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BEWEL (Breast - Evaluation of Weight and Exercise for Lymphoedema): a feasibility study to compare four different weight control and exercise programmes for women with breast cancer related lymphoedema

Submission date
09/08/2012

Recruitment status
No longer recruiting

Registration date
10/10/2012

Overall study status
Completed

Last Edited
20/05/2024

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims:
Arm swelling (lymphoedema) affects 1 in 5 breast cancer patients. Weight control and exercise may help to reduce arm swelling and improve wellbeing, but are not part of usual treatment. This study aims to assess the benefits of weight control and exercise for reducing arm swelling and whether this advice is best delivered in supervised classes or as a home based programme.

Who can participate?
Women with lymphoedema who are being managed by the Lymphoedema Team at The Nightingale Centre. We recruited 60 women, who live in the Greater Manchester or Cheshire area and are otherwise in good health.

What does the study involve?
All participants will be asked to attend a class at The Nightingale Centre with our trial physiotherapist who will reinforce self management of lymphoedema including skincare and, arm exercises. At this visit the participants were weighed and had the volume and shape of their arms measured. The amounts of fluid in their arms were measured using a bioimpedance device. The bioimpedance machine passes an extremely small electrical current through arms and legs and measures the resistance to the flow of this current. The participants did not feel anything when the measurement is carried out as the current is very small.
The participants were asked to re-attend 2-3 weeks later when they were allocated to one of four different weight control and exercise programmes:
Group 1: Received comprehensive written diet and exercise information
Group 2: 12 weekly exercise and diet education classes
Group 3: 12 week home based diet and exercise programme

Group 4: 12 week home based exercise programme
Allocation to the groups was done by chance (randomly) which means neither the participants nor the study co-ordinators will be able to choose which group they joined.

What are the possible benefits and risks of participating?
The recommended diet and exercise programme are known to be safe for breast cancer patients. The diet meets all nutritional needs. The exercise programmes are supervised by a specialist physiotherapist and participants received individualised advice to ensure they exercised at a safe level. The DXA scan exposed participants to a very low dose of x-rays. Each scan is the equivalent to one tenth of the dose of a standard chest x-ray, equivalent to one day of normal background radiation.
All four groups were encouraged to lead a healthy active lifestyle and eat a healthy diet. Following this advice promoted weight loss which should improve future health and well being. There were no known risks of participating,

Where is the study run from?
Nightingale Centre and Genesis Prevention Centre, Wythenshawe Hospital, Manchester, UK

When is study starting and how long is it expected to run for?
The study started in April 2011 and recruitment was completed in December 2011

Who is funding the study?
University Hospital of South Manchester Research Endowment Fund

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
R&D Ref 2011BR003

Study information

Scientific Title
BEWEL (Breast - Evaluation of Weight and Exercise for Lymphoedema): A randomised controlled feasibility study to compare four different weight control and exercise programmes for women with breast cancer related lymphoedema

Acronym
BEWEL

Study objectives
This pilot study aims to determine the relative efficacy and acceptability of two different weight control and upper body arm exercise programme (home based and supervised) and an upper body arm exercise only intervention as compared to usual care for overweight women with breast cancer related lymphoedema. This study will inform which of the interventions should be tested in the future large scale randomised study.

Primary research question:
To assess any changes in arm swelling achieved with our interventions and usual care groups measured with a perometer.

Secondary research questions:
1. To assess any changes in arm volume achieved with our interventions and usual care groups measured with a multi-frequency bioimpedance electrical analysis (BEA)
2. To test the uptake and acceptability of two different weight control and upper body arm exercise programmes (home based and supervised) and an upper body arm exercise only intervention as compared to usual care.
3. To assess any changes in arm function (questionnaire and range of movement), and quality of life in the three intervention groups as compared with the usual care group.
4. To validate changes in total body fat assessed by a total body multifrequency 8-electrode BEA meter (Tanita MC180) compared to the criterion method of total body DXA amongst patients with arm lymphoedema to assess whether BEA can be used to assess changes in body fat in these patients.
5. To validate 2 self report methods for assessing physical activity [7 day physical activity diaries and the Recent Physical Activity Questionnaire (RPAQ)](1;2) as compared to the criterion method of accelerometers in this population to assess whether self reports can be used in the future study.
6. To determine whether perometer or multi-frequency bioimpedance electrical analysis (BEA) is best for monitoring the interventions. The size of changes in arm swelling with the perometer achieved with the interventions will inform the required sample size for the future definitive randomised study.
7. To assess changes in systolic and diastolic blood pressure with the 3 interventions as compared to usual care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North West 10 Research Ethics Committee Greater Manchester North ,24/01/ 2011, ref: 11 /H1011/2

Study design
Single-centre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Lymphoedema, Breast Cancer

Interventions
Group 1 Control standard written advice
This group will receive comprehensive standard written advice outlining the importance of weight control, a healthy diet, and the importance of cardiovascular exercise (Healthy Living with Breast Cancer booklet, UHSM). At the end of the trial participants in the control group will receive individualised advice from the trial dietitian and physiotherapist.

Group 2 - Supervised weight control plus upper body exercise programme
This group receive initial individualised diet and cardiovascular advice from the study dietitian and physiotherapist. Women are subsequently invited to attend 12 weekly group exercises and diet education classes at the gym facility at UHSM delivered. These sessions comprise a warm up, 20-30 minutes cardiovascular exercise (50-80% age-adjusted heart rate maximum) and progressive stretch and flexibility exercises to improve arm mobility, strength and improve posture. The diet and behaviour change educational component based on the trans theoretical model of behaviour change will be delivered by the study dietitian and covers topics including healthy cooking, motivation, problem solving, body image.

Group 3 Home based weight control plus upper body exercise programme
This group receive initial individualised diet and cardiovascular from the study dietitian and physiotherapist. The physiotherapist will also demonstrate the key exercises for the upper body exercise programme and provide a booklet for a progressive 12 week programme of strengthening, toning and flexibility exercises to increase arm and shoulder mobility. Individual diet and exercise goals and recommendations will be reinforced with bi-weekly phone calls (from either study dietitian/ physiotherapist). These calls will check compliance, changes in diet,

physical activity and address individual problems. Subjects will mailed a summary of key motivational, behavioural, diet and exercise issues after each call. This group will also receive 6 bi weekly mailings to include all of the diet, exercise and weight control information received by Group 2 in their supervised sessions.

Group 4 Upper body exercise only
The physiotherapist will demonstrate the key exercises for the upper body exercise programme and provide a booklet for a progressive 12 week programme of strengthening, toning and flexibility exercises to increase arm and shoulder mobility. Progress will be reinforced with bi-weekly phone calls from the study physiotherapist. These calls will check compliance and address individual problems.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Changes in excess arm volume in affected arm assessed with a perometer (Pero-Systems 350S) assessed at baseline and 12 weeks.

Secondary outcome measures
1. Changes in excess arm volume in affected arm assessed with multi frequency bioelectrical impedance (L-DEX U400 bioimpedance spectroscopy device)
2. Uptake to the trial
3. Acceptability and adherence to the supervised and home based weight loss and exercise only interventions, and any adverse effects associated with the programmes
4. Change in weight, body fat and fat free mass (FFM) (DXA) waist and hip circumferences assessed with DXA and multifrequency 8-electrode BIA method (Tanita MC180)
5. Change in arm mobility, function (quick DASH)
6. Change in quality of life including arm morbidity and fatigue sub scales (FACT-B+ 4, FACT F)
7. Change in hand grip strength
8. Change in range of movement in affected arm and shoulder, elbow, wrist and cervical spine; flexion, abduction, extension, adduction, medial and lateral rotation
9. Change in dietary intake (7 -day diet diary)
10. Change in levels of physical activity assessed with a 7 day activity diary, Recent Physical Activity Questionnaire (RPAQ) and 7 day accelerometer

Overall study start date
05/04/2011

Completion date
30/11/2011

Eligibility

Key inclusion criteria
1. Women receiving maintenance therapy for breast cancer related arm lymphoedema i.e. compression sleeves + / - manual lymphatic drainage
2. Overweight/obese BMI > 25 Kg /m2

3. Stable lymphoedema over the past 3 months defined as:
3.1. No intensive therapy (i.e. no manual decongestive treatment)
3.2. No recorded 10% change in volume of the affected arm lasting > 7 days (assessed with perometer)
3.3. No lymphoedema related infections (cellulitis) requiring antibiotics
4. Had lymphoedema sleeve reassessed by lymphoedema practitioner within the last 3 months
5. Any age
6. Able to understand written instructions and record diet diaries
7. No chemotherapy in previous 3 months or radiotherapy in the previous 12 months
8. Live within Greater Manchester / Cheshire area to maximise uptake and retention to programme and study
9. Sedentary < 40 minute moderate exercise / week
10. Willing to be randomised to the 4 treatment groups
11. Written informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
60

Key exclusion criteria
1. Metastatic disease or axillary recurrence
2. Physical/psychiatric condition which limits compliance to diet and exercise interventions
3. Eastern Cooperative Oncology Group (ECOG) performance status < 2
4. Already losing weight or following exercise programme
5. Plans for surgery during the study period
6. Pace maker

Date of first enrolment
05/04/2011

Date of final enrolment
30/11/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Nightingale Centre and Genesis Prevention Centre
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Sponsor information

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Sponsor type
University/education

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ROR
https://ror.org/00he80998

Funder(s)

Funder type
University/education

Funder Name
University Hospital of South Manchester Research Endowment Fund (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

30/09/2020

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		17/05/2024	20/05/2024	Yes	No