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Investigating the relationship between physical activity and side effects associated with systemic anti-cancer therapies

Submission date 29/01/2026	**Recruitment status** Not yet recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 05/02/2026	**Overall study status** Ongoing	
Last Edited 02/02/2026	**Condition category** Cancer	

Plain English summary of protocol

Background and study aims

Cancer treatments such as chemotherapy and other systemic anti-cancer therapies (SACT) can cause side effects that affect people physically and emotionally, impacting daily activities, quality of life and wellbeing. Research suggests physical activity may help people cope better with treatment, but it is not yet clear how practical it is to measure activity levels or deliver exercise programmes during SACT. Before a larger study can be developed, we need to understand whether this type of research is feasible.

The ACTIVATE study will explore whether it is possible to recruit participants, collect the necessary information and, in some cases, deliver an exercise programme to people with cancer starting their first course of SACT. The study will include adults with breast, colorectal, prostate or lung cancer.

Who can participate?

Patients aged ≥16 years who have been diagnosed with breast, lung, colorectal or prostate cancer and are planned to commence first-line SACT.

What does the study involve?

This feasibility study will recruit 16 participants, eight will take part in Part One and a separate group of eight in Part Two.

The study has two parts.

Part One will examine whether it is feasible to measure physical activity before treatment begins and to collect information on side effects and wellbeing during SACT. Participants will take part for up to six months. All study visits will take place alongside routine hospital appointments for standard cancer care, with no additional visits required. Participants are expected to attend approximately 4–10 study visits, depending on treatment schedules.

Part Two follows a similar approach, but participants will also receive a personalised exercise programme starting 2–4 weeks before SACT and continuing during treatment. Participants will attend a physiotherapy visit to receive their exercise programme, which may take place face to face or online. Participation will last for up to six months and involve a similar number of visits.

This study will provide essential information to help design a future, larger study to improve care for people undergoing SACT.

What are the possible benefits and risks of participating?
Benefits and risks not provided at time of registration

Where is the study run from?
Sir Bobby Robson Cancer Trials Research Centre, Freeman Hospital, High Heaton, UK.

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

Who is funding the study?
Newcastle upon Tyne Hospitals NHS Foundation Trust, UK.

Who is the main contact?
Dr Ben Hood, ben.hood@nhs.net

Contact information

Type(s)
Scientific, Public, Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)
346177

Study information

Scientific Title
A feasibility study investigating the relationship between physical activity and side effects associated with systemic anti-cancer therapies

Acronym
ACTIVATE

Study objectives
To evaluate the feasibility and acceptability of delivering a personalised prehabilitation programme prior to and during systemic anti-cancer therapy.
• To assess the feasibility of recruiting and retaining participants to the study.
• To explore the impact of prehabilitation on physical activity levels, quality of life and treatment tolerance during systemic anti-cancer therapy.
• To assess the safety and adherence of the prehabilitation intervention.
• To generate data to inform the design of a future larger-scale evaluation.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 29/01/2026, London - Harrow Research Ethics Committee (2 Redman Place Stratford, London, E20 1JQ, United Kingdom; +44 (0)300 303 8490; harrow.rec@hra.nhs.uk), ref: 26/LO/0051

Primary study design
Interventional

Allocation
Non-randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Sequential

Purpose
Device feasibility, Health services research, Supportive care

Study type(s)

Health condition(s) or problem(s) studied
Cancer-related functional decline and reduced physical activity in adults receiving systemic anti-cancer therapy

Interventions

Participants will be identified through routine oncology clinics and screened for eligibility prior to commencing first-line systemic anti-cancer therapy (SACT). Following informed consent and baseline assessment, participants will be enrolled into one of two sequential cohorts.

Participants enrolled during the first recruitment phase (control cohort) will undergo baseline assessment and receive usual oncology care only, with no additional prehabilitation intervention. Participants enrolled during the second recruitment phase (intervention cohort) will undergo the same baseline assessment and, in addition to usual care, will receive a personalised prehabilitation programme.

The prehabilitation programme consists of an individualised physical activity plan developed following baseline assessment and supported by a physiotherapist. The intervention is delivered using a hybrid model combining face-to-face and supported home-based exercise. The intervention commences prior to SACT and continues throughout the period of systemic treatment.

Participants will be observed from enrolment through completion of systemic anti-cancer therapy. The total duration of follow-up for each participant is from baseline to completion of SACT. This is a pragmatic, non-randomised study using sequential cohort allocation based on recruitment period; no randomisation methods are used.

Intervention Type
Behavioural

Primary outcome(s)
1. Attitudes towards prehabilitation and willingness to engage in an exercise programme measured using the study-specific PREHAB acceptability questionnaire at baseline only (part one participants only)

2. Acceptability and feasibility further measured using data on completion and adherence collected from study records, and participant feedback captured via study diaries and end-of-study assessments at the end-of-study visit

Key secondary outcome(s))
1. Cancer-specific quality of life measured using the Functional Assessment of Cancer Therapy - General (FACT-G) at baseline (visit 1), day 1 of SACT (visit 2), 7 days post each SACT cycle, and end of study

2. General health-related quality of life measured using the EuroQoL 5-level EQ-5D version (EQ-5D-5L) at baseline, day 1 of SACT, 7 days post each SACT cycle, and end of study

3. Physical activity levels measured using the Global physical activity questionnaire (GPAQ) at baseline and end of study

4. Self-reported diet type measured using a dietary questionnaire at baseline only

5. Symptoms, side effects, wellbeing changes measured using a participant study diary at 7 days after each SACT cycle

6. Hormones, inflammation, metabolic markers measured using Blood tests at baseline, day 1 of SACT, and end of study

Completion date
01/02/2027

Eligibility

Key inclusion criteria
1. Adults aged ≥16 years
2. Diagnosis of breast, lung, colorectal or prostate cancer
3. Planned to commence first-line systemic anti-cancer therapy (SACT)
4. Able to provide written informed consent
5. ECOG performance status 0–1
6. Able to participate in a physical activity-based intervention

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
16 years

Upper age limit
80 years

Sex
All

Total final enrolment
16

Key exclusion criteria
1. Contraindications to exercise or physical activity, as identified by clinical assessment
2. Unstable or uncontrolled comorbidities that would preclude safe participation
3. Cognitive impairment or other factors preventing informed consent
4. Already participating in a structured prehabilitation or exercise programme

Date of first enrolment
15/02/2026

Date of final enrolment
01/02/2027

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
The Newcastle upon Tyne Hospitals NHS Foundation Trust
Freeman Hospital
Freeman Road
High Heaton
Newcastle upon Tyne
England
NE7 7DN

Sponsor information

Organisation
Newcastle upon Tyne Hospitals NHS Foundation Trust

ROR
https://ror.org/05p40t847

Funder(s)

Funder type

Funder Name
Newcastle upon Tyne Hospitals NHS Foundation Trust

Alternative Name(s)
Newcastle upon Tyne Hospitals NHS Trust

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available