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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

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Additional identifiers

Protocol serial number
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

Primary study design
Interventional

Study design
Multicentre randomised controlled clinical trial

Study type(s)
Prevention

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(s)
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)

Key secondary outcome(s)
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)

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
Female

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
United Kingdom

England

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
Wolverhampton
United Kingdom
WV10 0QP

Study participating centre
Walsall Healthcare NHS Trust
Walsall Manor Hospital
Moat Road
Walsall
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WS2 9PS

Study participating centre
Chesterfield Royal Hospital NHS Foundation Trust
Calow
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United Kingdom
S44 5BL

Study participating centre
The Hillingdon Hospitals NHS Foundation Trust
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United Kingdom
UB8 3NN

Study participating centre
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BB22 3HH

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Royal Blackburn Hospital
Haslingden Road
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Study participating centre

Birmingham City Hospital, Sandwell & West Birmingham NHS Trust
Birmingham City Hospital
Dudley Road
Birmingham
United Kingdom
B18 7QH

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

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

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Victoria Road
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SK10 3BL

Study participating centre

Milton Keynes University Hospital NHS Foundation Trust
Standing Way
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United Kingdom
MK6 5LD

Study participating centre
Musgrove Park Hospital
Taunton & Somerset NHS Foundation Trust
Parkfield Road
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TA1 5DA

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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

ROR
https://ror.org/01a77tt86

Organisation
University Hospitals Coventry & Warwickshire NHS Foundation Trust

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

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

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

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?
Results article	qualitative results	11/05/2021	13/05/2021	Yes	No
Results article		10/11/2021	12/11/2021	Yes	No
Results article		01/02/2022	01/03/2022	Yes	No
Protocol article	protocol	23/03/2018		Yes	No

HRA research summary			28/06/2023	No	No
Other publications	intervention development	18/06/2018		Yes	No
Plain English results		23/11/2021	23/11/2021	No	Yes
Plain English results			02/03/2023	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes