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# Lymphoedema prevention in breast cancer

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| **Submission date**<br>24/09/2008 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[X] Results<br>[_] Individual participant data |
| **Registration date**<br>08/10/2008 | **Overall study status**<br>Completed | |
| **Last Edited**<br>15/09/2015 | **Condition category**<br>Cancer | |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
ID1124

## Study information

**Scientific Title**

Lymphoedema prevention in breast cancer: a simple blind, randomised, prospective clinical trial of the efficacy of early physical therapy

## Study objectives
Physical therapy could be an effective measure to prevent lymphoedema in patients undergoing breast cancer surgery including axillary lymph-node dissection.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Principe de Asturias Hospital's Human Research Ethics Committee approved the study in February 2005

## Study design
Prospective randomised single-centre controlled single-blinded trial

## Primary study design
Interventional

## Secondary study design
Randomised controlled trial

## Study setting(s)
Hospital

## Study type(s)
Treatment

## Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet (Spanish only)

## Health condition(s) or problem(s) studied
Breast cancer

## Interventions
Intervention group:
Physical including a manual lymph-drainage technique, progressive massage of the scar, and progressive active and action-assisted shoulder exercises started in conjunction with functional activities and proprioceptive neuromuscular facilitation without resistance and educational strategy including instruction with printed materials about the lymphatic system, concepts of normal load versus overload, lymphoedema source, the identification of possible precipitating factors, etc.

Control group:
Educational strategy including instruction with printed materials about the lymphatic system, concepts of normal load versus overload, lymphoedema source, the identification of possible precipitating factors, etc.

In order to use the same ES in both groups, a consensus was achieved before starting the study. In both groups patients were taken immediately after hospital discharge to either the EPT or to the CG programs. Both programs consisted of a three-week period with three visits per week. Each participant was assessed pre-operatively prior to randomisation and then post-operatively on hospital discharge (between day 3 and day 5), 4 weeks, and 3, 6 and 12 months after surgery.

This intervention study was conducted as a single-blinded randomised-controlled trial, as the physical therapist performing follow-up assessments remained blinded to the group allocation of the subjects.

### Intervention Type
Other

### Phase
Not Specified

### Primary outcome measure
Circumference measurements of the upper limbs using a standard 1 cm wide, at 5 cm intervals from the elbow fold pre-operatively prior to randomisation and then post-operatively on hospital discharge (between day 3 and day 5), 4 weeks, and 3, 6, 12 and 24 months after surgery.

### Secondary outcome measures
1. Pain, measured using the Visual Analogue Scale (VAS) score (0 = no pain, 10 = unbearable pain) pre-operatively prior to randomisation and then post-operatively on hospital discharge (between day 3 and day 5), 4 weeks, and 3, 6, 12 and 24 months after surgery
2. Range of shoulder abduction using a digital goniometer pre-operatively prior to randomisation and then post-operatively on hospital discharge (between day 3 and day 5), 4 weeks, and 3, 6, 12 and 24 months after surgery

### Overall study start date
15/05/2005

### Completion date
15/05/2009

## Eligibility

### Key inclusion criteria
1. Consecutive women diagnosed with breast cancer and undergoing unilateral surgery with axillary lymph-node dissection at the Principe de Asturias Hospital in Alcala de Henares, Madrid (Spain)
2. Aged 18 to 70 years old

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit

18 Years

### Sex
Female

### Target number of participants
120 women

### Key exclusion criteria
1. Without axillary lymph-node dissection or with bilateral breast cancer (BC)
2. Systemic disease
3. Locoregional recurrence
4. Any contraindication to physical therapy

### Date of first enrolment
15/05/2005

### Date of final enrolment
15/05/2009

## Locations

### Countries of recruitment
Spain

### Study participating centre
**Universidad de Alcala**
Alcala de Henares, Madrid
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## Sponsor information

### Organisation
The Carlos III Health Institute (Instituto de Salud Carlos III) (Spain)

### Sponsor details
C/ Sinesio Delgado no 6
Pabellon 6
Madrid
Spain
28029

### Sponsor type
Government

**Website**
http://www.isciii.es/htdocs/index.jsp

**ROR**
https://ror.org/00ca2c886

# Funder(s)

**Funder type**
Government

**Funder Name**
The Carlos III Health Institute (Instituto de Salud Carlos III) (Spain) (ref: PI071124)

# Results and Publications

**Publication and dissemination plan**
Not provided at time of registration

**Intention to publish date**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**
Not provided at time of registration

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 12/01/2010 | | Yes | No |
| Results article | results | 01/02/2015 | | Yes | No |