

# Exercise to prevent shoulder problems in patients undergoing breast cancer treatment

<b>Submission date</b> 23/01/2015	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 04/02/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 02/03/2023	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## 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>

## Contact information

### Type(s)

Public

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### Type(s)

Scientific

### Contact name

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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](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

## **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  $\geq$  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  
United Kingdom  
WS2 9PS

**Study participating centre**  
**Chesterfield Royal Hospital NHS Foundation Trust**  
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S44 5BL

**Study participating centre**  
**The Hillingdon Hospitals NHS Foundation Trust**  
Hillingdon Hospital  
Pield Heath Road  
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**Study participating centre**  
**Royal Blackburn Hospital**  
East Lancashire Hospitals NHS Trust  
Haslingden Road  
Blackburn  
United Kingdom  
BB22 3HH

**Study participating centre**  
**East Lancashire Hospitals NHS Trust**  
Royal Blackburn Hospital  
Haslingden Road  
Blackburn  
United Kingdom  
BB2 3HH

**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  
Dorset  
United Kingdom  
DT1 2JY

**Study participating centre**

**George Elliot Hospital NHS Trust**

College Street  
Nuneaton  
Warwickshire  
Nuneaton  
United Kingdom  
CV10 7DJ

**Study participating centre**

**Hereford County Hospital Wye Valley NHS Trust**

Stonebow Road  
Hereford  
United Kingdom  
HR1 2BN

**Study participating centre**

**Macclesfield District General Hospital**

East Cheshire NHS Trust  
Victoria Road  
Macclesfield  
United Kingdom  
SK10 3BL

**Study participating centre**

**Milton Keynes University Hospital NHS Foundation Trust**

Standing Way  
Milton Keynes  
United Kingdom  
MK6 5LD

**Study participating centre**

**Musgrove Park Hospital**

Taunton & Somerset NHS Foundation Trust  
Parkfield Road  
Taunton  
Somerset  
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**Study participating centre**

**Queen Alexandra Hospital**

Portsmouth Hospitals and Solent NHS Trust  
Southwick Hill Road  
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**Study participating centre**

**Royal Cornwall Hospitals NHS Trust**

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**Study participating centre**

**Royal Stoke University Hospitals**

Newcastle Road  
Stoke-on-Trent  
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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?
<a href="#">Results article</a>	qualitative results	11/05/2021	13/05/2021	Yes	No
<a href="#">Results article</a>		10/11/2021	12/11/2021	Yes	No
<a href="#">Results article</a>		01/02/2022	01/03/2022	Yes	No
<a href="#">Protocol article</a>	protocol	23/03/2018		Yes	No

<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Other publications</a>	intervention development	18/06/2018		Yes	No
<a href="#">Plain English results</a>		23/11/2021	23/11/2021	No	Yes
<a href="#">Plain English results</a>			02/03/2023	No	Yes
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes