TO BE PRINTED ON HOSPITAL HEADED PAPER

Patient Information Sheet: PROSPER

PROSPER: PRevention **O**f **S**houlder **P**robl**E**ms T**R**ial

Patient Information Sheet

We would like to invite you to take part in a research study called PROSPER which is being carried out at your local hospital. This information sheet explains why the research is being done and what it will mean for you. Please take the time to read it carefully and feel free to talk it over with friends, relatives and your GP. Please ask us if there is anything that is not clear or you would like more information.

1. What is the purpose of the study?

We are looking at the recovery of women after treatment for breast cancer. You are undergoing treatment for your breast cancer which may include surgery and/or radiotherapy. These treatments can sometimes affect the shoulder area and arm which means that, for some women, it can take longer to return to their normal daily activities. The aim of this study is to find out the best way to prevent and treat shoulder problems after breast cancer treatment.

The standard NHS care during breast cancer treatment is to give written information leaflets that include advice and exercises to help with recovery. We want to find out whether a prescribed exercise programme, which is led by a physiotherapist, can improve recovery and return to usual activities.

2. What is being tested?

We are testing whether arm and shoulder exercises that are prescribed and supported by a trained physiotherapist can help improve recovery and return to usual activities after breast cancer treatment. This will be compared with usual NHS care which is advice about exercise given in information leaflets from the breast care team.

3. Why have I been invited?

You have been invited because you are having cancer treatment which may include surgery to the breast and/or axilla (armpit) or radiotherapy. You may have been invited because the breast care team may think you might be at risk of shoulder problems after your cancer treatment. Our aim is to recruit 350 women from different Breast Cancer Centres around the UK. Your hospital is taking part in the study which is why you have been given this leaflet.

4. Do I have to take part?

No. It is entirely up to you whether or not to take part. If you decide not to take part, your decision will be respected and your medical care will not be affected in any way. If you do take part, you will be asked to sign a Consent Form. If you change your mind, you can withdraw at any time, without giving a reason. This information sheet is yours to keep whatever you decide.

5. What will happen to me if I take part?

All women taking part will be allocated to one of two treatment groups using a process called randomisation. This means that a computer is used to randomly allocate which treatment you will receive. This process ensures that the two treatment groups are compared fully and fairly. You will have an equal chance of being in either treatment group. Neither you nor your treating doctor can choose which group you will be in.

Group 1: Usual Care (Advice Leaflets)

Usual care in the NHS is to provide written information about exercises to do after your treatment. If you are allocated to this group then you will receive written information given to you by the breast care team. These leaflets have been produced by Breast Cancer Care and are used within the NHS. One leaflet explains your surgery and the other leaflet describes exercises for you to do at different stages after your surgery. You will attend all the usual follow up appointments and support that is offered at your hospital.

Group 2: Exercise programme

In addition to the written information leaflets from Breast Cancer Care, you will also be invited for an assessment by a trained physiotherapist. The first session with your physiotherapist will last approximately 45 minutes. During this appointment, your physiotherapist will prescribe a programme of arm and shoulder exercises and will arrange other follow-up appointments to review your progress. You may have up to a total of 6 face-to-face or telephone appointments with the physiotherapist if you want or need them. You should have at least 3 face-to-face appointments.

6. What do I have to do?

If you take part in the trial, you will be asked to fill in some questionnaires about how you are feeling in general, about your arm and shoulder movement, and about your usual daily activities. We will ask you to complete these questionnaires at the start of the study, and at 6 and 12 months, and to return them via a freepost envelope. We will also ask you about your pain levels and wound healing at 6 weeks, either by post or by telephone. With your permission, we may send you a mobile text message to inform you that a questionnaire is due.

7. What else might I be asked to do?

We would also like to conduct an interview sub-study with a small group of approximately 20 women. You may be invited for an interview. This would involve an individual interview with a researcher or a small group discussion - called a focus group. The focus group will include other women who are at a similar stage after treatment. If you would like to take part in the interview sub-study we will ask you to complete a separate consent form. We will also provide you with a separate information sheet. Patients in both Group 1 and Group 2 can take part in the interview study. You can still take part in the interview study only, even if you decide not to take part in the main trial.

8. What are the potential disadvantages and risks of taking part in PROSPER?

Occasionally people experience some discomfort after taking up new exercises for the first time. If you are not used to stretching or strengthening exercises then you might experience some muscle soreness initially. This is a normal response and is not usually long lasting. If you are allocated to Group 2, you will need to attend your local hospital for your physiotherapy appointments. Wherever possible, your physiotherapist will arrange your follow-up appointment on the day of your other clinic appointments to reduce inconvenience and extra travel.

9. What are the possible benefits of taking part?

We hope that being in either of the groups will help you. However, there is no guarantee that you as an individual will benefit directly from taking part in PROSPER. The information gained from this study should help improve the care of women at risk of shoulder problems after breast cancer surgery in the future.

10. What happens when the research study stops?

After you have completed your 12 month period in the PROSPER trial, your hospital will continue to treat you. If appropriate, they will refer you onto other health care professionals.

11. Will my taking part in the study be kept confidential?

Yes. All information collected in the study will be confidential at all times and in compliance with the Data Protection Act 1998. You will be given a unique study number, and we will use this and your initials only in communication about you. All information will be kept in a secure place and only selected personnel involved in the study will have access to it. For some patients, we will request data on your NHS treatment from the Health and Social Care Information Centre. We will ask for your consent to do this.

12. What if relevant new information becomes available?

Sometimes during the course of a research study, new information becomes available about the treatment that is being studied. If this happens, your doctor or researchers will tell you and discuss with you whether you want to continue in the study. It will be up to you to decide whether or not to continue. If you decide not to continue in the study, your doctor will arrange your future care. If you do continue, you may be asked to sign an updated Consent Form.

13. What will happen if I don't want to carry on with the study?

You can withdraw your participation from the study at any time and without giving a reason. Information already collected may still be used unless you request that it should not be used. If you decide to withdraw it will have no impact on your future care.

14. What will happen to the results of the research study?

The data will be analysed and the results will be used to write a research report and journal articles for doctors, physiotherapists and other health professionals. You will not be identified in person in any report about the study or in the study results.

15. Who is organising and funding the research?

The person responsible for the research is Dr Julie Bruce from the Warwick Clinical Trials Unit at the University of Warwick. The University of Warwick and University Hospitals Coventry and Warwickshire NHS Trust are joint sponsors for the research. The study is paid for by the National Institute for Health Research (NIHR), who have identified this as important research for the NHS. It is funded by the Health Technology Assessment programme.

16. Who has reviewed the study?

The study has been approved by the NIHR and a UK National Research Ethics Committee. Study materials have been reviewed and approved by patient representatives.

17. What if there is a problem?

This study is covered by the University of Warwick's insurance and indemnity cover. If you have an issue, please contact the Chief Investigator of the study by using the contact details at the bottom of this page.

18. Who should I contact if I wish to make a complaint?

Any complaint about the way you have been dealt with during the study or any possible harm you might have suffered will be addressed. Please address your complaint to the person below, who is a senior University of Warwick official entirely independent of the PROSPER study:

Director of Delivery Assurance
Registrar's Office, University House
University of Warwick, Coventry CV4 8UW
complaints@warwick.ac.uk
024 7657 4774

19. How can I contact the study team?

The contact details for your local PROSPER team are below – they are your first point of contact if you have any questions about the study:

Principal Investigator – (Name / Contact Number)
Research Nurse – (Name / Contact Number)
Breast Care Nurse – (Name / Contact Number)

If you have any other questions about the study you can contact the central study team either by telephone (Freephone: 0800 XXX XXXX), by email (prosper@warwick.ac.uk), or write to:

FREEPOST XXX XXX XXX

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If you would like any independent information about taking part in research, you may find it useful to contact the Patient Advice and Liaison Service (PALS) – please ask your GP or your hospital clinic, or phone NHS 111 for details.

Thank you for taking time to read this information sheet.

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