Far Eastern Memorial Hospital
Participant Information Sheet and Informed Consent Form

You are being invited to participate in this research study. This document provides important information about the study. The Principal Investigator or research team will explain the study to you and answer any questions you may have. Your participation is entirely voluntary. If you choose not to participate, your current medical care and rights will not be affected.

Study Title: Effects of Combined Upper Extremity Exercise and Pneumatic Compression Therapy on Breast Cancer–Related Upper Limb Lymphedema: A Single-Group Pretest–Posttest Follow-Up Study	
Principal Investigator: Yung-Hsin Lin, PT	
Co-Investigators: Hui Pan, PT; Ting-Wei Chi, PT	
Contact Person: Yung-Hsin Lin	Telephone: +886-2-8966-7000 ext. 2232
Department: Department of Rehabilitation	Sponsor: None
Participant Name：	Medical Record Number:

I. Background and Purpose：

Breast cancer–related lymphedema (BCRL) is a common long-term complication after breast cancer surgery. It may cause arm swelling, heaviness, pain, and limited shoulder movement, which can affect daily activities and quality of life. Physical therapy interventions, such as upper extremity exercise and pneumatic compression therapy, have been shown to help improve lymphedema.

The purpose of this study is to investigate the therapeutic effects of combining upper extremity exercise with pneumatic compression therapy in patients with BCRL.

II. Study Procedures：

1. Study Overview

A total of 20 patients with upper limb lymphedema after breast cancer surgery will be recruited.

The study duration is approximately 5 weeks. You will receive combined upper extremity exercise and pneumatic compression therapy and undergo assessments at different time points.

2. Inclusion Criteria

You may participate if you:

- Are a female breast cancer patient aged 20–70 years
- Have unilateral breast cancer surgery and clinically diagnosed unilateral lymphedema (Stage I or II, with at least one measurement point showing >2 cm and <8 cm difference)
- Completed chemotherapy and/or radiotherapy at least 3 months prior

- Are able to complete 12 treatment sessions and all assessments and sign this consent form

3. Exclusion Criteria
   You cannot participate if you:

   - Have recurrence or metastasis of breast cancer
   - Have severe upper limb infection (e.g., cellulitis)
   - Have uncontrolled heart failure, deep vein thrombosis (DVT), or severe peripheral vascular disease
   - Have Stage III lymphedema, bilateral lymphedema, or are taking medications affecting upper limb sweat glands
   - Have other significant upper limb musculoskeletal disorders, joint deformity, or surgical history
   - Are pregnant or otherwise unsuitable for participation

4. Recruitment
   Participants will be recruited from the outpatient Department of Rehabilitation at Far Eastern Memorial Hospital. The research team will evaluate your eligibility. The study will be explained to you in detail before you decide whether to participate.

5. Study Location
Department of Rehabilitation, Physical Therapy/Electrotherapy Room.

6. Your Responsibilities
You will attend 12 treatment sessions over 4 weeks (3 sessions per week).
Each session includes upper extremity exercise and pneumatic compression therapy.
You will complete assessments and questionnaires during the study and return one week after completing treatment for follow-up evaluation.
If you experience discomfort during treatment, please inform the research staff immediately. You may withdraw at any time without affecting your medical care.

III. Possible Risks and Management

This is a low-risk study. However, you may experience temporary muscle soreness or fatigue in the arm or shoulder.
Before each session, your physical condition will be assessed. If you experience discomfort during treatment or testing, the procedure will be stopped immediately, and appropriate care will be provided.
If the same discomfort occurs three times, the research team will discuss discontinuing your participation to ensure your safety.

IV. Expected Benefits

You may experience:

1. Reduced arm swelling

2. Improved shoulder range of motion

3. Improved ability to use your arm in daily activities

4. Improved overall quality of life

Your participation may also help healthcare professionals better understand whether combining exercise and pneumatic compression therapy is effective for treating BCRL and contribute to improving future clinical care.

V. Alternative Treatments

If you choose not to participate, you may still receive standard treatments, including complete decongestive therapy, compression garments, pneumatic compression therapy, or other rehabilitation interventions. Your medical rights will not be affected.

VI. Other Possible Risks or Benefits

Participation may require additional time and transportation. There is a small risk of mild discomfort or privacy concerns. Overall, this study is considered low risk.

VII. Compensation and Insurance

1. If injury occurs due to study procedures, Far Eastern Memorial Hospital will provide compensation in accordance with applicable regulations.
2. Necessary medical treatment for study-related injury will be provided without cost to you.
3. No additional compensation will be provided beyond legally required compensation and medical care.
4. By signing this consent form, you do not waive any legal rights.
5. This study does not carry liability insurance.

VIII. Data Storage and Confidentiality

Your data will be coded to protect your identity. The identification key will be stored separately. Data will only be used for research purposes and will not reveal your identity in any publication. Paper records will be stored in locked cabinets. Electronic data will be stored on a password-protected computer.

All data will be retained for five years after study completion and then securely destroyed.

IX. Withdrawal and Data Handling

You may withdraw at any time without affecting your medical care.
De-identified data collected before withdrawal may still be used for analysis. If you request data destruction, electronic data will be deleted, and paper documents will be destroyed according to hospital procedures.
Contact: Yung-Hsin Lin
Phone: +886-2-8966-7000 ext. 2232

X. Participant Rights

1. You will receive NT$500 transportation reimbursement after completing all sessions and follow-up.
2. You will be informed of any significant findings that may affect your willingness to continue participation.
3. For questions regarding your rights or concerns, you may contact:

   Institutional Review Board (IRB): +886-2-7728-2152
   Research Participant Protection Center: +886-2-7728-2546
   The IRB may contact you by phone to verify the consent process. You have the right to decline.
   You will receive a signed copy of this consent form.

XI. Confidentiality

Your data will be treated as confidential in accordance with legal requirements. Regulatory authorities and the hospital IRB may review your records under strict confidentiality.

XII. Conflict of Interest

This study is funded internally by Far Eastern Memorial Hospital. There is no commercial sponsorship and no related financial conflict of interest.

XIII. Signatures

I confirm that the study has been explained, including its purpose, procedures, risks, and benefits.
Principal Investigator / Co-Investigator Signature:_____
Date: _____
Research Staff Signature: _____
Date: _____

I have read and understood the information above. I voluntarily agree to participate.

Participant Signature: _____ Date: _____
Date of Birth: _____ Phone: _____
National ID Number: _____
Address: _____

Participant Information：

1. What is research?
   Research is conducted to answer scientific questions and is different from medical treatment. Participation is voluntary.
2. Institutional Review Board (IRB)
   The IRB ensures research meets ethical and scientific standards and protects participant rights.
3. Participant Rights
   You have the right to be informed, to decide freely, to ask questions at any time, to privacy and confidentiality, to retain your legal rights, and to be treated with dignity and respect.

For more information: https://www.femh-irb.org