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Supporting women to be active after breast cancer

Submission date 01/12/2025	**Recruitment status** Recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 07/01/2026	**Overall study status** Ongoing	
Last Edited 07/01/2026	**Condition category** Cancer	

Plain English summary of protocol

Background and study aims

More women are surviving breast cancer than ever before. But women often experience low mood, reduced strength and fitness, and extreme tiredness. These issues can last for years after treatment. Being active after breast cancer treatment can help. It can make women feel less tired, help them return to full strength, and improve their overall health and wellbeing. It may also lower the chances of cancer coming back. Unfortunately, most women do not get support to be active after treatment. The main issue is that there aren't enough suitable physical activity classes for women to join. There are also no easy ways for healthcare professionals (such as breast care doctors and nurses) to refer women to classes. We have developed a programme called PURE-EX that allows women to be referred to suitable and supportive physical activity classes after their treatment.

This study aims to test the PURE-EX programme with 45 women who have completed surgery for breast cancer. We want to find out if they liked the programme, if it helped them, and how we can improve it. We also want to understand how the programme is viewed by the healthcare professionals and exercise instructors involved in delivering it.

Who can participate?

Women aged ≥18 years who have: i) received a clinical diagnosis of early-stage breast cancer (stage I-III); ii) completed surgery for breast cancer; and iii) received clearance from a treating clinician to participate in the study. Women must also be willing and able to provide written informed consent.

What does the study involve?

The study involves women being offered, and if they accept, participation in the following:
i. An exercise referral from a healthcare professional whilst attending a routine clinical appointment
ii. A one-to-one review with an exercise instructor
iii. A 12-week community-based group physical activity programme has been especially designed for women who have had breast cancer treatment, and which will be held in a location in the local community.

What are the possible benefits and risks of participating?
The study will find out if offering a referral to a community-based physical activity intervention, and participation in a 12-week community-based group exercise programme is feasible and acceptable to women who have had surgery for breast cancer.

Just like all forms of exercise, there is a small risk of tripping/falling or an adverse cardiovascular event during the exercise sessions. However, this type of exercise is considered extremely low risk and the exercise programme has been designed by a clinical exercise physiologist and a senior physiotherapist who have extensive experience of delivering safe exercise to cancer patients. All patients will be medically cleared to participate by their breast cancer team and will undergo a thorough screening process. Healthworks instructors, who will be delivering the exercise sessions, are also experienced in carrying out exercise sessions with people who have multiple long-term conditions.

Where is the study run from?
The Newcastle University, Newcastle upon Tyne, UK.

When is the study starting and how long is it expected to run for?
February 2026 to April 2027

Who is funding the study?
Breast Cancer Now

Who is the main contact?
Dr Morven Brown; morven.brown@newcastle.ac.uk

Contact information

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Public, Scientific

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Additional identifiers

Integrated Research Application System (IRAS)
361493

Central Portfolio Management System (CPMS)
71188

Breast Cancer Now grant codes
2022.11PR1567

Study information

Scientific Title
Feasibility study: EXpanding into communities to imProve physical activity sUpport foR womEn after breast cancer (PURE-EX)

Acronym
PURE-EX feasibility study v1.1

Study objectives

Study objectives
To assess:
i. The feasibility and acceptability of being offered referral to, and attending, a community-based physical activity programme in women who have completed surgery for breast cancer.
ii. The feasibility and acceptability of breast cancer healthcare professionals offering physical activity referrals.
iii. The feasibility, acceptability, and views of instructors delivering a community-based physical activity programme to women after breast cancer treatment.
iv. The feasibility of data collection, measures of adherence and retention to the intervention.
v. Potential signals of intervention efficacy.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 27/11/2025, Wales Research Ethics Committee 3 (Health and Care Research Wales, Floor 4, Crown Building, Cardiff, CF10 3NQE, United Kingdom; -; Wales.REC3@wales.nhs.uk), ref: 25/WA/0330

Primary study design
Interventional

Allocation
N/A: single arm study

Masking
Open (masking not used)

Control
Uncontrolled

Assignment
Single

Purpose
Treatment

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Malignant neoplasm of breast

Interventions
This is a prospective, single-arm, pretest-posttest feasibility trial.
The intervention that women will be invited to take part in consists of three main components:
[1] An offer of exercise referral from a healthcare professional
[2] A one-to-one review with an exercise instructor
[3] A 12-week community-based group exercise programme

THE PURE-EX INTERVENTION

[1] An offer of exercise referral from a healthcare professional

The referral offer (from a healthcare professional) is designed to be concise (30–60 seconds), addressing concerns about limited time and competing priorities. We envisage that the referral will most commonly be delivered by the treating surgeon in breast cancer clinics during a follow-up appointment approximately 2 weeks - 6 months post-surgery.

At the breast cancer clinic, the healthcare professional will:

• ASK about previous and current physical activity levels

• ADVISE that being active after breast cancer surgery can reduce fatigue and other side effects (e.g., nerve pain), support physical and mental recovery, improve fitness for any planned treatments, and reduce recurrence risk by ~35%

• ASSIST by: 1) Providing a brief information booklet on exercise after breast cancer (https://breastcancernow.org/download-and-order-publications/exer cises-after-breast-cancer-surgery-bcc6); 2) Recommending joining a local exercise class as one of the best ways to support recovery; 3) Asking whether the woman would like a free referral into a 12-week group exercise class with other women recovering from breast cancer surgery.

If the woman agrees to the referral a research nurse, clinical team member, or clinical trials officer will complete a referral proforma including the woman's contact details, preferred method of contact, and brief medical history (e.g., type of surgery, other treatments).

The completed proforma will be securely sent (via post or secure email, depending on site preference) to a qualified exercise instructor at Healthworks, a community health charity in North East England (see below).

The instructor will then contact the woman to arrange a one-to-one review before she joins the group class. If the woman declines the referral, the reason will be recorded on the screening log.

[2] One-to-one review

The one-to-one review will take place at the same location as the exercise class (Health Resource Centre, Adelaide Terrace, Newcastle upon Tyne, NE4 8BE). The instructor will collect background and medical information using a Case Report Form (CRF).

The exercise instructor will then collect baseline data, including questionnaires and basic tests of cardiorespiratory fitness, strength and physical function. A wrist-worn accelerometer (for measurement of physical activity) to take home and return by post in a pre-paid envelope.

[3] A community-based group exercise programme

The group exercise programme will be delivered by the same Healthworks-employed instructor who conducted the one-to-one review. Participants will be invited to attend one class per week for 12 weeks.

Each class will last 50 minutes and include up to 12 women, consisting of:

1. A brief welcome/introduction to any attendees
2. A 15-minute warm-up (pulse-raising activities, full-body stretches, arm/shoulder movements)
3. A 25-minute main session (aerobic, strength, and balance exercises)
4. A 10-minute cool-down (static stretches held for ~20 seconds at the point of slight discomfort)

Exercises will be delivered in a circuit format: each movement performed for 60 seconds with ~15-second rest intervals, allowing participants to ready themselves for the next exercise in the sequence.

Equipment will include dumbbells and resistance bands, and chair-based options will be available for those who need them.

Throughout the 12-week programme, each participant will be provided with personalised recommendations and support for engaging in additional suitable physical activity (e.g., through local physical activity/exercise classes and groups; home-based exercises).

The primary outcome of this study is the feasibility of the PURE-EX intervention. This will be assessed via the outcomes.

Intervention Type
Behavioural

Primary outcome(s)
1. Acceptability of PURE-EX programme components measured using a validated acceptability questionnaire based on the theoretical framework of acceptability (TFA) at post-intervention

2. Recruitment rate (the number of consenting participants divided by the number of women approached) measured using data collected from screening logs will document each woman who was approached and consented (and, if not consented, reasons why will be recorded where possible to enable identification of issues regarding feasibility/acceptability in those who decline) at one time point

3. Participant acceptance of the physical activity referral (defined as whether the woman agrees for their contact details to be shared with the intervention provider) measured using data documented by the HCP at one time point

4. Attendance at the community-based exercise programme and any adverse events measured using data recorded by the exercise instructor at one time point

5. Adverse events and serious adverse events, as well as all non-serious adverse events that are deemed to be related to study participation measured using data collected in electronic Case Report Forms (eCRF) at one time point

6. Experiences of participants, healthcare professionals and exercise instructors of taking part in, and delivering, the intervention measured using qualitative semi-structured interviews at post-intervention

Key secondary outcome(s)
1. Health-related quality of life measured using the Functional Assessment of Cancer Therapy-Breast (FACT-B) at baseline and post-intervention

2. Fatigue assessed measured using the Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT-F) at baseline and post-intervention

3. Anxiety and depression measured using the Depression, Anxiety and Stress Scale - 21 Items (DASS-21) at baseline and post-intervention

4. Self-reported physical activity measured using the International Physical Activity Questionnaire – Short Form (IPAQ-SF) at baseline and post-intervention

5. Participants engagement in health-promoting behaviours measured using the Health-Promoting Lifestyle Profile-II (HPLP-II) at baseline and post-intervention

6. Cardiorespiratory fitness measured using the six-minute walk test (6MWT) at baseline and post-intervention

7. Physical function measured using the Short Physical Performance Battery (SPPB), a composite measure of standing balance, five chair stands, and 4-meter gait speed at baseline and post-intervention

8. Handgrip strength measured using a hand-held digital grip dynamometer – participants will use their dominant hand to squeeze at baseline and post-intervention

9. Device-based physical activity measured using a tri-axial accelerometer (Axivity AX3, Axivity Ltd, Newcastle upon Tyne) at baseline and post-intervention

Completion date
01/05/2027

Eligibility

Key inclusion criteria
1. Women aged >= 18 years
2. Clinical diagnosis of early-stage locally advanced breast cancer (stage I-III)
3. Have completed surgery for breast cancer
4. Have received clearance from a treating clinician to participate in the study
5. Willing and able to provide written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
120 Years

Sex
Female

Total final enrolment
0

Key exclusion criteria
1. Diagnosis of metastatic breast cancer (stage IV)
2. Currently undergoing chemotherapy or scheduled to start chemotherapy during the study period
3. Not sufficiently recovered from surgery in a manner that would contraindicate exercise, as determined by the treating clinician (e.g. inadequate wound healing, reduced range of motion, or other clinical concerns)
4. Musculoskeletal, neurological, or rheumatological condition that could be exacerbated by exercise, as determined by the treating clinician
5. Uncontrolled cardiovascular or metabolic disease
6. Pregnant or planning pregnancy during the study period

Date of first enrolment
02/02/2026

Date of final enrolment
31/12/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Queen Elizabeth Hospital (Lead)
Queen Elizabeth Avenue
Gateshead
England
NE9 6SX

Study participating centre
Royal Victoria Infirmary
Queen Victoria Road
Newcastle upon Tyne
England
NE1 4LP

Study participating centre
Healthworks Newcastle
Health Resource Centre
Adelaide Terrace
Newcastle upon Tyne
England
NE4 8BE

Sponsor information

Organisation
Newcastle University

ROR

https://ror.org/01kj2bm70

Funder(s)

Funder type
Government

Funder Name
Breast Cancer Now

Alternative Name(s)
BCN

Funding Body Type
Government organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
• The quantitative datasets analysed during the current study will be stored in a publicly available repository (Open Science Framework; https://osf.io/) and will be made available within one month of publication in a peer-reviewed journal. Participants consented to the information collected about them to support other research in the future, and that it may be shared anonymously with other researchers. In line with Newcastle University guidance, research data will be stored for 10 years.

• The qualitative datasets (interviews and focus groups) analysed during the current study will be available upon reasonable request from Professor Bernard Corfe; bernard.corfe; newcastle.ac.uk, this will be in the form of anonymised transcripts and will be available after publication of the datasets in a peer-reviewed journal. Participants consented to the information collected about them to support other research in the future, and that it may be shared anonymously with other researchers. Interview transcripts will be anonymised and any identifiable data removed. Participants will also be given study numbers/pseudonyms. In line with Newcastle University guidance, research data will be stored for 10 years.

IPD sharing plan summary
Available on request, Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 2	19/11/2025	12/12/2025	No	Yes
Protocol (preprint)		08/01/2025	12/12/2025	No	No
Protocol file	version 1.1	03/09/2025	12/12/2025	No	No