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Health-related quality of life in postmastectomy lymphedema patients

Submission date	Recruitment status	[_] Prospectively registered
27/03/2016	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
07/04/2016	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
25/09/2017	Cancer	

Plain English summary of protocol

Background and study aims
Lymphedema is a long term (chronic) health condition that results in swelling of body tissues, most commonly developing in the arms or legs. It is caused by a problem with the lymphatic system, a network of vessels and glands important in fighting infection and removing excess fluid from body tissues. Secondary lymphedema is caused by damage to the lymphatic system or issues with the draining of excess fluid; this is often due to an infection, injury or cancer treatment. The condition is
common in women treated for breast cancer, the damage often the result of surgery or radiotherapy. The swelling (edema) commonly affects the arm, leading to discomfort, reduced arm movements, pain and diminished quality of life. Quality of life of a patient with lymphedema after a mastectomy (surgery to remove the breast) is an important consideration when treating breast cancer survivors. The aim of this study is to see whether an exercise and home program in addition to conventional treatment results in a better quality of life among postmastectomy lymphedema patients.

Who can participate?
Women aged between 50 and 70 that have had a mastectomy for breast cancer and have developed lymphedema as a result.

What does the study involve?
Participants are allocated to one of two groups depending on whether are assessed for the study on Monday or Wednesday. Those assessed on Monday are assigned to the conventional therapy (CT) group. Those assessed on Wednesday are assigned to the complete decongestive therapy (CDT) group. Participants in the CT group are given manual lymphatic drainage, a low elastic compression garment, gleno-humeral mobilization (a technique for moving the shoulder joint) and deep breathing exercises. Participants in the CDT group are given manual lymphatic drainage, a compression garment, remedial exercises and a home program. Both groups receive treatment 5 times a week for 6 weeks. Their pain and quality of life are assessed at the start of the study and then 4 and 6 weeks into the study.

What are the possible benefits and risks of participating?
The participation is voluntary and there are no potential risks of participation. Benefits may include an improvement in quality of life after treatment.

Where is the study run from?
Maharishi Markendeshwar University Hospital (India)

When is the study starting and how long is it expected to run for?
June 2013 to July 2014

Who is funding the study?
King Saud University (Saudi Arabia)

Who is the main contact?
Mrs Syamala Buragadda

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
RGP-VPP-256-1

Study information

Scientific Title
Effect of complete decongestive therapy and home program on health-related quality of life in post mastectomy lymphedema patients.

Study objectives
Remedial exercises and home program in addition to manual lymphatic drainage and compression bandaging results in better quality of life among postmastectomy lymphedema patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Maharishi Markendeshwar University Ethical Committee, Haryana, 07/09/2013, ref: MMU/MMIPR /013

Study design
This is a mixed factorial design that includes both between and within subjects variables

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Postmastectomy lymphedema

Interventions
Sixty participants were divided into two groups: conventional treatment (CT) group and complete decongestive therapy (CDT) group.

A systematic random sampling procedure was used to include the participants into the study. Volunteer participants assessed on Monday were assigned to the conventional therapy (CT) group, whereas participants assessed on Wednesday were assigned to the complete decongestive therapy (CDT) group. Each group comprised of 30 participants.

1. Conventional therapy (CT) group participants received manual lymphatic drainage, low elastic compression garment, gleno-humeral mobilization and deep breathing exercises
2. Complete Decongestive Therapy (CDT) group received manual lymphatic drainage, compression garment worn 23 hours daily, remedial exercises and a home program

Both groups received treatment 5 times a week for 6 weeks.

Intervention Type
Mixed

Primary outcome(s)
1. Pain measured using the visual analogue score (VAS) at baseline, 4th week and 6th week
2. Health-related Quality of Life, evaluated with the EORTC QLQ C30 and EORTC QLQ-BR23 questionnaires

Measurements were taken at baseline, 4 and 6 weeks.

Key secondary outcome(s))
Quality of life measured using European Organization of Research and Treatment for Cancer quality of life questionnaire (EORTC QLQ-C30) and the EORTC QLQ-BR23 breast cancer-specific questionnaire.

Measured at baseline, 4th week and 6th week.

Completion date
01/07/2014

Eligibility

Key inclusion criteria
1. Females aged between 50 and 70 years
2. Unilateral mastectomy for stage I and II breast cancer
3. Completed radiotherapy and chemotherapy sessions
4. Developed lymphedema more than 3cm compared to contralateral extremity

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
1. Primary lymphedema
2. Bilateral lymphedema
3. Pulmonary edema
4. Congestive heart failure
5. Contraindications limiting therapy

Date of first enrolment
01/07/2013

Date of final enrolment
01/04/2014

Locations

Countries of recruitment
India

Study participating centre
Maharishi Markendeshwar University Hospital
Mullana University Road
Mullana
Ambala

Haryana
India
133207

Sponsor information

Organisation
King Saud University

ROR
https://ror.org/02f81g417

Funder(s)

Funder type
University/education

Funder Name
King Saud University

Alternative Name(s)
, KSU

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Saudi Arabia

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Results article	results	04/05/2016		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes