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**Prevention of Shoulder Problems trial (PROSPER) :
Physiotherapist Manual**

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2020

Coventry, UK: University of Warwick; Warwick Medical School. (Unpublished).

<https://wrap.warwick.ac.uk/144049>

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PREVENTION OF SHOULDER PROBLEMS TRIAL

Physiotherapist Manual

Final Version 2.0

12th April 2016



Getting Started

This Physiotherapist Manual contains the relevant information to prepare physiotherapists for delivering the PROSPER exercise programme. The main concepts from each chapter will be covered in detail during your PROSPER training. This is your own reference manual with the relevant background information about trial processes and procedures. The trial is run by the Warwick Clinical Trials Unit based at the University of Warwick and is funded by the National Institute for Health Research (NIHR) under the Health Technology Assessment (HTA) funding stream. The purpose of the trial is to investigate whether postoperative exercise can improve function and quality of life in women at high risk of developing shoulder problems after breast cancer treatment.

Some physiotherapists will have considerable experience of treating women with breast cancer or treating patients with musculoskeletal shoulder problems. However, not everyone will have the same skill and experience level, therefore this manual has been written to account for differences in background training, skill and clinical expertise.

The **aims** of this Physiotherapist Manual are:

- To explain the trial design;
- To describe common side effects from breast cancer treatment;
- To provide the research evidence for the PROSPER exercise intervention;
- To describe procedures for the assessment and treatment of PROSPER study participants;
- To describe trial documentation and reporting procedures.

This manual has been produced to ‘standardise’ treatment and to reduce the risk of differences between physiotherapists and centres providing care. For all trial participants referred to your service, we ask that you adhere to the manual. This does not affect the care of non-trial participants, please treat your other patients in your usual way. You may even decide to use some of the approaches within the manual for non-trial patients. Thank you again for taking part in PROSPER. We hope you enjoy reading the manual and we very much look forward to working with you!

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Acknowledgements

This manual is based on the latest published evidence and clinical expertise from experienced cancer and musculoskeletal physiotherapists. It has been written by the PROSPER team (Julie Bruce, Clare Lait and Cynthia Srikesavan) and has been reviewed by our collaborators (Esther Williamson, Sallie Lamb). Grateful thanks are due to Jane Moser and Meredith Newman for their input in the early stages of intervention development. Thanks to Jane for being willing to be photographed in patient materials. Dr Beth Fordham wrote sections of Chapter 8. Additional thanks are due to physiotherapists and patient representatives who attended an Intervention Development day at the University of Warwick: Lyn Ankcorn, Jocelyn Choyce, Lizzie Fort, Catherine Hegarty, Alison Jelly, Wendy Leonard, Nicola Lidstone, Kelvin Marshall, Kat Tunnicliffe, Sally Winterbourne, Jo Dixey, Leah Dalby and Karen Wilkinson. We also thank Janet Lowe for reviewing the manual. This project was funded by the National Institute for Health Research HTA Programme (project number: 13/84/10).

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Glossary and Definitions

ACSM	American College of Sports Medicine
Action Planning	An action plan lists what steps must be taken in order to achieve a specific goal.
Adverse event	Refer to Chapter 10 for trial definitions of an adverse event.
Axillary node clearance	Removal of some or all of lymph nodes from the axilla (also axillary lymph node dissection or ALND). Different levels of clearance depend on the size and amount of fatty tissue removed that contains lymph nodes. Pathology then reveals how many nodes are there and how many are positive. The number of lymph nodes each woman can vary widely (e.g. breastcancer.org report from 5 to over 30 nodes).
Balance	The ability to maintain the projection of the body's centre of mass within manageable limits of the base of support, as in standing, sitting or in transit to a new base of support, such as walking ¹ .
Cancer-related fatigue	Defined as an unusual, persistent, subjective sense of tiredness related to cancer or cancer treatment that interferes with usual functioning ² .
Clinical Trial	A clinical trial is a research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes.
Cording	Cording or 'axillary web syndrome' is where a rope-like structure forms under the arm and can extend down towards the elbow, causing pain and limited movement. Sometimes referred to as Mondor's cords.
DASH	Disabilities of the Arm, Hand and Shoulder (DASH) questionnaire
DN4	Dolour Neuropathique-4 is a short questionnaire designed to capture features of pain. It was originally developed in French but has been translated for use in other countries. Questions ask about tingling, burning sensations. The DN4 is included in PROSPER follow-up questionnaires.
Ductal carcinoma in situ (DCIS)	DCIS is presence of abnormal cells inside a milk duct in the breast. DCIS is considered the earliest form of breast cancer, or precancerous condition. It is non-invasive meaning it hasn't spread out of the milk duct to invade other parts of the breast (see non-invasive breast cancer). It is a risk factor for invasive breast cancer development.
Lymphoedema	Swelling caused by a build-up of lymph fluid in the tissues. Occurs as a result of damage to the lymphatic system from surgery and/or radiotherapy to the lymph nodes in the axilla and surrounding area. Sometimes it can be caused by cancer cells blocking the lymph system.

Invasive breast cancer	This is where cancer cells have spread into normal, healthy surrounding tissue. Most breast cancers are invasive.
Neuropathic pain	This is pain that arises from nerve damage, where the nerve fibres may be injured or damaged e.g. during surgery. Neuropathic pain can occur from other causes e.g. shingles, chemotherapy, diabetes etc. It can settle over time but may need treatment if severe.
Non-invasive breast cancer	Where abnormal cells grow inside the milk ducts, but have not spread to nearby tissue or beyond. This is called 'ductal carcinoma in situ' (DCIS) where it means the abnormal cells have remained "in place" inside the ducts. Sometimes referred to as pre-invasive breast cancer.
Pragmatic trial	A trial that is designed to reflect how the intervention works within the real life situation e.g. within the usual healthcare setting.
PROSPER Trial	Prevention of Shoulder Problems Trial
Progressive overload	The gradual increase of stress placed upon the body during exercise training.
Proprioception	The unconscious perception of movement and spatial orientation. Awareness or sense of position, location and orientation of the body.
Quality of life (QoL)	General well-being. The PROSPER trial will capture health-related quality of life before surgery, at 6 and 12 months after treatment.
Radiotherapy (RT)	High energy radiation used to treat cancer cells, causing DNA of cells to die. Common side effects include skin soreness, tiredness and sometimes hair loss.
Random allocation	A method that uses the play of chance to assign participants to different groups in a trial. For PROSPER, the randomisation procedure is done by a computer using a computer-generated random sequence.
Randomised Controlled Trial (RCT)	An experiment is where an intervention is tested against a control or comparison group. Random allocation is used which means that each patient has an equal chance of being in one or other arm, similar to tossing a coin.
Range of Movement (ROM)	The full movement potential of a joint, usually its range of flexion and extension.
Rate of Perceived Exertion (RPE)	Rate of Perceived Exertion, usually measured by the Borg Scale.
Sentinel lymph node	The 'sentinel node' is defined as the first lymph node to which cancer cells are most likely to spread from a primary tumour. Sometimes there can be more than one sentinel lymph node.
Sentinel lymph node biopsy (SLNB)	A procedure where the sentinel node is identified removed and examined. This is used for cancer staging (negative = not spread; positive = present in the sentinel node and may be present in other

	nodes, possibly organs). Involves radioactive blue dye injection to locate the sentinel node.
Serious Adverse Event	An adverse event that results in: death, life-threatening, hospitalisation or prolongation of hospitalisation, disability, congenital abnormality or requires an important medical intervention. Additional criteria should be considered: whether the SAE is related to the intervention and whether it is unexpected.
Seroma	Accumulation of serous fluid can leak into tissues from damaged blood and lymphatic vessels. When small blood vessels are damaged, blood plasma seeps out – is usually a clear fluid. Seroma differs from lymph and is common after breast surgery.
Strength	Strength is defined as the ability of a muscle to exert a force to overcome a resistance. Muscle strength refers to the force a muscle can produce with a single effort.
Sub acromial pain syndrome (SAPS)	Defined as non-traumatic, usually unilateral, shoulder problem localised around the acromion, often worsened during or after lifting the arm. Different names include: bursitis, partial tear of rotator cuff, tendinopathy, tendon cuff degeneration etc.

Chapter 1. Overview of PROSPER Trial

1.1 Rationale for the PROSPER Trial

The Prevention of Shoulder ProbleMs TRial (PROSPER) will investigate the clinical and cost effectiveness of an early physiotherapy-led exercise programme compared to usual care after breast cancer surgery. The trial will focus on recruiting women considered to be at **high-risk** of developing shoulder problems after surgery and cancer treatment and will measure outcomes of function, pain and quality of life at 12 months after randomization. The PROSPER trial is funded by the NIHR HTA programme because of a need to provide evidence about whether the NHS should invest services in providing physiotherapy to women at high risk of shoulder problems after breast cancer treatment.

1.2 Aim of the trial

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

1.3 Study design

The PROSPER study is a multicentre 2-arm pragmatic randomised controlled trial (RCT). A **clinical trial** is used when you want to compare or test different interventions against each other (see glossary). A **pragmatic** trial means that the study has been designed to reflect the real life situation within the healthcare setting. Rather than test the exercise intervention (referred throughout as exercise programme) in a tightly controlled experiment, PROSPER will examine whether the exercise programme can be delivered within the pressures and constraints of the busy NHS environment. This is important to know for future policy decisions.

1.4 Interventions

1.4.1 Usual Care (Control Arm)

Participants randomised to this arm will receive usual or standard care. For most breast cancer centres across the UK, usual NHS care is a written information leaflet. For the PROSPER trial, we have selected two information leaflets published by Breast Cancer Care. This is described in more detail in Chapter 3.

1.4.2 Exercise Programme (Experimental Arm)

Participants randomised to this arm of the trial will be offered a physiotherapy-led exercise programme that incorporates behavioural modification tools and individualised monitoring. The exercise programme is described in detail in the manual (Chapter 4).

In brief, the exercise programme is 12 months in duration. Participants will be offered between 3 and 6 sessions with a trained physiotherapist – these can be either face to face or by telephone. The exercise programme includes a menu of stretching and strengthening exercises which can be progressed in difficulty over time. The programme includes advice on general physical activity and also includes behavioural strategies to help and support patients to adhere to their exercise programme and to increase physical activity throughout recovery from cancer treatment. Refer to Table 1.1 for a brief overview of the exercise programme.

Table 1.1 Brief Overview of PROSPER Exercise Programme

Key time points	Exercises
Days 0 - 7* after surgery	Usual Care (All participants): Restricted range of motion to below 90 degrees in accordance with Breast Cancer Care leaflet
From 7 days onwards	Unrestricted ROM exercises Daily stretch and hold Encourage gentle physical activity
From 4 weeks onwards	Introduce strengthening exercises Continue with daily stretch and hold Progress to moderate physical activity
From 12 weeks onwards	Advanced ROM and strengthening Progress to more intense physical activity
	Telephone support with up to 3 additional face to face appointments as required up to 12 months after randomisation.

*The majority of women should be seen by the physiotherapist at **7-10 days** after surgery (see Box 2).

1.5 Outcomes

1.5.1 Primary outcome

The primary outcome for the trial is arm function captured using the Disabilities of Arm, Shoulder and Hand (DASH) questionnaire at 12 months. Arm, hand and shoulder function will be measured in both intervention groups and differences will be calculated. The DASH Scale measures self-reported gross and fine upper limb function. The scale includes questions about functional impairments to the arm and performance of simple daily activities, including dressing, writing, opening or closing jars, and lifting and/or holding shopping bags, amongst others. The DASH includes 6 items on symptoms, 21 items on function and 3 items on social/role function. Although range of movement is important after surgery, it is return to function and daily activities that matter to women after cancer treatment.

Previous trials have measured range of movement or grip strength as outcomes but few measure function or return to daily activities as the primary outcome after breast cancer

treatment. Return to usual activities and function may be the most important outcomes for women. Improvements in upper limb mobility and strength should translate through to better patient reported functional outcomes.

1.5.2 Secondary outcomes

Other outcomes will be recorded, including health-related quality of life (QoL), postoperative complications (surgical site infection, acute and chronic postoperative pain), lymphoedema symptoms and healthcare resource use. These items will be collected by postal questionnaire at different time points after surgery. Other data will be collected from medical records.

1.6 Participant Recruitment and Eligibility

1.6.1 How many women will take part?

The trial will recruit 350 participants. Thus, 175 women will be randomised to usual care and 175 randomised to the exercise programme. This will be spread over 10 – 12 different centres to ensure a broad representation of patients coming into the trial but also to ensure that clinical services/physiotherapy departments are not overloaded with additional patients. This broadly equates to 2 or 3 trial patients in each site per month.

1.6.2 Who can take part in the trial?

Women aged 18 years or over, considered to be at high risk of developing shoulder problems are eligible to be invited to take part. Box 1 shows the inclusion criteria.

1.6.3 Who is not eligible to take part?

We have excluded men from the trial, also women having bilateral breast surgery and those having immediate reconstructive surgery because their treatment pathways are different. Women only having a sentinel lymph node biopsy (SLNB), regardless of their breast surgery, are excluded because of their lower risk profile **UNLESS** they have other ‘high-risk’ criteria e.g. high body mass index or existing shoulder conditions. Finally, those with known metastatic disease at the time of recruitment are ineligible.

Box 1. Inclusion criteria

Any of the following:

- Planned axillary node clearance (ANC);
- Planned radiotherapy to the axilla and/or supraclavicular area;
- Existing shoulder problems - based upon PROSPER screening criteria;
- Obesity defined as BMI ≥ 30 ;
- Any further axillary surgery after the first surgery e.g. ANC conducted after a sentinel lymph node biopsy (SLNB)
- Any later decision (made within 6 weeks of surgery) to refer for radiotherapy to the axilla and/or supraclavicular area.

1.7 Timing of referral to the Exercise Programme

There are 2 time points when women can enter the trial and timing of delivery of the exercise programme may vary by treatment group. Women will either be ‘immediate’ entry or ‘delayed’ entry – this depends on whether their treatment pathway changes because of the pathology results from surgery. Box 2 explains the entry points into the trial.

Box 2. Entry points into the trial

Immediate or early entry:

Most women will be in this category. They will be recruited before surgery and should be assessed by the physiotherapist at about **7 to 10 days after surgery**. These women will follow the exercise programme as expected. These will be the patients who know **before or at the time of surgery** that they are to have axillary node clearance **OR** that they are to have radiotherapy to the axilla or shoulder region (supraclavicular). Or it may also include women who have another characteristic to put them at increased risk e.g. existing shoulder problem or are overweight/obese.

Some women will be asked to return for an axillary node clearance (ANC) **after** having had a sentinel lymph node biopsy. These women will already have had one surgical procedure but they are then eligible to enter the trial because they are going to have ANC. Their risk profile has changed from low to high risk.

Delayed or late entry:

A small number of women will be informed of the need for radiotherapy to the axilla region or near the shoulder (supraclavicular area) **after** their surgery. They can still come into the trial but will need to be recruited post-operatively. In this case, the first physiotherapy assessment should be undertaken within **6 weeks of their surgery**. These women need to be seen fairly urgently after randomisation. The reason for this is that the exercise programme cannot be considered an “early” exercise programme if the delay from surgery to treatment is longer than 6 weeks.

1.8 Patient Screening and Consent

Breast care nurses and research nurses will screen women attending pre and postoperative clinics. Screening logs will be completed to capture details of patients who are eligible to be invited. The logs will record the number of women approached and the number who declined to be given any further information. All patients will be asked to sign written informed consent before they are randomised.

1.9 Ethical approval

The trial has been granted multicentre ethical approval by the Solihull Research Ethics Committee. The REC reference number for the trial is 15/WM/0224.

1.10 Key points from Chapter 1

- PROSPER is funded by the National Institute for Health Research
- It is a multi-centre, pragmatic randomised controlled trial (RCT)
- 350 women from 10-12 NHS breast cancer centres across England will be recruited and followed up for 1 year after randomisation
- Only women at high-risk of shoulder problems will be eligible to participate
- Women will be randomised to either usual care or the PROSPER physiotherapy-led exercise programme (intervention arm)
- The PROSPER exercise programme consists of stretching, strengthening exercises and general physical activity – it also includes behavioural strategies to encourage adherence over the long-term
- The main (primary) outcome is arm function at 12 months, measured using the Disability of Arm, Shoulder and Hand (DASH) questionnaire
- Women will complete study questionnaires before surgery, at 6 weeks, 6 months and 12 months after randomisation.

Chapter 2. Breast Cancer and treatment-related problems

This chapter provides a brief background about breast cancer and some common side effects of treatment. In Chapter 10, strategies for the management of complications are presented.

2.1 How common is breast cancer?

Breast cancer is the most common form of cancer affecting women worldwide and is the leading cause of cancer related death. The number of women diagnosed with breast cancer continues to rise; almost 50,000 women were newly diagnosed with breast cancer in the UK in 2011.³ Advances in early detection and improved treatment have resulted in increased survival after diagnosis. In England, the 5-year survival rate reached 87% in 2010-11 and almost two-thirds of women are now expected to survive 20 years or more.³ This has resulted in many more women living with the consequences of cancer treatment so it is important to consider how we can improve patient function and reduce the impact of treatment side effects.

2.2 Treatment of breast cancer

Treatment for breast cancer can be complex and delivered over many months and even years after diagnosis. Surgery to the breast and/or axilla is the main treatment of choice. The type of breast surgery performed depends on the extent of the disease. Axillary surgery can involve a sentinel lymph node biopsy, axillary node sampling or partial or full node clearance.³ Surgery is often supplemented with radiotherapy, chemotherapy and endocrine therapy, depending upon tumour stage and other clinical criteria.⁴ Radiotherapy can be administered to the breast, chest wall or axilla. Endocrine/ hormone therapies are prescribed if the breast cancer cells have oestrogen receptors – in this case, the cancer is classed as oestrogen receptor (ER) positive. Treatment decisions are based upon disease stage and tumour type.

2.3 Types of breast surgery

Type of surgery depends upon the type, size and spread of cancer tissue, breast size and personal preference. The main types of breast surgery are mastectomy (whole breast removal) or lumpectomy, often called wide local excision (WLE), where the lump and a margin

of surrounding tissue are removed. Breast conserving surgery is another term used for lumpectomy or WLE. Breast reconstruction surgery is common and this can be immediate, at the time of lump removal, or delayed. Reconstructive surgery may involve implants or tissue expanders, or flaps of tissue taken from the abdomen, buttocks, back or thigh. The PROSPER trial will **exclude** women having planned immediate reconstruction surgery. However, it is likely that a small proportion of women who are recruited to the trial may later decide to undergo breast reconstruction e.g. at 9-12 months after their first surgery. These women will remain in the trial for the purposes of follow-up as their PROSPER treatment pathway will be mostly completed. Women having late reconstruction during the follow-up period will be accounted for in the final analysis.

2.4 Types of axillary surgery

Preoperative investigations, such as a biopsy or fine needle aspiration, are undertaken to determine whether cancerous cells have spread to axillary lymph nodes. One axillary procedure is **axillary node sampling**, where a sample of about 4 nodes is taken to provide information on cell type and spread and to plan further treatment. This is not used very often in clinical practice as it has been replaced by **sentinel lymph node biopsy** (SLNB). A SLNB is where a small amount of radioactive blue dye is injected close to the tumour – the dye then drains from the breast to the lymph nodes (see Figure 2.1). The first set of nodes that the coloured tracer reaches are called the “sentinel nodes” which are then removed. If pathology testing reveals that the sentinel nodes are free of cells, then there is a high likelihood of no further spread. If cancer cells are present, then the patient requires further surgery for an **axillary node clearance** – also called axillary lymph node dissection. There is a lower risk of side effects, such as pain and numbness, after SLNB compared to full axillary clearance. Women due to undergo axillary node clearance are eligible to take part in PROSPER due to the risk of developing shoulder problems.

Figure 2.1 Sentinel lymph node biopsy

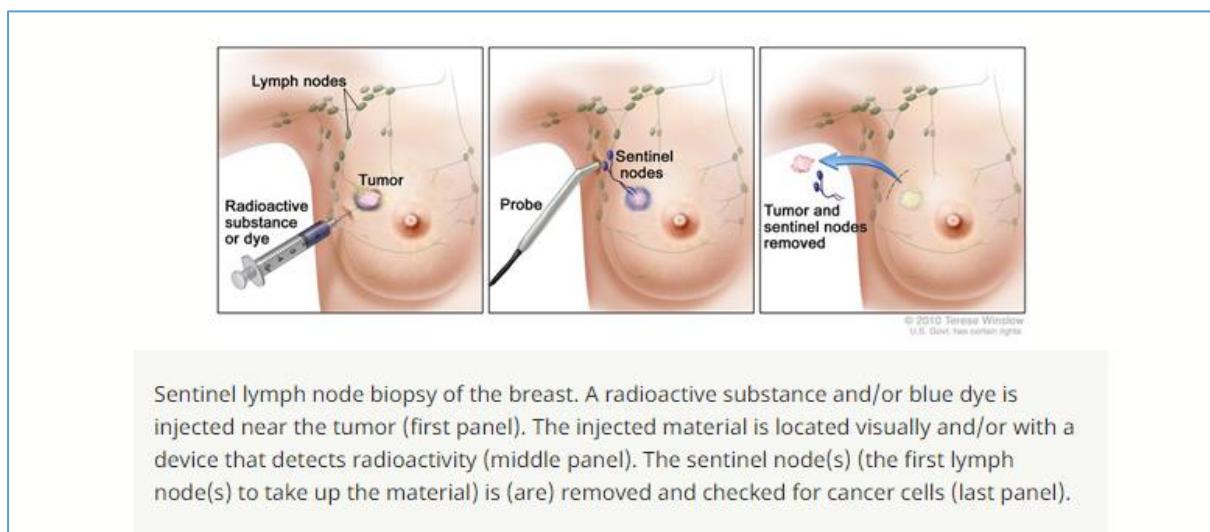
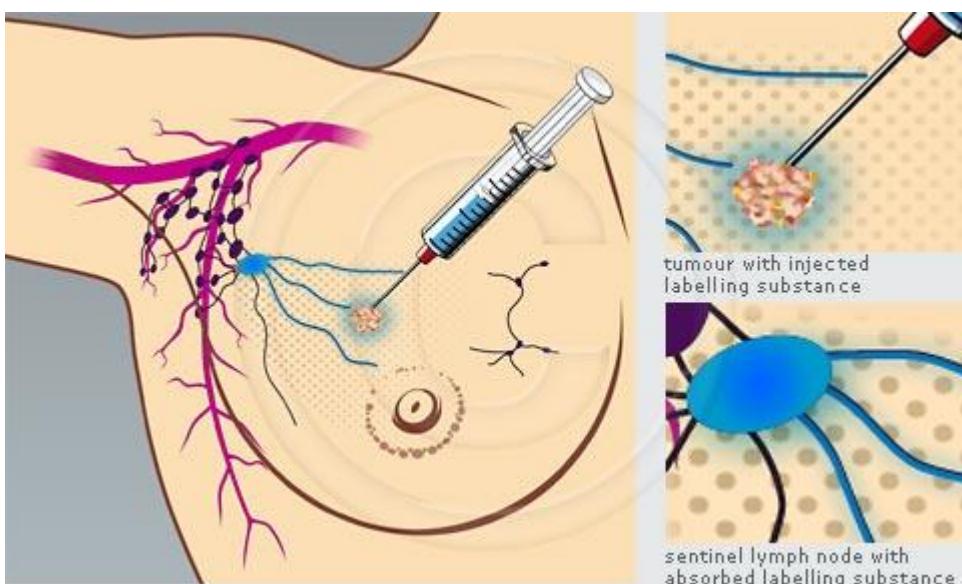


Image source: www.cancer.gov

2.3 Common side effects after breast cancer treatment

Treatments for breast cancer can have **local effects** on the muscles, nerves and lymph vessels in the upper body as well as more general **systemic effects**, such as fatigue. Breast cancer survivors often experience multiple, overlapping symptoms. Some common side effects of treatment are described below.

2.3.1 Wound infection and Seroma

As with any surgery, there is a risk of postoperative wound infection. Breast surgery is a ‘clean’ surgical procedure compared to contaminated surgeries (e.g. bowel procedures) and has low rates of postoperative infection within the hospital setting. However, studies that include careful wound monitoring *after* hospital discharge report that around **9%** of women develop a **wound infection** within 30 days after breast surgery.⁵ After mastectomy, the majority of wound infections develop after the second postoperative week.⁶ Usual care is to give information on wound management and instruct women on checking their wound(s) for signs and symptoms of wound infection: redness; swelling; purulent discharge; pain or warmth at or near the wound site, and increased body temperature.

Seroma is a clear fluid that leaks from damaged blood and lymphatic vessels into tissues and is common after breast surgery. Seroma can sometimes build up around the wound or in any cavity space and may need drainage with a syringe.

2.3.2 Postoperative pain

Pain is to be expected after any surgery - pain occurs because of tissue injury and inflammation but this should gradually settle within a few days or weeks after surgery. It is important that women take painkillers in this immediate postoperative period to ensure that they can mobilise without too much discomfort. Anti-inflammatory painkillers can also reduce wound inflammation.

Chronic or persistent pain is where the postoperative pain lasts for longer than expected. This is broadly defined as pain that wasn’t there before surgery but has lasted for more than three months after surgery. Breast cancer studies show that many women report different sensations at or near the wound/scar site e.g. pain, discomfort, numbness or altered sensations; sometimes lasting for months or years. Symptoms may arise because of disruption to the nerve pathways in the axilla or breast area. Sensory loss or numbness is common – one study found that more than half of women had numbness (reduced sensation) in the scar area compared to their opposite non-operated side.⁷ For most women, these symptoms do settle over time.

Neuropathic (nerve) pain is a specific type of pain which can be described as burning, pins and needles, electric shocks or tingling sensations. A subset of women may have neuropathic characteristics after surgery, and if severe, this pain can be difficult to treat.

2.3.3 Lymphoedema

Damage to the lymph transport system can occur after surgery or radiotherapy which can lead to accumulations of lymph fluid, known as **secondary lymphoedema**.⁸ **Lymph** is a thin, clear fluid that circulates throughout the body to remove waste, bacteria and other substances from tissues. **Oedema** is the buildup of excess fluid. **Lymphoedema** occurs when too much lymph collects in any area of the body – it tends to affect the arm and hand, but sometimes can affect the breast, underarm, chest, trunk, and/or back and can occur months or years after cancer treatment ends.⁹ Patients with early signs of lymphoedema may experience a feeling of heaviness or tightness in the arm, with or without swelling compared to the opposite arm.

One of the main **risk factors** for developing lymphoedema is complete or partial removal of the lymph nodes that drain fluid, thus women having **axillary node clearance**. Many women need radiation therapy to the chest area and/or axilla which can also damage the nodes and vessels through which lymph flows. Over time, the flow of lymph can overwhelm the remaining pathways, resulting in a backup of fluid into the body's tissues causing swelling.⁹

Postoperative wound infection and high volumes of wound drainage or seroma may also increase the risk of developing lymphoedema.⁸ There is good evidence to show that it is safe for women to start upper limb exercises (restricted to 90 degrees) in the first week as this does not increase the risk of lymphoedema. Evidence suggests that gradual return to full functional use supported by moderate intensity progressive resistance training for the upper limb may also protect against lymphoedema.¹⁰

2.3.4 Problems in the upper limb

Upper limb problems are common after breast cancer treatment and mostly occur within the first 12 months after surgery, although again can persist for many years after treatment has

finished.^{11 12} Common functional problems include difficulties with activities of daily living such as combing hair, reaching overhead, carrying or pushing objects, leading to limited participating in work and social life.¹³ Extensive scar tissue can restrict movement e.g. skin and subcutaneous tissue can adhere to underlying muscles.^{14 15} Fibrotic changes to soft tissues as a result of radiotherapy can also restrict soft tissue extensibility. Together these changes may cause pain or stiffness and restrict arm movement and function.¹⁶

2.3.5 Cording

Cording is a complication of axillary surgery. Cording is also referred to as **axillary web syndrome**, vascular strings or Mondor's cords.^{17 18} Cording presents as taut, stretched fibrous bands underneath the skin in the affected arm, either at rest or on movement. It usually occurs in the early weeks after surgery but can develop at any time after treatment.^{18 19} Cording is assumed to be a lymphovenous injury as a result of axillary surgery and radiotherapy although its exact pathophysiology is not well understood.^{18 20}

2.3.6 Specific shoulder problems

Breast cancer treatments can lead to patients presenting with pain and loss of range of movement. Specific shoulder problems include **adhesive capsulitis** (frozen shoulder) or **sub-acromial pain syndrome (SAPS)**.^{21 22} Frozen shoulder can be idiopathic or can occur as a result of injury or surgery to the upper arm. Frozen shoulder presents with intense and constant pain, often with pain at night. Sub-acromial pain syndrome is often characterised by painful arc and can restrict overhead and loaded arm activities.

2.3.7 Musculoskeletal aches and pain

Aching joints (arthralgia) and muscle pains (myalgia) can occur during and after breast cancer treatment, often as a side effect of chemotherapy or other drug treatments. The drug class called aromatase inhibitors may be prescribed for women with oestrogen receptor (ER)-positive breast cancer e.g. arimidex, aromasin. One of the side effects of these drugs is painful joints which can be managed by mild painkillers and gentle range of movement exercises.

2.3.8 Cancer-Related Fatigue

Cancer-related fatigue is a common side effect often experienced during treatment but again, can persist for months after treatment has finished. Cancer-related fatigue is described as a persistent sense of physical, cognitive or emotional tiredness that is not proportional to activity and interferes with functioning.²³ It is different from normal tiredness in that it is unpredictable, more extreme and often not improved by a good night's sleep. Fatigue is multifactorial and must be considered alongside treatment side effects and related problems including: sleep disturbances; anaemia; depression; endocrine changes; reduced lung function and possible cancer recurrence. Up to 80% of cancer patients report experiencing fatigue during or after their treatment.²³

The next chapters describe usual and the trial exercise programme in more detail.

Chapter 3. Usual care

3.1 Usual care

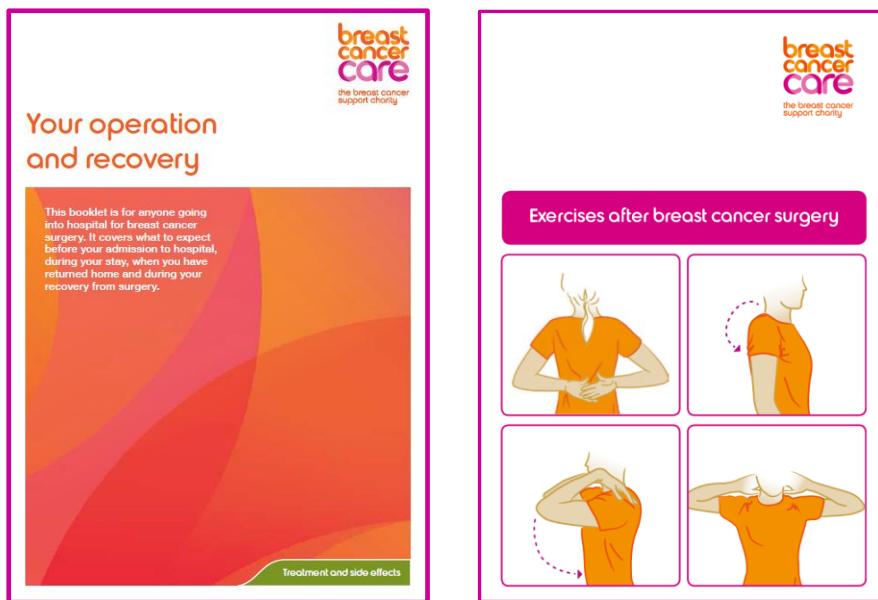
Participants randomised to the usual care arm of the PROSPER trial will receive best practice usual care, namely written information leaflets about exercises and recovery after treatment for breast cancer. These leaflets are widely used in the NHS and are usually given to patients before surgery. Guidance on best practice for written materials is available from the NHS brand guidelines patient information website.²⁴

The leaflets ‘Your Operation and Recovery (BCC151)’ and ‘Exercises after Breast Cancer Surgery (BCC6)’ (Figure 3.1) are published by and freely available from the charity Breast Cancer Care (www.breastcancer.org.uk).²⁵ Copies are provided in Appendix 13.

3.2 Process of selecting usual care leaflets

The PROSPER team reviewed many different exercise information leaflets used by breast cancer centres across England. Many centres use the Breast Cancer Care leaflets but modify them slightly to fit with local practice. We have selected these leaflets based upon the content, style and clarity of presentation of information. Patient representatives and professionals, including physiotherapists specialising in shoulder/breast cancer treatment, were invited to contribute to this selection process. It is important to ensure that standard care reflects best practice across recruiting centres. It is also crucial that information materials are clear, readable and accessible to patients. Delivery of the control programme will be done by breast care nursing staff or other healthcare professionals depending upon local practice.

Figure 3.1 Breast Cancer Care Leaflets



The exercises and the **instructions** in the BCC leaflet are replicated below.

Figure 3.2 BCC Leaflet: Warm up and cool down exercises

Warm-up and cool-down

Do exercises 1 and 2 to warm up before you do any other exercises on this leaflet. Repeat them at the end to cool down. You can do them standing up or sitting down.

1 Shoulder shrugs

Keep your arms loose and relaxed by your sides. Shrug your shoulders up towards your ears and lower gently back down.

2 Shoulder circling

Keep your arms loose and relaxed by your sides. Shrug your shoulders up towards your ears, then circle them back and down.

Instructions for Participants

First week after surgery: do the warm-up, basic exercises and cool-down.

Do exercises 1 and 2 to warm up before you do any other exercises on this leaflet. Repeat them at the end to cool down. You can do them standing up or sitting down.

Figure 3.3 BCC Leaflet: Basic exercises

Instructions for Participants: Basic exercises can be done in the first week after surgery. You can do them sitting down or standing up. Remember to warm up first. In these exercises, **do not** raise your arms above shoulder level (90 degrees).

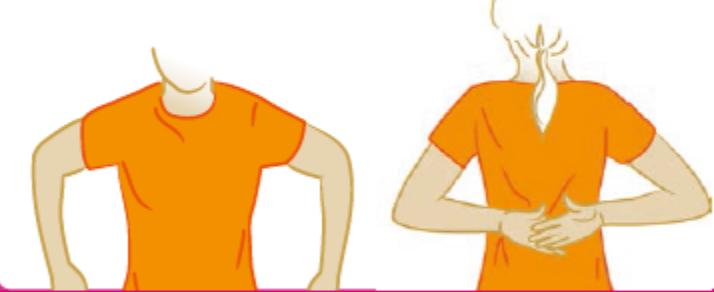
Basic exercises

Basic exercises can be done in the first week after surgery. You can do them sitting down or standing up. Remember to warm up first.

In these exercises, do not raise your arms above shoulder level (90 degrees).

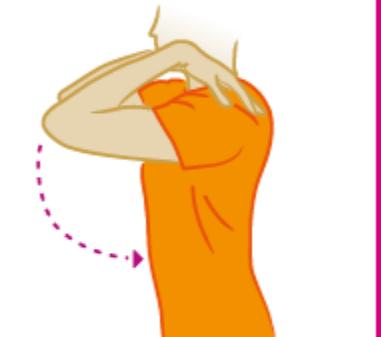
4 Back scratching

- Hold your arms out to the sides and bend your arms from the elbow.
- Slowly reach up behind your back to just under your shoulder blades.



3 Bent arm

- Raise both your arms forward so they are at right angles to your body.
- Bend your elbows and rest your hands lightly on your shoulders.
- Lower your elbows slowly, then raise them again.



Alternative

- Rest your hands on your shoulders but take your elbows out to the sides.
- Lower your elbows slowly, then raise them again.



Figure 3.4 BCC Leaflet: More advanced exercises

Instructions: you can start these more advanced exercises in the **second week** after surgery (if you have removable stitches or a drain, wait until these have been removed). In these exercises, you **should** raise your arms above shoulder level. Remember to do the warm-up and basic exercises first each time. If you're having problems with fluid collecting at your operation site, wound infection or prolonged or worsening pain, stop exercising and speak to your surgeon or breast care nurse.

6

Wall climbing

- With your feet apart, stand close to and facing a wall.
- Put both hands on the wall at shoulder level.
- Looking straight ahead, gradually work your hands up the wall – sliding them or using your fingers to climb – as far as you can, feeling a stretch but not pain.
- Hold here and count to 10.
- Slide your hands back to shoulder level before repeating the exercise.
- Try to get higher each time.



- Then stand sideways with your affected side nearest the wall.
- Put your hand on the wall, keeping your elbow bent and your shoulders relaxed.
- Looking straight ahead, gradually creep your hand up the wall as far as you can, allowing your elbow to straighten.
- Hold here and count to 10, then lower your hand back down.

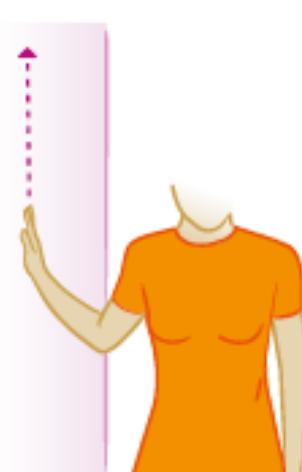


Figure 3.4 More advanced exercises continued...



7 Arm lifts

- Lie on the bed or floor with a cushion or pillow to support your head.
- While lying down take three or four really deep breaths and concentrate on relaxing your shoulders so they are not hunched up towards your ears.
- Clasp your hands together or hold onto a stick or broom handle. Keeping your elbows straight, lift your arms up and over your head as far as you feel comfortable.

- Hold them here and count to 10, then lower your arms slowly. You may find it useful to put a pillow behind you to support your arms until you're able to get them further back.

Alternative

If you have difficulty lying down – for example because of breathlessness – you can do this exercise in a sitting position, leaning back in your chair.



8 Elbow push

- Lie on your back with your hands behind your head and your elbows out to the sides.
- Gently push your elbows downwards into the bed or floor as far as is comfortable.

- Hold and count to 10, then relax.

This exercise is particularly helpful if you go on to have radiotherapy as the treatment will often require you to be in a similar position.

Chapter 4. The PROSPER Exercise Programme

4.1 Overview

This chapter presents an overview of PROSPER exercise programme. It is a home-based programme that includes warm-up and posture exercises, a daily sustained stretch, range of movement (ROM) and strengthening exercises and advice about physical activity. It also incorporates behavioural strategies to encourage and facilitate adherence. The PROSPER exercise programme is designed to start from the **7th postoperative day** onwards. In the first week after surgery, all trial participants will follow usual care advice as per the Breast Cancer Care leaflet, with arm movement restricted to 90⁰. From 7 days onwards, you will prescribe unrestricted ROM exercises into flexion, abduction, abduction and external rotation. All women will be asked to do a daily sustained stretch. At the end of the 4th postoperative week, strength exercises will be introduced using therabands. Throughout the whole programme, participants will also be encouraged to undertake regular physical activity which is also progressed over the postoperative time period e.g. from gentle to moderate to more vigorous physical activity depending upon ability.

Table 4.1 Recommended appointment times

Appointment		Time after surgery	Purpose
1 st	Face to face	7-10 days	Assess & prescribe exercises, complete exercise planner and diary and set goals.
2 nd	Face to face	4 - 6 weeks	Assess, review & progress, complete exercise planner and diary and set goals.
3 rd	Face to face	12 - 16 weeks	Assess, review, progress & encourage self-management, complete exercise planner and diary and set goals.
Additional appointments – up to 3 recommended, at any time			
Telephone support OR face to face		Respond to concerns, reassess and review, progress exercises.	

4.2 How many physiotherapy appointments?

We ask you to arrange **3 face to face appointments** with participant at key time points after surgery (Table 4.1). Women will undergo different combinations of cancer treatments and clinical pathways will vary, but the programme has been designed taking “surgery” as the baseline starting point. Participants start the PROSPER exercise programme at the first appointment which should be arranged, wherever possible, **for the end of the first postoperative week**. The aim then is to progress from restricted to unrestricted stretching and ROM exercises. At the end of the first postoperative month, theraband (strength) work can be introduced (see Table 4.2). These time points are **flexible** and women can have additional face-to-face appointments or telephone contact as needed. Please try to arrange appointments to fit around other scheduled hospital appointments or follow-up clinics wherever possible e.g. those having radiotherapy attend for treatment every day over a period of weeks - we want to avoid additional appointments which may contribute to fatigue.

Table 4.2 PROSPER Exercise Menu

Warm up	Posture check Shoulder circles Trunk Twists (1- 4)
Daily Stretch	Daily stretch & hold
Range of Movement Exercises – from 1 week onwards	
Forward	Clasp hand raise Forward wall slide
Side	Morning stretch Sideways wall slide
Open chest	Back broom lift Surrender
Strength Exercises – from 1 month onwards	
Forward	Forward Band Lift Rocker
Side	Sideways Band Stretch Wood Chopper
Open chest	Over Head Band Stretch Front Band Stretch Low Band Row
Physical activity	Gentle / Moderate / Hard

4.3 Individualised participant physiotherapy folder

Each participant will be given their own PROSPER Physiotherapy Folder. Draft versions of this folder have been reviewed by patients treated for breast cancer. This folder contains separate pages with pictures and instructions for every exercise and blank diaries to record when exercises have been done (Exercise Diary). It contains education about the post-operative period and how to monitor for common complications. You should add your contact details in the first section of the folder (telephone number for physiotherapy department). You should write any instructions about repetitions in this folder and ask the participant **to stick to prescribed exercises only**. Move any other exercises to the back of the folder.

4.4 Overview of PROSPER Exercise Menu

A brief overview of the different exercises is given here, including the warm up, daily stretch, ROM and strength exercises. Each exercise has a coloured heading corresponding to the type of exercise or movement direction. These coloured headings are used in the patient folders.

a) Warm-up exercises

Posture and Warm Up Exercises

There are three warm up exercises – a posture check, shoulder circles and trunk twists. There are four different types of trunk twists. These should be done before starting any other exercises. These are in Section 2 of the Patient Physiotherapy Folder.

b) Daily stretch and hold

Daily Stretch and Hold

There is one prolonged stretch and hold to the pectoral muscles called ‘daily stretch and hold’ which can be prescribed from the 7th postoperative day onwards. This stretch can be progressed by holding it for longer or extending the arm or by dropping the legs to the side when in the lying position. The aim is to do this for 10 minutes a day, this can be split into 5 minutes in the morning and evening e.g. when lying in bed or on the floor.

c) Range of movement (ROM) exercises

The PROSPER exercise programme targets three movement directions: **flexion** (forward), **abduction** (side) and **abduction with external rotation** (open chest) and includes a mixture of active-assisted, active, stretches, strength and proprioceptive exercises. There are 6 ROM

exercises to choose from and you should select **ONE** from each movement direction – thus prescribe **one** forward, **one** side and **one** open chest. At follow-up review, these can be swapped or progressed as needed. For the ROM exercises, we recommend that the exercise is **held 3 seconds and then repeated 5 times**. This can be adapted to the individual's ability. These are in Section 2 of the Participant Physiotherapy Folder.

Forward Exercises

The forward ROM exercises are: a Clasp Hand Raise and Forward Wall Slide. The Forward Wall Slide can be progressed by incorporating a lift off the wall.

Side Exercises

The side ROM exercises are: Morning Stretch and Sideways Wall Slide which range from easy to very advanced.

Open Chest Exercises

The open chest ROM exercises are: Back Broom Lift and Surrender pose. The Surrender pose can be progressed by stepping away from the wall to enhance the stretch.

d) Strength exercises

The strengthening exercises involve therabands and again target forward, side and open chest movement directions. These are in Section 3 of the Participant Physiotherapy Folder. The forward strength exercises are: a Forward Band Lift and Rocker which ranges in difficulty from easy to advanced. The side strength exercises are Sideways Band Stretch (easy to intermediate) and a Wood Chopper. The open chest strength exercises are: Over Head Band Stretch, Front Band Stretch and Low Band Row (easy to intermediate).

e) Lymphoedema Prevention

Lymphoedema Prevention Exercises

Finally, there are specific exercises to prescribe if you or the participant suspects lymphoedema. These are: Fist Pumps and also Fist Pumps with the arms raised. These should be kept in the back of the Participant Physiotherapy Folder and prescribed if you or the

participant themselves suspects they have swelling, tightness or heaviness in the affected arm.

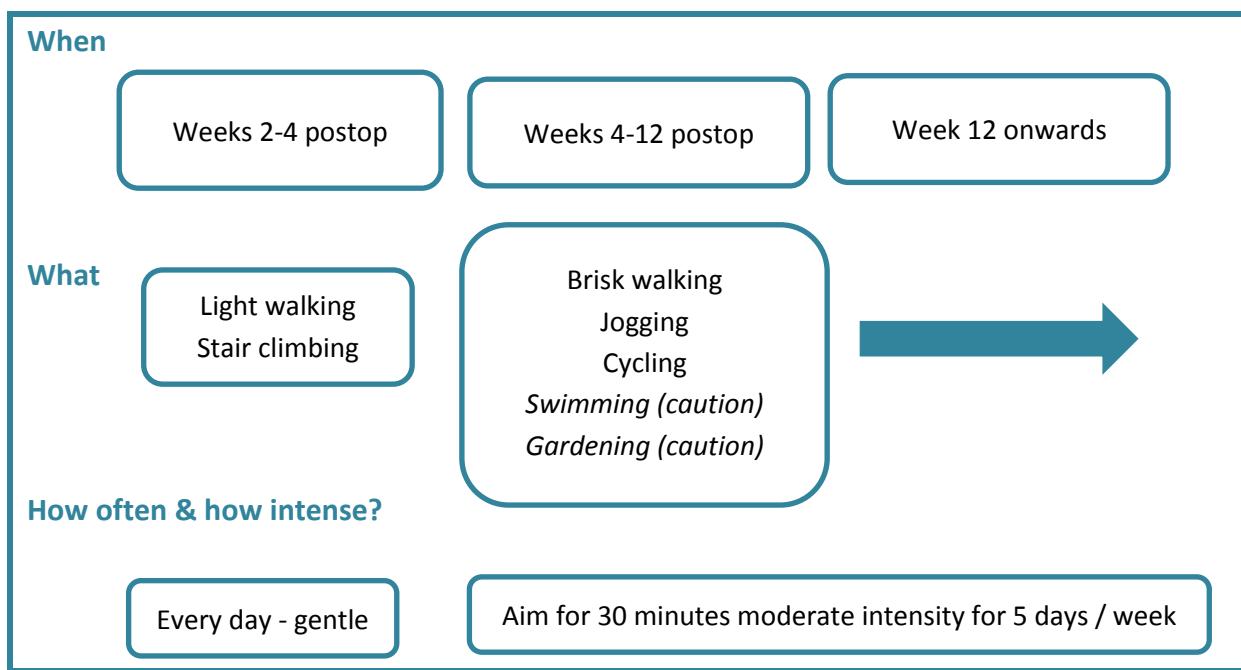
4.5 Advice on physical activity

You should give guidance on frequency, intensity, level and type of physical activity at every appointment or contact. Participants can recommence gentle or light physical activity (walking) during the first postoperative week and then progress to moderate and harder intensity activity over time (Figure 4.1). You should advise caution for activities such as swimming during chemotherapy and radiotherapy, because of the risk of infection and possible skin reaction to chlorine. Also care should be taken when gardening to prevent cuts and grazes as per lymphoedema prevention advice. Type of activity will vary depending upon lifestyle, levels of baseline fitness and future goals e.g. return to active sport or specific activity. If they are not regular exercisers, you should encourage the recommended WHO activity guidelines of 150 minutes per week. Explain that there is good evidence that staying physically active improves health outcomes during and after cancer treatment (more in Chapter 5). Advice on physical activity is a core component of the PROSPER exercise programme therefore try to promote the benefits of being active. Simple advice is to encourage participants to start an activity that they enjoy. They can keep a record of activity in their exercise diary.

4.6 The Exercise Planner and Diary

Instructions on how to complete the Exercise Planner and Diary are given in Chapter 9. These are adherence tools and should be completed with every participant. The Exercise Planner is used for goal setting and assessing level of confidence in completing the exercises. Once goals are agreed, this form is signed by the therapist and the participant – it is a “contract” agreement between you and the participant. The Exercise Diary is also a tool to encourage adherence – copies of these are stored in the back of the Participant Physiotherapy Folder (see copies in Appendix 5). You should review these materials during follow-up appointments.

Figure 4.1 Physical activity after surgery



4.7 Physiotherapy appointments

4.7.1 The 1st Appointment (7 -10 days after surgery)

The first appointment should be booked for **one hour**. Wherever possible, please **try to arrange the first appointment around the end of the first postoperative week**. Chapter 7 describes how to do the first assessment. You then select and prescribe appropriate exercises for the postoperative time point. You give the Participant Physiotherapy Folder, set goals and help complete the Exercise Planner. At this first appointment, the key aims are to encourage them to start exercising (tell them it is safe), encourage good posture and stretching, with the aim of recovering arm ROM. Advise to self-monitor for complications.

Reminder:

Some women are 'late' entrants to the trial e.g. they need radiotherapy to the axilla or shoulder area. This means they can enter the trial up to 6 weeks after their surgery – it is important that you arrange their first appointment as soon as possible after randomisation.

4.7.2 The 2nd Appointment (4 – 6 weeks after surgery)

This review appointment should be booked for **30 minutes**. The purpose is to assess progress with prescribed exercises and monitor for any difficulties or complications. You should review their completed Exercise Diary and Planner. You can introduce strength training from 4 weeks after surgery, depending upon their progress and individual ability. At this stage, you should be encouraging women to use their arm normally for general activities of daily living. You can give advice to promote a steady increase in the complexity and load of functional tasks undertaken.

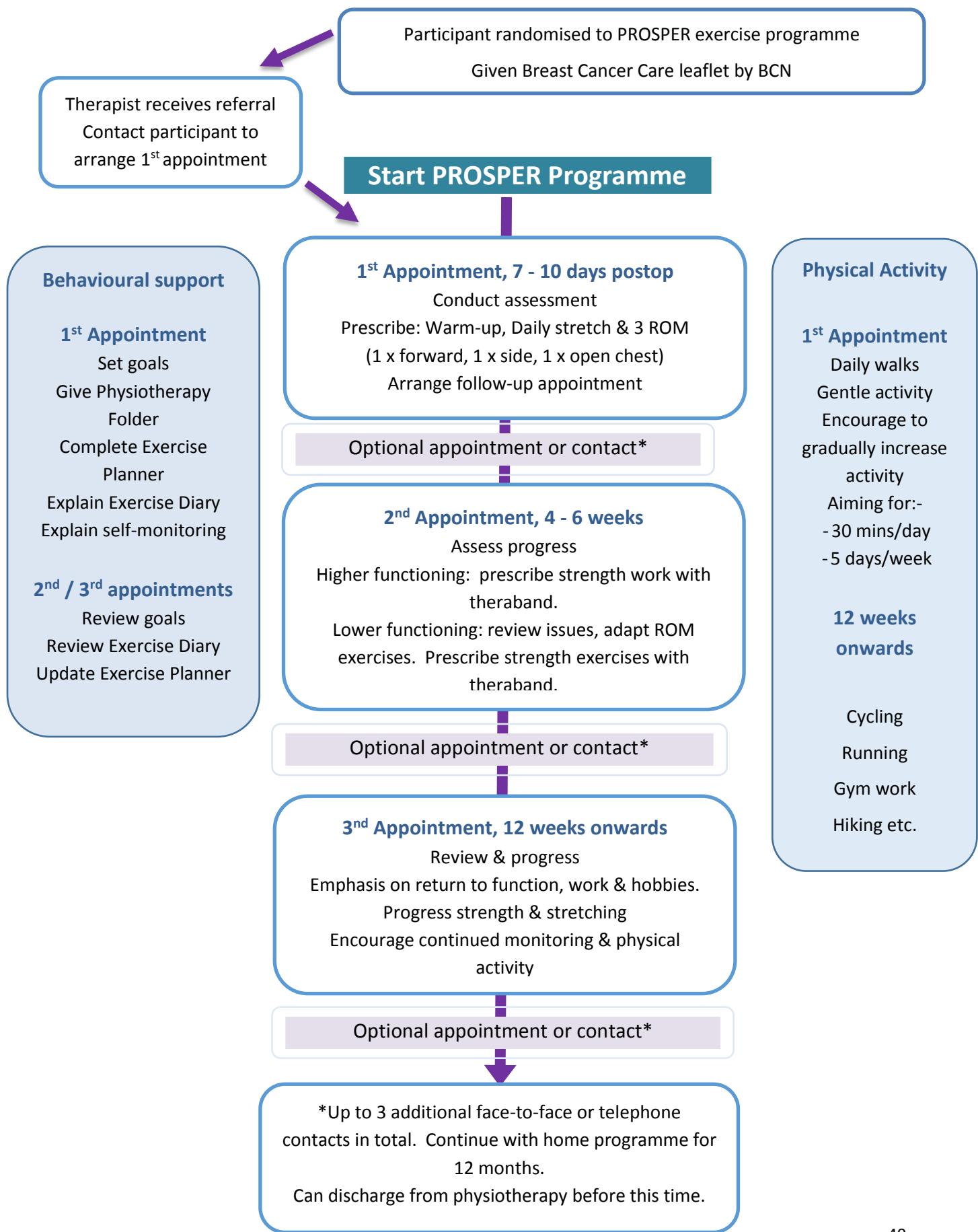
4.7.3 The 3rd Appointment (from 12 weeks after surgery)

The third appointment will also take approximately **30 minutes**. The purpose is to assess progress, to monitor any complications and to review the original and revised goals. The emphasis is on the need to return to higher level function and goal orientated activities e.g. hobbies, sport or work.

4.8 Additional physiotherapy contacts

Participants can also access **3 flexible appointments**, either by telephone support or other face to face appointments. You can decide whether you want to schedule these appointments and what format they should be. Some women may prefer a telephone call whilst others may wish to only contact you should an issue arise. These contacts will involve assessing progress, discussing barriers or complications that may have arisen, reviewing goals and progressing exercises/activity as appropriate or arranging a further face to face appointment to address specific problems. Chapter 7 includes a list of issues that may prompt one of these extra appointments. See Figure 4.2 for an overview of the PROSPER programme.

Figure 4.2 Flowchart of exercise programme



Chapter 5. Principles of exercise & evidence for PROSPER Exercise Programme

5.1. Development of the PROSPER Exercise Programme

This chapter presents an overview of the theoretical principles of exercise and best available scientific evidence for the selection of types of exercises and advice included within the PROSPER exercise programme. This chapter also describes the evidence for including behavioural strategies to encourage and promote exercise adherence which is vital to achieve and maintain treatment benefits. Many randomised controlled trials (RCTs) have investigated exercise after breast cancer treatment. As the quality of individual research studies varies widely, it is important to focus on rigorously conducted systematic reviews and high quality clinical trials. Given that surgical procedures and treatment options have changed over the last 20 years or so, it is also important to consider evidence from more recent clinical studies as they reflect current healthcare practice.

The PROSPER exercise programme has been developed based upon evidence from the published literature and from consensus agreement with clinical experts attending an Intervention Development day held at the Warwick Clinical Trials Unit in February 2015. We invited specialist physiotherapists experienced in breast cancer care and/or the treatment of musculoskeletal and upper limb injuries. The day was structured to firstly discuss and review the published evidence, followed by workshop discussion on the key exercises to include in the exercise programme. Workshop participants also discussed the timing, structure and format of the programme. We achieved broad consensus agreement for the trial intervention and developed a fairly extensive list of exercises. This initial list was then reviewed by the PROSPER trial team and reduced down to a more useable ‘exercise menu’ which is described in Chapter 4. These exercises are widely used by therapists in clinical practice. A brief overview of the principles of therapeutic exercise is described below, along with best available evidence from the breast cancer literature.

5.2 Joint Range of Movement Exercises

Range of movement (or motion) exercises are important for maintaining limb function. Joint **range of movement** exercises are defined as passive, active assisted or active. These movements promote maintenance of articular cartilage, connective tissue homeostasis and repair by mechanical stimulation.²⁶ These exercises are defined as:

- **Passive range of movement** - carried out on an inactive joint or limb. The purpose is to maintain muscle activity and prevent stiffness and when an individual is unable to move their own joint or limb due to muscle loss, weakness or other dysfunction.
- **Active-assistive range of movement** – is a progression from passive and refers to any support or assistance with a particular movement, either from the opposite limb, a person, or external object such as a towel, band or pulley. Both passive and active assisted exercises can be performed if active range of movement is not possible.
- **Active range of movement** – when exercises are performed unaided.

Range of movement exercises activate a physiological mechanism called the trans-synovial pump which encourages synovial fluid drainage and facilitates lymphatic flow.²⁷ Encouraging lymphatic flow is particularly important in the postoperative period after breast and axillary surgery.²⁶ Immobilization after surgery can also result in length changes within the muscle and surrounding connective tissues.^{28 29} Immobilization can impact on the contractile properties of the muscle leading to shortening, pain and weakness.³⁰ Range of movement exercises maintain the blood and lymphatic flow to ensure adequate nutrition to the joints and soft tissues, and prevent shortening and weakness of the surrounding muscles. For the purpose of PROSPER, a combination of **active assisted** and **active** exercises have been selected. The evidence for range of movement and strength exercises are described below.

5.3 Evidence for exercise after breast cancer surgery

The exercise interventions tested in previous clinical trials varies widely although often the exact movements are not clearly described in detail. The format for delivery of exercises also varies, thus programmes or ‘packages’ have been tested in different settings, including home exercises, individual physiotherapy sessions, home videos and group/gym classes held in the

community settings. Appendix 1 presents a brief overview of the content and format structured exercise programmes included in published trials. The majority of physical therapy interventions target upper quadrant movements because limited shoulder movements can be a problem after surgery. Shoulder flexion, abduction and abduction combined with external rotation are the most frequently reported restricted movements.^{31 32}

A Cochrane systematic review investigated the effectiveness of exercise interventions in preventing, minimising or improving upper-limb dysfunction due to breast cancer treatment.¹² This review included 24 different trials and classified exercise type as: (1) active or active-assisted; (2) passive range of movement and manual stretching exercises; (3) stretching exercise, including yoga and Tai Chi; and (4) strengthening or resistance exercises.

Another recent systematic review included 18 studies and grouped exercise interventions into four broad types: (1) passive mobilization exercise; (2) manual stretching; (3) myofascial therapy; and (4) active exercises.²¹ Several trials confirmed that the combination of general exercises and stretching is effective for the treatment of impaired range of movement. This review found **no evidence** for the effectiveness of postoperative myofascial therapy. In terms of timing of starting exercise, studies show a beneficial effect on shoulder ROM when exercises are started on the first day after breast cancer surgery *but* care should be taken in the first week to avoid prolonged wound drainage and healing. Todd (2008)³³ recommended to restrict shoulder movement to below 90 degrees in the first week. The findings from these systematic reviews are highly relevant for PROSPER and the key messages are replicated in Box 3. We also considered good quality RCTs published after the date of these systematic reviews.^{8 31 34}

Box 3 Key findings from McNeely (2010)¹² Systematic Review

1) Early exercise is more effective than delayed exercise in the short term recovery of shoulder flexion and abduction ROM. For 10 trials, the combined analysis (meta-analysis) found an overall improvement of 10.6 degrees ROM (range from 4.5⁰ to 16.6⁰ improvement). However, there is inconclusive evidence of benefit in the long term because few trials follow-up women for longer than 3 or 6 months.

Message:

- Upper limb exercise, e.g. **shoulder ROM** and **stretching**, is helpful in recovering upper-limb movements after breast cancer surgery.
- Exercise started in the “early” postoperative period, defined as between day 1 and day 3, may result in better shoulder movement in the short term. (This matches with Breast Cancer Care guidance in the usual leaflet).

2) More **structured** exercise programmes delivered in the early weeks following surgery are beneficial for regaining upper limb movement when compared to usual care. **Structured exercise programmes** after surgery significantly improved shoulder flexion ROM in the short term (6 RCTs - average ROM improvement of 13⁰). Structured physical therapy was also found to improve shoulder function at six month follow-up. There was **no evidence of increased risk** of lymphoedema from exercise at any time point.

Message: Structured exercise programmes delivered in the early weeks after surgery are beneficial for regaining movement and use of the shoulder and arm for daily activities. **There are proven benefits on shoulder flexion ROM in the short and long-term and shoulder abduction ROM in the long-term.** Exercise during and after breast cancer treatment is safe.

5.4 Evidence for restricting movement in the first postoperative week

The upper limb exercises in PROSPER have been selected to target upper limb range of movement and strength. Early exercise needs to be carefully implemented to avoid increases in wound drainage and risk of seroma.¹² Avoiding aggressive actions and curtailing movement to 90 degrees in the **first postoperative week** may reduce potential wound-related side effects. Restricting ROM to shoulder height in the first week is widely recommended in clinical

practice and this advice is included in the Breast Cancer Care leaflets.³³ Therefore for PROSPER, we recommend adherence to accepted practice and exercises should be **restricted** to 90° in the first postoperative week.

5.5 After the first postoperative week

After the first postoperative week, the aim is for women to regain full range of movement with progression to active and active-assisted exercises. The PROSPER exercises target three movement directions: flexion, abduction and external rotation. In the PROSPER participant materials, these are referred to as forward, side exercises and open chest.

5.6 Range of Movement – Daily prolonged stretch

A **sustained stretch** is defined as a stretch that is held for a variable period of time. This can help maintain flexibility of the soft tissues and joints. Evidence suggests that prolonged daily stretching can prevent negative physiological adaptations to the muscle spindles, to the stretch reflex and proprioceptors and also prevent shortening of the muscle fibres.³⁵ Animal models have shown that daily stretching can play a key role in connective tissue remodelling and production of collagen in response to injury.³⁶ Several clinical trials of breast cancer patients have incorporated prolonged stretches e.g. a stretch of the pectoral muscles, in conjunction with other exercises.¹²⁻³¹ This stretch may help women achieve the correct extended arm position for radiotherapy treatment. One trial studied the effects of prolonged passive stretching of pectoral muscles and found no differences in shoulder range of movement at 7 months follow up, however this study was in a very small sample (n=61).³⁴ Other trials have included sustained stretches or a stretching programme with positive outcomes.³⁷ Importantly, adverse effects such as lymphoedema have not been linked with prolonged stretches.³⁸ The PROSPER exercise programme therefore includes a **daily stretch and hold** over one 10 minute period or two 5 minute periods.

5.7 Evidence for strength exercises

Muscle strength is defined as the ability of a muscle to exert a force to overcome a **resistance** e.g. pushing against a theraband or moving body weight against gravity. As breast cancer is

more common in older women, the impact of ageing on muscle strength should be considered when designing an exercise programme. As people get older, muscle atrophy and reduction in strength occurs as a result of a gradual loss of both muscle fibre size and number.^{39 40} By the age of 50, about 10% of our muscle mass is lost but after the age of 50, the rate of decline accelerates. Muscle strength declines by approximately 15% per decade for ages 60s and 70s, and by about 30% thereafter.⁴⁰ However, for many, muscles become weak and atrophy because of lack of use rather than purely from ageing and this process will be exaggerated in those who have had surgery and cancer treatments. A targeted **strength training** stimulus can lead to significant improvements in both muscle mass and strength associated with ageing and as a consequence of breast cancer treatment. Strength training, in addition to effects on muscle mass, can lead to other physiological changes including improvements in insulin action, bone density and energy metabolism.⁴⁰

Traditionally, therapists have avoided adding strength training or providing higher load resistance using weights, bands or machines due to concerns about lymphoedema.⁴¹ One study investigated a gym programme of free weights and resistance machines in women 4 to 12 weeks after breast surgery and reported an improvement in physical function.⁴² Another recent Australian trial tested a supervised weekly session and home exercise strength training programme targeted at shoulder muscles using therabands of varying grades – this trial included 81 women who were progressed over eight weeks using the Borg scale.³¹ The control group (n=79) did not receive any education or exercises although had biweekly visits for lymphoedema checks. The exercise group had significant improvements in shoulder abductors and flexors strength of 10N and 7.3N respectively, favouring the strength programme. More importantly, arm circumference measurements and bio-impedance spectroscopy confirmed that strength training **did not** increase the risk of lymphoedema and hence **strength training was considered to be clinically safe.**

A **progressive resistance** exercise programme that is **individualised** will address muscle weakness and lead to benefits to upper limb strength and function. Thus for PROSPER, we recommend that strength exercises using therabands should be started at an appropriate intensity for each participant and progressed gradually to ensure sufficient load to prompt muscle adaptation of key muscle groups.

5.8 Principles of strength training and progression

Important aspects to consider with any exercise programme include the duration of the programme, the specificity of exercises and ‘individualisation’. **Progression** needs to be included to maintain improvement and to prevent plateauing or potential reversal of training effects. Progression in resistance training is defined as “the act of moving forward or advancing toward a specific goal over time until the target goal has been achieved”.⁴⁰

Generally accepted **physiological principles** are that an increase in strength requires a **sufficient training stimulus**. This can be achieved by manipulation of the load, number of sets and repetitions, and rest intervals. The **load** is the amount of weight lifted in a given set, which is based on a percentage of the 1-repetition maximum (1RM). The %1RM that is chosen will depend on the outcome that is being targeted e.g. muscle strength. In PROSPER, we want to improve upper limb strength which requires a target of 70-80% 1RM. Table 5.1 shows the correlation between the number of repetitions required and %1RM to achieve an adequate training stimulus.

Table 5.1 Resistance and repetitions for strength training protocols⁴³

		Higher strength stimulus Higher injury risk		High strength stimulus Low injury risk			Lower strength stimulus Lower injury risk				
Resistance % 1RM	100%	95%	90%	85%	80%	75%	70%	65%	60%	55%	50%
Repetitions	1	2	4	6	8	10	12	14	16	18	20
		Acceptable					Acceptable				
										Recommended	

5.9 Baseline setting of resistance for strength training

The correct level of resistance should be carefully prescribed to avoid injury and to gain the desired benefits. In PROSPER, we ask you to use therabands rather than free weights. Bear

in mind that the participants have recently had surgery and we do not want to increase the risk of harm. Given the difficulties in objective measurement of %1RM, we ask you to use the Borg Scale to assess effort. It has been shown that the BORG scale is appropriate, timely and has been demonstrated to be just as effective as calculating the %1RM rather than lifting the 1RM, which in this population group, may do harm.⁴⁴ The Borg scale of perceived exertion is shown in Table 5.2. Research has shown that a resistance band that achieves **5-6 on the BORG scale** after 2 repetitions is the correct resistance to use to start off training.⁴⁴ This will be used in PROSPER when participants are ready to progress from ROM onto strengthening exercises, at approximately 4 weeks after surgery.

Table 5.2 Borg Scale of Perceived Exertion⁴⁴



1-10 Borg Rating of Perceived Exertion Scale		
0	Rest	
1	Really easy	
2	Easy	
3	Moderate	
4	Sort of hard	
5	Hard	
6		
7	Really hard	
8		
9	Really, really hard	
10	Maximal, just like my hardest race	

5.10 Resistance using Therabands

Theraband tubing works on the principle of force elongation. The resistance from the tubing bands depends on the level at which the bands are stretched. The resistance can be measured in pounds or kilogram (kg) per force depending on how much it is **stretched beyond its resting length**. The TheraBand Company offer different resistance options represented by bands of different colours which increase in resistance by 25% as you progress from colour to colour.

For the PROSPER trial, we have selected 3 colours which represent easy, moderate and hard - Tan, Red and Blue (Table 5.3). These have been selected bearing in mind the age and ability of our breast cancer population. These bands should be manageable but challenging enough for use.

Table 5.3 TheraBand resistance levels in kilogram (kg) by colour

Theraband Tubing Colour	Increase from preceding colour at 100% Elongation	Resistance in kg at 100% Elongation
Tan	-	1.1
Red	25%	1.7
Blue	25%	2.6

Source: www.thera-bandacademy.com

5.11 Overload, rest and recovery

As the participant becomes stronger and the baseline strengthening exercises become easier (i.e. no longer rating them as 5-6 on the Borg Scale) you can then **progress** their exercises. One approach to progression is to increase the number of repetitions to a maximum of 12 or sets to 3. However, another important aspect of progression is **overload** – this refers to having to work longer or harder than normal. Overload is when greater than normal stress or load is placed on the body and it is required for adaptation. When training, the body will gradually adapt to exercise repetitions and increasing weights over time. When the body has adapted, there is a need to apply overload (again) in order to progress and improve further. However, if prescribed exercises are increased too quickly (too much overload), this will not only hamper progression but will also lead to demotivation and could cause injury. Therefore it is important to consider the principles of safe progression as you add more load. **Rest** and **recovery** are also important. Over-exercising can lead to pain and muscle injury therefore it is important to rest between each set of exercises to allow muscle fibres a chance to rebuild and recover. For that reason, the PROSPER exercise programme recommends that strength /theraband exercises should be carried out with rest periods between sets (refer to Table 7.2) and done **two to three times a week** rather than every day.

5.12 Evidence for general physical activity

In order to mitigate the various side effects of breast cancer treatments, trial participants will be encouraged to be more physically active. Most exercise trials of breast cancer patients focus on upper body exercises and rarely include a general exercise programme or target deconditioning that can occur as a consequence of treatment. Evidence suggests that only a small proportion of women diagnosed with breast cancer achieve the recommended levels of exercise and many fail to return to their pre-diagnosis physical activity levels.⁴⁵ However, survival is increased in women who are more physically active after their breast cancer diagnosis. A large USA study followed up almost 3000 women after breast cancer treatment and found that those who were more physically active, thus walking at an average pace for 3 to 5 hours per week, reduced the rate of cancer death compared to women who did little or no activity.⁴⁶ This study recommended that all women diagnosed with breast cancer should follow physical activity guidelines.

Systematic reviews have investigated the benefits of physical activity during and after breast cancer treatment.^{47 48} Physical activity programmes are safe and have been shown to have positive effects on fitness, muscle strength and function – also importantly, on fatigue, depression and anxiety.^{47 48} Activity may include gym classes or different aerobic activities such as walking, cycling or more gentle activity such as Pilates, yoga or Tai Chi. A recent trial compared a standard aerobic programme of 25-30 minute sessions delivered three times per week with a high aerobic programme (50-60 minute sessions, three times per week) and a combination dosage of 50-60 minutes of aerobic and standard resisted exercises (2 sets of 10-12 repetitions, three times per week).⁴⁹ Authors found that high intensity aerobic exercises were safe in breast cancer patients and that a combination of aerobic and resisted exercises resulted in better treatment outcomes, such as increased muscle strength and quality of life compared to aerobic exercises alone.

It has been shown that moderate intensity exercise at **150 minutes** per week is sufficient to achieve health benefits.⁵⁰ However, others recommend that these 150 minutes should combine aerobic with strength training on at least 2 days per week.⁵¹ It is important to ‘individualise’ a physical activity programme, thus exercises should be enjoyable and be safely prescribed taking account of previous experience and current level of physical activity.⁵¹ The

PROSPER exercise programme therefore incorporates advice on general physical activity as per WHO advice – thus 150 minutes per week.⁵⁰ This can be achieved by doing 30 minutes per day for 5 days a week as per Table 5.4.

Table 5.4 Physical activity recommendations

Recommended activity levels (World Health Organisation)⁵⁰	PROSPER Physical activity recommendations
150 minutes per week	150 minutes = 30 minutes per day. Aim to do 5 days a week

5.13 Evidence for behavioural strategies

The PROSPER exercise programme includes behavioural strategies to encourage adherence with arm exercises and general physical activity. **Adherence** has been defined as the extent to which a person's behaviour corresponds with agreed recommendations from a health care provider.⁵⁰ The challenge with every exercise programme is to encourage adherence over time. Exercise programs supported with behavioural support strategies such as self-monitoring, self-efficacy, motivational encouragement, goal setting and action planning can help promote adherence. These strategies have been successfully used in other exercise trials. However, breast cancer patients face additional challenges as they are being asked to exercise whilst undergoing debilitating, cancer-related treatments. This last section describes some behavioural strategies that have been shown to encourage exercise adherence.⁵²⁻⁵⁴

5.14 Behavioural frameworks

Different theoretical frameworks and models have been used to better understand behaviour and motivations for health behaviour change. These models analyse the various processes and stages that people go through when trying to change a particular behaviour, regardless of the lifestyle behaviour, whether it be drinking, smoking, diet or exercise. These stages include thinking about change (contemplation), preparing for change, action and maintenance. We know that adherence with exercise may depend upon which stage someone is at. It is important that exercises are **individualised**, taking account of the stage of

treatment, attitudes towards exercise and by exploring pre-diagnosis exercise history. It has been shown that breast cancer patients who receive tailored counselling are more likely to adhere to an exercise intervention.⁵⁵

There is also good evidence that **action planning** can be used as a technique for increasing physical activity.^{53 56} Consideration of exercise history and preferences for type of activity will help in the setting of targets and may promote adherence. Breast cancer studies have found that women who exercised regularly *before* their diagnosis (thus already in an action or maintenance stage), are less likely to report exercise barriers after treatment.⁵⁵ Another review found that **exercise history** was the biggest predictor of adherence, whereas other factors such as age, clinical, social and environmental factors were not related.⁵⁷

5.15 Strategies for adherence to exercise

A realistic and specific detailed action plan focussing on setting the when, where and how to achieve a goal and influence behaviour change has been shown to improve self-efficacy.^{56 58} **Self-efficacy** is defined as ‘the belief in one’s capabilities to organise and execute the courses of action required to produce given attainments’.⁵⁹ Targeting self-efficacy is an effective method of increasing physical activity and exercise adherence.⁵⁸ Barriers to exercise should be considered and addressed when planning exercise interventions.⁵⁵

Self-monitoring is another method associated with a positive change in physical activity uptake.^{53 60 40} Self-monitoring using an **exercise diary** or calendar to record activity increases awareness of physical activity levels, helps to develop a sense of achievement, enhance accountability and helps in identifying barriers to exercise.^{52 61} Qualitative research with breast cancer patients revealed that a supportive environment and **feedback on performance** from health professionals influenced self-efficacy and exercise motivation levels.⁵⁵ Although the gold standard is face to face communication to encourage physical activity, evidence also supports the use of the telephone as a method to support and encourage adherence.^{54 62 63} PROSPER will combine these approaches.

The PROSPER exercise programme includes behavioural strategies in the form of an **exercise planner** and **exercise diary**. You will work with each trial participant to assess their exercise history and assist them to set exercise goals, help plan when and where to do their exercises. Face to face sessions will be supported by telephone follow-up, to encourage adherence and motivation.

5.16 Summary

In summary, the PROSPER trial exercise programme has been developed based on research evidence and informed by current clinical practice. The final trial intervention is a **physiotherapy-led, progressive home based programme** that incorporates **behavioural strategies** to encourage and facilitate adherence. The next chapter describes how to do the first and subsequent assessments.

Chapter 6. The First Assessment

This Chapter explains how to assess the participant during the first appointment.

6.1 Referral to Physiotherapy

Participants randomised to the PROSPER exercise programme will be referred to a named physiotherapist in your department by the breast care team or research nurse. The referral forms provide contact details for participants taking part in the study – these participants have **already consented**. We will liaise with individual physiotherapy teams to determine the optimal method for referrals, whether paper or electronic, and how best to manage communication and tracking of all trial participants.

6.2 Arranging the first appointment

The first stage is for you or someone delegated within your therapy service to contact the trial participant to arrange a suitable date and time for their first appointment. It is your responsibility to ensure than anyone delegated to do this is fully aware of the trial and is competent in explaining why an appointment will be made. It **very important** that you explain to participants why you have invited them in, and the purpose of the appointment. Remember to allow **one hour** for the first appointment.

Please note that there may be a delay between recruitment/consent and you contacting the participant. Some women may have forgotten that they are going to be contacted by a physiotherapist. Be prepared to explain that they are being offered the opportunity to have one-to-one appointments with a trained physiotherapist to help recovery from breast cancer treatment.

6.3 At the first appointment – Establish a good relationship

Introduce yourself and explain that you are the physiotherapist responsible for looking after for them over the coming months. Explain that this is a **home-based exercise programme** and

that you are there to support them. This will be the first of at least 3 face to face physiotherapy sessions and therefore it is important to establish a good working relationship. Show the participant their own folder (“Your Physiotherapy Folder”) and explain that the goal is to gradually work through the folder with guidance from you and that exercises will be added each time you meet. This will help to set expectations and sets the scene around what to do at home and in the subsequent sessions. Give them plenty of opportunity to ask questions and give realistic explanations of what is involved. This programme does take commitment but we have designed it with input from patients who have been treated for breast cancer thus it should be manageable in addition to ongoing cancer treatment.

6.4 Emphasize the benefits of exercise

When explaining the exercises, **emphasize the benefits** of carrying out the exercises and from physical activity rather than focusing on any negative aspects or stating they may be at risk of developing complications. Recruited participants have already agreed to take part in the study and they may be more motivated to do their arm exercises. However, we do request that you emphasize the benefits of exercise, especially around helping them to return to usual activities and also to help manage symptoms such as fatigue. Women are not usually offered physiotherapy during and after treatment but our consultation with patient support groups who have completed treatment have been very supportive of this trial. Presenting the exercise programme as something that is **useful to help them recover quicker** may encourage both the uptake and compliance with prescribed exercises.

This first session is an opportunity to ask how the participant feels about undertaking an exercise programme as it will help you to understand their beliefs about exercises and potentially identify any barriers or problems.

6.5 Complete the Physiotherapy Treatment Log

Please refer to the Physiotherapy Treatment Log (Appendix 3). You will use this same form to record all information during every physiotherapy session. The form allows up to six treatment sessions to be recorded. Should a participant require more than six treatment sessions, please use a new Physiotherapy Treatment Log form, starting from session two on

the form (as the space to record strength exercises is shaded out in session one). You should keep these forms in your PROSPER Box File or other secure location. Each section of the form is described below.

6.5.1 Clinical information and background screening (Page 1 of Treatment Log)

In the first section, complete the participant's unique trial identification number and treatment details. Record details of history of neck, shoulder or arm problems, any shoulder surgery, other painful conditions, allergies, social situation (whether living alone or caring for children), hobbies, their 'exercise habits' before being diagnosed with cancer, current level of physical activity, and any regular medications. Consider any repetitive activities that may occur from their hobbies, home-life or work e.g. lifting grandchildren, using a computer mouse. This will be relevant when talking about setting future goals.

Previous illness or co-morbidities may have an impact on ability to exercise. Previous surgery and scars may impact on the soft tissues around the newly operated area and may contribute to restricted movement. Patients who have a history of shoulder or arm problems, diabetes or thyroid complaints may be more prone to shoulder dysfunctions.

6.5.2 Assess pain and surgical wounds (Page 2 of Treatment Log)

Tell the participant that you are going to look at their operation site and check shoulder and arm movement. Ask them to remove their outer garments including their bra. Remember that this may be a sensitive or upsetting process for women so be respectful and understanding at all times. Before checking their range of movement, you are going to do a brief assessment of their wound and ask about postoperative pain.

a) Postoperative Pain

There are many different pain assessment tools. We would like you to use a simple Numerical Rating Scale (NRS) which is scored from 0 (no pain) to 10 (most severe pain) to measure pain intensity **on average** today (Table 6.1). The NRS scale is provided as a laminate sheet and can be shown to the participant as a visual prompt. Some pain is to be expected after surgery and during radiotherapy. Ask them to think about pain at or around the operation site, not other

bodily pains. If someone reports a pain score of 7 or higher, then you should examine them and advise them to seek help from the breast care team or GP - they may need stronger analgesia (refer to Chapter 9).

Table 6.1 Assess level of postoperative pain

No pain (0)											Worst pain (10)
0	1	2	3	4	5	6	7	8	9	10	
Ask: "On a scale of 0 – 10, how would you rate your pain on average today?"											

Pain scores		Action to take
0	No pain	Nil
1 – 3	Mild pain	Encourage use of analgesia as and when needed.
4 – 6	Moderate pain	Assess patient and explore whether specific movements cause pain. Encourage use of analgesia before exercising.
7 -10	Severe pain	Assess patient. Seek further advice from breast cancer team or advise to see GP for medication review.

b) Check all surgical wounds

Observe the surgical wounds and drain sites for any signs of redness, inflammation and purulent discharge. Most women will have a breast and/or axillary wound. Ask the participant how their wound(s) feel – is the area hot or painful? If wounds have recently been dressed by the nursing team, we ask that you don't remove the clean dressing. Ensure that the participant knows how to check for signs of infection. If you suspect infection, they may need antibiotics and therefore refer to the breast care team or advise to see their GP. Complete the assessment section to record whether the wound(s) are healed, or whether you suspect infection. Continue to monitor wounds and scars at every appointment. As the shoulder moves so should the area around the scar. As the scar heals, it may adhere to underlying tissue and limit shoulder range of movement which can cause pain or tightness.

c) Lymphoedema

There are many different methods to objectively measure lymphoedema e.g. tape measure to record arm circumference on both arms, water displacement methods etc. For PROSPER,

we ask you to use using simple screening questions because there is evidence that self-report of heaviness and swelling is predictive of early lymphoedema.⁶⁴ There are two questions you should ask during each assessment, in Table 6.2 below. If the participant answers ‘yes’ to either of these questions then you should prescribe the lymphoedema prevention exercises. Chapter 9 presents a lymphoedema management pathway.

Table 6.2 Screen for lymphoedema

Screening questions	Record on Form	Action
Does your arm feel heavy today?	Yes / No	Prescribe lymphoedema prevention exercises
Does your hand /arm feel or look swollen?	Yes / No	

d) *Check for signs of cording*

In the first assessment and for the first few postoperative days, it may not be possible to palpate under the arm as the wound will be tender and healing. In later follow-up sessions, you can gently palpate the area to feel for any cord-like structures in the participant’s axilla or down their arm. Ask about any tightness or burning sensations while moving axilla or arm. Complete the form by scoring from 0 to 3, from no signs or symptoms to 3 – cording with pain or movement restriction (see Table 6.3). Teach the patient can check for this themselves at home. Use the scale below to grade for cording at each assessment. Chapter 9 and Appendix 4 provide more information on treatment and self-management.

Table 6.3 Grading of cording

0	1	2
No evidence of cording	Some signs of cording but not painful or restrictive	Cording with pain and /or restriction of movement

6.5.3 General Observations (Page 2 of Treatment Log)

Check their posture whilst seated. After surgery, the participant may feel they need to protect the operated area and therefore may adopt a slightly flexed posture. Assess position and how

they hold their arm on the affected side. Note for any asymmetry, muscle wasting, any scars or skin changes around the shoulder, neck and abdomen regions, and record your observation. Use this section of the form to record any changes observed during follow-up appointments.

6.5.4. Assessment of range of movement and muscle strength (Page 3)

You can assess active range of movement in the sitting position. However if someone is struggling, you can assess this when lying passively or through active assisted movement. Range of movement is assessed through observation. Each action and corresponding verbal instruction is given below.

- 1) Action: Active shoulder girdle elevation

Position	Sitting
Instructions	“Shrug both your shoulders up towards your ears as much as possible”
Grading	Record whether full movement (F) or restricted movement (R)

- 2) Action: Active shoulder girdle protraction

Position	Sitting
Instructions	“Pull both your shoulder blades (as curving) forward”
Grading	Full or restricted

- 3) Action: Active shoulder girdle retraction

Position	Sitting
Instructions	“Pull both your shoulder blades backwards”
Grading	Full or restricted

4) Action: Active shoulder flexion (0 to 180 degrees)

Position	Sitting
Instructions	“With your elbows straight, lift both arms forward and overhead as much as possible”. Compare both sides
Grading	Full or restricted
<i>*Note - Do not test above 90 degrees during the first week after surgery</i>	

5) Action: Active shoulder abduction (0 to 180 degrees)

Position	Sitting
Instructions	“With your elbows straight, lift both arms sideward and upward as much as possible”. Compare both sides
Grading	Enter the range of abduction in degrees
<i>*Note - Do not test above 90 degrees during the first week after surgery</i>	

6) Action: Active shoulder external rotation (0 to 90 degrees)

Position	Sitting, elbow bent to 90 degrees, forearm in mid-prone with thumb facing up
Instructions	“Take both arms out (externally rotate) as much as possible”. Compare both sides
Grading	Full or restricted
<i>*Note - Do not test above 90 degrees during the first week after surgery. If below 90 degrees test the shoulder in neutral position with the elbow placed at 90 degrees at the side of the body</i>	

7) Action: Active shoulder internal rotation (0 to 70-90 degrees)

Position	Sitting
Instructions	“Take your hands to the back and try to touch your mid-back region as much as possible” (The participant should be able to touch approximately the T7 level) Compare both sides
Grading	Full or restricted
<i>*Note - Do not test above 90 degrees during the first week after surgery</i>	

6.5.5. Assessment of muscle strength (Page 3)

Next, assess the strength of upper limb muscle groups. Do not do this in the first assessment. Assessing strength against resistance in the affected arm is not appropriate **until 4-6 weeks after surgery** depending on the individual. Assessment of strength is a pre-requisite for the prescription and progression of therabands. Muscle strength is tested using resisted isometric

movements – the Isometric Hold Method. The participant is asked to contract the muscle as strongly as possible while the physiotherapist resists to prevent any movement and to ensure that the participant is using maximum effort. This is then measured according to Kendall's method (grades 3-5), shown below (Table 6.4).

Table 6.4 Muscle strength grading scale

What the patient can do	Comment	Grade
Holds position against maximal resistance	Normal	5
Holds position against moderate to strong resistance	Good+	4+
Holds position against moderate resistance	Good	4
Holds position against slight to moderate resistance	Good-	4-
Holds position against slight resistance	Fair	3+
Holds position with no resistance	Fair	3

a) Shoulder flexors strength

Position	Participant sitting on a chair, feet on floor
Procedure:	With elbow bent at 90 degrees and a fisted hand, provide slight support around the shoulder with one hand and with your other hand, apply resistance just above the elbow region
Instructions:	“I am now going to push your arm backward with my hand. Try to hold it and do not let me push it backward”.
Grading	Record a score between 3 - 5

b) Shoulder abductors strength

Position	Participant sitting on a chair, feet on floor
Procedure:	With elbow bent at 90 degrees and a fisted hand, provide slight support around the shoulder with one hand and with your other hand; apply resistance just above the elbow region
Instructions:	“I am now going to push your arm down with my hand. Try to hold it and do not let me push it down”
Grading	Record a score between 3 - 5

c) Shoulder external rotators strength

Position	Participant sitting on a chair, feet on floor
Procedure:	With elbow bent at 90 degrees and a fisted hand, provide slight support around the shoulder with one hand and with your other hand; apply resistance at the dorsum (back) of the wrist
Instructions:	“I am now going to push your arm inwards with my hand. Try to hold it and do not let me push it in”
Grading	Record a score between 3 - 5

d) Shoulder internal rotators strength

Position	Participant sitting on a chair, feet on floor
Procedure:	With elbow bent at 90 degrees and a fisted hand, provide slight support around the shoulder with one hand and with your other hand; apply resistance at the inside of the wrist
Instructions:	"I am now going to push your arm outwards with my hand. Try to hold it and do not let me push it out"
Grading	Record a score between 3-5

6.5.6 Physiotherapy Summary Section (Page 4 of Treatment Log)

In the treatment log form there is a summary page to document findings. Please use this to record your clinical notes at each contact, whether by face to face or by telephone. This form is your clinical record.

The next chapter explains how to prescribe and progress exercises.

Chapter 7. Exercise Prescription and Progression

7.1 Prescribe warm-up, daily stretch and ROM exercises (1st Appointment)

After you have completed the assessment, you are ready to then select exercises from the PROSPER exercise menu. Start with the warm-up exercises: the posture check, shoulder circles and a trunk twist. Pick a trunk twist according to personal preference – these are numbered from 1 to 4. You should **always** include the participant when selecting exercises. If you actively involve them with decision-making, this will hopefully encourage adherence. The purpose of the first appointment is to ensure the person is **engaged with the exercise programme** and that they understand why you have prescribed these exercises. The choice of ROM exercises is given below as a reminder (Table 7.1). Before you start, explain to the participant that you will demonstrate each exercise before watching them do each exercise. You or they can write notes in the Participant Physiotherapy Folder. Ensure that they understand instructions for each exercise. Also remind them to do the warm-ups before progressing to ROM exercises.

Table 7.1 Reminder of ROM Exercises, Weeks 2 - 4 postoperatively

	PROSPER ROM Exercises	
	Exercises	How often / Instructions
Warm up	Posture check	Every day Hold stretch for 5 minutes or once a day for 10 minutes
	Shoulder circles	
	Trunk Twists 1, 2, 3, or 4	
Daily stretch	Daily stretch & hold	Do every day Twice a day
Forward ROM	Clasp hand raise OR Forward wall slide	
	Morning stretch OR Sideways wall slide	
Side ROM	Back broom lift OR Surrender	

7.2 Explain about self-monitoring (1st Appointment)

Participants should be confident enough to continue with their daily exercises until the next appointment. Explain about self-monitoring of their wound and pain control. If they are struggling with any issue, reassure them that they can contact you at any time to arrange a telephone call or another review appointment (see section 8.6).

7.3 Arrange the next appointment (1st Appointment)

Clinical pathways will vary from patient to patient and it will not be possible to arrange every appointment according to our recommended timetable. Try to book the second appointment 4 -6 weeks after their surgery or sooner if you or they have concerns about their understanding or ability.

7.4 At the next appointment - Prescribe Strength exercises (2nd Appointment)

At this 30 minute appointment you will review progress and reassess using the same assessment form. Progress or adapt the exercises accordingly, ideally adding in the resistance /theraband exercises according to the menu. Progression should be tailored according to whether they are higher or lower functioning.

a) Higher functioning women

These participants include those able to reach full range of movement of the shoulder, wounds have healed well, and relatively pain-free and they are confident about doing their exercises regularly. For these ladies, assess strength and progress exercises.

b) Mid to lower functioning women

Some participants will struggle to achieve full shoulder range of movement, or may have wound problems etc. Or they may be fearful and lack confidence in doing their exercises or they may admit they are not doing them as promised. Discuss barriers with these individuals in accordance with Chapter 9 and make revisions to the prescription.

As per Chapter 5, there are 3 theraband colours to choose from: Tan (easy), Red (moderate) and Blue (hard). Start the strength assessment using the Tan (easy) theraband. Select **one** of the resistance exercises from each movement direction, thus one each of **forward, side** and

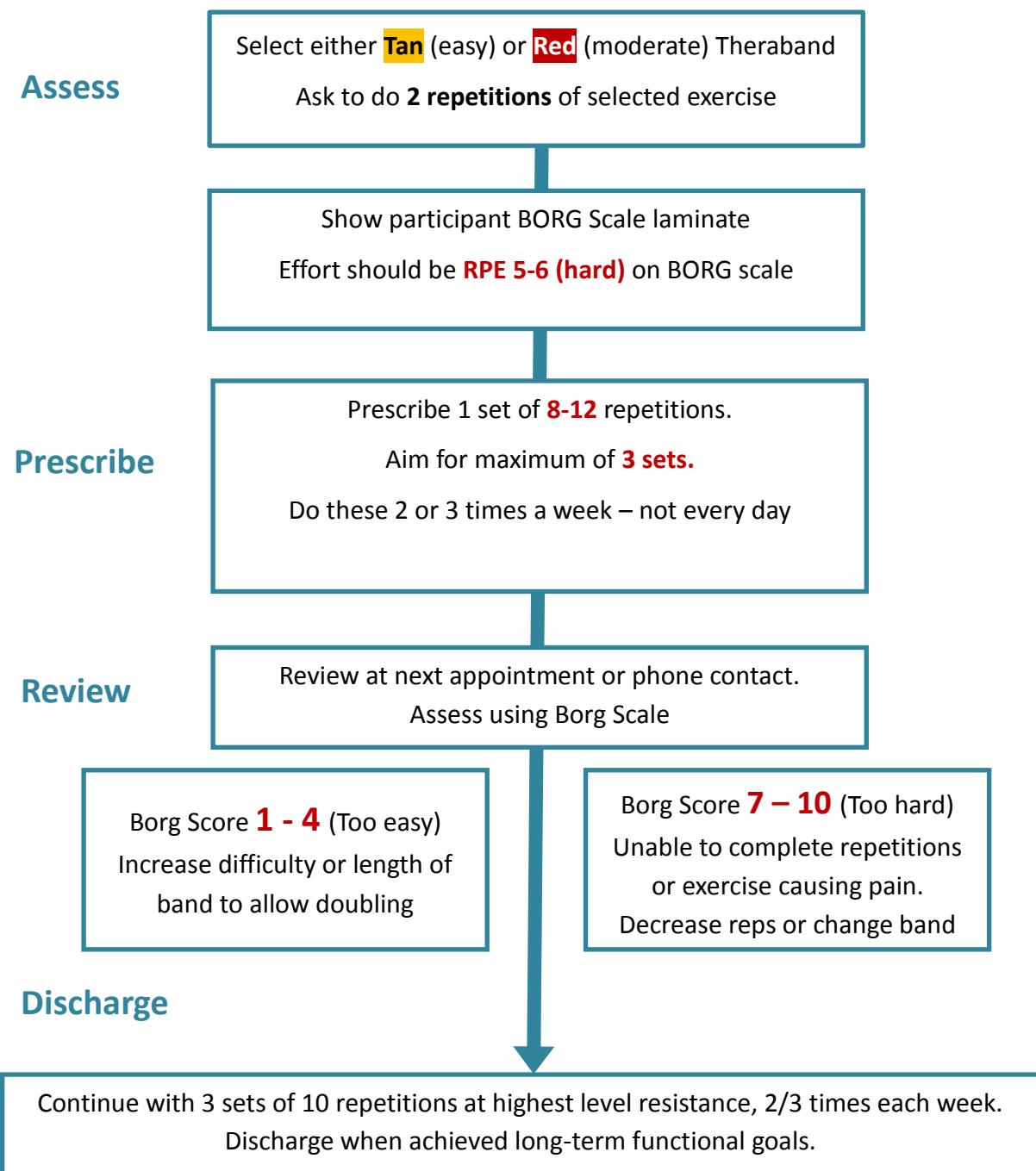
open chest. As a reminder, Table 7.2 presents the menu of strength exercises. Ask the participant to perform 2 repetitions of the exercise using the Tan theraband. Show them the Borg Scale laminate and ask them to rate their level of exertion or difficulty. You are aiming for them to select 5 or 6 (hard effort) on the Borg Scale.

If they find it too easy, you can select the next band (Red, moderate). If they find it too difficult altogether, you may want to progress with ROM exercises or start with isometric strengthening using the opposite hand. Or you could ask them to try another movement using the Tan theraband. See Figure 7.1 on how to assess, prescribe and progress strength exercises. Depending on their level of functioning, you can progress or adapt an exercise by changing start position, length of lever (short to long lever), or by increasing the number of repetitions or sets.

Table 7.2 Prescription of Strength Exercises – from Week 4 onwards

Pick one of each movement	PROSPER Strength Exercises	
	Exercises	How often / Instructions
Forward	Forward Band Lift OR Rocker (easy, intermediate or advanced)	Starting Prescription Borg Scale Rating 5-6 Aiming for 8 – 12 reps
	Sideways Band Stretch (easy or intermediate) OR Wood-Chopper	
Open Chest	Overhead Band Stretch OR Front Band Stretch OR Low Band Row (easy or intermediate)	1 -3 sets Progression Alter band strength accordingly
Rest period	For lower intensity with light loads, rest 1 -2 minutes in between. For higher intensity with heavier loads, rest 2-3 minutes in between.	

Figure 7.1 Flowchart for prescription of strength exercises



7.5 At the next Appointment (3rd Appointment)

Assess, review, progress and encourage self-management. This 30 minute appointment is to assess progress and review any barriers. The aim of this appointment is to encourage self-management at the highest level required for that individual.

7.6 Physical Activity (All Appointments)

You should also encourage them to keep physically active throughout their treatment journey. They should aim for 30 minutes of physical activity 5 times a week. Try to encourage ladies to stick to their twice daily stretching and strength work 2-3 times a week. There are some useful resources included that provide different ideas on how to keep physically active should they be struggling for ideas about how to incorporate into daily life. See also the breast cancer charity websites e.g. Breast Cancer Care (www.breastcancercare.org.uk) and Cancer Research UK (www.cancerresearch.org.uk).

7.7 The Final Appointment / Discharge

When the patient has achieved their long-term goals and you consider them to have good range of movement and strength that allows them to function according to their needs, you can discharge this patient. They can contact you again at any time during the 12 month period if they have a physiotherapy-related problem. As a reminder, we allow up to 6 contacts per participant but this is flexible – some participants may need more but we expect the majority to have less than 6 contacts with your service.

Note: It is important to note that many women will be having chemotherapy. This is a challenging and tiring experience. Try to encourage women to continue with their exercises. Ask them to be honest when recording how many of their exercises they manage. Be clear this is not about judging them – it is being realistic about how challenging it can be to continue with exercising during a stressful phase of treatment.

Chapter 8. Promoting Adherence to Exercise

8.1 Introduction

This chapter describes strategies that can be used to promote **behaviour change**. Ultimately we want participants to incorporate their prescribed exercises into their daily lives. The PROSPER exercise programme aims to share the responsibility of rehabilitation and recovery between the participant and the therapist by developing a collaborative rehabilitation plan. PROSPER is a **home-based** exercise programme and therefore to improve and promote adherence, each participant should be involved in the decision-making process from the outset and be comfortable and ‘on board’ with what you prescribe.

8.2 Beliefs about exercise

An individual’s beliefs about exercise will be shaped by their previous experiences with family, friends, society and health care professionals. If you give someone new information which does not fit with their existing health beliefs then they are more likely to disregard the advice and stick with their own established beliefs. If, however, you work together in generating a “client-centred concept” about exercise and activity-related behaviour, this is more likely to be accepted and incorporated in their daily life. It is useful to think of **every interaction** that you have with a trial participant is an intervention in itself. Every contact is an opportunity to support and encourage adherence and **reinforce positive behaviours**.

8.3 Behavioural support strategies

The aim of this chapter is to equip you with techniques and strategies to help promote confidence and to encourage participants to remain motivated over time. We will share some simple communication techniques to help you support participants’ to identify their own goals and, more importantly, to stick to them. These **behavioural support** strategies are underpinned by health psychology theory and have been successfully used in other clinical studies. These strategies can help promote and maintain behavioural change. Two key processes to behavioural change and encouraging adherence are: planning ahead and recording progress. These are covered in the two PROSPER documents: the **Personal Exercise Planner** and the **Exercise Diary**. Every participant will already have consented to take part so

this does mean that, to some extent, they are willing and hopefully open to the concept of changing behaviour by sticking to the exercises you prescribe for them. The broader challenge is to encourage participants to integrate these exercises and general activity into their daily life, bearing in mind they are currently coping with a potentially life changing diagnosis of breast cancer. Table 8.1 lists some behavioural strategies to use at each contact point – **remember** each contact is an opportunity for support and encouragement.

Table 8.1 Overview of behavioural support activities

Sessions	Behavioural support activities
All sessions	<ul style="list-style-type: none"> • Get to know the participant and respond to any concerns raised • Provide positive feedback and support • Appreciate and praise their efforts in completing exercises or filling the exercise diary, irrespective of how small or large the changes may be. • Arrange telephone calls or encourage re-attendance as needed
1 st appointment	<ul style="list-style-type: none"> • Work together to set broad and specific goals • Show them how to complete the Exercise Planner and Diary • Discuss barriers and facilitators for exercise • Ask them to complete the Exercise Diary
2 nd appointment	<ul style="list-style-type: none"> • Review their Exercise Diary
3 rd appointment	<ul style="list-style-type: none"> • Progress exercises
All other sessions up to 12 months post randomisation	<ul style="list-style-type: none"> • Provide further education and encouragement • Complete new Exercise Planner and Exercise Diary, as required • Continuing support via face-to-face sessions or phone calls provided by the same therapist (if possible)

8.4 Completing the Personal Exercise Planner and Exercise Diary

Complete the **Personal Exercise Planner** and show them how to complete their **Exercise Diary**. This is a joint decision-making process which involves the participant in setting **general** and **specific exercise goals** and planning how best to achieve them. The aim is to encourage commitment to achieving the specified objectives in the hope that they will be more willing

to adhere to the programme. For this to be successful, it is important for them to see a link between doing their exercises and achieving their personal longer-term goals. See the later section (8.5.2) on ‘**Motivational Interviewing**’ which gives techniques to encourage compliance and participation.

8.4.1 Personal Exercise Planner - “My long-term goal”

The first section of the **Personal Exercise Planner** is to set a long-term exercise goal that is specific and likely to be achieved. Goals should be SMART that is: Specific, Measureable, ARelevant and Timely (Table 8.2). Help them set a long-term goal and complete the **Personal Exercise Planner**. This goal can be anything as long as it personal (i.e. they choose it) and they see it as worth the effort of doing exercise to achieve it. If they are having difficulty with this, use information discussed during the assessment where you asked about usual work/leisure activities or hobbies. Any activity could be a long-term goal. Ask them what they would like to get back to – what is most important to them? There must be some relation between their long-term goal and the prescribed exercises otherwise they may not see the benefit in sticking to the exercises.

8.4.2 Personal Exercise Planner - “My specific exercise goal”

The next section is to set a **specific exercise goal**. The specific goal is **ALWAYS** the exercise program that you have prescribed for them. This short-term goal is the means to achieving their long-term goal. It is important to share your knowledge without preaching. Explain by sticking to their exercises, this will help improve shoulder movement on the operated side, help them recover quicker and get back to usual activities. Try to motivate participants to continue without telling them they **MUST** do something. Explain that the evidence that shows that women who stick to their exercises have a better outcome in the longer term. Try the following approach: **“There is evidence to show that by using these exercises daily, women become more mobile and can perform activities such as gardening (use their general goal example). I am wondering if you feel they will be helpful for you.”**

Table 8.2 SMART Goals

Specific 	<p>Some goals can be vague and difficult to measure. Set goals that are clear and precise. For example, a vague goal would be 'I want to be fit and athletic'. A clear and specific goal would be "I will work out at the local gym for at least 30 minutes 3 times a week at 7pm on Monday and Thursday and 10am on Saturday."</p> <p>To help make goals specific, ask questions such as:</p> <ul style="list-style-type: none"> - What exercises/activity will you do? <i>You give help here</i> - How and where are you going to do them? - When will you do them? - With whom are you going to do your exercises? Is there anyone you could exercise with?
Measurable 	<p>The goal should be easy to measure whether or not they have achieved it. The example "I will work out at the local gym for at least 30 minutes 3 times a week at 7pm on Monday and Thursday and 10am on Saturday," is measurable. You ask <u>them</u> to record in the Exercise Diary how many times they have done the exercises, how many repetitions etc.</p>
Achievable 	<p>Set goals that are within reach. Failing to achieve a goal has a negative effect on motivation. It is important to make the first goal quite easy to achieve to boost self-confidence and encourage them to carry on. Remind them that building on small successes is the best way to change behaviour in the long-term.</p>
Relevant 	<p>Is the goal relevant to them? You should cover this in the appointment. You should check that they see a clear link between their goal and their health or how they feel, and that it is a behaviour that they want to change.</p>
Timely 	<p>Is this goal the right thing for them to try to achieve right now? If so, set a time frame in which the goal can be achieved. If you don't set a target date, it could go on and on without them ever achieving it. E.g. their next appointment is a month away, aim to complete the goal by then. You may want to set them mini-goals for them each week in between.</p>

8.4.3 Personal Exercise Planner - “My confidence”

Use the confidence scale below to ask about confidence in ability to achieve or complete the exercises you have prescribed (Table 8.3). Do this in the first assessment as it will impact on future progress. The scale ranges from 0 to 10 and we have taken **7** as the cut-off point for “confidence in ability to exercise”.

Table 8.3 Confidence scale

Not confident											Very confident
0	1	2	3	4	5	6	7	8	9	10	
Instructions:											
On a scale of 0 to 10, how confident am I that I can achieve my specific exercise goal?											

- If they score 7 or higher**

Record the score and move onto the next section. It is worth asking why they are so confident just to make sure that they are **realistic in their expectations**. You might find it useful to use the **Barriers and Facilitators** sheet to explore fears that they may not initially divulge (Appendix 6). Section 8.4 has sample questions to encourage open ended conversations.

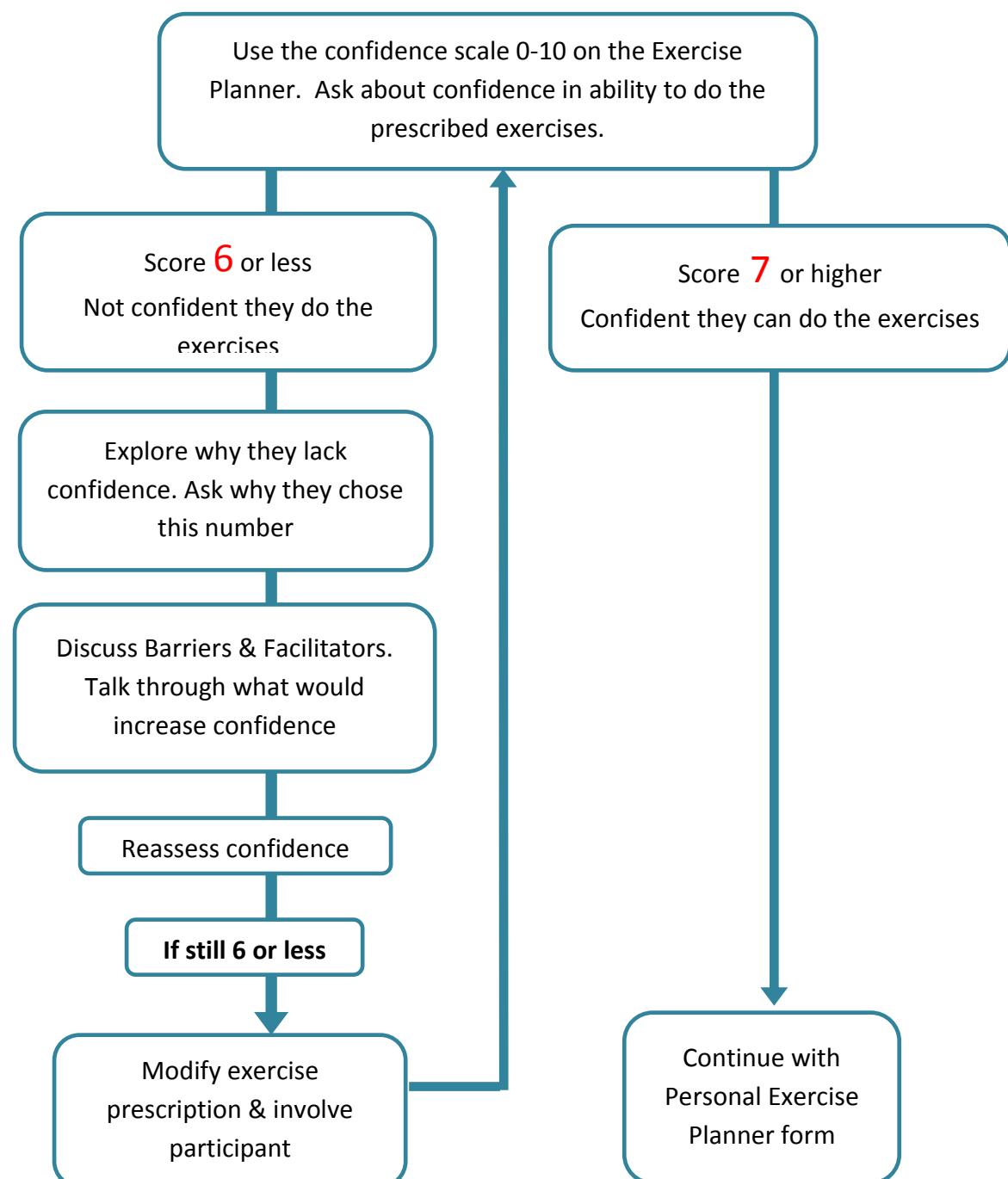
- If they score lower than 7 on confidence scale**

Your aim is to try and improve their confidence. Start by asking why they chose this number. Hopefully they will explain why they lack confidence and you can make helpful suggestions. Use the **Barriers and Facilitators** sheet as a guide. Ask what would help them to be more confident e.g. finding someone to exercise with, or explore any negative thoughts or worries.

They may raise issues that you can use to try and increase their confidence further. Some women will be fearful of pain or causing damage which can lead to **fear avoidance** behaviour. This will affect self-efficacy which may reduce their ability to adhere to their exercise programme. Listening and reassurance will help. Ask about the past to find out when they have achieved something which gave them confidence e.g. they managed to lose weight, or run a 5km or other goal. By questioning about past successes you could find ways to increase confidence in doing their exercises. Reassess confidence level at each follow-up appointment. Reassure them that they can be honest, there are no right or wrong answers. **If they still**

score less than 7 on the confidence scale, then select new exercises or adjust the prescription e.g. reduce load, repetitions or change the actual exercises – but again involve them in this process. See Figure 8.1 for confidence assessment flowchart.

Figure 8.1 Flow chart for assessing confidence in ability to exercise



8.4.4. Where and when to do the exercises

Ask when and where they will do their daily exercises. Discuss a regular time or place e.g. first thing in the morning or when watching a particular TV programme. By associating the activity with an event, it will help to remind them to do their exercises and, hopefully, become a habit. Think about the time, location and space needed, especially if they are using equipment such as a resistance band or pole. Ask them to record this linking event in their exercise diary so that you can review it at the next session.

8.4.5. Completing the Exercise diary

Ask when and where they will fill out their exercise diary e.g. "*I will fill in my exercise diary every day after I have done my exercises / or before going to bed.*" Again, you should link completion of the exercise diary with an event to remind them. They should bring the completed diary with them for review at the next session.

8.4.6 The exercise contract

At the end of each appointment, ensure that they understand what they need to do before the next appointment i.e. they are comfortable with doing their exercises, they understand the paperwork and how to self-monitor for complications. Summarise and reiterate when and where they are going to do their exercises to ensure they are comfortable with the agreed plan. The Personal Exercise Planner contract should be signed by you both and you each have a copy.

8.5 Follow-up appointments

Ask them to bring their Physiotherapy Folder to the next review appointment. Review the exercise diary and planner at the next physiotherapy session and complete a new exercise diary and planner. In follow-up sessions, please review participants' progress and use the **exercise diary** as a basis for discussion. Ask about how they have managed with their exercise programme and then consider how you want them to progress (refer to Table 8.4). You will keep the exercise diary and help the participant to complete a new one at each session. Remember to **develop a new personal exercise planner during each of the review**

sessions. Encourage participants to contact you if they are at home and concerned about their exercises. Some common barriers to exercise are listed below:

- Time constraints, too busy to exercise
- Changes in breast appearance, embarrassment or self-conscious
- Lack of social support
- Chemotherapy side-effects e.g. nausea or fatigue
- Getting bored with exercises
- Priority given to other activities
- Bra or clothes too uncomfortable
- Low self-efficacy
- Low motivation

8.6 When to arrange an additional appointment

You should arrange another appointment for any of the reasons listed below. We have also listed example scenarios for when participants should contact their physiotherapist. These examples are described in the Participant Physiotherapy Folder as a laminated back page.

Physiotherapist / Participant prompts for additional contact

- Lack of range of movement, especially if due to have radiotherapy
- After a medication review, may want to review / progress exercises
- Review after any short-term illness /break
- Lack of confidence to exercise independently
- Cording or soft tissue causing tightness
- Failing to return to usual daily activities
- Wound problems (refer onto breast care team)
- Arm swelling, heaviness or tightness
- Exercises too easy or too difficult
- Difficulties returning to hobbies or work

Table 8.4 Actions during follow-up review appointments

Review appointment	Actions
 Conducted exercises and exercise diary fully completed	 Congratulations – well done on completing.  Progress exercises as required Complete a new Personal Exercise Planner
 Partly completed exercises and/or exercise diary	 Congratulations! Explore barriers and facilitators  Brainstorm solutions & revise goals Complete a new Personal Exercise Planner
 Exercises not done and exercise diary incomplete	Highlight that problems & setbacks are learning opportunities, not failures. Explore what the problems were and problem solve together to discuss solutions.  Complete a new Personal Exercise Planner and be positive about what they did achieve e.g. attended appointment and remembered to bring their folder.
 Forgot to bring exercise folder or diary	 Fill in a blank diary together. Ask them what they wanted to achieve and how they got on. Set new goals and plan for the next appointment.

8.7 Key principles of therapist-participant interaction

1) Avoid confrontation or arguments

When you are presented with a negative response from a participant, remember there are always some grey areas to work with. Despite you having good intentions, if you confront them too much, this may lead to despondency, irritation and lack of cooperation. They will have the solution to why they do or do not adhere to their exercises and you have an opportunity here to uncover these reasons.

2) Discuss ambivalence and elicit, clarify and resolve

When you interact, they may overtly display their uncertainty, "*I don't know if I can fit all of these in to my daily life*" or you may notice non-verbal cues which signal ambivalence (over confidence, non-committal shrugs). We share some tips to explore why someone may be uncertain, what could help them, who might support them and how to identify solutions.

3) Direct persuasion of the benefits is not effective

There is evidence to show that an authoritarian method of telling people to do something e.g. "give up smoking, stop drinking, exercise more" just leads to resistance. It reduces the probability of someone changing their behaviour.⁶⁵ Instead we aim for the participant to **WANT** to change. Your role is to identify their health goals and challenge maladaptive thoughts and behaviours. See Box 8.1 as an example.

4) Fluctuate in readiness to adhere

A person's motivation to change can fluctuate over time. Someone might be receptive to messages initially but then find in a later appointment that they are no longer motivated and want to stop the programme. The readiness of a participant is not a trait but a consequence of their interpersonal interactions. It is important for you to gauge as closely as possible how ready they are to make sure you are both working from the same page and not to get frustrated with changes.

Box 8.1 Example conversation

Participant: "I don't want to do these exercises" Then you can roll with this....

Therapist: "Could you help me understand why you don't want to do them?"

Participant: "It is just an extra burden on my already stressed out life"

Therapist: "I can hear that you are under a lot of pressure. Can you explain to me the negatives and positives of incorporating these exercises into your life?"

Participant: "It is just another thing on my long list of things to do but I guess it might help reduce the pain that I am having?"

Therapist: "Can you explain to me how important it is for you to reduce this pain?"

Patient: "Ok well obviously I don't want to be in pain. I want to be as healthy as possible but it's just difficult..."

Therapist: "I understand that. Could we look at some of the things you have on your things to do list, take a typical day? If we work through this together we might be able to find some space to bring the exercises in so they do not become a burden but still help you as much as possible to avoid having pain.

5) Partnership

Your contact with them may only be a few minutes here and there, especially when following up progress by telephone. After the phone call, they go back to their busy daily life and unless they have a strong desire for taking control and for change, it is unlikely that behavioural change will occur. You must work together to generate a supportive and determined environment for change.

8.8 Examples of key conversational skills and techniques

When using motivational interviewing techniques, It can be helpful to think of the acronym **OARS** (Open ended questioning, Affirmations, Reflection and Summarising). See Box 8.2 for examples to conversational skills and techniques.

Box 8.2 Examples of conversation techniques

Open ended questioning	
Therapist:	"Can you explain to me why you think 10 minutes to not be an appropriate amount of time to spend on your exercises?" rather than "You wouldn't spend 10 minutes on your exercises?" which can be answered with "no". Encourage further discussion by probing.
Therapist:	"Can you elaborate on that?"
Therapist:	"I am glad you have brought that up. How do you feel about not having enough time to fit the exercises in?"
Affirmations	
Correctly pitch the level of affirmation to the person without being too over the top or overly enthusiastic. You are aiming to improve self-efficacy.	
Therapist:	"With your busy life, it's clear that you have tried really hard to integrate these exercises into your daily life"
Reflection	
Where you reflect back what they say to generate further "behaviour change talk".	
Therapist:	"It sounds like you are saying".....or....."I get the sense that..."
Therapist:	"It sounds as though you have a lot on your plate just now, do you think there is any way someone could help take some of your 'things to do' to allow you more time to fit in your exercises?"
Simple reflection	
Therapist:	" <u>I hear your concern</u> that the exercises will hurt, is that correct?"
Amplified reflection: Exaggerate the point which might lead them to disagree with it	
Therapist:	"So you feel that it is a <u>total impossibility</u> to fit the exercises into your morning routine?" Double-sided: if they have mentioned a positive behaviour statement earlier in the conversation, this can then be used to reflect or counteract a negative statement
Example:	"You have explained that it is impossible to do the exercises before work <u>but you still think they will make you feel more awake and positive?</u> "
Summarising at the end of the session	
Example	"It sounds as though you are keen to try these exercises but that you have some concerns about how you will fit them into daily life. Do you feel like we have explored some ideas of how best to try and fit them into your daily life?"
Example	"The picture that I see from what you have told me is that you have to juggle lots of things every day and you have suggested that if some of your family/friends could take some of these tasks on, this would give you some more time to perform these exercises?"

Another key skill is **ACTIVE LISTENING**. Don't be afraid to **stay quiet** and allow the participant to generate their own solution to problems. Pay attention to **non-verbal cues** which you can probe further with open questions if necessary. In addition to the key skills of motivational interviewing (OARS), there are other techniques which can be used when encountering resistance to change. Here are some techniques which can help when you encounter challenges.

8.8.1 Encountering resistance

Try rolling with resistance rather than opposing it as this can paradoxically bring the client to a balanced or opposing view. Example: "*That is true and only you know what is possible and what is not possible*". See the Box X below.

Box 8.3 Encountering Resistance

Rolling with resistance	
Therapist:	"This section of the form is about completing your exercise diary. When do you think you will record it?"
Participant:	"Well, ideally it would be straight after doing my exercises but, to be honest I am getting a bit fed up, there seems to be more and more things I have to do. I just do not think I will be completing this diary every day."
Therapist:	"Ok it may well be that this is not a feasible tool. You may decide not to use this diary because it is too difficult to integrate it into your life. That will be up to you."
Reframing	This is where you try presenting something that the client has said but from a different perspective to encourage continued behaviour change talk.
Participant:	"There just seem to be so many things I have been told to do since the surgery, this is just another one"
Therapist:	"Yes I can only assume that feels difficult. I am glad that you have had a good support from all the different healthcare professionals offering you things to do"
Participant:	I'm sorry I just feel like everyone is nagging me to do things. My husband is always reminding me that I have to do this and that to get better and be healthy again.
Therapist:	"It sounds as though your husband cares a great deal about you especially if he feels like he should keep reminding you even though he might see that it can make you angry."

Box 8.4 Tips to encourage adherence

- Set realistic targets and goals
- Encourage a variety of physical activities to avoid exercise boredom
- Always be positive and encouraging ☺
- Congratulate on achieving small goals
- Use the additional 3 contacts as ‘booster’ appointment sessions or telephone calls, if you feel the participant needs extra encouragement or support
- Exercises may need to be restarted or modified after short-term illness
- It is common to encounter setbacks – it doesn’t mean they have to drop out of the programme
- Suggest they use sticky notes or electronic phone reminders to exercise
- Advise to wear comfortable clothing and shoes during exercise sessions
- Try to make the sessions fun - play music or radio when exercising
- Ask their partner, friends or neighbours to encourage them and/or join in
- Be willing to discuss the programme with their spouse or other family members
- Be mindful and respectful of personal, social or cultural issues

Chapter 9. Management of complications

This chapter presents advice and recommended pathways for the management of common postoperative complications described in chapter 2.

9.1 Wound infection or seroma

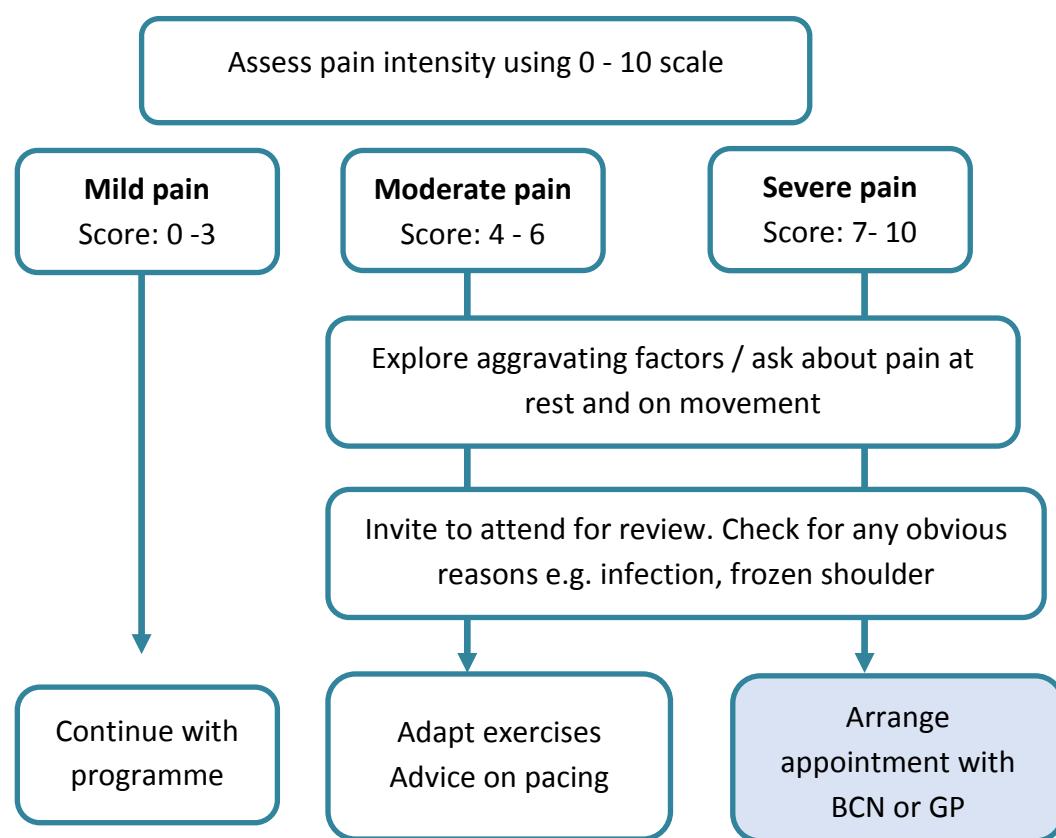
If you suspect a wound infection or seroma you should refer the participant to the breast care nurses or their own GP. Each hospital site may have a different postoperative protocol to follow although most breast cancer centers encourage their own patients to contact the breast care nurse in the first instance. It is safe to continue with gentle exercises in the presence of mild or superficial postoperative infection, as long as this is within the bounds of comfort. Remember that postoperative infection and seroma is fairly common and this is considered an ‘expected’ adverse event not a serious adverse event that needs reporting to the study office.

9.2 Management of postoperative pain

Assess pain using the 0-10 numerical rating scale (NRS). A pain score of 0-3 is considered mild pain, 4-6 is moderate pain and any score of 7 or above is considered severe or burdensome pain. You should assess pain intensity and ask about analgesic use at every contact, particularly when deciding about exercise progression. Refer to Figure 9.1 for the pain management pathway. Remind women to take painkillers *before exercising* if they feel discomfort. We do expect exercises to cause mild discomfort but if any exercise causes severe pain then you should arrange for a face-to face review and further assessment. Review range of movement and check for signs of infection or cording. Consider whether pain could be managed by reducing repetitions or changing exercises. Presentation may suggest general shoulder stiffness, from being overprotective, lack of use, overuse or from a specific pathology e.g. frozen shoulder rotator cuff tear. Where possible, explain the possible cause of pain as this can reduce fear, facilitate movement and continuing function. Pain management strategies such as **pacing** should also be taught if you think they are doing too much.

Anyone reporting **unexplained severe pain** should be referred back to the breast care team or their own GP for assessment and medication review. Similarly, if you suspect ongoing severe nerve pain (neuropathic pain) that is not resolving or is uncontrolled with current analgesia, refer the participant to the breast care team or ask them to make an appointment with their own GP.

Figure 9.1 Pathway for management of postoperative pain



9.3 Pathway for management of lymphoedema

All participants get the Breast Cancer Care leaflet 'Your Operation and Recovery' which has general advice about swelling in the breast/chest, arm or hand after surgery. Changes in sensations such as the arm feeling swollen, heavy or 'tight' may be the earliest indicators of lymphoedema, even before observable or measurable changes therefore it is important that women know how to monitor symptoms.⁶⁴ The lymphoedema management pathway is shown in Figure 9.2. Early signs include clothing or jewellery feeling tight, visible swelling,

feeling of heaviness, fullness or tightness. Self-monitoring is important because there is an ongoing lifetime increased risk of developing lymphoedema. The Breast Cancer Care leaflet ‘Living with lymphoedema after breast cancer’ gives more specific advice on reducing risk and management of symptoms. If you suspect a participant has signs of lymphoedema, we recommend that you give them this advice leaflet. If your hospital has a specialist lymphoedema nurse please make a referral. Some general advice from the BCC leaflet is replicated here:-

9.4 General advice for prevention of lymphoedema

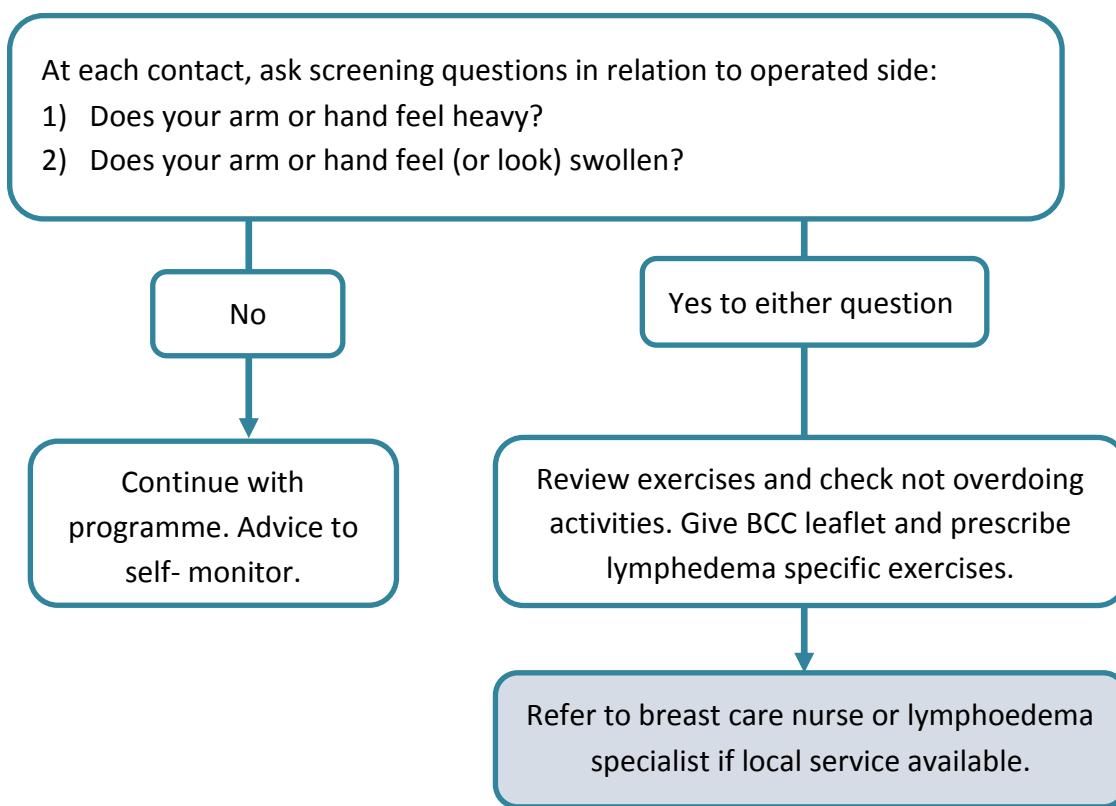
- Maintain a healthy weight – women who are overweight/obese are at greater risk of developing lymphoedema;
- Swimming is a good activity, advice to change type of stroke to avoid repetitive movement;
- Avoid injury to the affected arm – wear gloves when gardening and washing up;
- Avoid extremes of temperature, both hot and cold – avoid saunas, steam rooms and very hot baths or showers;
- Try to avoid cuts and stings on the affected arm;
- Although limited evidence, current advice remains to avoid having injections or blood taken from the affected arm or blood pressure taken on that side;
- If you don't have signs of lymphoedema, current advice is not to wear a compression garment when flying;
- If you do have signs of lymphoedema, current advice is to wear a properly fitting compression garment before, during and for a few hours after a flight.

9.5 Reassure that exercise is safe

As discussed in Chapter 4, we now know there is good evidence that **strength training is safe** and even beneficial.³¹⁻⁴¹ The PROSPER exercise programme recommends hand squeeze (fist pumps) exercises that may help reduce swelling. These and other exercises have been included in other clinical trials.⁶⁶⁻⁶⁸

Upper limb exercise is also recommended to treat established lymphoedema. Exercise may relieve symptoms of stiffness and discomfort and reduce the risk of further loss of upper limb mobility and function. Other recognised therapies for lymphoedema include manual lymph drainage and compression therapies.

Figure 9.2 Pathway for management of lymphoedema



9.6 Management of scars

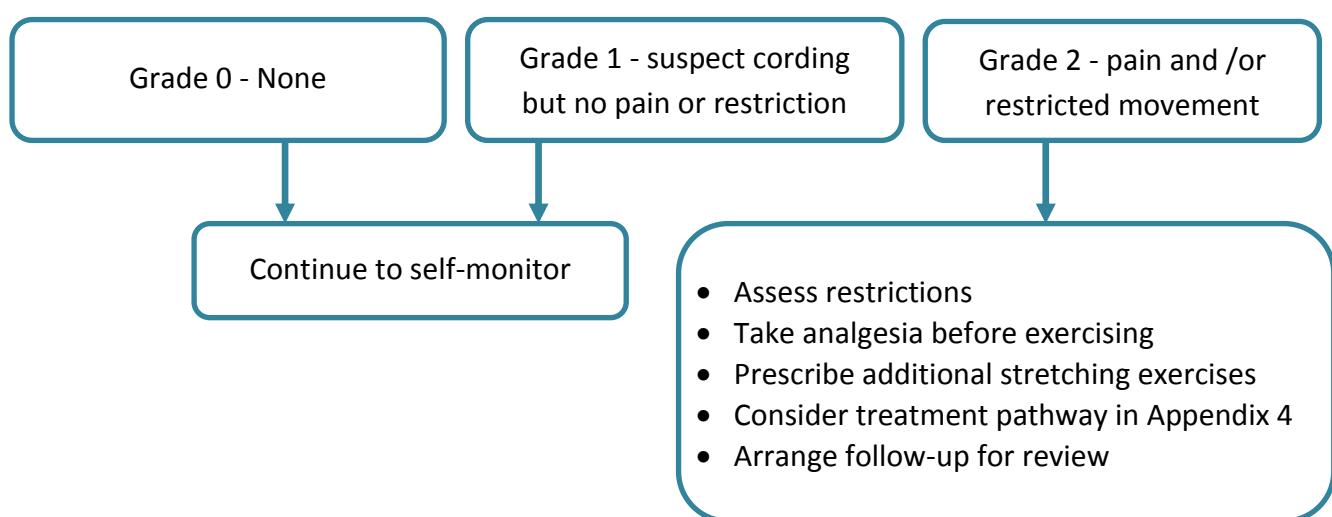
Scar massage may prevent the scar sticking to the underlying tissues and may help to improve cosmetic appearance.⁶⁹ Massaging the area may also help to reduce fear and avoidance of use of the affected arm. Touching the area may help with psychological adjustment to changes in body shape and appearance after breast surgery. However, the evidence-base for scar massage is very weak and it is not known whether one type of soft tissue massage is better than another, or indeed, whether massage works at all. For PROSPER, we are supportive of you advising women to gently massage wound sites using a non-perfumed

moisturiser (e.g. E45), but we **only** recommend this after wounds are fully healed and there are no signs of infection (see Appendix 4). Also, we **do not** recommend scar massage if a participant is having or has had radiotherapy in the last few weeks.⁷⁰ Women are advised to protect the radiotherapy site from bright sunlight (avoid sunbathing).

9.7 Management of cording

You should check for cording at each appointment. Cording is graded as 0 (none), 1 (cording but no pain or restriction) or 2 (cording with pain and restriction). If you suspect cording, encourage stretching and continued use of the arm rather than avoiding activity. Physiotherapy is recommended for cording in the Breast Cancer Care leaflet – it advises that stretching exercises can relieve symptoms. Figure 9.3 shows the cording management pathway for PROSPER participants. Soft tissue massage techniques may also help with symptoms although the evidence base is weaker because no clinical trials have tested the efficacy of different treatments.⁷¹ Soft tissue techniques can be referred to as myofascial release, cord stretches or gentle massage which include skin lifting, rolling and frictions along areas of tissue adhesion.¹⁸ (see Appendix 4 for more information).

Figure 9.3 Pathway for management of cording



9.8 Other shoulder problems

If a participant presents with any shoulder problems such as sub-acromial pain syndrome or adhesive capsulitis they may require a more detailed assessment. They may need referral to their own GP or consultant if you think a further assessment is required. If a participant does present with suspected sub-acromial pain syndrome, check that they are doing their exercises correctly. It may be that incorrect movement is causing impingement type patterns.

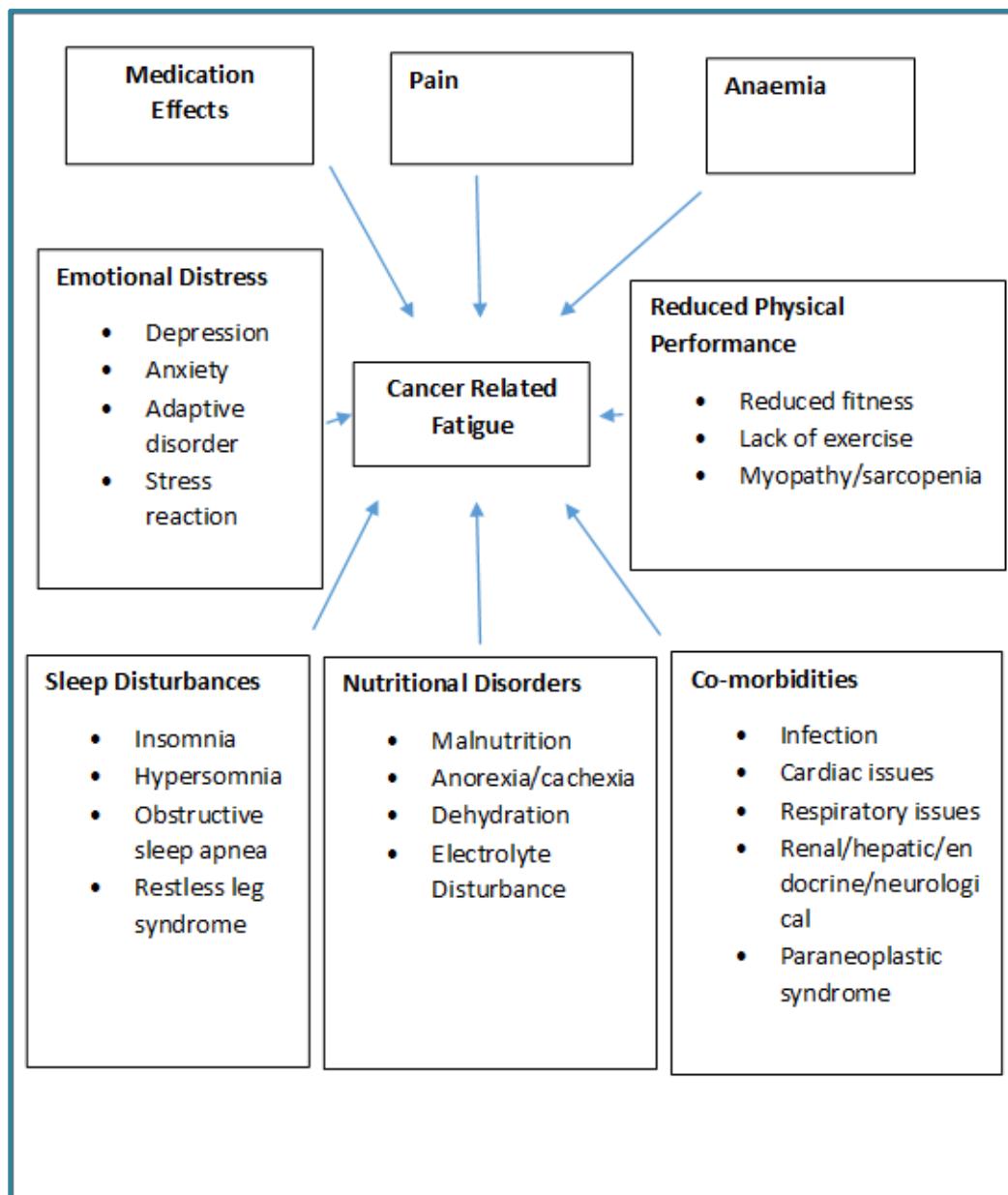
9.9 Joint arthralgia

Gentle exercises can improve the blood flow to joints which can alleviate stiffness and pain. If your participant reports joint aches, suggest they revisit their GP for a medication review.

9.10 Cancer-Related fatigue

The figure below describes different factors that may contribute to Cancer-Related Fatigue (Figure 9.4). Fatigue is a commonly reported barrier to exercise. You should reassure women that it is usual to feel extremely tired during and after treatment and that they should pace activities. They should accept offers of practical support from family and friends e.g. help with shopping, childcare and housework etc. Explain that gentle exercise can help improve fatigue – it has both physical and psychological benefits. Explore whether they are ‘over-doing’ things. If so, advise on pacing and balancing relaxation with physical activity. Often the hardest challenge is to start exercising – use the exercise planner as a tool to plan ahead. If you suspect that the participant may have a medical reason for their fatigue, then refer back to the breast care team or GP.

Figure 9.4 Possible causes of cancer-related fatigue²



Chapter 10. Trial Reporting Procedures

The procedures for reporting are described in this final chapter. There are various PROSPER documents that require completion by the physiotherapist, each of which is described below.

10.1 Your duties and responsibilities

Physiotherapists are required to act within recognised Good Clinical Practice (GCP) and the core standards of professional practice as defined by the regulatory and professional bodies, including the Health Professions Council and Chartered Society of Physiotherapy. You are responsible for high quality record keeping, clinical practice, maintaining confidentiality and patient and professional interactions. Each physiotherapist is responsible for ensuring their own fitness to practice and for the well-being and safety of trial participants. Each physiotherapist is responsible for adhering to the PROSPER trial protocol and procedures covered during training.



10.2 Physiotherapy Referral Form

Trial participants will be screened, consented and randomised by the clinical team. For the most part, these processes will occur pre-operatively but a small number of women will be recruited after surgery. As part of the screening process, the clinical team will review screening eligibility criteria to determine individual risk of shoulder problems after treatment.

The breast care nurses and/or research nurses will refer recruited trial participants to your physiotherapy department. Referrals should be sent directly using the paper form or by electronic methods (e.g. email or online referral system), depending upon the local hospital referral pathways. We will help to identify the most efficient and rapid method for receiving trial participant referrals. The **Physiotherapy Referral Form** is in Appendix 2. This form has the PROSPER logo to clearly distinguish trial participants from other clinical referrals. The physiotherapist should then contact the trial participant **as soon as possible after referral** to invite them to attend their first exercise therapy appointment - see the example script in the Appendix 7 for guidance. Ask them to wear a comfortable loose fitting top that can be easily

removed during the appointment. The referral form does **not** need to be returned to the PROSPER study team but it should be stored in PROSPER Box File in your Department.

10.3 Physiotherapy Treatment Log

 Complete the **Physiotherapy Treatment Log** during the first appointment (Appendix 3). We ask that you keep each participant log with your usual clinical records or in the PROSPER Box File. Please use a black pen when completing any trial documents. After the first appointment, you should continue to use the same Physiotherapy Treatment Log to record all further prescription details. The middle section allows you to record type of contact, details of therabands provided and number of repetitions. Continuation sheets are available on request. Different therapists may be involved with the care of an individual hence it is important to log each decision and any progression with therapy. As with other clinical records, these should be signed and dated as per GCP. These forms will be reviewed during follow-up quality assessment visits. At the end of treatment or on discharge, take a photocopy of the completed log before returning the original to the PROSPER study team (who does this will vary by site e.g. local research nurse or physiotherapist).

10.4 Treatment Withdrawal / Discharge Form

 **Withdrawal from Treatment:** There will be instances where participants become ill, require hospitalization or would like to withdraw altogether from their prescribed exercise programme. If they have a temporary health condition, it is acceptable to postpone or delay their appointments or take a short break from their exercises until they recover— then they can continue on with their programme (in this case, do not complete this form). If a participant is too ill to continue with treatment and unlikely to improve, or they just do not want to continue with the programme, then please complete the **Treatment Withdrawal / Discharge Form** and return to the PROSPER study team (Appendix 8). If you have any queries or would like to discuss a particular situation, please contact prosper@warwick.ac.uk.

Discharge from Treatment: If the participant has completed all their appointments (e.g. up to 6 contacts), and they are coping well with their exercises and are confident that they can continue independently without any further physiotherapy support, then you can discharge

them from your department. They will still be in the trial and will be followed up with postal questionnaires, but are “discharged” from treatment. Please complete the Discharge section of the Treatment Withdrawal/Discharge Form then return to the PROSPER study team. Remember also to complete and return the final sections of the Physiotherapy Treatment Log.

10.5 Reporting a death – use the Death Notification Form



Death: if you are notified of the death of a participant during the study period then **please let us know as soon as possible** to avoid any possible distress to the bereaved family caused by inappropriate follow-up. Please inform the research team using the **Death Notification Form** (Appendix 11). Please complete the form and **fax it immediately** to the PROSPER study team. We can provide you with spare copies of all forms. It is also important to ensure that your local research nurse is made aware of any participant deaths.

10.6 Reporting a complaint – use the Complaint Notification Form

Complaints procedure: in the unlikely event that a participant makes a complaint about any aspect of the trial, please inform the PROSPER study team. You should complete the **Complaint Notification Form** and fax this to the PROSPER office (Appendix 10). It is our experience from previous exercise trials that complaints are extremely rare. If a complaint does occur it can usually be dealt with most effectively if the Senior Investigator contacts the participant as soon as possible to discuss the issue.

10.7 Reporting a Withdrawal from the Trial

If a participant would like to **withdraw completely** from the PROSPER trial, please complete the **Withdrawal from Trial Notification Form** and fax this to the PROSPER study team (Appendix 9). It is important to distinguish between withdrawal from exercise treatment (see Section 10.4) and withdrawal from the whole trial and any further follow-up. If they do want to withdraw from the trial, ask whether they agree to use of any anonymised data collected to date.

10.8 Reporting Adverse Events

There are important safety issues to consider in relation to the trial exercise intervention. This last section defines Serious Adverse Events and the process for reporting. The accurate and timely reporting of adverse events is a requirement of GCP. The Chief Investigator of the PROSPER study, Dr Julie Bruce, is responsible for the reporting of relevant adverse events and on the safety of participants to the Study Sponsor (University of Warwick / University Hospital Coventry and Warwickshire) at regular time intervals. Safety reports are also submitted regularly to the funder, NHS Health Technology Assessment panel and to the Research Ethics Committee.

10.8.1 Serious Adverse Events

Physiotherapists are required to report **Serious Adverse Events**. A serious adverse event (SAE) is an event that has occurred during the course of the study **directly as a consequence of the treatment** and is **unexpected, unintended or unanticipated**. Events to be reported should only include those that require professional medical attention, including, but not restricted to:

- Death;
- Is immediately life threatening;
- Requires hospitalisation or prolongation of existing hospitalisation;
- Results in persistent or significant disability or incapacity;
- Requires an important medical intervention.

Although a number of adverse events may occur as a consequence of a cancer diagnosis, we do not expect SAEs to occur as a result of the exercises being evaluated in this trial. The PROSPER protocol defines an SAE as **an event that occurs during contact time with the healthcare professional (physiotherapist) delivering the intervention or whilst undertaking study exercise, either supervised or unsupervised (this could be at home)**. SAEs should be reported using the Serious Adverse Event forms (Appendix 12). The physiotherapist must report any SAEs to the Trial Co-ordinating Centre within **24 hours** of becoming aware of the event – the SAE form should be faxed to the dedicated number at Warwick CTU: **02476 150549**. The Trial Co-ordinating Centre is responsible for reporting SAEs to the sponsor and

ethics committee within required timelines, if appropriate. The relationship of SAEs to trial treatment will be assessed by the Chief Investigator (or appointed deputy) and this will be recorded on the SAE form. All SAEs will be recorded in the trial database and reported to and reviewed by the Trial Data Monitoring Committee (DMC) throughout the Trial, and will be followed up to resolution.

10.8.2 Adverse Events

PROSPER participants will range in age from younger women to those aged over 70 years therefore we do not consider the normal ups and downs of chronic diseases of old age to be adverse events e.g. osteoarthritis, musculoskeletal pains etc. We do anticipate that some women will experience discomfort when exercising, such as muscle aches or pains. These minor side effects are entirely to be expected - provided they are short lived or dealt with through clinical management and they should not be reported as adverse events.

It is also anticipated that up to 30% of trial participants will have one or more postoperative complications, such as superficial or deep surgical site infection, drain site infection, seroma, bruising/haematoma, lymphoedema and/or cording related to the cancer treatment. These events are expected post-operative complications and are not considered Adverse Events. They should be recorded on your treatment logs but not reported to the trial office. However, if you believe the participant has developed any of these post-operative complications as a direct result of the PROSPER Exercise Intervention, this is considered an Adverse Event and should be reported on the Adverse Event Form (Appendix 12) and returned to the trial office within 24 hours.

Additionally, should a participant experience any injury or complication as a direct result of the PROSPER Exercise Intervention, for example, hurting themselves with a theraband during their exercises, this should also be recorded on an Adverse Event form. All trial participants will be asked to complete information on complications at 6 weeks, 6 months and 12 months. We will also extract information on adverse events (postoperative complications) from medical records later in the trial.

10.9 Storage of PROSPER documentation

Confidentiality and security of data should be ensured at all times, in accordance with the Data Protection Act 1998, the Chartered Society of Physiotherapy (CSP) Guidelines and the NHS Code of Practice on confidentiality. Clinical records for PROSPER trial participants should be safely stored in a secure location with restricted access to therapists participating in the

trial. All relevant documentation should be completed as soon as possible after any face to face appointment or telephone contact, and must be completed within 24 hours.

Table 10.1 Overview of PROSPER documentation

Document	Who & when to complete	Action required by Physiotherapist
Referral to Physiotherapy Form	Who: BCN / Research Nurse When: When new participant randomised to exercise. Form used to notify Physiotherapy Department.	Keep in PROSPER Box File on site. Contact participant as soon as possible to book 1 st appointment.
Physiotherapy Treatment Log	Who: Physiotherapist When: Complete during each appointment or contact.	Keep in PROSPER Box File on site. These forms will be checked during QC visits. Copies of completed forms will be collected by research staff on a regular basis.
Treatment Withdrawal / Discharge Form	Who: Physiotherapist When: <ul style="list-style-type: none"> a) Withdrawal: A participant wants to withdraw from the exercise programme; b) Discharge: When a participant has completed all appointments & is confident to continue without further PT support. 	Return completed form to PROSPER study office.
Event Notification Forms <ul style="list-style-type: none"> a) Withdrawal from trial b) Complaint c) Death 	Who: Physiotherapist / Research Nurse When: If participant dies, complains or wants to withdraw completely from the trial.	Notify death or complaint within 24 hours. Notify withdrawal from trial within 7 days.
Adverse Event (AE) and Serious Adverse Event (SAE) Forms <ul style="list-style-type: none"> a) Adverse Event Form b) Initial SAE Form c) Follow-Up SAE Form d) SAE Continuation Form 	Who: Physiotherapist / Research Nurse When: See section 10.8.1 and 10.8.2 for criteria.	Within 24 hours of becoming aware of the AE and SAE.

10.10 Adhering to the protocol

We recognise that there will be differences between the PROSPER trial programme and your usual clinical care of patients presenting with either breast cancer and/or shoulder problems. This is to be expected as there is considerable variation in the type and delivery of both physiotherapy and postoperative care across the UK. However, for the purpose of a clinical trial, the interventions have to be “**standardised**” to ensure all physiotherapists and departments adhere to the same procedures. We therefore ask you to stick to the recommended exercise programme. If too many individual adaptations/variations are made then it will be impossible to find out whether this particular exercise programme has an impact on patient outcome. The trial is designed to attribute clinical effects to the intervention. Clinicians reading reports of a study with a standardised treatment protocol should be able to critically appraise the intervention used in order to assess its relevance to their clinical setting.

10.11 Quality assurance of intervention delivery

The trial lead is responsible for ensuring that intervention procedures are delivered according to the Therapist Manual across every hospital site. A nominated research physiotherapist will visit each site to conduct a Quality Control (QC) visit with each trained physiotherapist. The purpose of the QC visit is to ensure that the PROSPER exercise programme is delivered in a standardised manner and that each physiotherapist demonstrates competency in all aspects of the assessment and treatment protocols.

Assessments will be conducted after this training and after you have assessed your first few trial participants. The research physiotherapist will arrange a mutually suitable date and time for the QC visit. The QC visit is an opportunity to discuss any queries, problems or difficulties faced e.g. issues relating to participant assessment, intervention prescription and/or documentation issues. It is a chance to feedback on barriers and successes. The visit will be planned so that the research physiotherapist can observe you conducting a participant assessment and follow-up visit. The purpose is to learn from these QC visits and to consider whether any changes are needed to streamline or improve documentation or communication as necessary. Please note that you can contact the PROSPER study office or the research

physiotherapist **at any time** if you have any concerns or need advice on anything. A repeat QC visit will be scheduled if you would like more support or if any serious issues are identified during the visit e.g. repeated breaches of trial protocol or manual.

10.12 Procedure for Participant Non-Attendance

Any trial participant who does not attend a planned physiotherapy appointment without giving prior notification should be contacted by telephone to find out whether they want to reschedule their appointment. This may be an opportunity to have a brief problem solving discussion. You could use the **Barriers and Facilitators** form to guide your discussion. Once reasonable steps have been taken to contact the patient (e.g. we would suggest up to three telephone messages left or five attempted phone calls if unable to leave a message), then please notify the PROSPER Study Office or your local research nurse. If a participant does not attend for multiple consecutive appointments then please contact the PROSPER physiotherapist to discuss withdrawal from treatment e.g. unless there is a good reason, such as brief illness or relapse in health condition).

Finally....

This is your reference manual. If there is any other additional information that would be helpful to include, please let us know – thank you again for your help with the trial.

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This project was funded by the National Institute for Health Research HTA Programme (project number: 13/84/10).

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