I want to take part, what do I do next?

If you are interested in this trial or an interview, please contact your research team (named below). They will confirm if you are eligible for the trial and give you full information on how to participate.

(Label or stamp with site's contact information)

For more information:

http://www.warwick.ac.uk/go/prosper

THANK YOU FOR YOUR TIME

ISRCTN: 35358984

Participant Information Flyer v2.0 18.11.15

WARWICK
CLINICAL TRIALS UNIT

With your help we can make the PROSPER study a success and find out more about improving recovery after breast cancer treatment.

This trial is run by The University of Warwick and University Hospital Coventry and Warwickshire in collaboration with Warwick Clinical Trials Unit.

This project was funded by the National Institute for Health Research's HTA Programme (project number 13/84/10). The clinical and scientific rationale has been reviewed by national and international experts.

University Hospitals Coventry and Warwickshire NHS Trust

Have you just been diagnosed with breast cancer AND:

Are you due to have surgery in your axilla (armpit)?

Are you due to have radiotherapy to your armpit?

Do you have shoulder problems?

If so, you may be eligible to take part in the PROSPER Study

prosper
PREVENTION OF SHOULDER PROBLEMS TRIAL

What is the purpose of the study?

Some patients having surgery to the axilla (armpit) can experience pain, stiffness and difficulty returning to usual activities. Currently, we do not know the best approach to care for these patients. It may be that exercise can help prevent and treat shoulder problems after breast cancer surgery.

Women having an axillary 'clearance', where most or all of the lymph nodes are fully removed, may be at greater risk of shoulder problems.

PROSPER is a randomised controlled trial to investigate the most effective way of guiding exercise in women who have had breast cancer surgery.

The results will inform national guidelines about the best way to follow-up and support women who have had surgery for breast cancer.

What is a randomised controlled trial?

This is a trial where people are chosen at random (by chance alone) to be in one of two groups. Neither you nor your doctor will be able to decide which group you are in. The two groups of people are compared to find out any differences between the groups.

Am I eligible to take part?

You may be able to enter this trial if you have just been diagnosed with breast cancer and:

- You are due to have an axillary clearance – where your lymph nodes are being completely removed (not a biopsy)

OR

- You are due to have radiotherapy to your armpit

OR

- You have a history of shoulder problems (e.g. stiffness, arthritis, frozen shoulder)

What treatment will I receive?

Women allocated to **Group 1** will be given usual care of information leaflets describing exercise after your operation.

Women allocated to **Group 2** will be offered an exercise programme, supported by a physiotherapist. You will be offered up to six appointments with a trained physiotherapist soon after your operation.

prosper

PREVENTION OF SHOULDER PROBLEMS TRIAL

How long does the trial last?

You will be asked to stay in the study for one year. You will be asked to complete some questionnaires by post. These questionnaires will ask about your arm movement, your daily activities and quality of life. They will take about 15 – 20 minutes to complete.

The results of this study will help us to investigate the best way of caring for women at risk of shoulder problems as a result of their breast cancer treatment.

Interview study

If you are eligible for the trial, you may also be invited to have a short chat with a researcher. Even if you don't want to take part in the trial, it would be helpful to find out more about your reasons. This may help us improve how we approach women about the trial.

Do I have to take part?

No. It is up to you to decide whether you want to take part. You are free to change your mind and withdraw from the trial at any time and you do not have to give a reason why. Your decision

will not affect the care you receive from the NHS in any way. We would however, with your consent, continue to use data already collected from you.