you can accept the normal treatment process.

7. What are the risks of participating in a study?

Although this study is an intervention study, it will not cause any risk to you because it indirectly affects your recovery through nursing behaviors and health education.

8. What are the possible benefits of participating in a study?

By participating in this study, you can obtain the professional knowledge of lymphedema prevention, which is beneficial to your later prevention of lymphedema. At the same time, your participation can help medical staff understand whether the lymphedema prevention program can effectively prevent lymphedema, so as to provide reference for clinical nurses to improve the individualized nursing measures for patients.

9. Do I have to pay any fees to participate in the study?

The study will only use the questionnaire to collect your basic information and health condition. It will not charge you any fee and will not pay you any fee.

10. Is personal information confidential?

Your research data will be stored in the First Affiliated Hospital of Xi 'an Jiaotong University, and the investigators, research authorities, and ethics review board may review your medical records. Your personal identity will not be disclosed in any public report on the results of this study. We will make every effort to protect the privacy and personal information of your personal medical data within the scope permitted by law.

11. Do I have to take part in the study?

Participation in the study is completely voluntary. You may refuse to participate in the study or withdraw from the study at any time during the study without discrimination or retaliation, and your medical treatment and rights and interests will not be affected.

12. Who can I consult when I have questions?

If you have questions about the study information and the rights and interests of the subjects, as well as damages related to the study, you can contact the investigator and the ethics committee and their contact information. Researcher: Shi Bohui, Tel: 15398057172; Biomedical Ethics Committee, Xi 'an Jiaotong University Health Science Center, Tel: 029-82657512.

Informed Consent ˙ Signature page

Subject Statement: I have read the above introduction to the study, and my researcher has fully explained and explained to me the purpose and procedure of the study, as well as the possible risks and potential benefits of participating in the study, and answered all my relevant questions. Volunteer to participate in this study.

I consent □ or refuse □ to use my research data for any study other than this study.

Subject's signature: Date: __ __ __ __ Year _ _ Month _ _ day

Contact number of Subjects:

Relationship with Subjects: (if applicable)

Signature of legal representative: Date: __ __ __ __ year _ _ _ _ _ day

Reasons for signing by legal representative:

Signature of Witness: (if applicable) Date: __ __ __ __ Year _ month _ day

Reasons for witness signature:

Investigator statement:

I have explained the details of the study to the above volunteer and provided him/her with an original signed informed consent form. I confirm that I have explained to the subjects in detail the situation of this study, in particular the ethical principles and requirements of the risks and benefits, free of charge and compensation, damages and compensation, voluntariness and confidentiality that may arise from participating in this study.

Investigator's signature: Date: __ __ __ __ Year _ _ month _ _ day

Contact number of the researcher: