ISRCTN35358984 https://doi.org/10.1186/ISRCTN35358984

Exercise to prevent shoulder problems in patients undergoing breast cancer treatment

Submission date 23/01/2015	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 04/02/2015	**Overall study status** Completed	
Last Edited 02/03/2023	**Condition category** Cancer	

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-to-prevent-shoulder-problems-after-breast-cancer-treatment-prosper

Study website
www.warwick.ac.uk/go/prosper

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 13/84/10

Study information

Scientific Title
The PRevention Of Shoulder ProblEms Study (PROSPER): a randomised controlled clinical trial comparing physiotherapy-led exercise versus usual care in women at high risk of shoulder problems after breast cancer surgery

Acronym
PROSPER

Study objectives
The hypothesis for the study is that an early supervised exercise programme delivered to women at high risk of subsequent shoulder problems after breast cancer surgery, can improve upper arm function and health-related quality of life, reduce disability, pain and other adverse events, 12 months after treatment.

The overall aim of the study is to investigate the clinical and cost-effectiveness of early supervised exercise compared to usual care, on outcomes of shoulder/arm function, chronic pain and health-related quality of life after treatment for breast cancer.

More details can be found at: http://www.nets.nihr.ac.uk/projects/hta/138410
Protocol can be found at: http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0010/136999/PRO-13-84-10.pdf

Ethics approval required
Old ethics approval format

Ethics approval(s)
West Midlands – Solihull Research Ethics Committee, 20/07/2015, ref: 15/WM/0224

Study design
Multicentre randomised controlled clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Prevention

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

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

Interventions
Intervention:
A physiotherapy-led exercise programme incorporating behavioural strategies. The intervention package will involve different phases to encourage early restricted movement, progression of exercises to incorporate range of motion and strengthening, followed by a maintenance phase to ensure that flexibility and strength are maintained over time.

Control group:
Best practice usual care.

Intervention Type
Behavioural

Primary outcome measure
Arm, shoulder and hand function measured using the Disability of the Arm, Shoulder and Hand (DASH) questionnaire at 12 months (0=no functional problems, 100=maximal problems)

Secondary outcome measures
1. Assessment of arm, shoulder and hand function (DASH) subscales measured at baseline, 6 and 12 months
2. Health-related QoL as measured by SF-12 & EQ-5D-5L, measured at baseline, 6 and 12 months
3. Acute and chronic postoperative pain measured using pain items from DASH and Doleur Neuropathique (DN4) to capture neuropathic pain, measured at baseline, 6 weeks, 6 and 12 months
4. Surgical site infection measured at 6 weeks (clinical criteria)
5. Postoperative symptoms including indicators of lymphoedema at 6 and 12 months (DASH and

lymphoedema screening items [Armer et al., 2003])
6. Healthcare resource use measured at 6 and 12 months (self-report)

Overall study start date
01/03/2015

Completion date
14/03/2020

Eligibility

Key inclusion criteria
Inclusion criteria as of 31/03/2016:
1. Women, age > 18 years
2. Histologically confirmed invasive or non-invasive primary breast cancer scheduled for surgical excision
3. Considered high risk of developing shoulder problems after surgery, defined by one or more of the following:
3.1. Planned axillary node clearance (ANC)
3.2. Planned radiotherapy (RT) to axilla and/or supraclavicular
3.3. Existing shoulder problems (based upon PROSPER screening criteria)
3.4. Obesity defined as BMI >30
3.5. Any subsequent axillary surgery related to primary surgery e.g. ANC conducted after sentinel lymph node biopsy
4. Willing and able to comply with the protocol
5. Written informed consent
6. Any later decision (made within 6 weeks of surgery) to refer for RT to axilla and/or supraclavicular

Note:
1. Women who have had previous breast surgery (e.g. excision of benign tumour or breast cyst) are eligible for invitation
2. Women who have had previous contralateral (opposite side) mastectomy are eligible for invitation

Original inclusion criteria:
1. Female ≥ 18 years, no upper age limit
2. Histologically confirmed invasive or non-invasive early breast cancer scheduled for surgical excision of breast cancer
3. Predicted high risk of developing shoulder problems post breast cancer surgery (existing shoulder problems/planned axillary surgery/radiotherapy)
4. Willing and able to comply with the protocol

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
350

Total final enrolment
392

Key exclusion criteria
Exclusion criteria as of 31/03/2016:
1. Males
2. Women having immediate reconstructive surgery
3. Women having sentinel lymph node biopsy (SLNB) with or without breast surgery unless have other high risk criteria
4. Women having bilateral breast surgery
5. Evidence of known metastatic disease at time of recruitment

Original exclusion criteria:
1. Males with breast cancer
2. Major psychiatric disorder or psychological disorder, including substance abuse that would preclude engagement with the programme
3. Detectable metastatic disease
4. Planned immediate reconstructive surgery
5. Bilateral breast surgery

Date of first enrolment
01/10/2015

Date of final enrolment
31/07/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University Hospitals Coventry & Warwickshire NHS Trust
Clifford Bridge Road
Coventry
United Kingdom
CV2 2DX

Study participating centre
Oxford University Hospitals NHS Foundation Trust
Churchill Hospital
Old Road
Oxford
Oxford
United Kingdom
OX3 7LE

Study participating centre
The Royal Wolverhampton NHS Trust
New Cross Hospital
Wednesfield Road
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WV10 0QP

Study participating centre
Walsall Healthcare NHS Trust
Walsall Manor Hospital
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Study participating centre
Chesterfield Royal Hospital NHS Foundation Trust
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Study participating centre
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Study participating centre

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Study participating centre
Birmingham City Hospital, Sandwell & West Birmingham NHS Trust
Birmingham City Hospital
Dudley Road
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B18 7QH

Study participating centre
Dorset County Hospital NHS Foundation Trust
Dorset County Hospital
Williams Avenue
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DT1 2JY

Study participating centre
George Elliot Hospital NHS Trust
College Street
Nuneaton
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CV10 7DJ

Study participating centre
Hereford County Hospital Wye Valley NHS Trust
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Study participating centre
Macclesfield District General Hospital
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United Kingdom
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Study participating centre
Milton Keynes University Hospital NHS Foundation Trust
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MK6 5LD

Study participating centre
Musgrove Park Hospital
Taunton & Somerset NHS Foundation Trust
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Study participating centre
Queen Alexandra Hospital
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Study participating centre

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Study participating centre
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Sponsor information

Organisation
University of Warwick

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University House
Kirby Corner Road
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CV4 8UW

Sponsor type
University/education

Website
http://www2.warwick.ac.uk/

ROR
https://ror.org/01a77tt86

Organisation
University Hospitals Coventry & Warwickshire NHS Foundation Trust

Sponsor details
University Hospital
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Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The results of this trial will inform clinical practice on the identification and management of women at risk of shoulder conditions after breast cancer surgery. In addition to the main HTA report, results will be published in peer-reviewed journals and presented at scientific meetings. We intend to publish the trial protocol in an open access journal (e.g., BioMed Central or BMJ Open).

Intention to publish date
30/06/2020

Individual participant data (IPD) sharing plan
Not provided at registration.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	23/03/2018		Yes	No
Other publications	intervention development	18/06/2018		Yes	No
Results article	qualitative results	11/05/2021	13/05/2021	Yes	No
Results article		10/11/2021	12/11/2021	Yes	No
Plain English results		23/11/2021	23/11/2021	No	Yes
Results article		01/02/2022	01/03/2022	Yes	No
Plain English results			02/03/2023	No	Yes
HRA research summary			28/06/2023	No	No